CytoDyn Inc.
Form 10-K
July 20, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended May 31, 2017

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	**(I.R.S. Employer**
incorporation or organization)	**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 No

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

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

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

Large accelerated filer | Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) | Smaller reporting company

Emerging growth company

EXPLANATORY NOTE

The registrant met the accelerated filer requirements as of the end of its fiscal year ended May 31, 2017, pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended. However, pursuant to Rule 12b-2 and SEC Release No. 33-8876, the registrant (as a smaller reporting company transitioning to the larger reporting company system based on its public float as of the end of its second fiscal quarter ended November 30, 2016) is not required to satisfy the larger reporting company requirements until its first quarterly report on Form 10-Q for the 2018 fiscal year and thus remains eligible to check the Smaller Reporting Company box on the cover of this Form 10-K.

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter: $84,065,616 as of November 30, 2016.

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, 2017, the registrant had 152,763,243 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	**Parts Into Which Incorporated**
Portions of the Proxy Statement for the 2017 Annual Meeting of Stockholders	Part III

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CYTODYN INC.

FORM 10-K FOR THE YEAR ENDED MAY 31, 2017

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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 and our ongoing ability to raise additional capital to fund our operations, (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 of 1933, as amended (the Securities Act), to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this 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. was originally incorporated under the laws of Colorado on May 2, 2002 under the name RexRay Corporation (our previous name). Effective August 27, 2015, we completed a reincorporation from Colorado to Delaware. Our principal business office is 1111 Main Street, Suite 660, Vancouver, Washington 98660. Our website can be found at www.cytodyn.com. We do not intend to incorporate any contents from our website into this annual report. Unless the context otherwise requires, references to CytoDyn, the Company, we, our, or us are to CytoDy 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 other immunologic indications, such as graft-versus-host disease.

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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.

PRO 140

We believe the PRO 140 antibody shows promise as a powerful anti-viral agent with the advantage of fewer side effects, lower toxicity and less frequent dosing requirements, as compared to daily drug therapies currently in use for the treatment of HIV. The 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 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 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 compliance, which causes 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. PRO 140, as a single agent therapy, has also demonstrated that it could replace HAART altogether for a subpopulation of R5 patients who have suppressed viral load with HAART, but are seeking an alternative treatment that allows the patient an improved quality of life, with the advantages of fewer side effects, lower toxicity and less frequent dosing requirements.

To date, PRO 140 has been tested and administered to patients either intravenously or as a subcutaneous injection. We believe that, if PRO 140 is approved for use as an injectable by the U.S. Food and Drug Administration (the FDA), it may nonetheless be an attractive and marketable therapeutic option for patients, particularly in the following scenarios:

- Patients desiring a break from existing treatment regimens, whether due to side-effects or for any personal reasons;
- Patients with difficulty adhering to daily drug regimens;
- Patients who poorly tolerate existing therapies;

Patients with compromised organ function, such as 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 inhibits CCR5-tropic HIV while preserving CCR5 s natural function. 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 patients.

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 continue to suppress the viral load in certain HIV-infected, treatment-experienced patients who had suppressed viral load on HAART, but would like an alternative treatment that provides a higher quality of life with one dose a week through a self-injection. Once the viral load is undetectable, weekly administration of 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 three years). Based on the preliminary results of such studies, we believe that a PRO 140 treatment option could also address the unmet medical need for therapy options for certain HIV-infected patients with uncontrolled viral load, despite conventional HAART treatments.

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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.

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 that eight of the nine patients in this study have surpassed two and one-half years of suppressed viral load through a successful monotherapy of PRO 140 and are approaching three years of suppressed viral load with a monotherapy.

Our second ongoing clinical trial is a pivotal Phase 2b/3 trial for PRO 140 as a combination therapy with existing HAART drug regimens. The initial 25-week trial protocol included a requirement for 300 patients. The FDA reduced this requirement to 150 patients and finally down to 30 patients. The primary endpoint for efficacy is defined as the amount of viral load drop after one week of therapy with PRO 140 in combination with the patient s failing HAART regimen. Patient enrollment is expected to be completed in July 2017 and we will announce whether the trial has achieved its primary endpoint as soon as that determination is available. The first patients to have successfully completed this trial have transitioned into a FDA-cleared rollover study, in order to provide continued access to PRO 140 therapy, at the request of their treating physician.

Our third ongoing trial is an investigative Phase 2b/3 trial featuring 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 to assess the clinical safety of the PRO 140 monotherapy regimen and to evaluate the proportion of participants experiencing suppressed viral load. The secondary endpoint is the length of time to virologic failure. The first patients were enrolled in December 2016, and we expect enrollment to be completed by the end of calendar 2017.

Our fourth ongoing trial of PRO 140 is a Phase 2 study for Graft-versus-Host Disease (GvHD) and is the first non-HIV immunologic 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 was announced in May 2017.

Each of the foregoing trials are described more fully below.

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 patients 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.

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. Also, patients who had other infections before they were declared virologic failure are not categorized as a failure.

- 98% of the patients successfully completed 4 weeks of monotherapy;

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82% of the patients successfully completed 8 weeks of monotherapy; and

75% of the patients successfully completed 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 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 patients 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, 21 patients were eligible, 19 patients were screened for participation, 16 were allowed to enter and 15 patients successfully completed 29 weeks of PRO 140 monotherapy. Of these 15 patients, nine patients are currently ongoing and have surpassed two and one-half years 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). Four patients discontinued the extension protocol for reasons not attributed to PRO 140. The trial is ongoing and as a result, we are only able to discuss the clinical findings to date.

Phase 2b/3 Pivotal 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 reduced the original number of required patients in this trial from 300 to 150 and finally to 30 patients. We believe that, upon successful completion of this Phase 2b/3 study, we will have the opportunity to seek accelerated approval for PRO 140 based on previously granted FDA fast-track designation.

The Phase 2b/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 at least one antiretroviral drug from three different classes or at least one drug from two classes with 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. Patients will have one or more fully active, approved drugs available for construction of a viable alternative option. Enrollment is expected to be completed in July 2017 followed by an evaluation of the primary endpoint soon thereafter.

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 we submit data from the

population for which the breakthrough therapy is requested. We currently plan to submit additional data to the FDA as it becomes available to us from our pivotal Phase 2b/3 combination therapy trial.

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

An investigative Phase 2b/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 the first patients was announced in December 2016 and enrollment is well underway.

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This trial is entitled a Phase 2b/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 Patients with CCR5-tropic HIV-1 infection. This study is 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 patients 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 was announced in May 2017.

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 our request remains open at this time. We have submitted additional data from specific animal studies as requested by the FDA. 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.

Immunological Applications for PRO 140

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.

The target of PRO 140 is the important immunologic receptor CCR5. The CCR5 receptor is more than the door for HIV to enter T-cells; it is also a crucial component in inflammatory responses. This opens the potential for multiple pipeline opportunities for PRO 140.

The CCR5 receptor is a protein located on the surface of white blood cells that serves as a receptor for chemical attractants called chemokines. Chemokines are the key orchestrators of leukocyte trafficking by attracting immune cells to the sites of inflammation.

At the site of an inflammatory reaction, chemokines are released. These chemokines are specific for CCR5 and cause the migration of T-cells to these sites promoting further inflammation. The mechanism of action of PRO 140 has the potential to block the movement of T-cells to inflammatory sites, which could be instrumental in diminishing or eliminating inflammatory responses. Some disease processes that could benefit from CCR5 blockade include new reactions to cancer, transplantation rejection, autoimmunity and chronic inflammation such as rheumatoid arthritis and psoriasis.

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Due to its mechanism of action, PRO 140 has significant advantages in terms of safety and reduced side effects over other CCR5 antagonists. Prior studies have demonstrated that PRO 140 does not cause direct activation of T-cells. We have already reported encouraging human safety data for our clinical trials with PRO 140 in HIV-infected patients.

We have initiated our first clinical trial with PRO 140 in an immunological indication a Phase 2 clinical trial with PRO 140 for Graft-versus-Host Disease (GvHD) in patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) who are undergoing bone marrow stem cell transplantation. GvHD represents an unmet medical need, with patients who contract GvHD during stem cell transplant having a significantly decreased 1-year survival rate with relapsed GvHD as the leading cause of death. PRO 140 is also being investigated in animal models of cancer progression and autoimmunity with positive results. Our animal studies in GvHD have been submitted for publication in peer-reviewed journals.

As we progress in evaluating PRO 140 in different pathways of human disease and inflammation, we are encouraged by the opportunity to build a broad pipeline of indications.

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, we paid to Progenics $3,500,000 in cash to close the transaction. We are 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 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, we 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 us thereunder.

Payments to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the PDL License), between Protein Design Labs (now AbbVie Inc.) (PDL) and Progenics, which was assigned to us in the Progenics Purchase Agreement, pursuant to which we have an exclusive worldwide license to develop, make, have made, import, use, sell, offer to sell or have sold products that incorporate the humanized form of the PRO 140 antibody developed 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 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. During the year ended May 31, 2016, we 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 our license of PRO 140 thereunder. Pursuant to the foregoing Progenics Purchase Agreement and PDL License, we 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 fiscal year ended May 31, 2016.

Effective July 29, 2015, we entered into a License Agreement (the Lonza Agreement) with Lonza Sales AG (Lonza) covering Lonza s system know-how technology with respect to 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, we 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, our 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).

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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 us upon receipt of FDA regulatory approval, may be subject to up to a five-year patent term extension in certain instances. While the duration of foreign patents varies in accordance with the provisions of applicable local law, most countries provide for a patent term of 20 years measured from the application filing date and some may also allow for patent term extension to compensate for regulatory approval delay. We pursue opportunities for seeking new meaningful patent protection on an ongoing basis. We currently anticipate that, absent patent term extension, patent protection relating to the PRO 140 antibody itself will start to expire in 2023, certain methods of using PRO 140 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 below. We may also rely on data exclusivity, trade secrets and proprietary know-how to develop and attempt to achieve a competitive position with our product candidates. We generally require our employees, consultants and partners who have access to our proprietary information to sign confidentiality agreements in an effort to protect our intellectual property.

Separate from and in addition to the patent rights noted above, we expect that PRO 140 will be subject to at least 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.

Information with respect to our current patent portfolio as of May 31, 2017, is set forth below.

	Number of Patents		Expiration	Number of Patent Applications	
Product Candidates	**U.S.**	**International**	**Dates[1]**	**U.S.**	**International**
PRO 140[2]	8	26	2017-2031	7	28

(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.

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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 conduct of clinical research, the business relationships between health care providers and suppliers and the privacy and security of health information.

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 such as PRO 140 have long been subject to regulation by various federal and state agencies, primarily as to product research, development, approval, safety, efficacy, manufacturing, advertising, labeling, import, export and safety reporting. The exercise of broad regulatory powers by the FDA through its Center for Biological Evaluation and Research and other functions continues to require from companies large amounts of testing and documentation prior to FDA approval of current and new biologic products and while they are marketed. When marketing commences, 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 PRO 140 may not be commercially marketed without prior approval from the FDA and comparable agencies in foreign countries. In the United States, the process for obtaining FDA approval for products like PRO 140 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 proposed clinical trial protocols and other information must be submitted to the FDA as part of an IND that must be reviewed and become effective before clinical testing can begin. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent institutional review board, 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, protocols for new clinical trials must be submitted to the FDA and 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. Unless an exemption applies, a substantial user fee must accompany the application. 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

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effort in the areas of training, production and quality control within our own organization and at any contract manufacturing facilities that we use. 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 may 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 a BLA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting and submission of periodic reports to the FDA, recordkeeping, product sampling and distribution, and, as discussed above, may be subject to mandatory post-market study and REMS requirements. In addition, the FDA strictly regulates the promotional claims that may be made about prescription drug products and biologics. In particular, a drug or biologic may not be promoted for uses that are not approved by the FDA as reflected in the product s approved labeling. The FDA 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.

The U.S. Department of Justice, or DOJ, the Office of the Inspector General of the Department of Health and Human Services, or OIG, 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. In addition, our relationships with doctors and other healthcare professionals are regulated by the DOJ, the OIG and other law enforcement and regulatory agencies under the federal Anti-Kickback Statute, the False Claims Act, the Sunshine Act, and similar and related federal and state laws. Violations of these laws can result in significant liability, criminal penalties and being barred from government reimbursement programs such as Medicare and Medicaid.

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.

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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 2b/3 pivotal and investigative trials, to manage our Phase 2 trial for GvHD and to continue to explore other immunologic indications for PRO 140, as described above.

Phase 1

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

Phase 2

Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, often involving several hundred people. In some cases, depending upon the need for a new drug, a particular drug candidate may be licensed for sale in interstate commerce after a pivotal Phase 2 trial.

Phase 2 is often broken into Phase 2a, which can be used to refer to pilot trials, or more limited trials evaluating exposure response in patients, and Phase 2b trials that are designed to evaluate dosing efficacy and ranges.

Phase 3

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

Competition

The pharmaceutical 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. If approved, we believe that PRO 140 will be the only approved drug outside of the main four classes of drugs approved for HIV since 2007.

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

Research and Development Costs

Our research and development expenses totaled approximately $20.2 million and $13.7 million for the fiscal years ended May 31, 2017 and May 31, 2016, respectively. We expect our research and development expenses to continue to increase in future periods as the activity within our clinical trials expands and our biologics manufacturing processes and related regulatory compliance activities increase.

Employees and Consultants

We have six full-time employees, 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.

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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 continue with significant additional clinical trial activities and the ongoing preparation of a BLA for an anticipated filing in 2018, before we can seek the regulatory approvals necessary to begin commercial sales. During the fiscal years ended May 31, 2017 and 2016, we incurred net losses of approximately $25.8 million and $25.7 million, respectively, and at May 31, 2017, we had an accumulated deficit of approximately $123.0 million and a stockholders deficit of $1.1 million. We expect to incur losses for the foreseeable future as we continue development of, and seek regulatory approvals for, our drug candidate and commercialize any approved product usages. If our current drug candidate fails to gain regulatory approval, or if it or other candidates we own do not achieve approval and market acceptance, we will not be able to generate any revenue, or explore other opportunities to enhance stockholder value, such as through a sale. If we fail to generate revenue and eventually become and remain profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or part of their investments.

We will need substantial additional funding for our clinical trials and to operate our business, and such funding may not be available or, if it is available, such financing is likely to substantially dilute our existing stockholders.

The discovery, development, and commercialization of new treatments, such as our PRO 140 product candidate, entail significant costs. We expect the total estimated expenses for our pivotal Phase 2b/3 combination therapy trial may range from approximately $8 million to $9 million and the total estimated expenses for our Phase 2b/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. 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;
- 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);