CytoDyn Inc.
Form 10-K
July 19, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended May 31, 2016

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	**75-3056237**
(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: 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 x 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 x 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. x Yes ¨ No

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). x Yes ¨ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in rule 12b-2 of the Act). ¨ Yes x 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: $67,893,778 as of November 30, 2015.

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, 2016, the registrant had 124,534,105 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	**Parts Into Which Incorporated**
Portions of the Proxy Statement for the 2016 Annual Meeting of Shareholders	Part III

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CYTODYN INC.

FORM 10-K FOR THE YEAR ENDED MAY 31, 2016

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FORWARD-LOOKING STATEMENTS

This annual report contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as believes, hopes, intends, estimates, expects, projects, plans, anticipate 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 prospectus, 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, (ii) our ability to identify patients to enroll in our clinical trials in a timely fashion, (iii) our ability to achieve approval of a marketable product, (iv) design, implementation and conduct of clinical trials, (v) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (vi) the market for, and marketability of, any product that is approved, (vii) the existence or development of vaccines, drugs, or other treatments for infection with the Human Immunodeficiency Virus that are viewed by medical professionals or patients as superior to our products, (viii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (ix) general economic and business conditions, (x) changes in foreign, political, and social conditions, (xi) the specific risk factors discussed under the heading Risk Factors below, and (xii) 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 Form 10-K will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of 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 prospectus. 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. (the Company) was originally incorporated under the laws of Colorado on May 2, 2002 under the name RexRay Corporation (its previous name). Effective August 27, 2015, the Company 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 do not intend to incorporate any contents from our website into this annual report. Unless the context otherwise requires, references in this prospectus to CytoDyn, the Company, we, our, or us are to CytoDyn Inc. and its subsidiaries.

We are a clinical-stage biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies to treat Human Immunodeficiency Virus (HIV) infection. Our lead product candidate, PRO 140, belongs to a class of HIV therapies known as entry inhibitors that block HIV from entering into and infecting certain cells. We believe that monoclonal antibodies are a new emerging class of therapeutics for the treatment of HIV to address unmet medical needs in the area of HIV and graft versus host disease.

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 under PRO 140 Acquisition and Licensing Arrangements below.

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PRO 140

We believe the PRO 140 antibody shows promise as a powerful anti-viral agent while not being a chemically synthesized drug, which means 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 PRO 140 antibody belongs to a class of HIV therapies known as entry inhibitors that block HIV from entering into and infecting certain cells. PRO 140 blocks HIV from entering a cell by binding to a molecule called the C-C chemokine receptor type 5 (CCR5), a normal cell surface co-receptor protein to which certain strains of HIV, referred to as R5 strains, attach as part of HIV s entry into a cell.

PRO 140 is an antibody, and through several, short-term clinical trials it has demonstrated efficacy without issues relating to toxicity and autoimmune resistance. Moreover, these trials suggest that PRO 140 does not affect the normal function of the CCR5 co-receptor for HIV. Instead, PRO 140 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 affecting the cell s normal function. The R5 strains of HIV currently represent approximately 67% of all HIV infections in the U.S. As a result, we believe PRO 140 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 PRO 140 is uniquely positioned to address a growing HIV market as an alternative or in addition to current therapies, which are failing primarily due to drug resistance. In seven clinical trials previously conducted, PRO 140 was generally well tolerated, and no drug-related serious adverse events, or SAEs, or dose-proportional adverse events, or 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 PRO 140 s antiviral activity was potent, rapid, prolonged, dose-dependent, and statistically significant following a single dose. Because PRO 140 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.

To date, PRO 140 has been tested and administered to test subjects either intravenously or as a subcutaneous injection. We believe that, if PRO 140 is approved for use as an injectable by the FDA, it may nonetheless be an attractive and marketable therapeutic option for patients with healthy CCR5, 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 HCV (hepatitis C) co-infection;
- Patients with complex concomitant medical requirements; and

Patients who choose not to start their highly active antiretroviral therapy (HAART) regimen immediately after being infected with HIV.

We believe PRO 140 has demonstrated potent (as compared to existing treatments) antiretroviral activity and an encouraging safety profile in prior clinical testing, that PRO 140 has the potential to be the first long-acting (weekly or every other week), self-administered HIV therapy, and that PRO 140 inhibit CCR5-tropic HIV while preserving CCR5 s natural activity. We believe PRO 140 represents a distinct class of CCR5 inhibitors with unique virological and immunological properties and may provide another distinct tool to treat HIV-infected subjects.

Our ongoing HIV-related clinical trials, described in greater detail below, have been designed to demonstrate the proof of concept that PRO 140 monotherapy can reduce the viral load in certain HIV-infected, treatment-experienced patients. Once the viral load is undetectable, weekly administration of PRO 140 can help maintain the suppressed viral load in a subpopulation of R5 patients over an extended period of time (currently shown to be approaching two years). Based on the preliminary results of such studies, we believe that a PRO 140 treatment option could address the unmet medical need for therapy options for certain HIV-infected patients with uncontrolled viral load, despite conventional HAART treatments.

To facilitate our self-funded and sponsored clinical research plans and trials, we engaged Amarex Clinical Research, LLC (Amarex), as our principal contract research organization (CRO), to provide comprehensive clinical trial management services.

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Current Clinical Trials

PRO 140 is currently being studied in four ongoing clinical trials:

Our first ongoing clinical trial is an extension study of our Phase 2b treatment substitution trial, which was initially completed in January 2015. Several patients are continuing in extension studies of this monotherapy trial by taking a weekly injection of PRO 140. Results from these extension studies thus far indicate some patients are now reaching 24 months of suppressed viral load achieved through a successful monotherapy of PRO 140.

Our second ongoing clinical trial is a pivotal Phase 2b/3 trial for PRO 140 as a combination therapy to existing HAART drug regimens. The initial 25-week trial protocol included a requirement for 300 subjects. The FDA recently reduced this requirement to 150 subjects. The first subject to have successfully completed this trial has transitioned into a FDA-cleared compassionate use protocol, so as to continue on PRO 140 therapy at the request of the treating physician.

The third ongoing trial is a strategic Phase 3 trial including 300 patients to assess the treatment strategy of using PRO 140 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 number of patients who can maintain suppressed viral load under a PRO 140 monotherapy replacing their HAART regimen for 48 weeks. The secondary endpoint is the number of weeks a patient is off of their ART regimen. Enrollment of first patient is anticipated to occur within the next quarter.

Our fourth ongoing trial of PRO 140 is a Phase 2 study for Graft versus Host Disease (GvHD) and is the first non-HIV indication for PRO 140. This trial, a randomized, double-blind, placebo-controlled, multi-center 100-day study with 60 patients is designed to evaluate the feasibility of the use of PRO 140 as an add-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 has not been announced.

The Company s recently announced fifth clinical trial is expected to commence in the near future and will evaluate PRO 140 for treatment naïve HIV patients. The protocol for this trial provides for PRO 140 to be administered to HIV patients immediately upon their diagnosis of HIV and prior to waiting two weeks before receiving the results of their genotype test, which allows their physician to prescribe a specific HAART regimen. Treatment naïve or patients who have yet to begin an antiretroviral therapy are highly contagious and the Company believes such an application for PRO 140 can be highly advantageous to the patients and the HIV population.

Each of the foregoing trials are described more fully below. We are continuing to explore opportunities for clinical applications for PRO 140 involving the CCR5 receptor, other than HIV-related treatments, such as inflammatory conditions, autoimmune diseases and cancer.

Phase 2b Treatment Substitution Trial for HIV, as Monotherapy

Our first Phase 2b clinical trial of PRO 140 commenced in May 2014 and concluded in January 2015. This Phase 2b trial, referred to as a treatment substitution trial, investigated PRO 140 as a short-term treatment substitution (as a

monotherapy of PRO 140) for existing HAART drug regimens. An extension study of this trial is currently ongoing, as described in greater detail below.

The treatment substitution trial had two primary objectives: (1) to assess the efficacy of PRO 140 monotherapy for the maintenance of viral suppression after being used in substitution of a patient s HAART regimen, and (2) to assess the clinical safety and tolerability parameters for PRO 140 following use in substitution of HAART. The study protocol required patients to be stable on HAART with patient s viral load not more than 400 HIV RNA particles per milliliter of blood for two consecutive weeks. The trial design provided that patients would be shifted from HAART regimen to PRO 140 monotherapy for 12 weeks. PRO 140 was administered as a 350mg subcutaneous dosage weekly and participants were monitored for viral rebound on a weekly basis. Total treatment duration with PRO 140 was up to 14 weeks with one week overlap of existing retroviral regimen and PRO 140 at the beginning of the study period and also one week of overlap at the end for subjects who did not experience virologic failure, defined as a viral load above 400 HIV RNA particles per milliliter of blood for two consecutive weeks. An independent Data Safety Monitoring Board (DSMB) was required to monitor the study to ensure patient safety and to assess efficacy. The DSMB operates in conformance with the FDA guidelines for its independence. DSMB s management and oversight of the trial was successfully completed in January 2015.

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Below are the results from our Phase 2b treatment substitution clinical trial, excluding certain patients who violated trial protocol or were later categorized by third party tropism tests as not being infected by CCR5-tropic virus strains exclusively.

- 98% of the patients passed 4 weeks of monotherapy;
- 82% of the patients passed 8 weeks of monotherapy; and
- 75% of the patients passed 11 weeks of monotherapy (maximum allowable duration of monotherapy without an extension study)

Because only patients who have HIV R5 virus exclusively can benefit from PRO 140, prior to enrollment in the study, each patient was required to take a DNA tropism test to determine whether the strain of HIV present in the patient was exclusively the R5 strain, making the patient a suitable candidate for PRO 140 therapy. The tropism test, however, is not accurate in patients with an undetectable viral load, which was one of the primary inclusion criteria for the Phase 2b trial. The occurrence of a number of viral rebounds due to inaccurate tropism screening, as demonstrated in the trial data, was not unexpected.

The success of this initial monotherapy trial served as the foundation for the ongoing extension study described below.

Phase 2b Extension Study for HIV, as Monotherapy

The extension study of our initial Phase 2b trial was designed to evaluate the efficacy, safety, and tolerability of PRO 140 monotherapy for the maintenance of viral suppression in subjects who completed 12 weeks of monotherapy in the initial Phase 2b treatment substitution trial without experiencing virologic failure. The objectives and endpoint definitions are the same for the Phase 2b extension study, as they were for the initial Phase 2b treatment substitution trial, except that patients in the extension study were trained for weekly self-injection to be administered at home, and their viral load was monitored initially on a bi-weekly basis and then on a monthly basis later in the study.

For the Phase 2b extension study, 19 subjects were screened for participation and 16 were allowed to enter. 14 patients successfully passed 29 weeks of PRO 140 monotherapy. Out of these 14 patients, 10 patients are currently ongoing and have completed up to 23 months of PRO 140 monotherapy without experiencing virologic failure (defined, as in the initial study, as a viral load above 400 HIV RNA particles per milliliter of blood for two consecutive weeks). Three patients discontinued the extension protocol due to either violating protocol design or missing weekly treatments. The trial is ongoing and as a result, we are only able to discuss the clinical findings to date.

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

In view of PRO 140 being established as a safe and efficacious substitution therapy in the initial Phase 2b monotherapy trial and ongoing extension study, following the FDA s clearance of a new trial protocol, we initiated in mid-2015 a pivotal Phase 2b/3 trial for PRO 140 as combination therapy to existing HAART drug regimens. The FDA recently reduced the number of required subjects in this trial from 300 to 150. We believe that, upon successful completion of this Phase 3 study, we will have the opportunity to seek accelerated approval for PRO 140 based on previously granted FDA fast-track candidate designation.

The Phase 3 combination therapy trial is designed to allow PRO 140 as a component of a HAART regimen for treatment experienced patients. HAART is the current standard of medical care for individuals with HIV. The study population includes treatment-experienced HIV-infected patients with CCR5-tropic virus with documented genotypic or phenotypic resistance to antiretroviral drugs within one or more drug classes, which is a second-line therapy, with additional conditions to include patients who have demonstrated evidence of HIV replication despite ongoing antiretroviral therapy and have limited treatment options. The treatment options may be limited as a result of drug antiretroviral class cross-resistance, documented treatment intolerance, potential for hypersensitivity to one or more antiretroviral drugs, or potential drug interactions with treatment for co-morbid conditions. Subjects will have one or more fully active, approved drugs available for construction of a viable alternative option.

In late January 2016, we announced that we had filed a request with the FDA for designation as a breakthrough therapy treatment for certain HIV patients. In response to our filing, the FDA requested that the Company submit data from the population for which the breakthrough therapy is requested. The Company will respond to this request.

Phase 3 Trial for HIV, as Long-term Monotherapy

A strategic Phase 3 trial including 300 patients to assess the treatment strategy of using PRO 140 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 number of patients who can maintain suppressed viral load under a PRO 140 monotherapy replacing their HAART regimen for 48 weeks. The secondary endpoint is the number of weeks a patient is off of their ART regimen. Enrollment of first patient is anticipated to occur within the next quarter and is expected to accelerate, as experienced in the previous Phase 2b monotherapy trial.

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A Phase 3, Multicenter Study to Assess the Treatment Strategy of Using PRO 140 SC as Long-Acting Single-Agent Maintenance Therapy for 48 Weeks in Virologically Suppressed Subjects with CCR5-tropic HIV-1 infection. This study is a multi-center study designed to evaluate the efficacy, safety, and tolerability of the strategy of shifting clinically stable patients receiving suppressive combination antiretroviral therapy to PRO 140 monotherapy and maintaining viral suppression for 48 weeks following study entry. Consenting patients will be shifted from combination antiretroviral regimen to weekly PRO 140 monotherapy for 48 weeks during the Treatment Phase with the one week overlap of existing retroviral regimen and PRO 140 at the beginning of the study treatment and also one week overlap at the end of the treatment in subjects who do not experience virologic failure.

Phase 2 Trial for Graft versus Host Disease

In June 2015, we announced that Company-sponsored research data has expanded the potential clinical indications for PRO 140 to include certain inflammatory diseases, autoimmunity, transplantation and cancer.

The CCR5 receptor is expressed on a variety of cells that play a central role in inflammatory responses. The receptor is activated by a chemokine mediator called CCL5, which has been shown to be a central figure in many inflammatory disease processes. Blocking the interaction of CCL5 with the receptor CCR5 is believed to be of therapeutic benefit. PRO 140 targets the CCR5 receptor, binding to it in a way that prevents HIV from using it as an entry gateway without activating the immune function of the receptor. Our recent research data indicate that PRO 140 also interferes with activation of the receptor by the mediator CCL5.

Following new research data relating to PRO 140 s mechanism of action, in October 2015, we filed with the FDA an investigational new drug (or IND) application and a full protocol for a Phase 2 clinical trial for a transplantation indication called Graft versus Host Disease (or GvHD), as our first non-HIV clinical indication. GvHD is a life-threatening complication for patients undergoing stem cell transplants. The CCR5 receptor, the target for PRO 140, is an important mediator of GvHD, especially in the organ damage that is the usual cause of death. The only approved CCR5 inhibitor, Maraviroc, is currently in a Phase 2 study for GvHD indications, and results are expected in 2016. We believe that PRO 140 has significant advantages over Maraviroc in more favorable dosing and pharmacokinetics, less toxicity and side effects, and no direct stimulation (agonist activity) of the CCR5 receptor.

In December 2015, we received clearance from the FDA to conduct a Phase 2 trial to evaluate the safety and efficacy of PRO 140 for prophylaxis of acute GvHD in patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) undergoing allogeneic stem-cell transplantation. The trial is a 100-day study with 60 patients. Enrollment of the first patient has not been announced.

In late December 2015, we announced that we had filed with the FDA for designation of PRO 140 as an orphan drug, in connection with our GvHD Phase 2 trial and remains open at this time pending submission by the Company of additional clinical data. Designation as an orphan product provides potentially faster pathways to approval and other financial incentives for drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S.

Phase 2b Trial for HIV, as a Monotherapy for Treatment-Naïve Patients

We recently announced a Phase 2b, randomized, double-blind, placebo-controlled, multi-center study to assess the safety and efficacy of PRO 140 in treatment-naïve adults with HIV-1 infection. This trial is designed to evaluate the safety and efficacy of PRO 140 SC compared to placebo for the reduction of viral load in 60 treatment-naïve adults patients with HIV-1 infection for a period of two weeks.

All eligible and consenting participants will be randomized in a 1:1 ratio to one of two treatment arms:

Group A: PRO140 350mg weekly S.C. Inj.

Group B: Placebo weekly S.C. Inj.

Upon randomization, subjects will receive two doses of PRO 140 or placebo given seven days apart. The first dose of PRO 140 or placebo will be given on the day of randomization followed by second dose (one week after) at the initiation of HAART. Study participants will be monitored for one year following initiation of HAART.

Other Product Candidates

Until the clinical trials for PRO 140 have advanced further, we do not plan to devote any resources towards the development, research, testing, approval or commercialization of other product candidates.

PRO 140 Acquisition and Licensing Arrangements

We 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 (the Progenics Purchase Agreement), between CytoDyn and Progenics. On October 16, 2012, the Company paid to Progenics $3,500,000 in cash to close the transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) $1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-US equivalent, which was paid during the year ended May 31, 2016; (ii) $5,000,000 at the time of the first US new drug application approval by the FDA or other non-U.S. approval for the sale of PRO 140; and (iii) 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 $1.5 million of such milestones owed to Progenics as a result of the first dosing in a U.S. Phase 3 trial. To the extent that such milestone payments 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.

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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.) (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 and must pay additional milestone payments and royalties as follows: (i) $1,000,000 upon initiation of a Phase 3 clinical trial, which was paid during the year ended May 31, 2016; (ii) $500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) $500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iv) royalties of up to 7.5% 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. During the year ended May 31, 2016 the Company paid $1 million of such milestones. To the extent that such milestone payments 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. Pursuant to the foregoing Progenics Purchase Agreement and PDL License, the Company accrued an expense of $2,500,000 as of May 31, 2015 in connection with the anticipated milestone payments related to the first patient dosing in a Phase 3 clinical trial, all of which was paid during the year ended May 31, 2016.

Effective July 29, 2015, the Company entered into a License Agreement (the Lonza Agreement) with Lonza Sales AG (Lonza) covering Lonza s system know-how technology with respect to CytoDyn s use of proprietary cell lines to manufacture new PRO 140 material. The Lonza Agreement required payment of £600,000 (approximately US$915,000) by December 15, 2015, which was timely paid. In connection with this license agreement, the Company became the primary obligor of an additional £600,000, which was accrued in the first quarter of the fiscal year ended May 31, 2016 and was timely paid by June 30, 2016. Using the foreign currency exchange rates at the time of payment, the Company s license fee payment approximated US$807,000. Future annual license fees and royalty rate will vary depending on whether we manufacture PRO 140 ourselves, utilize the third-party licensor as a contract manufacturer, or utilize an independent party as a contract manufacturer. The licensor does not charge an annual license fee of £300,000 when it serves as the manufacturer. However, we currently use an independent party as a contract manufacturer. If that arrangement continues, the annual license fee of £300,000 would continue to apply, as well as a royalty of 1.0% 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, 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 the Company 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 will start to expire in 2026, and certain formulations comprising PRO 140 will start to expire in 2031.

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 above. 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 a 12-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 5-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.

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Information with respect to our current patent portfolio as of May 31, 2016, is set forth below.

Product Candidates	Number of Patents U.S.	Number of Patents International	Expiration Dates[1]	Number of Patent Applications U.S.	Number of Patent Applications International
PRO 140[2]	10	28	2016-2031	6	14
Cytolin				1	
CytoFeline				2	3

(1) Patent term extensions and pending patent applications may extend periods of patent protection.
(2) PRO 140 patents and applications relate to HIV-1 and GvHD 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 operation of clinical laboratories, 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 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 Center for Devices and Radiological Health and its Center for Biological Evaluation and Research continues to result in increases in the amounts of testing and documentation for FDA clearance of current and new biologic products. The FDA can ban certain biological products; detain or seize adulterated or misbranded biological products; order repair, replacement or refund of these products; and require notification of health professionals and others with regard to biological 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 biological products or

initiate action for criminal prosecution of such violations.

The lengthy process of seeking drug 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 PRO140 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 PRO140 typically includes pre-clinical studies, the filing of an Investigational New Drug application, or IND, human clinical trials and filing and approval of either a New Drug Application, or NDA, for chemical pharmaceutical products, or a BLA (biologics license application) for biological pharmaceutical products, such as 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

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begin. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent institutional review board, or 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, or GLP, and Good Clinical Practice, or 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, or 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, or 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 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 EMEA by inspectors from particular E.U. member countries that conduct inspections on behalf of the European Union 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 E.U. countries are similar in principle to those in the United States and can be at least as costly and uncertain. The European Union 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 REMS program, including distribution and/or use restrictions.

Once an NDA or 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 subjects are subject to regulation under Clinical Laboratory Improvement Amendments (CLIA). CLIA regulates clinical laboratories by requiring that the

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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 primarily on our PRO 140 Phase 3 trials, seeking additional indications in trials that we will sponsor and fund (subject to the availability of sufficient capital to pursue additional paths to approval), to manage our Phase 2 trial for GvHD and to continue to evaluate and leverage the clinical data from our recently completed Phase 2b treatment substitution trial.

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 subjects. 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 Dr. Jacobson and others 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 are required to pay significant fees to third parties upon the first patient dosing in a Phase 3 trial of PRO 140. See the discussion under the subheading PRO 140 Acquisition and Licensing Arrangements above.

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Competition

The pharmaceutical and biotechnology 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 PRO 140 to commercialization is our highest priority. PRO 140 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 are believed to have significant side effects. For these reasons, we believe that our lead product, PRO 140, 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. Each class of drugs has many drugs available in that class except the entry inhibitor (EI) class. The only drug in EI class approved by the FDA is Maraviroc, a drug taken orally twice a day. Upon approval, we believe that PRO 140 will be the only approved drug outside of the main four classes of drugs approved for HIV since 2007.

The only other monoclonal antibody in clinical development for HIV that we are aware of is TMB-335 referred to as ibalizumab being developed by TiaMed Biologics. Ibalizumab targets the CD4 receptor on T-cells which is one of the two co-receptors required for HIV entry into T-cells. However, CD4 is the T-cell receptor for recognizing targets of the immune response and critical for immunologic responses. We believe that targeting CD4 will interfere with immune function to an undesirable extent and if developed further will vastly limit the potential of ibalizumab as an effective anti-HIV therapy.

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.

Manufacturing

We do not own or operate manufacturing facilities for the production of PRO 140. We expect to depend on third-party suppliers and manufacturing organizations for all of our clinical trial quantities of PRO 140, in addition to previously manufactured supplies of PRO 140. 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 PRO 140 in a cost-efficient

manner.

We have developed and validated a current good manufacturing practice (cGMP) process to manufacture PRO 140, through a single contract manufacturer, FUJIFILM Diosynth Biotechnologies U.S.A., Inc. This contract manufacturer previously produced multi-Kg scale bulk batches of PRO 140 under cGMP for our Phase 2 clinical studies and is capable of producing sufficient quantities of PRO 140 for all the clinical studies required prior to submitting a BLA to the FDA. In addition, we have undertaken certain comparability studies which supported the use of previously manufactured amounts of PRO 140 in current and planned clinical studies. This process has been completed and all PRO 140 drug substance can be used in our clinical trials.

Research and Development Costs

Our research and development expenses totaled approximately $13.7 million and $15.2 million for the fiscal years ended May 31, 2016 and May 31, 2015, respectively. We expect the Company s research and development expenses to continue to increase in future periods as the activity within the Company s clinical trials expands and the Company s biologics manufacturing processes and related regulatory compliance activities increase.

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Employees and Consultants

We have five full-time employees, our CEO, CFO, Senior Vice President of Manufacturing, Associate Director Process Sciences and Director of Accounting, as well as several independent consultants assisting us with our clinical trials of PRO 140 and manufacturing activities. 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 an all-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 is in the later stages of clinical trials, and we expect to commence significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales. During the fiscal years ended May 31, 2016 and 2015, we incurred net losses of approximately $25.7 million and $25.1 million, respectively, and at May 31, 2016, we had an accumulated deficit of approximately $97.2 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 shareholder 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.

We will need substantial additional funding to complete our Phase 2b and Phase 3 clinical trials for PRO 140 for HIV-related treatments, to continue our Phase 2 clinical trial for Graft versus Host Disease, or GvHD, 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 shareholders.

The discovery, development, and commercialization of new treatments, such as our PRO 140 product candidate, entail significant costs. We expect the total estimated expenses for our Phase 3 combination therapy trial may range from approximately $12 million to $14 million and the total estimated expenses for our Phase 3 monotherapy trial may range from $15 million to $17 million. Our total estimated expenses for the Phase 2 GvHD trial are approximately $4 million. The total estimated expenses for our recently announced Phase X treatment naïve trial may range from $5 million to $6 million. In addition, to the extent further development and clinical trials of PRO 140 and other products 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;

build or access manufacturing and commercialization capabilities;

pay required license fees, milestone payments, and maintenance fees to Progenics (from which we acquired our PRO 140 product candidate), Lonza and AbbVie Inc. (formerly PDL);

develop, test, and, if approved, market our product candidate;

acquire or license additional internal systems and other infrastructure; and

hire and support additional management and scientific personnel.

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.

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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 shareholders 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 Phase 3 clinical trials for PRO 140 for HIV-related treatments, our Phase 2 clinical trial for GvHD and other clinical trials and 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 research program.

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 Phase 3 clinical trials for HIV-related treatments, our Phase 2 clinical trial for GvHD, and other clinical trials we are undertaking or may in the future pursue with PRO 140;
- the time and costs involved in obtaining regulatory approvals;
- whether we receive additional cash upon the exercise of our outstanding options and warrants 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 shareholder 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.

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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 PRO 140 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 PRO 140.

Under the Progenics Purchase Agreement, the PDL License and the Lonza Agreement, we must pay to Progenics, AbbVie Inc. (formerly PDL) 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 PRO 140. 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 PRO 140 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 Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on July 30, 2012, and Exhibit 10.21 to our Annual Report on Form 10-K for the fiscal year ended May 31, 2013, filed with the SEC on August 29, 2013, and Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on August 4, 2015, as amended on August 19, 2015.

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 and implement. 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. We estimate that it may take as much as two years to complete the necessary clinical trials, obtain regulatory approval from the FDA or other non-U.S. regulatory agency, and begin to commercialize PRO 140, even if trials are successful, of which there can be no assurance. Clinical trials for our other drug candidates may take significantly longer to complete, if they are pursued at all.

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

- 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;

- 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;

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;

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.

Testing of our primary product candidate, PRO 140, is ongoing and our clinical trial results may not ultimately confirm initial positive indications, which would materially and adversely affect our business, financial condition and stock price.

Our efforts to commercialize PRO 140 are dependent on obtaining FDA or other non-U.S. regulatory agency approval of its use in HIV-infected patients. 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 PRO 140, including negative results in future clinical trials, the development by competitors of other products with equal or better results, or inability to obtain sufficient additional funding to continue to pursue development. Failure to successfully develop PRO 140 would have a material and adverse effect on our business, financial condition and stock price, and would threaten our ability to continue to operate our business, particularly since PRO 140 is the only product candidate we are actively pursuing at this time.

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

The FDA designated PRO 140 as a candidate 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 Investigational New Drug (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 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 PRO 140, for certain HIV-related treatments, such a designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that PRO 140 will receive marketing approval in the United States.

We applied with the FDA for breakthrough therapy designation for PRO 140, for certain HIV-related treatments. The FDA, in its comments to us, requested additional trial data to support our request for such designation. We are currently evaluating the benefits of conducting a small trial or seeking other alternatives to provide the requested data. 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 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 PRO 140 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 PRO 140 does qualify as a breakthrough therapy, the FDA may later decide that PRO 140 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 PRO 140.

Although we have applied with the FDA for orphan drug designation for PRO 140, for certain GvHD-related treatments, we may not be able to obtain or maintain orphan drug designation or orphan drug exclusivity for PRO 140.

We have applied with the FDA for designation of PRO 140 as an orphan drug, in connection with our Phase 2 trial for GvHD. The FDA, in its comments, has provided us one year to provide certain requested data from our GvHD trial or alternatively from certain animal studies. Under the Orphan Drug Act, the FDA may designate a drug for relatively small patient populations as an orphan drug, if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Even if we obtain orphan drug designation for PRO 140, we may not be able to obtain orphan drug exclusivity for PRO 140. 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 if we obtain orphan drug exclusivity for PRO 140, that 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.

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

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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.

We do not have internal research and development personnel, making us dependent on consulting relationships and strategic alliances with industry partners.

We currently have no research and development staff or coordinators. We rely and intend to continue to rely on third parties for many of these functions. We engaged Amarex Clinical Research, LLC (Amarex), a full service clinical 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 approval of our PRO 140 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 candidates, 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.

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 additional 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 counter-parties. 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.

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

Prior to receiving approval to commercialize PRO 140 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 it or any other product candidate is sufficiently safe and effective with substantial evidence from well-controlled clinical trials. 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 candidates are 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 candidates, the results of preclinical studies do not necessarily predict the results of clinical trials. In addition, even if we

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believe the data collected from clinical trials of our product candidates 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 products or if we fail to maintain regulatory compliance, we would be unable to commercialize our products, and our business, results of operations and financial condition would be harmed.

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 candidates 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 candidates 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 potential product candidates 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 potential product candidates, or that gain or maintain greater market acceptance, we may not be able to compete effectively.

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 regulations and similar foreign laws and standards. If our contract manufacturers fail to maintain ongoing compliance at any time, the production of our product candidates could be interrupted, resulting in delays or discontinuance of our clinical trials, additional costs and loss of potential revenues.

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We may not be able to successfully manufacture our product candidates 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 candidates and commercializing approved products, 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. We may not be able to successfully increase the manufacturing capacity for any of our product candidates 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 candidates in sufficient quality and quantity, the regulatory approval or commercial launch of such product candidates may be delayed, which could significantly harm our business.

We may be subject to potential product liability and other claims that could materially impact 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 candidates 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.

Legislative, regulatory, or medical cost reimbursement changes may adversely impact 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 European Union, 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.

If we are unable to effectively implement or 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 both May 31, 2016, and May 31, 2015, 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 implement new or improved controls necessary to remedy the material weaknesses described above, or difficulties encountered in the implementation or operation of these controls, could harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Our 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

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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.

Known third party patent rights could delay or otherwise adversely affect our planned development and sale of PRO 140. 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 PRO 140 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 PRO 140, there can be no assurance that this will be the case. The relevant patent expires before we expect to commercially introduce PRO 140. 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 PRO 140 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 PRO 140 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 PRO 140, our patent counsel conducted a freedom-to-operate search that identified other patents that could relate to our proposed PRO 140 candidate. Sufficient research and analysis was conducted to enable us to reach the conclusion that PRO 140 likely does not infringe those patent rights. However, we did not have an exhaustive analysis conducted as to the identified patent rights, because doing so would have been more costly than appeared to be justified. If any of the holders of the identified patents were to assert patent rights against us, the development and sale of PRO 140 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 candidates depends on our ability to use, manufacture and sell those products 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 product candidates and seeking new potential product candidates. There may be existing patents, unknown to us, on which our activities with our product candidates 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.

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

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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 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 a going concern opinion in connection with the audit of our annual financial statements for the fiscal year ended May 31, 2016. A going concern opinion means that there is substantial doubt that the company 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.

Risks Relating to Our Common Stock

The significant number of shares of common stocks 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, 2016 , we have 7,245,158 shares subject to outstanding options under our stock option plans, 2,000,930 shares reserved for future issuance under our equity compensation plan and 56,062,092 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 market price for our common shares has been and is likely to continue to be volatile.

The market price for our common stock has been and is likely to continue to be volatile. 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 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.

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We do not expect any cash dividends to be paid on our shares in the foreseeable future.

We have never declared or paid a cash dividend 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, 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 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.

If the beneficial ownership of our stock continues to be 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 Stock Ownership by Principal Stockholders and Management 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 4,600,000 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

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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.

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 ay 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. Effective May 1, 2016, we entered into a new lease with our current landlord to increase our commercial office space from 1,383 to 1,812 square feet, pursuant to a lease that expires on April 30, 2021 at a cost of $3,209 per month, plus modest annual increases.

Item 3. Legal Proceedings.

From time to time, we are involved in claims and suits that arise in the ordinary course of the Company s 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.

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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, 2016:		
First quarter ended August 31, 2015	$ 1.08	$ 0.70
Second quarter ended November 30, 2015	$ 0.99	$ 0.67
Third quarter ended February 29, 2016	$ 1.40	$ 0.64
Fourth quarter ended May 31, 2016	$ 1.57	$ 0.76
Fiscal Year Ended May 31, 2015:		
First quarter ended August 31, 2014	$ 0.85	$ 0.72
Second quarter ended November 30, 2014	$ 1.25	$ 1.18
Third quarter ended February 28, 2015	$ 0.84	$ 0.78
Fourth quarter ended May 31, 2015	$ 1.09	$ 0.63

Holders

The number of record holders of our common stock on May 31, 2016, was approximately 570.

Dividends

Holders of our common stock are entitled to receive dividends as may be declared from time to time by our Board. We have not paid any cash dividends since inception on our common stock and do not anticipate paying any in the foreseeable future. The Company s current policy is to retain earnings, if any, for use in our operations.

Holders of 95,100 shares of Series B 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, 2016, if the Company declared a dividend and elected pay such dividend in the form of common stock, approximately 304,000 shares of common stock would be issued in the form of dividend.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of our equity securities during the year ended May 31, 2016 or subsequent interim period.

Item 6. Selected Financial Data.

This item is not required for smaller reporting companies.

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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

Over the past two fiscal years ending May 31, 2016 and 2015, the Company commenced several initiatives to advance our lead product candidate, PRO 140. The following is a brief summary of key accomplishments:

Raised approximately $33.7 million, net of offering costs, in capital through private equity offerings;

Raised approximately $7.1 million, net of offering costs, in capital through short-term private convertible debt offerings;

Received approximately $1.7 million in proceeds from the exercise of warrants;

Induced the conversion of approximately $10 million in aggregate principal amount of convertible promissory notes into common stock resulting in the retirement or conversion of all previously outstanding debt;

Prepared and delivered finished drug product of PRO 140 for our first self-sponsored Phase 2b monotherapy clinical trial, known as our treatment substitution study;

Successfully concluded the self-sponsored, self-funded Phase 2b clinical trial for a PRO 140 monotherapy study;

Obtained FDA clearance to initiate an extension study of the Phase 2b monotherapy trial;

Obtained FDA clearance to initiate two Phase 3 clinical trials for patients with HIV;

Obtained FDA clearance to initiate a Phase 2 trial for GvHD, the first non-HIV clinical indication for PRO 140;

Obtained FDA clearance for a compassionate use protocol to accommodate the first patient who successfully completed the Phase 3 combination trial;

Further advanced preparations for the manufacturing of new cGMP PRO 140 antibody material, including the hiring of a senior vice president to oversee all CMC activities;

Results of Operations

Clinical Trials Update

Phase 2b Treatment Substitution This monotherapy trial was initially completed in January 2015. Several patients are continuing in extension studies on this monotherapy of a weekly injection of PRO 140. Results from these extension studies thus far indicate patients are now reaching two years of suppressed viral load since their first date of enrollment. The trial s topline report was submitted to the FDA in February 2016.

Phase 2b/3 Combination Therapy Trial A pivotal 25-week trial for PRO 140 as a combination therapy to existing HAART drug regimens involving originally designed for 300 patients. Enrollment of the first patient was announced in October 2015 and the first patient to have completed this trial has now transitioned to a compassionate use protocol, as requested by the treating physician to enable the patient to continue with a suppressed viral load. In early March, 2016, the Company submitted to the FDA an amendment to its pivotal combination PRO 140 protocol. The FDA recently agreed to reduce the number of patients in this study from 300 to 150 patients. The protocol amendment has also received Institutional Review Board (IRB) approval. Management estimates the total cost of this trial to range from $12 million to $14 million.

Phase 3 Monotherapy Trial A strategic trial including 300 patients to assess the treatment strategy of using PRO 140 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 number of patients who can maintain suppressed viral load under a PRO 140 monotherapy replacing their HAART regimen for 48 weeks. The secondary endpoint is the number of weeks a patient is off of their ART regimen. Enrollment of first patient is expected to occur within the next quarter and is expected to accelerate, as experienced in the previous Phase 2b monotherapy trial. Management estimates the total cost of this trial to range from $15 million to $17 million.

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Phase 2 Graft versus Host Disease Trial This Phase 2, randomized, double-blind, placebo-controlled, multi-center 100-day study with 60 patients is designed to evaluate the feasibility of the use of PRO 140 as an add-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 has not been announced. Management estimates the cost of this trial to be approximately $3.5 million to $4 million.

Phase 2b Monotherapy for Treatment-Naïve Patients Trial This Phase 2b, randomized, double-blind, placebo-controlled, multi-center study is designed to evaluate the safety and efficacy of PRO 140 SC compared to placebo for the reduction of viral load in 60 treatment-nalve adults patients with HIV-1 infection for a period of two weeks. Upon randomization, subjects will receive two doses of PRO 140 or placebo given seven days apart. The first dose of PRO 140 or placebo will be given on the day of randomization followed by second dose (one week after) at the initiation of HAART. Study participants will be monitored for one year following initiation of HAART. Management estimates the total cost of this trail to be approximately $5 million to $6 million.

Results of operations for the year ended May 31, 2016, compared to May 31, 2015 are as follows:

For the years ended May 31, 2016 and 2015, the Company had no activities that produced revenues from operations.

For the years ended May 31, 2016 and 2015, The Company incurred net losses of approximately $25.7 million and $25.1 million, respectively. The increase in net loss of approximately $0.6 million for fiscal 2016 over fiscal 2015 was primarily attributable to an increase in general and administrative and legal, offset by a reduction in research and development expenses and the non-cash benefit from a change in derivative liability.

Total operating expenses for the years ended May 31, 2016 and 2015, are as follows:

	2016	2015
General and administrative:		
Salaries and other compensation	$ 1,341,000	$ 1,330,000
Stock-based compensation	2,353,000	631,000
Accounting and consulting	141,000	134,000
Other	1,952,000	1,188,000
Total general and administrative	5,787,000	3,283,000
Legal	1,295,000	797,000
Research and development	13,731,000	15,156,000
Amortization and depreciation	362,000	361,000
Total operating expenses	$ 21,175,000	$ 19,597,000

The increase in fiscal 2016 total operating expenses of approximately $1.6 million, or 8%, over fiscal 2015 was primarily related to the increase in legal and non-cash stock-based compensation expenses, offset in part by the reduction in research and development.

Salaries and other compensation increased slightly from approximately $1,330,000 in fiscal year 2015 to approximately $1,341,000 for the year ended May 31, 2016 due to the addition of an employee, offset by a reduction

in incentive compensation.

Stock-based compensation increased approximately $1.7 million, or 273%, from approximately $631,000 for the year ended May 31, 2015, to approximately $2,353,000 for the year ended May 31, 2016. The increase in expense was attributable to the achievement of specific performance milestones within certain long-term incentive stock options for management.

Other operating expenses of approximately $1,952,000 for fiscal 2016 increased approximately $764,000, or 64%, over fiscal 2015 owing to increased insurance costs, travel, investor relations and professional fees, offset in part by reductions in certain other administrative expenses.

Legal expenses increased approximately $498,000, or 62%, from approximately $797,000 for the year ended May 31, 2015 to approximately $1,295,000 for the year ended May 31, 2016. The trend in legal expenses will continue to reflect the Company s capital raising activities, complexity of certain regulatory filings, and continued effective management of its intellectual property portfolio.

Research and development (R&D) expenses of approximately $13.7 million for fiscal 2016 decreased approximately $1.4 million over fiscal 2015, principally due to milestone payments accrued and paid in 2015, offset in part by the incurrence of additional license fees in fiscal year 2016. The fiscal 2016 expenditures were primarily devoted to (1) clinical trial development and management of the recently completed Phase 2b monotherapy trial, extension study of the Phase 2b monotherapy trial, initiation of a Phase 2 GvHD trial, two Phase 3 trials and (2) CMC (chemistry, manufacturing and controls) activities to provide finished PRO 140 drug product for ongoing clinical trials, address regulatory compliance requirements of a future BLA filing and to advance the preparations for manufacturing new PRO 140.

The Company expects research and development expenses to continue to increase in future periods as the activity within its clinical trials expands and the biologics manufacturing processes and related regulatory compliance activities increase.

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The Company records research and development expenses where directly identifiable as follows:

	Year Ended May 31,	
	2016	2015
Research and development:		
Clinical	$ 6,468,000	$ 4,383,000
Non-Clinical	21,000	
CMC	6,214,000	7,181,000
Licenses and patent fees	1,028,000	1,092,000
Milestone payments		2,500,000
Total research and development	$ 13,731,000	$ 15,156,000

The Company issued two convertible promissory notes during the fiscal year ended May 31, 2015, to Alpha Venture Capital Partners, L.P. and it affiliate (AVCP) in the principal amount of approximately $3.5 million. Each contain a provision for potential adjustment of the conversion rate of the note, commonly known as an anti-dilution or round down provision. Carl C. Dockery, one of our directors, is the sole member of Alpha Advisors, LLC, and the investment advisor for AVCP. Pursuant to U.S. GAAP, each of the notes require the recognition of a derivative liability. Accordingly, the Company incurred a non-cash charge of approximately $0.8 million during fiscal year ended May 31, 2015 and a non-cash benefit or credit of approximately $0.6 million during fiscal year ended May 31, 2016. In June 2015, the Company entered into a Debt Conversion and Termination Agreement, whereby AVCP converted its two promissory notes into an aggregate of 5,237,966 shares of common stock and received a warrant to purchase up to 1,000,000 shares of common stock at an exercise price of $0.675 and agreed to terminate its rights under its purchase agreements, including future investment rights. The Company recognized a non-cash loss of approximately $584,000 in connection with the debt conversion and termination.

Interest expense for fiscal 2016 totaled approximately $4.7 million, of which all but approximately $0.1 million was non-cash. Interest expense for fiscal 2016 was comprised of approximately (i) $1.8 million (non-cash) related to amortization of debt discounts, (ii) $2.1 million (non-cash) arising from inducements to convert debt into shares of common stock by either a reduction in exercise price of debt, a reduction in exercise price of warrants upon immediate exercise or the extension of expiration dates on certain warrants for previously converted debt and (iii) $0.6 million related to the amortization of previously paid debt issuance costs. U.S. GAAP requires the recognition of debt discounts when the conversion feature of a convertible note is beneficial at the commitment date. The debt discounts represent the sum of the intrinsic value of the conversion feature and the fair value of the detachable warrants issued with the notes. The combined discounts are limited to the note proceeds. The value of the debt discount is amortized over the term of the note as interest expense and the amortization is accelerated upon conversion prior to maturity date.

The future trends in all expenses will be driven, in part, by the future outcomes of our clinical trials and the correlative effect on general and administrative expenses, especially FDA regulatory requirement, in addition to the manufacturing of new commercial grade POR 140, along with the necessary regulatory processes to confirm its qualification for future sale, if approved. The Company s ability to continue to fund operations will continue to depend on its ability to raise additional capital. See, in particular, Item 1A Risk Factors above.

Liquidity and Capital Resources

The Company had cash and cash equivalents of approximately $9.6 million as of May 31, 2016, compared with approximately $1.1 million as of May 31, 2015. The net increase in cash and cash equivalents over a year ago was attributable to net cash provided by financing activities of approximately $33.7 million from private equity raises and proceeds from the exercise of warrants, offset in part by repayment of convertible notes of approximately $0.8 million and net cash used in operating activities of approximately $24.8 million.

As of May 31, 2016, the Company had positive working capital of approximately $7.9 million, which compares to negative working capital of $8.7 million at May 31, 2015.

Cash Flows

Net cash used in operating activities was approximately $24.8 million during fiscal year 2016, which represents an increase of approximately $12.8 million from net cash used in operating activities of approximately $12 million in fiscal 2015. The increase in the net cash used in operating activities for fiscal 2016 as compared to fiscal 2015 was primarily attributable to the reduction in current liabilities by approximately $5.4 million, an increase in prepaid expenses of approximately $0.9 million and the change in fair value derivative of approximately $0.6 million, offset in part by non-cash amortization of debt related costs of approximately $2.5 million, loss on extinguishment of debt of approximately $0.6 million, stock-based compensation of approximately $2.3 million and non-cash inducement interest expense of approximately $1.9 million.

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Net cash provided by financing activities of approximately $33.4 million for the year ended May 31, 2016 included net proceeds of approximately $33.7 million from private equity offerings, proceeds of approximately $0.5 million from the exercise of warrants, offset by approximately $0.8 million for the repayment of convertible debt. As of May 31, 2016, the Company had no outstanding convertible promissory notes.

As mentioned above, the Company has no activities that produced revenue in fiscal year 2016 and 2015 and have sustained operating losses since inception. Since inception, the Company has financed its activities principally from the sale of private equity and debt securities. The Company intends to finance its future operating and development activities, including its working capital needs, largely from the sale of equity securities, combined with additional funding from other traditional financing sources. The sale of equity and convertible debt securities may result in dilution to the Company s stockholders and those securities may have rights senior to those of the Company s common stock. If the Company raises 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 the Company s operations. Any other third party funding arrangements could require the Company to relinquish valuable rights.

If the Company is unsuccessful in raising additional capital in the future, it may be required to reduce or cease its operations.

Capital Requirements

The Company has not generated revenue to date, and will not generate product revenue in the foreseeable future. The Company expects to continue to incur sizable operating losses as it proceeds with the clinical trials with PRO 140 and continue to advance it through the product development and regulatory process in an effort to seek FDA approval. In addition to increasing research and development expenses, the Company expects general and administrative and manufacturing costs to increase, as it adds personnel and other administrative expenses associated with its current operating objectives.

The Company has entered into project work orders for each of its clinical trials with its clinical research organization (CRO) and related laboratory vendors. Under the terms of these agreements, the Company has paid approximately $2.0 million towards execution fees for direct services costs. The fees are reflected as a current asset and have an unamortized balance of approximately $1.7 million at May 31, 2016. In connection with the Company s clinical trials, it has entered into separate project work orders for each trial with its CRO. 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 from an approximate low of $0.1 million to an approximate high of $0.4 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 $1.6 million.

Under the Progenics Purchase Agreement, the Company acquired PRO 140 from Progenics in October 2012 and paid $3,500,000 in cash to Progenics to close the acquisition transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) $1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-U.S. equivalent, which was paid during the fiscal year ended May 31, 2016; (ii) $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 (iii) royalty payments of up to five percent (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.

Payments to Progenics are in addition to certain milestone payments and royalties due to AbbVie Inc. (formerly PDL) under the PDL License as follows: (i) $1,000,000 upon initiation of a Phase 3 clinical trial, which was paid during the fiscal year ended May 31, 2016; (ii) $500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) $500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iv) royalties of up to 7.5% 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 more fully described above, the Company was obligated to Lonza, pursuant to the Lonza Agreement, for the approximate one-time amount of $807,000 (using exchange rates in effect at the time of payment) in connection with Lonza s system-know how technology with respect to the Company s use of proprietary cell lines to manufacture new PRO 140 material. This amount was previously accrued in the fiscal year ended May 31, 2016 and was timely paid to Lonza on June 30, 2016. Ongoing annual license fees with Lonza are £300,000 payable in December of each year.

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 Progenics and its sub-licensors are deemed contingent consideration and, therefore, are not currently accruable.

The future trends of all expenses will be driven, in part, by the future outcomes of the clinical trials and their correlative effect on general and administrative expenses, especially FDA regulatory requirements, in addition to the manufacturing of new commercial grade PRO 140, along with the necessary regulatory processes to confirm its qualification for future sale, if approved. The Company will require a significant amount of additional capital in the future to fulfill BLA requirements related to manufacturing PRO 140 for commercial use.

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Going Concern

The Company s ability to continue as a going concern is dependent upon its ability to raise additional capital, commence operations and achieve a level of profitability. The Company has not generated revenue to date, and will not generate product revenue in the foreseeable future. The Company expects to continue to incur operating losses as it proceeds with clinical trials with respect to PRO 140 and continue to advance it through the product development and regulatory process. In addition to increasing research and development expenses, the Company expects general and administrative and manufacturing costs to increase, as the Company adds personnel and other administrative expenses associated with its current efforts.

The Company s ability to continue as a going concern will be contingent upon its ability to raise additional capital to fund its operations. If the Company is unsuccessful in raising additional capital in the future, it may be required to cease its operations. See, in particular, Item 1A (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. The Company has incurred losses for all periods presented and has a substantial accumulated deficit. As of May 31, 2016, these factors, among others, raise substantial doubt about the Company s ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability 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 candidates, obtain FDA approval, outsource manufacturing of its products, and ultimately to attain profitability. The Company intends to seek additional funding through equity offerings or licensing agreements or strategic alliances to implement its business plan. There are no assurances, however, that the Company 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 ASC 815 Derivatives and Hedging (ASC 815), FASB ASC 480 Distinguishing liabilities from equity , ASC 470, Debt and debt with conversion and other options. 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., interest rates, security price, variable conversion rate or other variable), require no initial net investment and permit net settlement. Derivative financial instruments may be

free-standing or embedded in other financial instruments. The Company has induced conversion of certain instruments with bifurcated conversion options. The Company has followed the general extinguishment model to record certain conversion and the extinguishment of derivative liabilities. The Company 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.

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We have historically issued convertible promissory notes with detachable warrants to purchase common stock. The conversion options are fixed, but 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 6 and 10 to the consolidated financial statements, we have significant contingent potential milestone and royalty liabilities. We must estimate the likelihood of paying these contingent liabilities periodically based on the progress of our clinical trials.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

This item is not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

CYTODYN INC.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders

CytoDyn Inc.

Vancouver, Washington

We have audited the accompanying consolidated balance sheets of CytoDyn Inc. as of May 31, 2016 and 2015, and the related consolidated statements of operations, changes in stockholders equity (deficit), and cash flows for each of the years in the two-year period ended May 31, 2016. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required at this time, to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CytoDyn Inc. as of May 31, 2016 and 2015 and the results of its operations and its cash flows for each of the years in the two-year period ended May 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

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 $25,703,612 for the year ended May 31, 2016, and has an accumulated deficit of $97,225,914 through May 31, 2016, which raises a 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.

/s/ Warren Averett, LLC

Warren Averett, LLC

Certified Public Accountants

Tampa, Florida

July 19, 2016

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CytoDyn Inc.

Consolidated Balance Sheets

	May 31, 2016	May 31, 2015
Assets		
Current assets:		
Cash	$ 9,641,776	$ 1,050,060
Prepaid expenses	141,714	253,833
Prepaid clinical trial fees	1,710,852	733,916
Total current assets	11,494,342	2,037,809
Furniture and equipment, net	24,550	24,213
Intangibles, net	2,267,239	2,617,239
Total Assets	$ 13,786,131	$ 4,679,261
Liabilities and Shareholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,467,973	$ 5,016,261
Accrued milestone payments		2,500,000
Accrued liabilities and salaries	242,708	644,533
Accrued license fee	870,000	930,000
Convertible notes payable, net		1,634,458
Total current liabilities	3,580,681	10,725,252
Long-term liabilities		
Related party, convertible note payable, net		2,637,618
Related party, derivative liability		2,008,907
Total liabilities	3,580,681	15,371,777
Shareholders equity (deficit):		
Series B convertible preferred stock, $.001 par value; 400,000 shares authorized, 95,100 shares issued and outstanding at May 31, 2016 and May 31, 2015, respectively	95	95
Common stock, $.001 par value; 250,000,000 and 100,000,000 shares authorized, 123,335,634 and 63,644,348 issued and outstanding at May 31, 2016 and May 31, 2015, respectively	123,336	63,644
Additional paid-in capital	107,307,933	60,766,047
Accumulated (deficit)	(97,225,914)	(71,522,302)
Total shareholders equity (deficit)	10,205,450	(10,692,516)
Total liabilities and shareholders equity	$ 13,786,131	$ 4,679,261

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Operations

	Year ended May 31, 2016	2015
Operating expenses:		
General and administrative	$ 5,787,366	$ 3,292,908
Amortization and depreciation	361,610	360,582
Research and development	13,731,426	15,156,365
Legal fees	1,295,109	786,671
Total operating expenses	21,175,511	19,596,526
Operating loss	(21,175,511)	(19,596,526)
Interest income	7,918	2,199
Gain on settlement of accounts payable	72,898	
Loss on extinguishment of convertible notes	(584,177)	
Change in fair value of derivative liability	646,505	(838,643)
Interest expense:		
Amortization of discounts on convertible notes	(1,791,967)	(2,145,010)
Amortization of discounts on related party convertible notes	(94,344)	(523,614)
Amortization of debt issuance costs	(604,625)	(103,598)
Inducement interest	(2,061,600)	(1,526,254)
Interest on notes payable	(118,709)	(356,624)
Total interest expense	(4,671,245)	(4,655,100)
Loss before income taxes	(25,703,612)	(25,088,070)
Provision for taxes on income		
Net loss	$ (25,703,612)	$ (25,088,070)
Basic and diluted loss per share	$ (0.27)	$ (0.43)
Basic and diluted weighted average common shares outstanding	95,437,594	58,375,637

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statement of Changes in Shareholders Equity (Deficit)

	Preferred Stock		Common Stock		Additional Paid-In
	Shares	Amount	Shares	Amount	Capital
Balance May 31, 2014	95,100	$ 95	55,753,311	$ 55,753	50,678,616
Rescission expirations and exclusions					
Amortization of deferred offering costs related to rescission liability					(68,292)
Common stock for interest on convertible note			104,153	104	51,973
OID, intrinsic value related to warrants					2,505,261
Conversion of convertible debt to common stock ($0.75)/share			5,628,330	5,628	4,215,622
Conversion of accrued interest on convertible debt to common stock ($0.75/share)			119,580	120	86,176
Exercise of common stock warrants ($0.55/share)			1,938,974	1,939	1,064,496
Exercise of common stock warrants ($0.75/share)			100,000	100	74,900
Stock-based compensation					631,302
Inducement interest on note conversions and warrant exercises					555,626
Inducement interest on reissued warrants					970,367
Net (loss) for year ended May 31, 2015					
Balance at May 31, 2015	95,100	$ 95	63,644,348	$ 63,644	$ 60,766,047

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statement of Changes in Shareholders Equity (Deficit)

	Rescission Amount	Accumulated Deficit	Total
Balance May 31, 2014	$ (378,000)	$ (46,434,232)	$ 3,922,232
Rescission expirations and exclusions	378,000		378,000
Amortization of deferred offering costs related to rescission liability			(68,292)
Common stock for interest on convertible note			52,077
OID, intrinsic value related to warrants			2,505,261
Conversion of convertible debt to common stock ($0.75)/share			4,221,250
Conversion of accrued interest on convertible debt to common stock ($0.75/share)			86,296
Exercise of common stock warrants ($0.55/share)			1,066,435
Exercise of common stock warrants ($0.75/share)			75,000
Stock-based compensation			631,302
Inducement interest on note conversions and warrant exercises			555,626
Inducement interest on reissued warrants			970,367
Net (loss) for year ended May 31, 2015		(25,088,070)	(25,088,070)
Balance at May 31, 2015	$	$ (71,522,302)	$ (10,692,516)

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statement of Changes in Shareholders Equity (Deficit)

	Preferred Stock		Common Stock		Additional Paid-In
	Shares	Amount	Shares	Amount	Capital
Balance May 31, 2015	95,100	$ 95	63,644,348	$ 63,644	$ 60,766,047
Warrant issued related to conversion inducement					757,871
Modification of warrants related to conversion inducement					866,713
Debt discount due to reduction in note conversion price from ($0.75 to $0.675/share)					329,524
Conversion of convertible debt & accrued, unpaid interest to common stock ($0.675/share)			4,095,008	4,095	2,760,059
Conversion of convertible debt and extinguishment of derivative liability			5,274,656	5,275	4,727,239
Conversion of convertible debt & accrued, unpaid interest to common stock ($0.75/share)			792,201	792	593,360
Exercise of common stock warrants (cashless)			74,490	74	(74)
Exercise of common stock warrants ($0.50/share)			192,307	192	95,962
Exercise of common stock warrants ($0.75/share)			603,286	604	451,861
Stock-based compensation					2,353,194
Proceeds from private equity offering ($0.75/share)			44,357,838	44,358	33,224,106
Proceeds from private equity offering ($1.00/share)			4,301,500	4,302	4,297,198
Deferred offering costs					(3,915,127)
Net (loss) for year ended May 31, 2016					
Balance at May 31, 2016	95,100	$ 95	123,335,634	$ 123,336	$ 107,307,933

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CytoDyn Inc.

Consolidated Statement of Changes in Shareholders Equity (Deficit)

	Rescission Amount	Accumulated Deficit	Total
Balance May 31, 2015	$	$ (71,522,302)	$ (10,692,516)
Warrant issued related to conversion inducement			757,871
Modification of warrants related to conversion inducement			866,713
Debt discount due to reduction in note conversion price from ($0.75 to $0.675/share)			329,524
Conversion of convertible debt & accrued, unpaid interest to common stock ($0.675/share)			2,764,154
Conversion of convertible debt and extinguishment of derivative liability			4,732,514
Conversion of convertible debt & accrued, unpaid interest to common stock ($0.75/share)			594,152
Exercise of common stock warrants (cashless)			
Exercise of common stock warrants ($0.50/share)			96,154
Exercise of common stock warrants ($0.75/share)			452,465
Stock-based compensation			2,353,194
Proceeds from private equity offering ($0.75/share)			33,268,464
Proceeds from private equity offering ($1.00/share)			4,301,500
Deferred offering costs			(3,915,127)
Net (loss) for year ended May 31, 2016		(25,703,612)	(25,703,612)
Balance at May 31, 2016	$	$ (97,225,914)	$ 10,205,450

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Cash Flows

	Year Ended May 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (25,703,612)	$ (25,088,070)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	361,610	360,582
Amortization of debt issuance costs	604,625	103,598
Amortization of discounts on convertible notes	1,791,967	2,145,010
Amortization of discounts on related party notes	94,344	523,614
Loss on the sale of fixed asset		583
Gain on extinguishment of accounts payable	72,898	
Loss on extinguishment of convertible notes	584,177	
Change in fair value of derivative liability	(646,505)	838,643
Inducement interest expense	1,954,108	1,526,254
Stock-based compensation	2,353,194	631,302
Changes in current assets and liabilities:		
(Increase) in prepaid expenses	(864,817)	(498,928)
(Decrease) increase in accounts payable, accrued salaries and severance, accrued interest and accrued liabilities	(5,412,640)	7,440,554
Net cash used in operating activities	(24,810,651)	(12,016,858)
Cash flows from investing activities:		
Furniture and equipment purchases	(11,949)	(18,585)
Net cash used in investing activities	(11,949)	(18,585)
Cash flows from financing activities:		
Payments of offering costs	(3,915,127)	(423,104)
Proceeds from sale of common stock	37,569,964	
Proceeds from issuance of convertible notes payable		7,481,050
Payment of principal and interest on convertible notes payable	(789,140)	
Proceeds from exercise of warrants	548,619	1,141,435
Net cash provided by financing activities	33,414,316	8,199,381
Net change in cash	8,591,716	(3,836,062)
Cash, beginning of period	1,050,060	4,886,122
Cash, end of period	$ 9,641,776	$ 1,050,060

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Cash Flows

	Year Ended May 31, 2016	2015
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Income taxes	$	$ 3,142
Interest	$ 26,890	$ 203,864
Non-cash investing and financing transactions:		
Common stock issued upon conversion of convertible debt	$ 7,947,842	$ 4,221,250
Common stock issued or to be issued for accrued interest payable	$ 143,479	$ 138,373
Preferred and common stock subject to rescission liability	$	$ 378,000
Amortization of deferred offering costs related to rescission liability	$	$ 68,292
Accounts payable extinguished through settlements	$ 72,898	$
Original issue discount related to valuation of compound embedded derivative of convertible note payable issued with anti-dilution feature	$	$ 1,170,264
Original issue discount related to valuation of relative fair value of warrants issued with convertible notes payable	$	$ 2,220,143
Warrants issued for debt discount on convertible notes payable	$	$ 285,118

See accompanying notes to consolidated financial statements.

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CYTODYN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF MAY 31, 2016

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. We are a clinical-stage biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies to treat Human Immunodeficiency Virus (HIV) infection. Our lead product candidate, PRO 140, belongs to a class of HIV therapies known as entry inhibitors. These therapies block HIV from entering into and infecting certain cells.

The Company is developing a class of therapeutic monoclonal antibodies to address unmet medical needs in the areas of HIV and graft versus host disease.

Advanced Genetic Technologies, Inc. (AGTI) was incorporated under the laws of Florida on December 18, 2006 pursuant to an acquisition during 2006 and is currently a dormant subsidiary.

On May 16, 2011, the Company formed a wholly owned subsidiary, CytoDyn Veterinary Medicine LLC (CVM), to explore the possible application of the Company s existing monoclonal antibody technology to the treatment of Feline Immunodeficiency Virus. The Company views the formation of CVM as an effort to strategically diversify the use of its monoclonal antibody technology. This entity is currently a dormant subsidiary.

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, AGTI and CVM, both of which 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 2016 presentation. These reclassifications did not have any effect on total current assets, total assets, total current liabilities, total liabilities, total shareholders equity (deficit), net loss or earnings per share. The Company reincorporated in Delaware on August 27, 2015, which required a reclassification to reflect par value of common and preferred stock at $0.001 as of May 31, 2016 and May 31, 2015.

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 $25,703,612 and $25,088,070 for the years ended May 31, 2016 and May 31, 2015, respectively,

and has an accumulated deficit of $97,225,914 as of May 31, 2016. These factors, among others, raise substantial doubt about the Company s ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company s continuation as a going concern is dependent upon its ability to obtain additional operating capital, complete development of its product candidates, obtain U.S. Food & Drug Administration (FDA) approval, outsource manufacturing of the product candidates, and ultimately achieve initial revenues and attain profitability. The Company is currently engaging in significant research and development activities related to these product candidates, and expects to incur significant research and development expenses in the future. These research and development activities are subject to significant risks and uncertainties. The Company intends to finance future development activities and 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 accounting principles generally accepted in the United States of America, 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 expenses during the reporting period. Actual results could differ from those estimates.

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Cash

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. Balances in excess of federally insured limits at May 31, 2016 and May 31, 2015 approximated $9,392,000 and $1,164,000, 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 year ended May 31, 2016 and May 31, 2015. 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 9 and 10.

Research and Development

Research and development costs are expensed as incurred. Clinical trials 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 marketing 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 Biologics License Application 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, 2016 and May 31, 2015, the Company did not have pre-launch inventory that qualified for capitalization pursuant to U.S. GAAP ASC 330 Inventory.

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).

The Company accounts for stock based awards based on 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 at 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. U.S. GAAP requires forfeitures to be estimated 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 March 18, 2016, at a special meeting of shareholders, a proposal was approved to increase the total number of authorized shares of common stock of the Company from 200,000,000 to 250,000,000.

Preferred Stock

The Company s Board of Directors is currently authorized to issue up to 5,000,000 shares of preferred stock without shareholder approval. As of May 31, 2016, the Company has authorized the issuance of 400,000 shares of Series B convertible preferred stock, of which 95,100 shares are outstanding. The remaining preferred shares authorized have no specified rights.

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Debt Issuance Costs

The Company has early adopted ASU 2015-03, as described in Note 8, which requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability and to be amortized over the life on the debt. During the year ended May 31, 2015, the Company incurred direct costs associated with the issuance of short-term convertible notes as described in Note 3, and recorded approximately $709,000 of debt issuance costs and approximately $605,000 and $104,000 of related amortization for the years ended May 31, 2016 and May 31, 2015, respectively.

Offering Costs

During the year ended May 31, 2016, the Company incurred approximately $3.9 million 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 Note 7.

Stock for Services

The Company periodically issues stock based awards to consultants for various services. Costs of these transactions are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. The value of the award is measured at the earlier of (i) the date at which a firm commitment for performance by the counterparty to earn the equity instruments is reached or (ii) the date at which the counterparty s performance is complete.

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 63,307,150 and 31,008,915 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, 2016 and May 31, 2015, respectively. Additionally, as of May 31, 2016, shares of Series B convertible preferred stock in the aggregate of 95,100 shares can potentially convert into 951,000 shares of common stock.

Fair Value of Financial Instruments

At May 31, 2016 and May 31, 2015 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 FASB ASC 815 Derivatives and Hedging (ASC 815), as their instruments are recorded as a derivative liability, at fair value, 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 we were unable to corroborate with observable market data.

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Liability measured at fair value on a recurring basis by level within the fair value hierarchy as of May 31, 2016 and May 31, 2015 is as follows:

	Fair Value Measurement at May 31, 2016(1)		Fair Value Measurement at May 31, 2015 (1)	
	Using Level 3	Total	Using Level 3	Total
Liability:				
Derivative liability	$	$	$ 2,008,907	$ 2,008,907
Total liability	$	$	$ 2,008,907	$ 2,008,907

(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, 2016 and 2015.

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, so the Company uses a Binomial Lattice Model to estimate the value of the derivative liability. A Binomial Lattice Model was used because management believes it reflects all the assumptions that market participants would likely consider in negotiating the transfer of the convertible notes including the potential for early conversion or adjustment of the conversion price due to a future dilutive issuance. The Company s derivative liability is classified within Level 3 of the fair value hierarchy because certain unobservable inputs were used in the valuation model.

The following is a reconciliation of the beginning and ending balances for the liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the years ended May 31, 2016 and 2015:

Balance at May 31, 2014	$
Note issuance, September 26, 2014	767,038
Note issuance, February 6, 2015	403,226
Fair value adjustments	838,643
Balance at May 31, 2015	$ 2,008,907
Note conversion June 24, 2015	(521,133)
Note conversion June 24, 2015	(841,269)
Fair value adjustments	(646,505)
Balance at May 31, 2016	$

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 ASC 740-10 Uncertainty in Income Taxes (ASC 740-10). 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.

Note 3 Convertible Instruments

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) at $5.00 per share for cash proceeds totaling $2,009,000, of which 95,100 shares remain outstanding at May 31, 2016. Each share of the Series B 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 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

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shareholders approved an increase in the authorized shares of common stock to 100,000,000. At the commitment date, which occurred upon such shareholder approval, the conversion option related to the Series B was beneficial. The intrinsic value of the conversion option at the commitment date resulted in a constructive dividend to the Series B holders of approximately $6,000,000. The constructive dividend increased and decreased additional paid-in capital by identical amounts. The Series B has liquidation preferences over the common shares at $5.00 per share plus any accrued dividends. Dividends are payable to the Series B 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 holders have no voting rights.

2013 Convertible Notes

During the year ended May 31, 2013, the Company issued $6,588,250 in aggregate original principal amount of unsecured convertible notes (the 2013 Convertible Notes) to investors for cash. Each outstanding 2013 Convertible Note was convertible at the election of the holder at any time into common shares at a fixed conversion price. At issuance, total principal of $6,208,250 was convertible at $0.75 per share, and $380,000 was convertible at $0.65 per share. The 2013 Convertible Notes were payable in full between November 30, 2013 and March 6, 2016, with interest rates ranging from 5% to 10% per year, payable in cash semi-annually in arrears beginning on April 1, 2013. At May 31, 2016, there were no outstanding 2013 Convertible Notes. At May 31, 2015 there was one 2013 Convertible Note outstanding with an aggregate original principal amount of $50,000, convertible at $0.75 per share, bearing interest at a rate of 5% per year, and was payable in full on October 15, 2015. This note converted into common stock during the year ended May 31, 2016 as detailed below.

In connection with the initial sale of the 2013 Convertible Notes, detachable common stock warrants with a two-year term to purchase a total of 8,527,984 common shares at exercise prices ranging from $0.75 to $2.00 per share 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, term of the warrants, risk-free interest rates, and expected dividend yield at the grant date.

Additionally, at the commitment date, the Company determined that the conversion feature related to the 2013 Convertible Notes was beneficial to the investors. As a result, the Company determined the intrinsic value of the conversion feature utilizing the fair value of the underlying common stock at the commitment date and the effective conversion price after discounting the 2013 Convertible Notes for the fair value of the warrants. The fair value of the warrants and the intrinsic value of the beneficial conversion feature were recorded as a debt discount to the 2013 Convertible Notes, with a corresponding increase to additional paid-in capital. The debt discount was amortized over the life of the 2013 Convertible Notes. During the year ended May 31, 2016 and May 31, 2015, the Company recognized approximately $7,000 and $1,926,000, respectively, as interest expense related to amortization of the debt discount. The unamortized discount was fully amortized upon any conversion of the 2013 Convertible Notes before maturity.

During the year ended May 31, 2016, the remaining 2013 Convertible Note in the aggregate principal amount of $50,000, plus accrued but unpaid interest of $1,322, converted into 68,428 shares of common stock. Activity related to the 2013 Convertible Notes for the fiscal year ended May 31, 2016 and May 31, 2015 was as follows:

	May 31, 2016	May 31, 2015
Face amount of Notes	$ 50,000	$ 4,271,250

Unamortized discount		(6,529)
Tender offer conversions		
Conversions	(50,000)	(4,221,250)
Total carrying value of Notes	$	$ 43,471

During the year ended May 31, 2015, certain holders of the 2013 Convertible Notes in the aggregate principal amount of $1,175,000, plus accrued but unpaid interest of $4,703, were induced to convert their 2013 Convertible Notes into common stock, at the rate of $0.75 per share, conditioned upon their immediate exercise of certain of the foregoing warrants, covering an aggregate of 1,413,333 shares of common stock, at an exercise price reduced from $2.00 down to $0.55 per share. The note conversions resulted in the issuance of 1,556,667 shares of common stock, a cash interest payment of $3,793 and the Company s receipt of $777,333 from the exercise of such warrants.

In addition, during the year ended May 31, 2015, certain holders of the 2013 Convertible Notes in the aggregate principal amount of $3,046,250, plus accrued but unpaid interest of $86,296, were induced to convert their 2013 Convertible Notes into 4,181,079 shares of common stock at a conversion price of $0.75, conditioned upon the Company issuing new warrants to replace certain of the foregoing warrants which had previously expired, covering an aggregate of 6,310,677 shares of common stock, at an exercise price of $1.00 per share, with an approximate term of seven months from date of issuance.

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The Company determined the fair value of the new warrants using the Black-Scholes option pricing model utilizing certain weighted-average assumptions, such as expected stock price volatility, term of the warrants, risk-free interest rate and expected dividend yield at the commitment date.

	2015
Expected dividend yield	0%
Stock price volatility	80.68%
Expected term	.50 year
Risk-free interest rate	0.12%
Grant-date fair value	$0.15

During the fiscal year ended May 31, 2016, the board approved a one-year extension of expiration dates on the aforementioned detachable common stock warrants with an original term of two years, covering approximately 6.3 million shares of common stock, with an exercise price of $1.00 per share. Current expiration dates ranging from October 2015 through January 2016 were extended to October 2016 through January 2017. The extensions were effective October 1, 2015 upon the receipt of certain executed documentation from the warrant holders. Pursuant to U.S. GAAP, the Company recognized non-cash interest expense of approximately $866,700 in connection with this extension, which represented the incremental increase in the fair value of the modified warrants.

The Company determined the fair value of the new warrants using the Black-Scholes option pricing model utilizing certain weighted-average assumptions, such as expected stock price volatility, term of the warrants, risk-free interest rate and expected dividend yield at the commitment date.

	2016
Expected dividend yield	0%
Stock price volatility	64.56%-69.30%
Expected term	1 year
Risk-free interest rate	0.33%
Grant-date fair value	$0.15-$0.18

AVCP Convertible Notes

During the year ended May 31, 2015, the Company issued an additional two-year term unsecured convertible promissory note (the AVCP Two-Year Note) in the aggregate principal amount of $2,000,000 to Alpha Venture Capital Partners, L.P. (AVCP), an affiliate of one of the Company s directors as described under Note 9 below. As described in greater detail below, along with the AVCP Bridge Note, the AVCP Two-Year Note has subsequently been converted in a transaction occurring during the year ended May 31, 2016. The AVCP Two-Year Note bore simple interest at the annual rate of 5%, payable quarterly. The principal balance of the AVCP Two-Year Note was due and payable in full on September 26, 2016, subject to acceleration of payment in the event of default. Prepayment was permitted without penalty. The AVCP Two-Year Note included events of default for nonpayment of principal or interest when due or other breaches of the AVCP Two-Year Note, as well as for breach of any term of the AVCP Two-Year Note and related warrant agreement. The principal amount of the AVCP Two-Year Note plus unpaid accrued interest was convertible at the election of the holder into shares of the Company s common stock at any time prior to maturity at an initial conversion price of $1.00 per share. The conversion price was subject to adjustment on the same terms, and contained similar consent rights to the issuance of additional indebtedness, as the AVCP Bridge Note above.

During the year ended May 31, 2015, the Company issued a three-month unsecured convertible promissory note (the AVCP Bridge Note and together with the AVCP Two-Year Note, the AVCP Convertible Notes) in the aggregate principal amount of $1,500,000 to AVCP. As described in greater detail below, the AVCP Bridge Note, along with the AVCP Two-Year Note, were subsequently converted in a transaction occurring during the year ended May 31, 2016. The principal amount of the AVCP Bridge Note plus unpaid accrued interest was convertible at the election of the holder into shares of the Company s common stock at any time prior to maturity at an initial conversion price of $1.00 per share. The AVCP Bridge Note bore simple interest of 1.2% per month, payable at maturity on May 5, 2015, and monthly thereafter, upon the Company s election to exercise a one-time option to extend the maturity by an additional three months, which the Company exercised on April 1, 2015 (extending the maturity date to August 5, 2015). Prepayment was permitted without penalty subject to the Company s obligation to pay at least three months interest on the principal amount. The conversion price was subject to (i) adjustment for stock splits and similar corporate events and (ii) reduction to a price per share that is 10% below the lowest sale price that is below $.9444 per share, for shares of common stock sold or deemed sold in future securities offerings, including sales to AVCP and its designees subject to certain exempt transactions. Without AVCP s prior written consent, the Company was not permitted to incur additional indebtedness for borrowed money, other than up to an additional $6.0 million in convertible promissory notes that may be issued to AVCP or related parties, unless such indebtedness was subordinated in right of payment to the Company s obligations under the AVCP Bridge Note and any additional notes issued to AVCP or related parties.

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As a result of the private placement of approximately $4 million in convertible notes during the fourth quarter of fiscal year ended May 31, 2015, as described below, the conversion price of the AVCP Convertible Notes was reduced to $0.675 per share of common stock, which was 90% of the weighted-average price of the deemed issued shares of $0.75 related to the approximately $4 million offering of 2015 Convertible Notes described below. The decrease in the conversion price caused the number of shares of common stock issuable upon conversion of the AVCP Convertible Notes to increase from 3,500,000 to 5,185,185 shares of common stock.

The Company accounted for the AVCP Convertible Notes and related warrants, fully described below, as a financing transaction, wherein proceeds were allocated to the financial instruments issued. Prior to making the accounting allocation, the AVCP Convertible Notes and warrants were evaluated for proper classification under FASB ASC 480 Distinguishing Liabilities from Equity and ASC 815. The debt discounts associated with the notes were amortized over the term of the notes and the Company recognized approximately $94,000 and $524,000 in non-cash amortization expense for the periods ended May 31, 2016 and 2015, respectively.

ASC 815 generally requires embedded terms and features that have characteristics of derivatives to be evaluated for bifurcation and separate accounting in instances where their economic risks and characteristics are not clearly and closely related to the risks of the host contract. The embedded derivative features consisted of the conversion price being subject to (i) adjustment for stock splits and similar corporate events and (ii) reduction to a conversion price per share that is 10% below the lowest sale price that is below $.9444 per share for common stock sold or deemed sold in future securities offerings, subject to certain exempt transactions. The note conversion round down (or anti-dilution) provision terms were not consistent with the definition for financial instruments indexed to the Company s stock. As such, the conversion option and conversion reset price protection in the AVCP Convertible Notes required bifurcation as a derivative liability.

In connection with the original issuance of the two AVCP Convertible Notes, the Company issued warrants to AVCP covering 250,000 and 75,000 shares of the Company s common stock exercisable at a price of $0.50 per share on September 26, 2014 and February 6, 2015, respectively. The warrants are currently exercisable in full, include a cashless exercise feature, and will expire on December 31, 2019 and February 29, 2020, respectively. The aforementioned warrants have a term of five years from inception and an exercise price of $0.50 per share and meet the conditions for equity classification per ASC 815. The fair value of the warrants was determined using a Black-Scholes option model using the following assumptions:

	Warrants issued on September 26, 2014	Warrants issued on February 6, 2015
Risk free interest rate	1.82%	1.48%
Expected life	5 years	5 years
Expected volatility	136%	119%
Dividend yield	0.00%	0.00%

Based on the previous conclusions, the Company allocated the cash proceeds first to the derivative liability at its fair value and then to the warrants at their relative fair value, with the residual allocated to the host AVCP Convertible Notes as presented below.

On June 23, 2015, the Company, Alpha Venture Capital Management, LLC and AVCP entered into a Debt Conversion and Termination Agreement pursuant to which (i) AVCP agreed to convert the $3,535,627 in aggregate indebtedness as of June 23, 2015 under the AVCP Convertible Notes in exchange for 5,237,966 shares of the Company s common stock; (ii) subject to the conversion of the two AVCP Convertible Notes, the Company agreed to

issue AVCP an additional five-year warrant covering 1,000,000 shares of common stock at an exercise price of $0.675 per share and (iii) subject to the AVCP s receipt of the common shares and warrant, the parties agreed to (a) terminate the subscription agreements; and (b) release and discharge each other party from all claims and obligations arising under the two AVCP Convertible Notes and subscription agreements. As a result of the debt conversion, the Company recognized a loss on extinguishment of the AVCP Convertible Notes of $584,177, a non-cash gain on the change in the fair value of the derivative liability of approximately $647,000 and non-cash inducement interest expense of approximately $758,000 arising from the aforementioned warrant.

		Year Ended May 31, 2016			
	May 31, 2015	Debt Discount	Fair Value	Conversion	May 31, 2016
AVCP Convertible note payable	$ 2,637,618	$ 94,344	$	$ (2,731,962)	$
Compound embedded derivative	2,008,907		(646,505)	(1,362,402)	
Warrants (equity allocation)	215,732				
Accrued interest on note payable				(35,627)	
Fair Value of Common Stock Issued				4,714,168	
Loss on conversion				(584,177)	
	$ 4,862,257	$ 94,344	$ (646,505)	$	$

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Short-Term Convertible Notes

During the year ended May 31, 2015, the Company issued approximately $4.0 million of six-month unsecured convertible promissory notes (the Short-Term Convertible Notes) and related warrants to investors for cash. Each Short-Term Convertible Note was originally convertible, at the election of the holder, at any time into common shares at a $0.75 per share. The Short-Term Convertible Notes bore interest of 7% per annum, payable in cash upon maturity. In connection with the issuance of the Short-Term Convertible Notes, the Company also issued warrants with a five-year term to purchase a total of 1,061,586 shares of common stock at an exercise price of $0.75. The Company determined the fair value of the warrants using the Black-Scholes option pricing model utilizing certain weighted-average assumptions, such as expected stock price volatility, term of the warrants, risk-free interest rate and expected dividend yield at the commitment date.

The Company utilized the following weighted-average assumptions to value the above investor warrants:

	2015
Expected dividend yield	0%
Stock price volatility	88.79%
Expected term	5 years
Risk-free interest rate	1.46%-1.58%
Grant-date fair value	$0.52-$0.76

Additionally, at the commitment date, the Company determined that the conversion feature related to the Short-Term Convertible Notes was beneficial to the investors. As a result, the Company determined the intrinsic value of the beneficial conversion feature utilizing the fair value of the underlying common stock at the commitment date and the effective conversion price after discounting the Short-Term Convertible Notes for the fair value of the warrants. The fair value of the warrants and the intrinsic value of the conversion feature were recorded as a debt discounts to the Short-Term Convertible Notes, and a corresponding increase to additional paid-in capital. The debt discounts are amortized over the life of the Short-Term Convertible Notes. The Company recognized approximately $ 1,784,000 and $219,000 as interest expense related to the amortization of the debt during the year ended May 31, 2016 and 2015, respectively. There were no Short-Term Convertible Notes outstanding at May 31, 2016. The unamortized discounts were fully amortized upon any conversion of the Short-Term Convertible Notes before maturity.

During the year ended May 31, 2016, the Company tendered an offer to settle the balances of the Short-Term Convertible Notes. The Company offered to exchange the Short-Term Convertible Notes for (i) the issuance of restricted shares of common stock, for the settlement of the balance of the Short-Term Convertible Notes, principal and accrued but unpaid interest as of September 21, 2015, which was the commitment date, at a conversion price of $0.675 per share, and (ii) the amendment of the related warrants to reduce the exercise price to $0.675 per share. The offer represented a 10.0% discount to $0.75, which was the current conversion price of the Short-Term Convertible Notes and current exercise price of the related warrants. On September 21, 2015, the offering period and withdrawal rights for the exchange offer expired, and the Company completed the exchange offer for approximately $2.7 million in aggregate original principal amount of Short-Term Convertible Notes.

Following the consummation of the exchange offer described above, an aggregate principal amount of $525,000 and accrued but unpaid interest of $17,830 converted into 723,773 shares of common stock. The principal and interest for Short-Term Convertible Notes that were not exchanged in the exchange offer, or that are not otherwise converted pursuant to their terms, became due and payable between October 30, 2015 and November 15, 2015, six months from their issuance. The Company repaid the remaining aggregate principal and interest on such Convertible Notes of

approximately $789,000 Short-Term Convertible Notes on their respective maturity dates. Related to the tender offer conversions, the Company recognized approximately $330,000 in non-cash interest expense and approximately $108,000 commission expense to assist the Company in conversion of the debt at the commitment date.

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Activity related to the Short-Term Convertible Notes for fiscal year ended May 31, 2016 and May 31, 2015 was as follows:

	May 31, 2016	May 31, 2015
Face amount of Notes	$ 3,981,050	$ 3,981,050
Unamortized discount		(2,390,063)
Tender offer conversions	(2,693,800)	
Conversions	(525,000)	
Payments upon maturity	(762,250)	
Total carrying value of Notes	$	$ 1,590,987

Note 4 Derivative Liability:

The following tables summarize the fair value of the derivative liability and linked common shares as of the derivative liability inception dates (September 26, 2014 and February 6, 2015) and fiscal year end May 31, 2016 and May 31, 2015:

	September 26, 2014	February 6, 2015	May 31, 2015	May 31, 2016
Total derivative liability	$ 767,038	$ 403,266	$ 2,008,907	$
Shares indexed to derivative liability	2,000,000	1,500,000	5,185,185	

Changes in the fair value of the derivative liability, carried at fair value, are reported as Change in fair value of derivative liability in the Consolidated Statements of Operations. During the year ended May 31, 2016 and May 31, 2015, the Company recognized a non-cash loss/gain of approximately $647,000 and $839,000, respectively, due to the change in derivative liability related to the embedded derivative in the AVCP Notes.

ASC 815 does not permit an issuer to account separately for individual derivative terms and features embedded in hybrid financial instruments that require bifurcation and liability classification as derivative financial instruments. Rather, such terms and features must be combined together and fair valued as a single, compound embedded derivative. The Company selected a Binomial Lattice Model to value the compound embedded derivative because it believes this technique is reflective of all significant assumptions that market participants would likely consider in negotiating the transfer of this convertible note. Such assumptions include, among other inputs, stock price volatility, risk-free rates, credit risk assumptions, early redemption and conversion assumptions, and the potential for future adjustment of the conversion price due to a future dilutive financing.

Significant inputs and assumptions used in the Binomial Lattice Model for the derivative liability are as follows:

	September 26, 2014	February 6, 2015	May 31, 2015	June 24, 2015
Quoted market price on valuation date	$ 0.79	$ 0.96	$0.99	$ 0.90
Contractual conversion rate	$ 1.00	$ 1.00	$1.00	$ 1.00
Adjusted conversion price (a)	$ 0.9759	$ 1.0000	$0.675	$ 0.675
Contractual term to maturity (years)	2.00	0.49	0.18-1.33	0.12
Expected volatility	123%	124%	90%-114%	48%
Contractual interest rate	5%	2%	1.5%-5.0%	1.2%
Risk-free rate	0.59%	0.045%	0.041%-0.48%	0.001%
Risk adjusted rate	2.69%	2.78%	2.80%	2.80%
Probability of event of default	5.00%	5.00%	5.00%	5.00%

(a) The adjusted conversion price input used in the Binomial Lattice Model considers both (i) the reduction of the conversion price to $0.675 on April 30, 2015, as result of a private placement offering in which Common Stock was sold for a weighted average price of $0.75 and (ii) potential adjustment to the stated conversion price due to a future dilutive issuance. This input was calculated using a probability-weighted approach which considered the likelihood of various scenarios occurring including (i) potential success or failure of various phases for PRO 140, (ii) the probability the Company will enter into a future financing and (iii) and the potential price of a future financing.

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The fair value of the derivative liability is significantly influenced by the Company s trading market price, stock price volatility, changes in interest, assumptions regarding the adjusted conversion price and early redemption or conversion of the AVCP Notes.

Note 5 Stock Options and Warrants

The Company has one active stock-based equity plan at May 31, 2016, 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 shareholders at the Company s 2012 annual meeting to replace the 2004 Plan. The 2012 Plan was and was subsequently amended by shareholder 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. As of May 31, 2016, the Company had 2,000,930 shares available for future stock-based grants under the 2012 Plan.

Stock Options

During the year ended May 31, 2016, the Company granted annual stock option awards to directors to purchase a total of 350,000 shares of common stock with an exercise price of $0.975 per share. These option awards vest quarterly over one year. The grant date fair value related to these options was $0.49 per share.

During the year ended May 31, 2016, the Company granted a director a stock option, covering 250,000 shares of common stock. The option has a per share exercise price of $0.97, a term of five years and was fully vested upon grant date. The grant date fair value related to this option award was $0.43 per share. In addition, the Company granted another director a stock option, covering 100,000 shares of common stock, with a per share exercise price of $0.84, a five-year term that vests equally upon issuance date and one year from issuance date. The grant date fair value related to this option award was $0.58 per share.

During the year ended May 31, 2016, the Company granted options to executive management and employees to purchase a total of 2,054,000 shares of common stock. The exercise prices range from $0.75 to $0.90 per share. Of these option grants 1,554,000 shares vest based on certain performance targets, as set forth in the stock option agreements, of which 50% was achieved as of May 31, 2016. The remaining 500,000 shares vest as follows; 400,000 annually over three years and 100,000 vest 50% upon issuance and 50% on the first anniversary of the grant date. Each of the foregoing options has a ten-year term and grant date fair values which range from $0.48 to $0.61 per share.

During the year ended May 31, 2016, the Compensation Committee of the Board of Directors of the Company determined to extend the expiration dates of certain outstanding stock option awards under the 2004 Plan and 2012 Plan. For each outstanding award issued to a current employee or director of the Company under the Incentive Plans that had an original five-year term, whether such award was vested or unvested, the term was extended by an additional five years, but only to the extent that the award was not in-the-money based upon the closing price of the Company s Common Stock, or $0.81 per share. The other terms and conditions of such stock option awards, and all of the terms and conditions of any other stock option awards outstanding under the Incentive Plans, remained unchanged. The Company recognized a non-cash stock-based compensation expense of approximately $548,000 in the current period in connection with this extension.

In total, the Company extended the expiration dates on stock options covering 1,924,513 shares, with a weighted average exercise price of approximately $1.39 per share.

Warrants

During the year ended May 31, 2016, in connection with private equity offerings, as fully described in Notes 3 and 7, the Company issued common stock warrants to investors and placement agent, covering 28,214,535 shares of common stock. The warrants have an exercise price of $0.75 or $1.35 per share, a five-year term and are exercisable immediately.

During the year ended May 31, 2016, in connection with debt conversion, as fully described in Note 3, the Company issued a warrant covering 1,000,000 shares of common stock to AVCP. The warrant has an exercise price of $0.675, a five-year term and is immediately exercisable.

Additionally, the Company granted warrants to consultants covering a total of 1,870,000 shares of common stock at exercise prices ranging from $0.81 to $1.35 per share. The warrants are subject to various vesting schedules, have an expiration date of five or ten years and grant date fair values range from $0.25 to $0.60 per share.

During the year ended May 31, 2016, holders of warrants covering 795,593 shares of common stock exercised the right to purchase such shares at either $0.50 or $0.75 per share and the Company received proceeds of approximately $549,000. Additionally, 254,708 warrants at $0.75 per share were subject to a cashless exercise.

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Compensation expense related to stock options and warrants issued as compensation was approximately $2,353,000 and $631,000 for the year ended May 31, 2016 and 2015, respectively. The grant date fair value of options and warrants vested during the years ended May 31, 2016 and 2015, was approximately $1,711,500 and $886,000, respectively. As of May 31, 2016, there was approximately $712,000 of unrecognized compensation costs related to share-based payments for unvested options, which is expected to be recognized over a weighted-average period 1.10 years.

The following table represents stock option and warrant activity for the periods ended May 31, 2016 and 2015:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options and warrants outstanding - May 31, 2014	30,806,361	$ 1.13	3.29	$ 177,042
Granted	9,262,038	0.93		
Exercised	(2,038,974)	0.55		
Forfeited/expired/cancelled	(7,020,510)	1.76		
Options and warrants outstanding - May 31, 2015	31,008,915	0.88	2.94	5,538,335
Granted	33,838,536	0.80		
Exercised	(1,050,301)	0.70		
Forfeited/expired/cancelled	(490,000)	2.01		
Options and warrants outstanding - May 31, 2016	63,307,150	0.83	3.20	9,863,492
Outstanding exercisable - May 31, 2016	60,648,362	0.83	3.42	9,795,753

Note 6 License Agreements

During the year ended May 31, 2016, the Company executed a license agreement with a third-party licensor covering the licensor s system know-how technology with respect to the Company s use of proprietary cell lines to manufacture new PRO 140 material. The agreement required payment of £600,000 (approximately US$915,000) by December 15, 2015, which was timely paid during the year ended May 31, 2016. In connection with this license agreement, the Company became the primary obligor of an additional £600,000 (approximately US$807,000 utilizing current exchange rates), which was timely paid by June 30, 2016. During the year ended May 31, 2016, the Company accrued an additional expense of £600,000 (approximately US$870,000) in connection with the June 30, 2016 obligation. Future annual license fees and royalty rate will vary depending on whether we manufacture PRO 140 ourselves, utilize the third-party licensor as a contract manufacturer, or utilize an independent party as a contract manufacturer. The licensor does not charge an annual license fee of £300,000 (approximately US$432,000) when it serves as the manufacturer.

Note 7 Private Securities Offerings

During the year ended May 31, 2015, the Company completed a private debt offering of convertible promissory notes in the aggregate principal amount of $3,981,050. At issuance, each note was convertible into common stock at the rate of $0.75 per share. Each note had a term of six-months and annual interest rate of 7% payable upon maturity. The Company also issued to each note holder a warrant covering 20% of the number of shares of common stock into which the related note was convertible. Each warrant has an exercise price of $0.75 per share and a five-year term. A tender offer was made on these notes by the Company on August 24, 2015, as fully described in Note 3, Short-Term Convertible Notes. Remaining outstanding principal, plus accrued but unpaid interest, was repaid in full upon maturity.

During the year ended May 31, 2016, the Company conducted private equity offerings (the Equity Offerings), in which accredited investors purchased unregistered common stock at either $0.75 or $1.00 per share with warrant coverage of 50% or 25%, respectively, based on the number of shares of common stock purchased. Pursuant to the Equity Offerings, the Company sold a total of 48,659,338 shares of common stock, $0.001 par value, for aggregate gross proceeds of approximately $37.6 million and issued five-year warrants covering 23,254,230 shares of common stock. In conjunction with the Equity Offerings, the Company paid an aggregate cash fee of approximately $3.9 million to the placement agent and issued warrants covering an aggregate of 4,960,314 shares of common stock to the placement agent as additional compensation. The placement agent warrants had aggregate Black-Scholes valuations of approximately $2.7 million at issuance. See Note 5 for a description of the warrants and offering costs related to the Equity Offerings.

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Note 8 Recent Accounting Pronouncements

Recent accounting pronouncements, other than those below, issued by the FASB, the AICPA and the SEC did not or are not believed by management to have a material effect on the Company s present or future financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), *Leases (Topic 842)* effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods. The ASU is to be applied using a modified retrospective approach with optional practical expedients and other special transition provisions. Early adoption is permitted.) The ASU supersedes FASB ASC 840, *Leases,* and adds FASB ASC 842. It also amends and supersedes a number of other paragraphs throughout the FASB ASC. Management is currently assessing the impact the adoption of ASU 2016-02 will have on the Company s Consolidated Financial Statements.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09 (ASU 2016-09), *Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early application is permitted for reporting periods where financial statements have not yet been made available for issuance. The ASU requires different transition methods and disclosures based on the type of amendment included in the ASU.). Management is currently assessing the impact the adoption of ASU 2016-09 will have on the Company s Consolidated Financial Statements.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03 Simplifying the Presentation of Debt Issuance Costs (ASU2015-03) The standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this standards update. The new guidance is effective for annual reporting periods beginning after December 15, 2015, including interim periods within that reporting period and early adoption is permitted. The Company evaluated this ASU and began early adoption beginning with the annual period ended May 31, 2015. The adoption of this guidance did not have a material impact on the Company s financial position, overall results of operations or cash flows.

In June 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-12, Compensation Stock Compensation (Topic 718), Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (ASU 2014-12). ASU 2014-12 provides guidance for awards with performance targets that could be achieved after the requisite service period has been met. The guidance is effective for annual periods beginning after December 15, 2015, and interim periods within those annual periods, with early adoption permitted. Management is currently assessing the impact the adoption of ASU 2014-12 will have on its Consolidated Financial Statements.

In August 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-15, Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern (ASU 2014-15). ASU 2014-15 is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. The amendments in this ASU are effective for reporting periods beginning after December 15, 2016, with early adoption permitted. Management is currently assessing the impact the adoption of ASU 2014-15 will have on the Company s Consolidated Financial Statements.

Note 9 Acquisition of patents

As discussed in Note 10 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 Financial Accounting Standards Topic 805 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, 2016, 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 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 2026 and 2031, respectively, in various countries.

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The following presents intangible assets activity:

	May 31, 2016	May 31, 2015
Gross carrying amounts	$ 3,500,000	$ 3,500,000
Accumulated amortization	(1,268,750)	(918,750)
Total amortizable intangible assets, net	2,231,250	2,581,250
Patents currently not amortized	35,989	35,989
Carrying value of intangibles, net	$ 2,267,239	$ 2,617,239

Amortization expense related to intangible patents was approximately $350,000 for the years ended May 31, 2016 and May 31, 2015. The estimated aggregate future amortization expense related to the Company s intangible assets with finite lives is estimated at approximately $350,000 per year for the next five years.

Note 10 Commitments and Contingencies

Under the Asset Purchase Agreement, dated July 25, 2012, between the Company and Progenics Pharmaceuticals, Inc. (Progenics) (the Asset Purchase Agreement), the Company acquired from Progenics its rights to the HIV viral-entry inhibitor drug candidate PRO 140 (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 U.S. Food and Drug administration (FDA) regulatory filings. On October 16, 2012, the Company paid to Progenics $3,500,000 in cash to close the transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) $1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-US equivalent, which was paid during the year ended May 31, 2016; (ii) $5,000,000 at the time of the first US new drug application approval by the FDA or other non-U.S. approval for the sale of PRO 140; and (iii) 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 $1.5 million of such milestones owed to Progenics as a return of the first dosing in a U.S. Phase 3 trial. To the extent that such milestone payments and royalties are not timely made, under the terms of the Asset Purchase Agreement, Progenics has certain repurchase rights relating to the assets sold to the Company thereunder.

Payments to the third-party licenser 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 Asset 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 and must pay additional milestone payments and royalties as follows: (i) $1,000,000 upon initiation of a Phase 3 clinical trial, which was paid during the year ended May 31, 2016; (ii) $500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) $500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iv) royalties of up to 7.5% 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. During the year ended May 31, 2016 the Company paid $1 million of such milestones. To the extent that such milestone payments 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. Pursuant to the foregoing Asset Purchase Agreement and PDL License, the Company accrued an expense of $2,500,000 as of May 31, 2015 in connection with the anticipated milestone payments related to the first patient dosing in a Phase 3 clinical trial, all of which was paid during the year ended May 31, 2016, as described above.

The Company has entered into project work orders for each of its clinical trials with its clinical research organization (CRO) and related laboratory vendors. Under the terms of these agreements, the Company has paid approximately $2.0 million towards execution fees for direct services costs. The fees are reflected as a current asset and have an unamortized balance of approximately $1.7 million at May 31, 2016. In connection with the Company s clinical trials, it has entered into separate project work orders for each trial with its CRO. 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 from an approximate low of $0.1 million to an approximate high of $0.4 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 $1.6 million.

Note 11 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. The Company incurred expenses for qualified non-elective contributions of approximately $25,400 and $22,000 for the years ended May 31, 2015 and 2016, respectively,

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Note 12 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. Due to the valuation allowance for deferred tax assets, as noted below, there was no net deferred tax benefit or expense for the periods ended May 31, 2015 and 2016.

Reconciliation of the federal statutory income tax rate of 34% to the effective income tax rate is as follows for all periods presented:

	2016	2015
Income tax provision at statutory rate	34.0%	34.0%
State income taxes, net		
Rate change		(0.6)
Derivative gain/loss	0.9	(1.2)
Loss on debt conversion	(0.8)	
Inducement charge	(1.0)	
Miscellaneous	(0.5)	
Valuation allowance	(32.9)	(32.2)
	0.0%	0.0%

Net deferred tax assets and liabilities are comprised of the following as of May 31, 2016 and 2015:

	2016	2015
Deferred tax asset (liability) current:		
Accrued salary and expenses	$ 378,321	$ 219,100
Valuation allowance	(378,321)	(219,100)
	$	$
Deferred tax asset (liability) non-current:		
Net operating loss	$ 23,510,608	$ 16,857,600
Debt discount		(902,700)
Expense on non-qualified stock options	3,873,597	3,073,500
Other	202,812	211,700
Valuation allowance	(27,587,017)	(19,240,100)
	$	$

The 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, 2016, the Company had available net operating loss carry forwards of approximately $69,149,000, which expire beginning in 2022.

The Company s income tax returns remain subject to examination by all tax jurisdictions for tax years May 31, 2013 through 2015.

Note 13 Related Party Transactions

On September 26, 2014, the Company entered into a $2 million convertible promissory note with AVCP, as more fully described in Note 3 above. In October of 2014, Mr. Carl C. Dockery, the principal of AVCP, was appointed a director of the Company. On February 6, 2015, the Company entered into a second convertible promissory note in the aggregate principal amount of $1.5 million, as more fully described in Note 3 above. On June 23, 2015, these notes and accrued but unpaid interest were converted into shares of common stock. In connection with the Debt Conversion and Termination Agreement dated June 23, 2015, the Company issued to AVCP a warrant covering 1,000,000 shares of common stock, as more fully described in Notes 3 and 5.

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On January 19, 2016, the Company entered into an amendment to its existing Consulting Agreement with Denis R. Burger, Ph.D., dated February 21, 2014, as previously amended November 3, 2014 (the Consulting Agreement). The Amendment names Dr. Burger, who is currently a member of the Board of Directors, to the non-executive position of Chief Science Officer and increases Dr. Burger s advisory responsibilities in that capacity. The Amendment also increases the compensation payable to Dr. Burger under the Consulting Agreement to $20,000 in cash per month, which is in addition to any fees that Dr. Burger currently earns as a director. The Amendment was approved by the Audit Committee of the Board of Directors.

On May 10, 2016, Jordan G. Naydenov, a director with the Company, participated in the private equity offerings as fully described in Note 7 above. Mr. Naydenov invested $1 million and received 1 million shares of common stock and a warrant covering 250,000 shares of common stock at an exercise price of $1.35. The terms and conditions of Mr. Naydenov s investment were identical to those offered to all other investors in the offering.

Only independent directors approve 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 14 Subsequent Events

On June 1, 2016 the Company issued to directors, as it relates to their annual compensation, options covering a total of 300,000 shares of common stock. The options have an exercise price of $1.09, a ten-year term and vest quarterly over one year. Additionally, in conjunction with incentive compensation, the Company issued options covering 950,000 shares of common stock to management. The options have an exercise price of $1.09, a ten-year term and vest annually over three years beginning June 1, 2017.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.
None.

Item 9A. Controls and Procedures.
Disclosure Controls and Procedures

As of May 31, 2016, under the supervision and with the participation of the Company s Chief Executive Officer and Chief Financial Officer, management has evaluated the effectiveness of the design and operations of the Company s disclosure controls and procedures. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures were not effective as of May 31, 2016 as a result of the material weakness in internal control over financial reporting discussed below.

Internal Control Over Financial Reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of our financial reporting

and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. 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 the Company s transactions; (ii) provide reasonable assurance that transactions are recorded as necessary for preparation of our financial statements and that receipts and expenditures of the Company s assets are made 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. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of the Company s financial statements would be prevented or detected.

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of May 31, 2016 using the criteria set forth in the Internal Control over Financial Reporting - Guidance for Smaller Public Companies issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon the evaluation, our management concluded that our internal control over financial reporting was not effective as of May 31, 2016 because of material weaknesses in our internal control over financial reporting. A material weakness is a control deficiency or combination of deficiencies in internal control, such that there is a reasonable possibility that a material misstatement of the entity s financial statements will not be prevented or detected and corrected on a timely basis. Our management concluded that the Company has material weaknesses in our internal control over financial reporting because of inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions. Management has, however, implemented numerous controls and procedures in recent years surrounding cash disbursements, internal financial accounting, including detailed internal financial reporting compared to regular projections, multiple-cross reconciliations covering all equity transactions and engaging a full service provider of information technology support, including daily offsite data back-up, among others. In December 2013, we also hired a second CPA to serve as our Director of Accounting to further enhance our internal controls.

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Despite the existence of these material weaknesses, the Company believes the financial information presented herein is materially correct and in accordance with generally accepted accounting principles in the United States.

While the implementation of numerous improved controls and procedures has strengthened our internal control framework and disclosure controls, we continue to believe we have a material weakness related to the lack of sufficient segregation of duties surrounding the cash disbursements cycle. Accordingly, among other things, we are engaging an independent third party with the relevant expertise to assist management with the development of a plan of remediation, with the goal of attempting to fully mitigate all material weaknesses by the end of the May 31, 2017 fiscal year.

This Annual Report does not include an attestation report of the Company s registered public accounting firm regarding internal control over financial reporting. Management s report is not subject to attestation by the Company s registered public accounting firm because the Company is not an accelerated filer under the Exchange Act.

Changes in Control Over Financial Reporting

No change in the Company s internal control over financial reporting occurred during the year ended May 31, 2016, that materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting. During the fiscal year ended May 31, 2016, management has, however, continued to strengthen internal controls and procedures through the implementation of entity-level controls.

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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 2016 Annual Meeting of Shareholders, to be filed with the SEC within 120 days of the end of the Company s fiscal year, May 31, 2016 (the 2016 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 2016 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 2016 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 2016 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 2016 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.
The following are filed as part of this Annual Report on Form 10-K:

Consolidated Financial Statements

The Consolidated Financial Statements for the years ended May 31, 2016 and 2015 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.

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SIGNATURES

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

Date: July 19, 2016

CYTODYN INC.
(Registrant)

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on July 19, 2016.

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:

Denis R. Burger, Ph.D.

*
Anthony D. Caracciolo

*
Carl C. Dockery

*
Gregory A. Gould

*

A. Bruce Montgomery, M.D.

*

Jordan G. Naydenov

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

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EXHIBIT INDEX

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).
	Articles of Incorporation and Bylaws
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K12G3 filed September 1, 2015).
3.2	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed March 21, 2016).
3.3	Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K12G3 filed September 1, 2015).
	Instruments Defining Rights of Security Holders
4.1	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).
4.2	Form of Investor Warrant (incorporated by reference to Exhibit 4.3 to the Registrant s Registration Statement on Form S-1 filed September 11, 2015).
4.3	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.4 to the Registrant s Registration Statement on Form S-1 filed September 11, 2015).
4.4	Form of Consultant Warrant (incorporated by reference to Exhibit 4.4 to the Registrant s Registration Statement on Form S-1 filed February 3, 2016).
	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 s Form SB-2/A filed March 21, 2005).
10.3*	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).
10.4*	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).
10.5*	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 (the 2013 10-K)).
10.6*	

	Form of Stock Option Award for Non-Employee Directors under the 2004 Plan (incorporated by reference to Exhibit 10.6 to the 2013 10-K).
10.7*	CytoDyn Inc. 2012 Equity Incentive Plan (the 2012 Plan) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed December 18, 2012).

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Exhibit Number	Description
10.8*	Form of Stock Option Award Agreement for Employees under the 2012 Plan (incorporated by reference to Exhibit 10.8 to the 2013 10-K).
10.9*	Form of Stock Option Award Agreement for Non-Employee Directors under the 2012 Plan (incorporated by reference to Exhibit 10.9 to the 2013 10-K).
10.10*	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 2013 10-K).
10.11*	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 2013 10-K).
10.12*	Form of Indemnification Agreement with directors and officers of the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q filed January 14, 2013).
10.13	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 2013 10-K).
10.14*	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)
10.15	Subscription and Investor Rights Agreement between Alpha Venture Capital Management, LLC, and CytoDyn Inc. dated September 26, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q filed October 10, 2014).
10.16	Convertible Promissory Note issued to Alpha Venture Capital Partners, L.P., by CytoDyn Inc. dated September 26, 2014 (incorporated by reference to Exhibit 4.1 to the Registrant s Quarterly Report on Form 10-Q filed October 10, 2014).
10.17	Warrant Agreement between Alpha Venture Capital Partners, L.P., and CytoDyn Inc. dated September 26, 2014 (incorporated by reference to Exhibit 4.2 to the Registrant s Quarterly Report on Form 10-Q filed October 10, 2014).
10.18	Side letter agreement Alpha Venture Capital Management, LLC, and CytoDyn Inc. (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q filed October 10, 2014).
10.19*	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).
10.20*	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).
10.21*	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).
10.22	

Subscription and Investor Rights Agreement between Alpha Venture Capital Management, LLC, and CytoDyn Inc. dated February 6, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 11, 2015).

10.23 Convertible Promissory Note issued to Alpha Venture Capital Partners, L.P., by CytoDyn Inc. dated February 6, 2015 (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed February 11, 2015).

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Exhibit Number	Description
10.24	Warrant Agreement between Alpha Venture Capital Partners, L.P., and CytoDyn Inc. dated February 6, 2015 (incorporated by reference to Exhibit 4.2 to the Registrant s Current Report on Form 8-K filed February 11, 2015).
10.25	Letter of Understanding between Alpha Venture Capital Partners, L.P., and CytoDyn Inc. dated February 10, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 11, 2015).
10.26	Amendment dated April 30, 2015 to Convertible Promissory Note issued to Alpha Venture Capital Partners, L.P. dated February 6, 2015 (incorporated by reference to Exhibit 4.10 to the Registrant s Annual Report on Form 10-K filed July 10, 2015).
10.27	Form of Subscription Agreement (May 2015) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed May 5, 2015).
10.28	Form of May 2015 Note (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed May 5, 2015).
10.29*	Summary of Non-Employee Director Compensation Program Effective June 1, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant s Form 10-Q filed October 9, 2015).
10.30	Debt Conversion and Termination Agreement between CytoDyn Inc., Alpha Venture Capital Management, LLC and Alpha Venture Capital Partners, LP dated June 23, 2015. (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed June 25, 2015).
10.31	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).
10.32	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).
10.33	Form of Subscription Agreement (July 2015) (incorporated by reference to Exhibit 10.35 to the Registrant s Registration Statement on Form S-1 filed September 11, 2015).
10.34	Form of Subscription Agreement (August 2015) (incorporated by reference to Exhibit 10.36 to the Registrant s Registration Statement on Form S-1 filed September 11, 2015).
10.35	Form of Registration Rights Agreement (July 2015 and August 2015) (incorporated by reference to Exhibit 10.37 to the Registrant s Registration Statement on Form S-1 filed September 11, 2015).
10.36*	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).
10.37	Form of Subscription Agreement (January 2016) (incorporated by reference to Exhibit 10.39 to the Registrant s Registration Statement on Form S-1 filed February 3, 2016).
10.38	Form of Registration Rights Agreement (January 2016) (incorporated by reference to Exhibit 10.40 to the Registrant s Registration Statement on Form S-1 filed February 3, 2016).
10.39	

Form of Subscription Agreement (May 2016) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed May 11, 2016).

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Exhibit Number	Description
	Other
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 to the 2013 10-K).
23	Consent of Warren Averett, LLP.
24	Power of Attorney of executive officers and directors.

Exhibit Number	Description
	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.
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.