

CYTODYN INC  
Form 10-K  
July 10, 2015  
Table of Contents

**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, 2015**

**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)**

**Colorado**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**75-3056237**  
**(I.R.S. Employer**  
**Identification No.)**

**1111 Main Street, Suite 660**

**Vancouver, Washington**  
**(Address of principal executive offices)**

**98660**  
**(Zip Code)**

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

**Securities registered pursuant to Section 12(b) of the Act: None**

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

**Title of class**

**Common Stock, no par value**

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

Edgar Filing: CYTODYN INC - Form 10-K

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, 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

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: \$64,183,157 (as of November 30, 2014).

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, 2015, the registrant had 70,142,332 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

<b>Document</b>	<b>Parts Into Which Incorporated</b>
Portions of the Proxy Statement for the 2015 Annual Meeting of Shareholders	Part III

**Table of Contents**

CYTODYN INC.

FORM 10-K FOR THE YEAR ENDED MAY 31, 2015

**Table of Contents**

	<b>Page</b>
<b><u>PART I</u></b>	1
ITEM 1. <u>BUSINESS</u>	1
ITEM 1A. <u>RISK FACTORS</u>	7
ITEM 1B. <u>UNRESOLVED STAFF COMMENTS</u>	17
ITEM 2. <u>PROPERTIES</u>	17
ITEM 3. <u>LEGAL PROCEEDINGS</u>	17
ITEM 4. <u>MINE SAFETY DISCLOSURES</u>	17
<b><u>PART II</u></b>	17
ITEM 5. <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	17
ITEM 6. <u>SELECTED FINANCIAL DATA</u>	18
ITEM 7. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	18
ITEM 7A. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	23
ITEM 8. <u>FINANCIAL STATEMENTS</u>	23
ITEM 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	47
ITEM 9A. <u>CONTROLS AND PROCEDURES</u>	47
ITEM 9B. <u>OTHER INFORMATION</u>	48
<b><u>PART III</u></b>	48
ITEM 10. <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	48
ITEM 11. <u>EXECUTIVE COMPENSATION</u>	48
ITEM 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	48
ITEM 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE</u>	48
ITEM 14. <u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	48
<b><u>PART IV</u></b>	48
ITEM 15. <u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	48



---

**Table of Contents**

**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 meet our debt obligations, (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 prospectus 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, 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. is a Colorado corporation with its principal business office at 1111 Main Street, Suite 660, Vancouver, Washington 98660. Our website can be found at [www.cytodyn.com](http://www.cytodyn.com). We do not intend to incorporate any contents from our website into this annual report.

We are a publicly traded 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. Although CytoDyn intends to focus its efforts on PRO 140, we also hold certain rights in two proprietary platform technologies: Cytolin<sup>®</sup>, a humanized monoclonal antibody targeting HIV with a mechanism of action which may prove to be synergistic to that of PRO 140 and other treatments, and CytoFeline , a felinized-monoclonal antibody targeting Feline Immunodeficiency Virus ( FIV ).

***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. 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 CCR5, a normal cell surface co-receptor protein to which HIV attaches as part of HIV s entry into a cell.

---

**Table of Contents**

PRO 140 is an antibody and not a chemically synthesized drug, and through preliminary, short-term trials it has demonstrated efficacy without issues relating to toxicity and autoimmune resistance. Moreover, these trials suggested 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 HIV uses to enter the cell and, in doing so, inhibits the ability of HIV to infect the cell without affecting the cell's normal function.

PRO 140 was originally developed by Progenics Pharmaceuticals, Inc. ( Progenics ), which led, and contributed to funding of, PRO 140 development and trials through 2011. We acquired the asset from Progenics in October 2012. Jeffrey M. Jacobson, M.D., Professor of Medicine, Microbiology and Immunology, Chief, Drexel University College of Medicine ( Drexel ), has conducted prior research relating to PRO 140, and is continuing to pursue one clinical trial partially funded through one grant awarded to Dr. Jacobson by the National Institutes of Health ( NIH ). We have also recently completed a successful Phase 2b clinical trial exploring PRO 140 as a short-term treatment substitution (as a monotherapy of PRO 140) for existing drug regimens.

To facilitate our self-funded and sponsored clinical research plans, we have engaged Amarex Clinical Research, LLC ( Amarex ), our principal contract research organization, to provide comprehensive clinical trial services, including managing our chemistry, manufacturing and controls ( CMC ) activities.

In furtherance of our business strategy, in mid-2014 we entered into a manufacturing agreement with a contract manufacturing organization to initiate preparations for the future manufacturing of additional PRO 140.

To date, PRO 140 has only 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 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. PRO 140 also appears to broadly inhibit drug-resistant CCR5-tropic HIV viruses, including



one resistant to small-molecule anti-CCR5 HIV therapies. PRO 140 has no effect on strains of HIV called X4 exclusive virus. Overall, 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.

### ***Current Clinical Trials***

PRO 140 is currently being studied in two clinical trials. One study is led by Dr. Jeffrey Jacobson. This study is funded directly through grants from NIH. Pursuant to a clinical trial agreement with us, Drexel is now carrying the investigational new drug ( IND ) application. As such, we are precluded from commenting on the NIH sponsored study. A second clinical trial of PRO 140 commenced in May 2014 and is sponsored and funded by CytoDyn. This Phase 2b trial is known as treatment substitution. This Phase 2b trial was completed in January 2015 and several patients are continuing in extension studies of this monotherapy of a weekly injection of PRO 140. Results from these extension studies thus far indicate some patients are now reaching eight months of suppressed viral load achieved through a successful monotherapy of PRO 140.

Our ongoing treatment substitution extension study has two 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 requires patients to be stable on HAART with an undetectable viral load. The trial design provided that patients will be shifted from HAART regimen to PRO 140 monotherapy for 12 weeks. PRO 140 is being administered as a 350mg subcutaneous dosage weekly and participants are monitored for viral rebound on a weekly basis. Total treatment duration with PRO 140 in the initial study 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 in subjects who did not experience virologic failure, which is defined as a viral load above 400 two weeks in a row. An independent Data Safety Monitoring Board ( DSMB ) is 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, management and oversight.

**Table of Contents**

The Company's Phase 2b treatment substitution clinical trial results through May 31, 2015, (excluding patients who failed due to having the Dual/Mix[III] virus, therefore were screening failures) are as follows:

98% of the patients passed 4 weeks of monotherapy

91% of the patients passed 6 weeks of monotherapy

82% of the patients passed 8 weeks of monotherapy

70% of the patients passed 11 weeks of monotherapy (maximum allowable monotherapy without an extension study)

14 patients, who were offered to continue in an extension study with this monotherapy, most are approaching 8 months without experiencing a virologic failure.

As only HIV patients who have CCR5 virus exclusively can benefit from PRO 140, each patient is required to take a DNA Trofile test prior to enrollment in the study. However, this test is not very accurate in patients with an undetectable viral load. Therefore, the occurrence of a number of viral rebounds due to inaccurate trofile screening was not unexpected. CytoDyn believes its clinical trial data demonstrates that patients with either R5 exclusive virus or Dual/Mix virus have all successfully passed four weeks of monotherapy, thus there would be no need for a trofile test, if this therapy were to be used for a three to four week treatment substitution. Furthermore, we believe if patients continue to remain on this monotherapy (as 14 patients are currently participating in an extension study, with some as long as eight months), then their viral load should only be tested periodically.

On May 4, 2015, the Company announced that it has reached an agreement with the FDA on the Company's previously submitted Phase 3 protocol synopsis for PRO 140 and submitted the full Phase 3 protocol to the FDA. The Company's Phase 3 protocol provides for a 25-week study with 300 HIV patients.

The Company believes that upon successful completion of this Phase 3 study, CytoDyn will have the opportunity to seek accelerated approval for PRO 140 based on previously granted FDA fast-track candidate designation. Additionally, the Company may apply for a breakthrough designation for PRO 140, as the first self-injectable antibody for HIV therapy.

The Company announced on June 9, 2015, the FDA's approval of the Company's Phase 3 protocol for an additional indication for PRO 140 and expects to commence its first Phase 3 clinical trial in mid-2015. The Company also plans to request a meeting with the FDA to discuss potential additional indications for HIV therapy following the submission of the top-line report of the recently completed Phase 2b treatment substitution study.

The Company's first Phase 3 study 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. Management believes the market size for a HAART therapy, which includes the PRO 140 antibody, along with other PRO 140 indications, could exceed a billion dollars. CytoDyn believes that its PRO 140 antibody has compelling advantages over Maraviroc, the only other CCR5 antagonist for HIV therapy (Maraviroc is a pill taken orally twice a day. PRO 140 is

currently being tested as a once-a-week subcutaneous injection of 350mg dose). These advantages include less toxicity, fewer side effects and once-a-week versus daily administration which together may improve patient compliance.

***Other Product Candidates***

Our second product candidate, Cytolin, is also a humanized monoclonal antibody for the treatment of HIV infection. It targets a normal cell molecule called CD11a, part of the heterodimer that makes up the cell adhesion molecule lymphocyte function cell associated antigen. Published reports have suggested that blocking or engaging CD11a might limit or prevent HIV infection of CD4 cells and monocytes.

We acquired rights to Cytolin in October 2003 pursuant to an agreement with CytoDyn of New Mexico, Inc. ( CytoDyn NM ). As part of the transaction, we acquired the drug candidate Cytolin and were assigned rights under the patent license agreement dated July 1, 1994, between CytoDyn NM and Allen D. Allen, covering United States Patent No. 5,651,970 (which describes a method for treating HIV disease with the use of monoclonal antibodies), including the worldwide, exclusive right to develop, market and sell compounds disclosed by the patent, to practice methods taught by the patent, and to exploit specified technology related to the patent. This patent is for a murine (mouse) version of the drug. The license agreement expired on the original expiration date of the patent in July 2014. On September 23, 2011, we filed a provisional patent application (Serial No. 61/534,942) in the United States for its humanized version of Cytolin. On September 13, 2012, we filed an international patent application (Serial No. PCT/US2012/055132) claiming priority to a United States provisional patent application for our humanized version of Cytolin. We now refer to Cytolin as the humanized version of the old Cytolin, which was the murine monoclonal antibody.

---

**Table of Contents**

In May 2011, we formed CytoDyn Veterinary Medicine LLC ( CVM ) to explore the possible application of feline reactive monoclonal antibodies for the treatment of Feline Immunodeficiency Virus ( FIV ). On June 17, 2011, we filed a provisional patent application in the United States (Serial No. 61/498,029) for the use of these antibodies, as well as selected small molecule antagonists and agonists for the treatment of FIV. On June 15, 2012, we filed an international patent application (Serial No. PCT/US2012/042693) and claimed priority to this provisional patent application. This international patent application has since entered European regional and U.S. and Canadian national stage examinations. CytoFeline is our felinized proprietary product targeted to treat FIV.

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 Cytolin or CytoFeline.

***PRO 140 Acquisition***

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 Agreement ), between CytoDyn and Progenics. The terms of the Progenics Agreement provided for an initial cash payment of \$3,500,000, which was paid at closing in October 2012, as well as the following milestone payments and royalties to be paid to Progenics in the future: (i) \$1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-US equivalent; (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 5% of 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 following the first commercialization sale of PRO 140, in each case determined on a country-by-country basis. The Progenics Agreement is filed as an exhibit to this annual report on Form 10-K.

Payments to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the PDL License ), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the PRO 140 transaction, pursuant to which we must pay additional milestone payments and royalties as follows: (i) \$1,000,000 upon initiation of a Phase 3 clinical trial; (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 of the date of this filing, management has reasonably estimated the likelihood of paying the first milestone payments, as probable, and accordingly, as of May 31, 2015, the Company has accrued \$2,500,000 for the initial milestone associated with the first dosing in a Phase 3 trial. See Note 7 to the financial statements included herein under Item 8.

As part of our acquisition of PRO 140, we entered into a collaboration agreement with Drexel, under which CytoDyn has provided Drexel with the necessary quantity of PRO 140 to conduct certain clinical trials. CytoDyn will have access to all clinical trial data and the right to use such data. During fiscal 2014, CytoDyn fulfilled its obligation to Drexel to deliver finished drug product for use in its clinical trials.

***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.

**Table of Contents**

Information with respect to our current patent portfolio as of May 31, 2015, is set forth below.

Product Candidates	Number of Patents		Expiration Dates <sup>(1)</sup>	Number of Patent Applications	
	U.S.	International		U.S.	International
PRO 140	16	27	2015-2031	7	15
Cytolin				1	
CytoFeline				2	3

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

*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 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.

## **Table of Contents**

### *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 the PRO 140 Phase 3 trial, seeking additional indications in Phase 3 trials, which we will sponsor and fund (subject to the availability of sufficient capital to pursue additional paths), and to continue to evaluate and leverage the clinical data from our recently completed Phase 2b treatment substitution trial. Additional clinical studies of our lead product candidate, PRO 140, are being sponsored by Drexel and funded at least in part by the NIH but are less critical to the viability of our business.

#### *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. We believe studies conducted under the direction of Dr. Jacobson at Drexel will collectively constitute a Phase 2b trial. Our treatment substitution clinical trial is a Phase 2b trial.

### *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 above.

## **Table of Contents**

### ***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 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. Another recent entry into the HIV treatment space is Truvada, an HIV drug produced by Gilead Sciences, Inc. Both of these 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 and Gilead Sciences, are very large, multi-national corporations with significant resources. We expect that these companies will compete fiercely to defend and expand their market share.

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

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. All of our potential competitors have considerably greater financial and management resources than we possess. 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.

### ***Research and Development Costs***

Our research and development expenses totaled approximately \$15.2 million and \$4.0 million for the fiscal years ended May 31, 2015 and May 31, 2014, respectively. We expect that research and development expenses will continue to be a significant expense as we seek to develop our current and future product pipeline.

### ***Employees and Consultants***

We have three full-time employees, our CEO, CFO 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

---

**Table of Contents**

sales. During the fiscal years ended May 31, 2015, 2014 and 2013, we have incurred net losses of approximately \$25.1 million, \$12.4 million and \$9.6 million and at May 31, 2015, we had an accumulated deficit of approximately \$71.5 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 3 clinical trial for PRO 140 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 first Phase 3 trial may range from approximately \$13 million to \$15 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 Pharmaceuticals, Inc. (from which we acquired our PRO 140 product candidate) ( Progenics ) and other third parties;

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. 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:

our stock price, which, if it declines, would serve as a disincentive to holders of our convertible promissory notes, totaling approximately \$4.0 million in face amount at June 30, 2015, to exercise their conversion rights, thereby prolonging our interest expense burden and increasing the probability that repayment of all of the outstanding principal of \$4.0 million will be required in fiscal 2016;

the costs of our Phase 3 clinical trial for PRO 140 and other clinical trials and development activities conducted by us directly, and our ability to successfully conclude the studies and achieve favorable results;

the rate of progress and commercial benefits to us, if any, related to clinical trials of PRO 140 being conducted at Drexel University College of Medicine ( Drexel );

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 and other third parties.

**Table of Contents**

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 trial 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 our outstanding convertible notes are converted into equity or we receive additional cash upon the exercise of our outstanding common stock warrants;

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;

the costs of general and administrative infrastructure required to manage our business and protect corporate assets and shareholder interests; and

the ability to maintain and benefit from our clinical trial agreement with Drexel.

If we fail to raise additional funds on a timely basis we will need to scale back our business plans, which would adversely affect our business, financial condition, and stock price, and we may even be forced to discontinue our operations and liquidate our assets.

***We have significant debt as a result of prior financings, all of which is scheduled to mature at various dates over the next two years. Our substantial indebtedness could adversely affect our business, financial condition and results of operations.***

Our level of debt, which includes convertible promissory notes totaling approximately \$4.0 million in face amount at June 30, 2015, could have significant consequences for our future operations, including, among others:

making it more difficult for us to meet our other obligations or raise additional capital;

resulting in an event of default, if we fail to comply with our payment obligations;

reducing the availability of any financing proceeds to fund operating expenses, other debt repayment, and working capital requirements; and

limiting our financial flexibility and hindering our ability to obtain additional financing.

Any of the above-listed factors could have a material adverse effect on our business, financial condition, results of operations, and ability to continue as a going concern.

Our ability to make interest and principal payments on our outstanding promissory notes will depend entirely on our ability to raise sufficient funds to satisfy our debt service obligations and our note holders' willingness to convert their notes to common shares, which will likely depend on our stock price from time to time. If note holders do not elect to convert, it is likely that we will need to borrow or raise additional funds to make required principal and interest payments, as such payments become due and payable, or undertake alternative financing plans, such as refinancing or restructuring our debt, selling additional shares of capital stock, selling assets or reducing or delaying investments in our business. Any inability to obtain additional funds or alternative financing on acceptable terms would likely cause us to be unable to meet our payment obligations, which could have a material adverse effect on our business, financial condition and results of operations and our ability to continue to operate.

---

**Table of Contents**

***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.***

Under the Progenics Agreement (see Our Business PRO 140 for a description), we must pay to Progenics and third-party licensors significant milestone payments, license fees for system know-how technology and royalties. For more information, see Business PRO 140 Acquisition and the Progenics Agreement, which is attached as Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission (the SEC) on July 30, 2012, and the PDL License Agreement, which is filed as 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.

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.

Subsequent to year end, the Company reached agreement in principle with a third-party licensor to enter into a licensing agreement 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 license will require payment of £600,000 (approximately US\$930,000) by December 31, 2015, and a contingent payment of up to an additional £600,000 (approximately US\$930,000) on June 30, 2016. The amount of the contingent payment depends on the outcome of pending litigation between the licensor and the company that sold PRO 140 to CytoDyn. The Company has accrued an expense for the payment of US\$930,000, as of May 31, 2015, for the amount due by December 31, 2015, but has not accrued the contingent payment due on June 30, 2016, as of May 31, 2015, as the amount and probability of payment cannot be reasonably estimated. Future annual license fees and royalty rate will vary depending on whether CytoDyn manufactures PRO 140 itself, utilizes the third-party licensor as a contract manufacturer, or utilizes an independent party as a contract manufacturer. The licensor does not charge an annual license fee of £300,000 when it serves as the manufacturer.

***Certain proposed clinical trials of PRO 140 depend on funding from National Institute of Health (NIH) grants awarded to Drexel and its principal investigator, Dr. Jeffrey M. Jacobson.***

Prior to our acquisition of PRO 140, Progenics and Drexel and its principal investigator, Dr. Jeffrey M. Jacobson, were awarded various grants from the NIH to fund clinical trials of PRO 140, including two grants that remain open. Our ability to benefit commercially from this continued funding will depend on whether Dr. Jacobson's protocols are structured in a manner that facilitates efforts to maintain PRO 140's fast track drug candidate designation by the United States Food and Drug Administration (FDA) and obtain regulatory approval of commercially viable uses of PRO 140 in HIV-infected patients. We believe these clinical trials may constitute a Phase 2 study of PRO 140, but there can be no assurance that will be the case. If study protocols are not designed in a manner that provides commercial and regulatory benefits for us or if NIH funding is not maintained, is withdrawn, or proves insufficient, we may not derive any benefit from these clinical trials.

***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 at least 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, including Cytolin, may take significantly longer to complete, if they are pursued at all.

The commencement and completion of clinical trials which we are undertaking ourselves or are being conducted by Drexel 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, 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;

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

---

**Table of Contents**

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.

***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.

***Any failure to attract and retain skilled directors, executives, employees and consultants could impair our drug development and commercialization activities.***

Our business depends on the skills, performance, and dedication of our directors, executive officers and key scientific and technical advisors. All of our current scientific advisors are independent contractors and are either self-employed or employed by other organizations. As a result, they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, which may affect their ability to provide services to us in a timely manner. We may need to recruit additional directors, executive management employees, and advisers, particularly scientific and technical personnel, which will require additional financial resources. In addition, there is currently intense competition for skilled directors, executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. If we are unable to attract and retain persons with sufficient scientific, technical and managerial experience, we may be forced to limit or delay our product development activities or may experience difficulties in successfully conducting our business, which would adversely affect our operations and financial condition.

***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 and chemistry and manufacturing control ( CMC ) endeavors. 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

## **Table of Contents**

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 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.

---

**Table of Contents**

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 anticipated 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 drug manufacturers often encounter difficulties involving production yields, quality control and quality assurance 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.

***We may not be able to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, 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 and for commercialization of any resulting product, if that candidate is approved for sale, we will need to manufacture it in larger quantities. 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 scale-up activities. If we are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development and testing of that product candidate and regulatory approval or commercial launch of any resulting product may be delayed, which could significantly harm our business.

***There is uncertainty relating to our product candidate Cytolin, and our business may be adversely affected if it later proves not to have the novel and beneficial characteristics we currently believe it to possess.***

Until late 2012, the primary focus of our business was on the development of Cytolin, a monoclonal antibody that has, what we believe are, novel mechanisms of action directed against the replication of HIV. We do not understand all of the biomechanical mechanisms of Cytolin and we are not actively pursuing its development and review at this time. If we cannot determine how Cytolin acts to reduce the viral load of HIV infection, we may not seek or be able to obtain regulatory approval of its use in human patients.

***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.***

---

**Table of Contents**

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, 2015, and May 31, 2014, 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 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.

## **Table of Contents**

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 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, 2015. 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.

---

**Table of Contents**

**Risks Relating to Our Common Stock**

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

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, we have 5,981,158 shares subject to outstanding options under our stock option plans, 1,754,930 shares reserved for future issuance under our equity compensation plan, 28,178,551 shares issuable upon exercise of outstanding warrants and 5,374,706 shares issuable upon conversion of our outstanding notes. 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 shares has been and is likely to continue to be volatile. The volatile nature of our common share price may cause investment losses for our shareholders. 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 shares are quoted on the OTCQB of the OTC Markets marketplace, which may increase price quotation volatility and could limit liquidity, all of which may adversely affect the market price of our shares.

***We 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, shareholders' 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 shareholders of a positive return on their investment when they sell their shares or that shareholders 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 shareholders from influencing significant corporate decisions.***

Our significant shareholders may exercise substantial influence over the outcome of corporate actions requiring shareholder 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 shareholders may also vote against a change of control, even if such a change of control would benefit our other shareholders. See "Stock Ownership by Principal Shareholders and Management" below.

***Our common shares are 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 shares are 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 shares.

**Table of Contents**

*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 shares 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.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

We relocated our principal office to our current address at 1111 Main Street, Suite 660, Vancouver, Washington 98660 effective as of October 1, 2013. We lease 1,383 square feet in a commercial office building pursuant to a lease that expires on September 30, 2016, at a cost of \$2,478 per month, plus modest annual increases. The lease also provides for early termination after 12 and 24 months.

**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.

**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.

**Table of Contents**

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
<b>Fiscal Year Ended May 31, 2015:</b>		
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
<b>Fiscal Year Ended May 31, 2014:</b>		
First quarter ended August 31, 2013	\$ 1.10	\$ 0.65
Second quarter ended November 30, 2013	\$ 1.50	\$ 0.70
Third quarter ended February 28, 2014	\$ 1.40	\$ 0.79
Fourth quarter ended May 31, 2014	\$ 1.00	\$ 0.54

**Holdings**

The number of record holders of our common stock on May 31, 2015, was approximately 285.

**Dividends**

Holdings 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.

Holdings 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, 2015, if the Company declared a dividend and elected to pay such dividend in the form of common stock, approximately 251,000 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 three months ended May 31, 2015.

**Item 6. Selected Financial Data.**

This item is not required for smaller reporting companies.

**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*

Since the beginning of fiscal 2014, we commenced several initiatives to advance our lead product candidate, PRO 140. The following is a brief summary of key accomplishments:

Raised \$14.5 million in capital through a private equity offering;

Engaged a full service clinical research organization to manage our regulatory affairs, clinical trials and CMC activities;

Advanced PRO 140 from a frozen bulk drug substance state through fill and finish and delivered finished drug product to Drexel University College of Medicine for its self-sponsored, NIH-funded clinical trials of PRO 140;

**Table of Contents**

Obtained FDA approval and successfully concluded a self-sponsored, self-funded Phase 2b clinical trial for a PRO 140 monotherapy study referred to as treatment substitution;

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

Raised \$7.5 million in capital through three private convertible debt offerings;

Induced the conversion of approximately \$4.2 million in aggregate principal amount of convertible promissory notes into common stock;

Further advanced preparations for the manufacturing of new cGMP PRO 140 antibody material; and

Obtained FDA approval of a Phase 3 clinical trial protocol, which is anticipated to commence in mid-2015.

**Results of Operations**

Results of operations for the year ended May 31, 2015, compared to May 31, 2014 are as follows:

For the years ended May 31, 2015 and 2014, we had no activities that produced revenues from operations.

For the years ended May 31, 2015 and 2014, we incurred net losses of approximately \$25.1 million and \$12.4 million, respectively. The increase in net loss of approximately \$12.7 million for fiscal 2015 over fiscal 2014 was primarily attributable to an increase in research and development expenses, higher non-cash inducement interest expense, the recognition of a derivative liability and higher amortization of debt discount.

Total operating expenses for the years ended May 31, 2015 and 2014, are as follows:

	2015	2014
<b>General and administrative:</b>		
Salaries and other compensation	\$ 1,330,000	\$ 900,000
Stock-based compensation	631,000	928,000
Accounting and consulting	134,000	216,000
Other	1,188,000	1,063,000
<b>Total general and administrative</b>	<b>3,283,000</b>	<b>3,107,000</b>
Legal	797,000	672,000
Research and development	15,156,000	3,982,000
Amortization and depreciation	361,000	352,000
<b>Total operating expenses</b>	<b>\$ 19,597,000</b>	<b>\$ 8,113,000</b>

The increase in fiscal 2015 total operating expenses of approximately \$11.5 million, or 142%, over fiscal 2014 was primarily related to the increase in research and development expenditures, and accrued incentive compensation, offset slightly by the reduction in stock-based compensation and consulting expenses.

Salaries and other compensation increased approximately \$430,000, or 48%, from approximately \$900,000 in fiscal year 2014 to approximately \$1,320,000 for the year ended May 31, 2015 due to accrued incentive compensation and to a lesser extent higher salary levels.

Stock-based compensation decreased approximately \$297,000, or 32%, from approximately \$928,000 for the year ended May 31, 2014, to approximately \$631,000 for the year ended May 31, 2015. The decrease was attributable to a reduction in stock option awards offset in part by an increase in warrants issued to third parties for compensation of services.

Accounting and consulting expenses decreased approximately \$82,000, or 37%, from \$216,000 in fiscal year 2014 to approximately \$134,000 for the year ended May 31, 2015. The decrease in accounting and consulting expenses for fiscal 2015 as compared to fiscal 2014 reflects a more efficient utilization of third party resources.

Legal expenses increased approximately \$125,000, or 19%, from approximately \$672,000 for the year ended May 31, 2014 to approximately \$797,000 for the year ended May 31, 2015. The trend in legal expenses will continue to reflect on the Company's capital raising activities, complexity of certain regulatory filings, and continued effective management of its intellectual property portfolio.

Other operating expenses of approximately \$1,188,000 for fiscal 2015 increased approximately \$125,000, or 11.7%, over fiscal 2014 owing to increased insurance costs, travel, investor relations and professional fees, offset in part by reductions in certain other administrative expenses.

**Table of Contents**

Research and development ( R&D ) expenses of approximately \$15.2 million for fiscal 2015 increased approximately \$11.2 million over fiscal 2014. The fiscal 2015 expenditures primarily included (1) CMC (chemistry, manufacturing and controls) activities to provide finished PRO 140 drug product for Drexel s clinical trials and to advance the preparations for manufacturing new PRO 140, (2) clinical trial development and management of the recently completed Phase 2b trial and preparations for a Phase 3 trial (3) the accrual of future certain milestone payments coincident with the Phase 3 trial and (4) an accrual of approximately \$0.9 million payable by December 31, 2015 in connection with the resolution of a third-party license agreement related to the licensor s system know-how technology. The increase in expenses associated with CMC activities in fiscal 2015 over fiscal 2014 was attributable in large part to the purchase of approximately \$3.2 million of resins utilized in biologics manufacturing. While these resins will provide future economic benefit to the Company through perhaps 10 to 12 future manufacturing batch runs, this expenditure does not meet the U.S. GAAP standards for capitalization under pre-launch inventory guidelines pursuant to ASC 330. Accordingly, the Company expensed the resin purchase as a period cost under CMC R&D expenses.

We record research and development where directly identifiable as follows:

	Year Ended May 31,	
	2015	2014
Research and development:		
Clinical	4,383,000	401,000
CMC	8,111,000	3,493,000
Patent and Licenses	162,000	87,500
Milestone Payments	2,500,000	
Total research and development	\$ 15,156,000	\$ 3,981,500

The Company s two convertible promissory notes held by Alpha Venture Capital Partners, L.P. and its affiliate ( AVCP ) in the principal amount of approximately \$3.5 million, which were issued during the fiscal year ended May 31, 2015, 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, the investment advisor for AVCP. Pursuant to U.S. GAAP, each of these notes require the recognition of a derivative liability. Accordingly, the Company incurred a non-cash net charge of approximately \$0.8 million during fiscal year ended May 31, 2015. In June 2015, the Company entered into a Debt Conversion and Termination Agreement, whereby AVCP converted its promissory notes into an aggregate of 5,237,966 shares of common stock and received warrants 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.

Interest expense for fiscal 2015 totaled approximately \$4.7 million, of which all but approximately \$0.4 million was non-cash. Interest expense for fiscal 2015 was comprised of approximately (i) \$2.7 million (non-cash) related to amortization of debt discounts, (ii) \$1.5 million (non-cash) arising from inducements to convert notes and the exercise of warrants, (iii) \$0.4 million payable on outstanding notes and (iv) \$0.1 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. Due to the timing of note

conversions in 2015, the debt discount and convertible note interest were both reduced by approximately \$1.7 million and \$226,000, respectively, in fiscal 2015 as compared to fiscal year 2014.

The future trends in all of our 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 requirements, in addition to the possibility that all or a portion of the holders of the Company's outstanding convertible notes may elect to convert their notes into common stock, which would reduce future interest expense. See, in particular, Item 1A Risk Factors above.

#### Liquidity and Capital Resources

We had cash and cash equivalents of approximately \$1 million as of May 31, 2015, compared with \$4.9 million as of May 31, 2014. The net decrease in our cash and cash equivalents over a year ago was attributable to net cash used in operating activities of approximately \$12 million, offset in part by proceeds from debt issuance and the exercise of warrants, which together totaled approximately \$8.6 million.

As of May 31, 2015, we had negative working capital of approximately \$8.7 million, which compares to working capital of \$3.3 million at May 31, 2014.

---

**Table of Contents**

**Cash Flows**

Net cash used in operating activities was approximately \$12.0 million during fiscal year 2015, which represents an increase of approximately \$4.6 million from net cash used in operating activities of approximately \$7.4 million in fiscal 2014. The increase in the net cash used in operating activities for fiscal 2015 as compared to fiscal 2014 was primarily attributable to an increase in R&D expenses of \$11.2 million, offset an increase in current liabilities of approximately \$7.4 million. The effect of the higher net loss was also offset in part by the non-cash components of interest expense, which totaled approximately \$4.3 million, the change in fair value of derivative liability of approximately \$0.8 million and stock-based compensation totally approximately \$0.6 million.

Net cash used in investing activities of approximately \$19,000 is comparable for fiscal years 2015 and 2014.

Cash flows provided by financing activities of approximately \$8.2 million during fiscal 2015 decreased approximately \$3.5 million from fiscal 2014. During fiscal year 2015, proceeds of approximately \$7.5 million were received in connection with issuance of convertible notes payable, net of \$423,000 in offering costs, along with approximately \$1.1 million received upon the exercise of warrants. The decrease in cash provided by financing activities in fiscal 2015 as compared to fiscal 2014 was principally due to a private equity offering during fiscal year 2014 that provided net cash of approximately \$11.6 million, after offering costs of approximately \$2.1 million. During fiscal year 2014, the Company issued \$1.2 million of convertible notes, of which \$250,000 in principal amount was repaid and \$950,000 in aggregate principal converted into the equity offering. The Company also paid, at maturity, two notes in the aggregate principal amount of \$1 million.

As mentioned above, we have no activities that produced revenue in fiscal year 2015 and 2014 and have sustained operating losses since inception. Our ability to continue as a going concern is dependent upon our ability to raise additional capital until we can commence sales operations and achieve a level of profitability. Since inception, we have financed our activities principally from the sale of private equity and debt securities. We intend to finance our future development activities and our working capital needs largely from the sale of equity securities, combined with additional funding from other traditional financing sources.

The Company is current with its interest payment obligations to all note holders and is in compliance with all other terms of outstanding promissory notes. As of May 31, 2015, the Company had a total of approximately \$7.5 million outstanding in face amount of convertible promissory notes. In the event our promissory notes are not converted into shares of common stock, the Company's ability to continue as a going concern will be contingent upon its ability to raise additional capital to meet these obligations, or refinance. If the Company is unsuccessful in raising additional capital or refinancing in the future, it may be required to cease its operations. In June 2015, the Company entered into a Debt Conversion and Termination Agreement, whereby AVCP converted its promissory notes into an aggregate of 5,237,966 shares of common stock and received warrants 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. See Note 14 to the financial statements included herein under Item 8. As such, the total amount of outstanding convertible promissory notes as of the date of the filing has been reduced from approximately \$7.5 million down to approximately \$4 million and the earliest maturity date is October 2015 rather than August 2015.

We have not generated revenue to date, and will not generate product revenue in the foreseeable future. We expect to continue to incur sizable operating losses as we proceed with our 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, we expect general and administrative and manufacturing costs to increase, as we add personnel and other administrative expenses associated with our current efforts.

In furtherance of our business strategy, the Company entered into a manufacturing agreement with a contract manufacturing organization to initiate preparations for the future manufacturing of additional PRO 140. The remaining costs to be incurred under this agreement, are approximately \$3.6 million, of which approximately \$3.2 million represent a fixed contractual obligation pursuant to various termination provisions. The total future estimated costs of manufacturing may vary materially depending on future decisions by management and its technical consultants with respect to various scientific and regulatory elements of the agreement. As of the date of this filing, all contractually incurred expenses have been recognized in the financial statements. In addition, the Company recently entered into an agreement with its incumbent clinical research organization to begin a Phase 3 trial and paid an execution fee of approximately \$0.7 million. The total estimated expenses for the Company's first Phase 3 trial may range from approximately \$13 million to \$15 million, as contracts with third-party service providers are still in negotiations. The Company will need sizable amounts of additional capital to complete these activities.

Under the Asset Purchase Agreement (the "Asset Purchase Agreement"), dated July 22, 2012, between the Company and Progenics Pharmaceuticals, Inc. ("Progenics"), the Company acquired from Progenics its proprietary 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 \$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 Phase 3 trial or non-US equivalent; (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 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 payments due under a Development and License Agreement, dated April 30, 1999 (the "PDL

---

## Table of Contents

License ), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the PRO 140 transaction, pursuant to which we must pay additional milestone payments and royalties as follows: (i) \$1,000,000 upon initiation of a Phase 3 clinical trial; (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 noted above and in the financial statements included herein under Item 8, the Company accrued milestone payments totaling \$2.5 million as of May 31, 2015 in connection with its Phase 3 clinical trial.

Subsequent to year end, the Company reached agreement in principle with a third-party licensor to enter into a licensing agreement 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 license will require payment of £600,000 (approximately US\$930,000) by December 31, 2015, and a contingent payment of up to an additional £600,000 (approximately US\$930,000) on June 30, 2016. The amount of the contingent payment depends on the outcome of pending litigation between the licensor and the company that sold PRO 140 to CytoDyn. The Company has accrued an expense for the payment of US\$930,000, as of May 31, 2015, for the amount due by December 31, 2015, but has not accrued the contingent payment due on June 30, 2016, as of May 31, 2015, as the amount and probability of payment cannot be reasonably estimated. Future annual license fees and royalty rate will vary depending on whether CytoDyn manufactures PRO 140 itself, utilizes the third-party licensor as a contract manufacturer, or utilizes an independent party as a contract manufacturer. The licensor does not charge an annual license fee of £300,000 when it serves as the manufacturer.

## Going Concern

We will require additional funding in order to continue to operate.

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, 2015, 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.

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 New Drug Application (an NDA ) that has been acknowledged by the FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely

**Table of Contents**

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, 2014 and 2015 the Company did not have pre-launch inventory.

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 follow the provisions of FASB ASC 815 Derivatives and Hedging ( ASC 815 ), as instruments are recorded as a derivative liability, at fair value, with changes in fair value reflected in income. 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.

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

We have 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 7 and 8 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.

CONTENTS	PAGE
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	24
<u>CONSOLIDATED BALANCE SHEETS AS OF MAY 31, 2015 AND MAY 31, 2014</u>	25
<u>CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEARS ENDED MAY 31, 2015 AND 2014</u>	26

<u>CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS (DEFICIT) EQUITY FOR THE YEARS ENDED MAY 31, 2015 AND 2014</u>	27
<u>CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED MAY 31, 2015 AND 2014</u>	31
<u>NOTES TO CONSOLIDATED FINANCIAL STATEMENTS</u>	33

**Table of Contents**

**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, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for the years then ended. 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 audits 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, 2015 and 2014 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

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 \$25,088,070 for the year ended May 31, 2015, and has an accumulated deficit of \$71,522,302 through May 31, 2015, 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 10, 2015

**Table of Contents**

## CytoDyn Inc.

## Consolidated Balance Sheets

	May 31,	
	2015	2014
<b>Assets</b>		
Current assets:		
Cash	\$ 1,050,060	\$ 4,886,122
Prepaid expenses	253,833	488,821
Prepaid clinical service fees	733,916	
Deferred offering costs		68,292
<b>Total current assets</b>	<b>2,037,809</b>	<b>5,443,235</b>
Furniture and equipment, net	24,213	16,797
Intangibles, net	2,617,239	2,967,239
<b>Total Assets</b>	<b>\$ 4,679,261</b>	<b>\$ 8,427,271</b>
<b>Liabilities and Shareholders (Deficit) Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,016,261	\$ 1,286,715
Accrued milestone payments	2,500,000	
Accrued liabilities, salaries and interest payable	644,533	501,640
Accrued license fees	930,000	
Convertible notes payable, net	1,634,458	
Stock rescission liability		378,000
<b>Total current liabilities</b>	<b>10,725,252</b>	<b>2,166,355</b>
Long-term liabilities		
Related party, convertible note payable, net	2,637,618	
Related party, derivative liability	2,008,907	
Convertible notes payable, net		2,338,684
<b>Total liabilities</b>	<b>15,371,777</b>	<b>4,505,039</b>
Shareholders (deficit) equity:		
Series B convertible preferred stock, no par value; 400,000 shares authorized, 95,100 shares issued and outstanding at May 31, 2015 and May 31, 2014, respectively	247,556	266,251
Common stock, no par value; 200,000,000 and 100,000,000 shares authorized, 63,644,348 and 55,753,311 issued and outstanding at May 31, 2015 and May 31, 2014, respectively	35,819,240	30,367,779
Additional paid-in capital	24,762,990	20,100,434
Common and preferred stock subject to rescission		(378,000)
Accumulated (deficit)	(71,522,302)	(46,434,232)

Total shareholders (deficit) equity	(10,692,516)	3,922,232
Total liabilities and shareholders (deficit) equity	\$ 4,679,261	\$ 8,427,271

See accompanying notes to consolidated financial statements.

**Table of Contents**

## CytoDyn Inc.

## Consolidated Statements of Operations

	Year ended May 31,	
	2015	2014
Operating expenses:		
General and administrative	\$ 3,282,908	\$ 3,106,678
Amortization and depreciation	360,582	352,429
Research and development	15,156,365	3,981,468
Legal fees	796,671	672,153
Total operating expenses	19,596,526	8,112,728
Operating loss	(19,596,526)	(8,112,728)
Interest income	2,199	7,767
Gain on settlement of accounts payable		183,944
Change in fair value of derivative liability	(838,643)	
Interest expense:		
Amortization of discount on convertible notes	(2,145,010)	(3,807,320)
Amortization of discount on related party convertible notes	(523,614)	
Amortization of debt issuance costs	(103,598)	(120,000)
Inducement interest	(1,526,254)	
Interest on notes payable	(356,624)	(583,076)
Total interest expense	(4,655,100)	(4,510,396)
Loss before income taxes	(25,088,070)	(12,431,413)
Provision for taxes on income		
Net loss	\$ (25,088,070)	\$ (12,431,413)
Basic and diluted loss per share	\$ (0.43)	\$ (0.27)
Basic and diluted weighted average common shares outstanding	58,375,637	46,900,643

See accompanying notes to consolidated financial statements.

**Table of Contents**

## CytoDyn Inc.

## Consolidated Statement of Changes in Shareholders (Deficit) Equity

	Preferred Stock		Common Stock		Common Stock Payable
	Shares	Amount	Shares	Amount	
Balance May 31, 2013	95,100	\$ 274,091	30,908,292	\$ 16,144,673	\$ 117,778
Rescission expirations and exclusions					
Amortization of deferred offering costs related to rescission liability		(7,840)		(20,796)	
Proceeds from unit offering (\$1.30/unit)			20,989,494	13,642,667	
Deferred offering costs				(2,084,063)	
Inducement warrants					
Conversion of convertible debt to common stock (\$.65/share)			2,046,148	1,330,000	
Conversion of convertible debt to common stock (\$.75/share)			1,493,333	1,120,000	
Conversion of accrued interest on convertible debt to common stock (\$.65/share)			24,363	15,837	
Conversion of accrued interest on convertible debt to common stock (\$.75/share)			16,117	12,088	
Exercise of common stock warrants (\$1.00/share)			50,000	50,000	
Common stock issued for accrued interest			150,000	75,000	(10,278)
Common stock issued for bonuses			53,601	72,361	(107,500)
Conversion of note payable and accrued interest to common stock (\$.45/share)			21,963	10,012	
Stock-based compensation					
Debt discount related to warrants and beneficial conversion feature associated with convertible debt					
Net (loss) for year ended May 31, 2014					
Balance at May 31, 2014	95,100	\$ 266,251	55,753,311	\$ 30,367,779	

See accompanying notes to consolidated financial statements.



**Table of Contents**

## CytoDyn Inc.

## Consolidated Statement of Changes in Shareholders (Deficit) Equity

	Additional Paid-In Capital	Rescission Amount	Accumulated Deficit	Total
Balance May 31, 2013	17,778,861	\$ (536,500)	\$ (34,002,819)	\$ (223,916)
Rescission expirations and exclusions		158,500		158,500
Amortization of deferred offering costs related to rescission liability				(28,636)
Proceeds from unit offering (\$1.30/unit)				13,642,667
Deferred offering costs				(2,084,063)
Inducement warrants	193,160			193,160
Conversion of convertible debt to common stock (\$.65/share)				1,330,000
Conversion of convertible debt to common stock (\$.75/share)				1,120,000
Conversion of accrued interest on convertible debt to common stock (\$.65/share)				15,837
Conversion of accrued interest on convertible debt to common stock (\$.75/share)				12,088
Exercise of common stock warrants (\$1.00/share)				50,000
Common stock issued for accrued interest				64,722
Common stock issued for bonuses				(35,139)
Conversion of note payable and accrued interest to common stock (\$.45/share)				10,012
Stock-based compensation	928,413			928,413
Debt discount related to warrants and beneficial conversion feature associated with convertible debt	1,200,000			1,200,000
Net (loss) for year ended May 31, 2014			(12,431,413)	(12,431,413)
Balance at May 31, 2014	\$ 20,100,434	\$ (378,000)	\$ (46,434,232)	\$ 3,922,232

See accompanying notes to consolidated financial statements.

**Table of Contents**

## CytoDyn Inc.

## Consolidated Statement of Changes in Shareholders (Deficit) Equity

	Preferred Stock		Common Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Balance May 31, 2014	95,100	\$ 266,251	55,753,311	\$ 30,367,779	\$ 20,100,434
Rescission expirations and exclusions					
Amortization of deferred offering costs related to rescission liability		(18,695)		(49,597)	
Common stock for interest on convertible note OID, intrinsic value related to warrants			104,153	52,077	2,505,261
Conversion of convertible debt to common stock (\$.75)/share			5,628,330	4,221,250	
Conversion of accrued interest on convertible debt to common stock (\$.75/share)			119,580	86,296	
Exercise of common stock warrants (\$.55/share)			1,938,974	1,066,435	
Exercise of common stock warrants (\$.75/share)			100,000	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					
Balance at May 31, 2015	95,100	\$ 247,556	63,644,348	\$ 35,819,240	\$ 24,762,990

See accompanying notes to consolidated financial statements.

**Table of Contents**

## CytoDyn Inc.

## Consolidated Statement of Changes in Shareholders (Deficit) Equity

	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 (\$.75)/share			4,221,250
Conversion of accrued interest on convertible debt to common stock (\$.75/share)			86,296
Exercise of common stock warrants (\$.55/share)			1,066,435
Exercise of common stock warrants (\$.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.

**Table of Contents**

## CytoDyn Inc.

## Consolidated Statements of Cash Flows

	Year Ended May 31,	
	2015	2014
<b>Cash flows from operating activities:</b>		
Net loss	\$ (25,088,070)	\$ (12,431,413)
<b>Adjustments to reconcile net loss to net cash used by operating activities:</b>		
Amortization and depreciation	360,582	352,429
Amortization of debt issuance costs	103,598	120,000
Amortization of discount on convertible notes	2,145,010	3,807,320
Amortization of discount on related party notes	523,614	
Gain on settlement of accounts payable		(183,944)
Loss on the sale of fixed asset	583	
Change in fair value of derivative liability	838,643	
Inducement interest expense	1,526,254	193,160
Stock-based compensation	631,302	928,413
<b>Changes in current assets and liabilities:</b>		
Decrease (increase) in prepaid expenses	(498,928)	(348,972)
Increase (decrease) in accounts payable, accrued salaries and severance, accrued license fees, accrued interest and accrued liabilities	7,440,554	176,064
Net cash used in operating activities	(12,016,858)	(7,386,943)
<b>Cash flows from investing activities:</b>		
Furniture and equipment purchases	(18,585)	(19,220)
Net cash used in investing activities	(18,585)	(19,220)
<b>Cash flows from financing activities:</b>		
Payments on indebtedness to related parties		(500,000)
Payments on convertible notes payable		(500,000)
Payments of debt issuance costs	(423,104)	(120,000)
Payments of offering costs		(2,084,063)
Proceeds from sale of common stock		13,642,667
Proceeds from issuance of convertible notes payable	7,481,050	1,200,000
Proceeds from exercise of warrants	1,141,435	50,000
Net cash provided by financing activities	8,199,381	11,688,604
Net change in cash	(3,836,062)	4,282,441
Cash, beginning of period	4,886,122	603,681
Cash, end of period	\$ 1,050,060	\$ 4,886,122

See accompanying notes to consolidated financial statements.

**Table of Contents**

## CytoDyn Inc.

## Consolidated Statements of Cash Flows

	Year Ended May 31,	
	2015	2014
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for:		
Income taxes	\$ 3,142	\$
Interest	\$ 203,864	\$ 311,991
<b>Non-cash investing and financing transactions:</b>		
Common stock issued upon conversion of convertible debt	\$ 4,221,250	\$ 2,459,000
Common stock issued or to be issued for accrued interest payable	\$ 138,373	\$ 58,518
Original issue discount and intrinsic value of beneficial conversion feature related to debt issued with warrants	\$	\$ 1,200,000
Preferred and common stock subject to rescission liability	\$ 378,000	\$ 158,500
Amortization of deferred offering costs related to rescission liability	\$ 68,292	\$ 28,638
Accounts payable extinguished through settlements	\$	\$ 183,944
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.

---

**Table of Contents**

CYTODYN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF MAY 31, 2015

**1 Organization**

CytoDyn Inc. (the Company) was incorporated under the laws of Colorado on May 2, 2002 under the name Rexray Corporation (Rexray). In October 2003, the Company (under its previous name RexRay Corporation) entered into an Acquisition Agreement with CytoDyn of New Mexico, Inc. Pursuant to the acquisition agreement, the Company acquired assets related to its drug candidate Cytolin, including the assignment of the patent license agreement dated July 1, 1994 between CytoDyn of New Mexico, Inc. and Allen D. Allen covering three United States patents along with foreign counterpart patents which describe a method for treating Human Immunodeficiency Virus (HIV) disease with the use of monoclonal antibodies.

The Company is developing a class of therapeutic monoclonal antibodies to address unmet medical needs in the areas of HIV and Acquired Immune Deficiency Syndrome (AIDS).

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

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 proprietary monoclonal antibody technology to the treatment of Feline Immunodeficiency Virus (FIV). The Company views the formation of CVM as an effort to strategically diversify the use of its proprietary monoclonal antibody technology.

**2 Summary of Significant Accounting Policies**

**Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries; AGTI and CVM. 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 2015 presentation. These reclassifications did not have any effect on total current assets, total assets, total current liabilities, total liabilities, total shareholders' (deficit) equity or net loss.

**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 \$25,088,070 and \$12,431,413 for the years ended May 31, 2015, and May 31, 2014, respectively. Additionally, the Company has a working capital deficit of \$8,687,443 as of May 31, 2015. 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. We intend to finance our future development activities and our working capital needs largely from the sale of debt and equity 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 revenues and expenses during the reporting period. Actual results could differ from those estimates.



## **Table of Contents**

### **Cash**

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. We have never experienced any losses related to these balances. Balances in excess of federally insured limits at May 31, 2015 and 2014 approximated \$1,164,000 and \$4,589,000, 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 (See Note 12 for acquisition of patents). There were no impairment charges for the years ended May 31, 2015 and 2014. The value of the Company's patents would be significantly impaired by any adverse developments as they relate to the clinical trials pursuant to the patents acquired as discussed in Notes 7 and 13.

### **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 New Drug Application (an NDA) 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, 2014 and 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 common stock options and common stock warrants based on the fair market value of the instrument using the Black-Scholes option pricing model utilizing certain weighted average assumptions such as expected stock price volatility, term of the options and warrants, risk-free interest rates, and expected dividend yield at the grant date. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the stock options. The expected volatility is based on the historical volatility of the Company's common stock at consistent intervals. The Company has not paid any dividends on its common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future. The computation of the expected option term is based on the simplified method, as the Company's stock options are plain vanilla options and the Company has a limited history of exercise data. For common stock options and warrants with periodic vesting, the Company recognizes the related compensation costs associated with these options and warrants on a straight-line basis over the requisite service period.

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 option forfeitures at 0% for all periods presented.

## **Table of Contents**

### **Preferred Stock**

As of May 31, 2015, the Company's Board of Directors is authorized to issue up to 5,000,000 shares of preferred stock without shareholder approval. As of May 31, 2015, the Company has authorized the issuance of 400,000 shares of Series B convertible preferred stock, as to which there are 95,100 shares outstanding at May 31, 2015 (see Note 4). The remaining preferred shares authorized have no specified rights other than the shares are non-voting.

### **Deferred Offering Costs**

In connection with a stock rescission liability as discussed at Note 3, the Company has recorded approximately \$ -0- and \$68,300 in deferred offering costs as of May 31, 2015 and May 31, 2014, respectively. Due to the expiration of remaining rescission rights, the asset has been reclassified as a reduction of equity at May 31, 2015.

During the year ended May 31, 2014, the Company incurred approximately \$2,084,000 in direct incremental costs associated with sale of debt and equity securities as described in Note 6. The offering costs were recorded as a component of equity when the proceeds were received. The offering was completed on October 23, 2013.

### **Debt Issuance Costs**

The Company has early adopted Accounting Standards Update ( ASU ) 2015-03, as described in Note 10, 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 4, and recorded approximately \$708,000 of debt issuance costs and approximately \$104,000 of related amortization at May 31, 2015. During the year ended May 31, 2014, the Company incurred \$120,000 in direct costs associated with the issuance of the 2014 convertible bridge notes as described in Note 4, and recorded \$120,000 in amortization expense for the year ended May 31, 2014.

### **Stock for Services**

The Company periodically issues common stock, warrants to purchase common stock and common stock options 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 common stock 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 is computed by dividing net loss by the weighted average common shares and potentially dilutive common share equivalents. The effects of potential common stock equivalents are not included in computations when their effect is anti-dilutive. 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 calculation. Common stock options and warrants to purchase 31,008,915 and 30,806,361 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, 2015 and May 31, 2014, respectively, as inclusion would be anti-dilutive for these periods. Additionally, as of May 31, 2015, shares of Series B convertible

preferred stock in the aggregate of 95,100 shares can potentially convert into 951,000 shares of common stock, and \$7,531,050 in aggregate principal of convertible debt can potentially convert into 10,559,919 shares of common stock.

### **Fair Value of Financial Instruments**

At May 31, 2015 and May 31, 2014 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.

**Table of Contents**

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.

Liability measured at fair value on a recurring basis by level within the fair value hierarchy as of May 31, 2015 and May 31, 2014 is as follows:

	Fair Value Measurement at May 31, 2015 <sup>(1)</sup>		Fair Value Measurement at May 31, 2014 <sup>(1)</sup>	
	Using Level 3	Total	Using Level 3	Total
<b>Liability:</b>				
Derivative liability	\$ 2,008,907	\$ 2,008,907	\$	\$
<b>Total liability</b>	<b>\$ 2,008,907</b>	<b>\$ 2,008,907</b>	<b>\$</b>	<b>\$</b>

(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, 2015 and 2014.

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 year ended May 31, 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
<b>Balance at May 31, 2015</b>	<b>\$ 2,008,907</b>

## **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 and penalties in operating expenses.

---

**Table of Contents****Note 3 Rescission Liabilities**

The Company's board of directors (the Board) was advised by outside legal counsel that compensation the Company previously paid to an employee and certain other non-employees who were acting as unlicensed, non-exempt broker-dealers soliciting investors on behalf of the Company from April 15, 2008 to February 18, 2011 was a violation of certain state and possibly federal securities laws. As a result, such investors and potentially others have rescission or monetary claims (Claims) against the Company, and the Company's liability for these potential Claims is reflected in the Company's financial statements. On March 16, 2011, the Company filed a Current Report on Form 8-K disclosing the potential rescission liability (the Liability Disclosure).

Rescission rights for individual investors and subscribers vary, based upon the laws of the states in which the investors or subscribers reside. Investments and subscriptions that are subject to rescission are recorded separately in our financial statements from shareholders' equity in the Company's balance sheet. As the statutory periods for pursuing such rights expire in the respective states, such amounts for those shares have been reclassified to shareholders' equity. Investors who have sold their shares of capital stock of the Company do not have rescission rights, but instead have claims for damages, to the extent their shares were sold at a net loss, which is determined by subtracting the purchase price plus statutory interest and costs, if any, from the sale price.

The Company considered methods to offer to rescind the previous investment purchase or subscription by persons who acquired or subscribed for investments during the period April 15, 2008 to February 18, 2011, but did not pursue any such methods.

The Company estimates an amount that is a probable indicator of the rescission liability and determined that such liability was remote, as of May 31, 2015, and accordingly, recorded rescission liabilities for May 31, 2015 and May 31, 2014 of \$ 0 and \$378,000, respectively. These amounts represent the believed remaining potential rescission liability as of the dates presented to investors who pursue their rescission rights and forfeit their shares. For the purpose of calculating and disclosing rescission liability, the Company has assumed that portions of the state Claims are barred by the statutes of limitations of certain states based upon a literal interpretation of the applicable statute. Although the Company has assumed that affirmative defenses based upon the application of the statutes of limitations in these states may be generally available to bar these state Claims, it has not had legal counsel undertake a detailed analysis of case law that might apply to defer or avoid application of a bar to such claims; thus, if rescission claims are made for those assumed to be barred by a statute of limitations and such claims are contested by the Company, until such affirmative defenses are ruled upon in a proceeding adjudicating the rights at issue, no assurances can be made that, if asserted, such defenses would actually bar the rescission claims in these states. Since the issue of potential rescission liability was first disclosed by us in early 2011, no investor has asserted rescission rights and some such investors had subsequently invested in the Company again. Accordingly, as of May 31, 2015, management has concluded that the probability of certain investors asserting their rescission rights was remote and no longer reasonably estimable. As such, management eliminated the previously accrued rescission liability as of May 31, 2015.

**Note 4 Convertible Instruments***Series B Convertible Preferred Stock*

During fiscal 2010, the Company issued 400,000 shares of Series B 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, 2015. Each share of the Series B is convertible into ten shares of the Company's common stock including any accrued dividend, with an effective fixed conversion price of \$.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 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 \$.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 unsecured convertible notes (the Notes) to investors for cash. Each Note is convertible at the election of the holder at any time into common shares at a fixed conversion price. Total principal of \$6,208,250 is convertible at \$0.75 per share, and \$380,000 is convertible at \$0.65 per share. The Notes are payable in full between November 30, 2013 and March 6, 2016. The Notes bear interest at rates that range from 5% to 10% per year, payable in cash semi-annually in arrears beginning on April 1, 2013. In connection with the sale of the 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 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 option related to the Notes was beneficial to the investors. As a result, the Company determined the intrinsic value of the conversion option utilizing the fair value of the common stock at the commitment date and the effective conversion price after discounting the Notes for the fair value of the warrants. The fair value of the warrants and the intrinsic value of the conversion option were recorded as debt discounts to



**Table of Contents**

the Notes, and a corresponding increase to additional paid-in capital. The debt discounts are amortized over the life of the Notes. At the time of conversion, any unamortized discounts associated with the Notes are fully amortized and recorded as interest expense. As of May 31, 2015, the outstanding principal of these Notes is \$50,000.

During fiscal year ended May 31, 2014, the holders of Notes in aggregate principal amount totaling \$1,500,000 and accrued but unpaid interest of \$6,351 converted their Notes into common stock. Of these conversions, \$1,120,000 and \$350,000 in principal were at a conversion price of \$0.75 and \$0.65 per share, respectively, resulting in the issuance of 2,087,717 shares of common stock. In addition, one holder of a Note with a principal amount of \$250,000 was paid in full upon maturity.

During the year ended May 31, 2015, holders of the Notes in the aggregate principal amount of \$1,175,000, plus accrued but unpaid interest of \$4,703, were induced to convert their Notes into common stock, at the rate of \$0.75 per share, conditioned upon their immediate exercise of warrants at an exercise price reduced from \$2.00 down to \$0.55 per share, as further described in Note 6. The note conversions resulted in the issuance of 1,556,667 shares of common stock and a cash interest payment of \$3,793.

During the year ended May 31, 2015, holders of the Notes in the aggregate principal amount of \$3,046,250, plus accrued but unpaid interest of \$86,296, were induced to convert their 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 previously expired warrants to purchase 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 and as further described in Note 6.

In connection with the issuance of the Company's convertible Notes in fiscal year ended 2013, detachable common stock warrants, with terms of two or three years, were issued to the investors to purchase a total of 9,451,056 common shares at exercise prices ranging from \$.50 to \$2.00 per share. During the year ended May 31, 2014, warrants covering 923,072 shares were issued to investors at an exercise price of \$.50 per share. All of the warrants are currently exercisable in full. 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 warrants:

	2015	2014
Expected dividend yield	0%	0%
Stock price volatility	80.68%	78-93%
Expected term	.50 yr	3-5 years
Risk-free interest rate	0.12%	.64-1.42%
Grant-date fair value	\$0.15	\$.66-\$.72

Additionally, at the commitment date, the Company determined that the conversion feature related to the 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 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 Notes, with a corresponding increase to additional paid-in capital. The debt discount is amortized over the life of the Notes. During the years ended May 31, 2015 and 2014, the Company recognized approximately \$2,145,000 and \$3,807,000, respectively, as interest expense

related to amortization of the debt discount. The unamortized discount is fully amortized upon any conversion of the Notes before maturity. Activity related to the Notes was as follows:

	May 31, 2015	May 31, 2014
Face amount of Notes	\$ 4,271,250	\$ 7,221,250
Unamortized discount	(6,529)	(1,932,566)
Repayments		(500,000)
Conversions	(4,221,250)	(2,450,000)
Total carrying value of Notes	\$ 43,471	\$ 2,338,684
Short-term portion of Notes	\$ 43,471	\$
Long-term portion of Notes	\$	\$ 2,338,684

---

**Table of Contents***2014 Convertible Bridge Notes*

During the year ended May 31, 2014, the Company issued in the aggregate principal amount of \$1,200,000 of unsecured short-term notes with a fixed conversion price, (the Notes) to investors for cash. The Notes bear interest of 5% per year and a maturity of six months. The Notes could be converted on or before October 1, 2013 into the Company's private equity offering, as further described in Note 9. During the year ended May 31, 2014, holders of the Notes converted an aggregate principal amount of \$950,000 into the private equity offering at a conversion price of \$0.65 and one holder of a Note in the principal amount of \$250,000 exercised their right to receive repayment.

*AVCP Convertible Notes*

During the year ended May 31, 2015, the Company issued a three-month unsecured convertible promissory note in the aggregate principal amount of \$1,500,000 to Alpha Venture Capital Partners, L.P. ( AVCP ). The principal amount of the Note plus unpaid accrued interest is 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 Note bears simple interest of 1.2% per month, payable at maturity on May 5, 2015, and monthly thereafter, if the Company exercises its one-time option to extend the maturity by an additional three months, which the Company exercised such right on April 1, 2015. The maturity date has been extended to August 5, 2015. Prepayment is permitted without penalty subject to the Company's obligation to pay at least three months' interest on the principal amount. The conversion price is 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 CytoDyn 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 may not 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 is subordinated in right of payment to the Company's obligations under the AVCP Note and any additional notes issued to AVCP or related parties.

During the year ended May 31, 2015, the Company issued a two-year term unsecured convertible promissory note (the AVCP Note ) in the aggregate principal amount of \$2,000,000 to Alpha Venture Capital Partners, L.P. ( AVCP ). The AVCP Note bears simple interest at the annual rate of 5%, payable quarterly. The principal balance of the AVCP Note is due and payable in full on September 26, 2016, subject to acceleration of payment in the event of default. Prepayment is permitted without penalty. The AVCP Note includes events of default for nonpayment of principal or interest when due or other breaches of the AVCP Note, as well as for breach of any term of the AVCP Note and related warrant agreement. The principal amount of the Note plus unpaid accrued interest is 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 is 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 CytoDyn 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 may not 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 is subordinated in right of payment to the Company's obligations under the AVCP Note and any additional notes issued to AVCP or related parties.

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, the conversion price of the existing AVCP Notes was reduced to \$0.675 per share of common stock, which was 90% of the weighted-average conversion price of \$0.75 related to the approximately \$4 million offering of convertible notes. The decrease in the conversion price caused the number of shares of common stock issuable upon conversion of the AVCP Notes to increase from 3,500,000 to 5,185,185 shares of common stock.

The Company accounted for the AVCP Notes and warrants as a financing transaction, wherein the proceeds received were allocated to the financial instruments issued. Prior to making the accounting allocation, the AVCP Notes and warrants were evaluated for proper classification under FASB ASC 480 Distinguishing Liabilities from Equity ( ASC 480 ) and ASC 815. 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 consist 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 are 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 Notes require bifurcation as a derivative liability.

In connection with the two AVCP 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 28, 2020, respectively.

**Table of Contents**

The aforementioned warrants have a term of five years from inception and an exercise price of \$.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 Notes as follows:

	September 26, 2014	February 6, 2015	Debt Discount	Fair Value	May 31, 2015
AVCP convertible notes payable	\$ 1,074,617	\$ 1,039,387	\$ 523,614	\$	\$ 2,637,618
Compound embedded derivative	767,038	403,226		838,643	2,008,907
Warrants (equity allocation)	158,345	57,387			215,732
	\$ 2,000,000	\$ 1,500,000	\$ 523,614	\$ 838,643	\$ 4,862,257

*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 Notes) and related warrants to investors for cash. Each Note is convertible, at the election of the holder, at any time into common shares at a \$0.75 per share. The Notes bear interest of 7% per annum, payable in cash upon maturity. In connection with the Notes, the Company 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 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 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 Notes, and a corresponding increase to additional paid-in capital. The debt discounts are amortized over the life of the Notes. During the year ended May 31, 2015, the Company recognized approximately \$219,000 as interest expense related to amortization of the debt

**Table of Contents**

discounts. The unamortized discounts are fully amortized upon any conversion of the Notes before maturity. Activity related to the Notes was as follows:

	May 31, 2015
Face amount of Notes	\$ 3,981,050
Unamortized discount	(2,390,063)
Repayments	
Conversions	
Total carrying value of Notes	\$ 1,590,987

**Note 5 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 May 31, 2015:

	AVCP Notes Dated as of		
	September 26, 2014	February 6, 2015	May 31, 2015
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, 2015, the Company recognized a non-cash expense of approximately \$839,000 due to an increase in the 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:

Edgar Filing: CYTODYN INC - Form 10-K

	September 26, 2014	February 6, 2015	May 31, 2015
Quoted market price on valuation date	\$0.79	\$0.96	\$0.99
Contractual conversion rate	\$1.00	\$1.00	\$1.00
Adjusted conversion price (a)	\$0.9759	\$1.0000	\$0.675
Contractual term to maturity (years)	2.00	0.49	0.18-1.33
Expected volatility	123%	124%	73% - 105%
Contractual interest rate	5%	2%	1.2%-5.0%
Risk-free rate	0.59%	0.045%	0.01%-0.35%
Risk-adjusted rate	2.69%	2.78%	2.80%
Probability of event of default	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 the short-term convertible notes 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.

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.



---

**Table of Contents****Note 6 Stock Options and Warrants**

The Company has one active stock-based equity plan at May 31, 2015, the CytoDyn Inc. 2012 Equity Incentive Plan (the 2012 Plan ), which was approved by shareholders at the Company's 2012 annual meeting of shareholders to replace the 2004 Stock Incentive Plan and 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. As of May 31, 2015, the Company had 2,754,930 shares available for future stock-based grants under the 2012 Plan.

During the year ended May 31, 2015, the Company granted options to purchase a total of 483,973 shares of common stock to directors and an employee, with exercise prices ranging from \$.66 to \$.81 per share. The director option awards covering 333,973 shares, vest at 25% per quarter over one year and an option covering 100,000 shares vest at 50% per year over two years, all with a five-year term. The grant date fair value related to these options was \$.35 per share. The employee award covering 50,000 shares of common stock vests ratably over three years with a five-year term. The grant date fair value related to the employee award was \$.43 per share.

During the year ended May 31, 2015, in connection with the two AVCP Notes (see Note 4), the Company issued warrants covering 250,000 and 75,000 shares of the Company's common stock exercisable at a price of \$0.50 per share. The warrants are currently exercisable in full, include a cashless exercise feature and have a five-year term.

During the year ended May 31, 2015 the Company granted a warrant to purchase a total of 150,000 shares of common stock at an exercise price of \$1.15 per share to a third party consulting firm retained by the Company. The warrant, which expires on December 8, 2019, vests and becomes exercisable cumulatively in three tranches of 50,000 shares each in March 2015, September 2015 and March 2016. In the event the Company terminates its contract with the holder, vesting terminates immediately. The Company's board of directors granted a warrant to purchase a total of 100,000 shares of common stock at an exercise price of \$1.15 per share to a scientific advisor retained by the Company. The warrant, which will terminate in December 2019, will become vested and exercisable cumulatively as follows, 33,334 shares in April 2015, and 33,333 shares each in August 2015 and December 2015, respectively. In addition, a warrant covering 150,000 shares of common stock was granted to an outside third party consultant retained by the Company. The exercise price was \$.83 per share, with a five-year term expiring in March 2020 and vests 50% in March of 2016 and March of 2017. A warrant for 150,000 shares of common stock at an exercise price of \$1.05 per share was granted to a consultant. The warrant vests based on certain milestones. The warrant expired during 2015, as the milestones were not achieved.

During the year ended May 31, 2015, in connection with an inducement to convert certain promissory notes into common stock, as described in Note 4, the Company issued warrants to replace previously expired warrants to purchase an aggregate of 6,310,677 shares of common stock at an exercise price of \$1.00 per share. All but two of the warrants are exercisable through October 2015. One warrant, for the purchase of 186,667 shares of common stock, is exercisable through December 2015 and one warrant, for the purchase of 160,000 shares of common stock, is exercisable until January 15, 2016. The Company agreed to register for resale the shares of common stock issuable upon exercise of the warrants. Pursuant to U.S. GAAP, issuance of warrants to induce the conversion debt is characterized as inducement interest expense and, as such, the Company recognized non-cash interest expense related to these replacement warrants of approximately \$970,000 during the year ended May 31, 2015, which was the Black-Scholes fair value of the warrants at the time of issuance.

During the year ended May 31, 2015, in connection with an offer to induce the exercise of warrants initially issued with convertible debt, the Company agreed to reduce the exercise prices, which ranged from \$0.75 and \$2.00 per share, down to \$0.55 per share, conditioned upon immediate exercise of the warrant. This inducement offer resulted in the issuance of 1,938,974 shares of common stock and receipt of proceeds by the Company of \$1,066,435. Pursuant to

U.S. GAAP, reducing the exercise price of warrants is characterized as inducement to convert the warrant and, as such, the Company recognized non-cash interest expense of approximately \$555,000 during the year ended May 31, 2015, which was the fair value of the warrants at the time of exercise. In addition, a warrant covering 100,000 shares of common stock was exercised during the year ended May 31, 2015, at an exercise price of \$0.75, with proceeds of \$75,000 received by the Company.

As discussed in Note 4 above, in connection with the sale of approximately \$4 million convertible Notes, the Company issued warrants to purchase a total of 1,061,586 common shares to investors. These warrants have a five-year term, an exercise price of \$0.75 and are fully exercisable. In addition, the placement agent received a warrant covering 530,802 shares of common stock at \$0.75 per share. The warrant has a five-year term, immediate vesting and a cashless exercise provision and is fully exercisable. The placement agent warrants were treated as debt issuance costs and the fair value of the warrants, which was approximately \$285,000, is included in the total debt issuance costs (see Note 4).

Compensation expense related to stock options and warrants issued as compensation was approximately \$631,000 and \$928,400 for the year ended May 31, 2015 and 2014, respectively. The grant date fair value of options and warrants vested during the years ended May 31, 2015 and 2014, was approximately \$886,000 and \$2,274,000, respectively. As of May 31, 2015, there was approximately \$527,000 of unrecognized compensation costs related to share-based payments for unvested options, which is expected to be recognized over a weighted-average period of 1.13 years.

**Table of Contents**

The estimated fair value of options and warrants is determined using the Black-Scholes option valuation model with the following weighted-average assumptions for the periods ended May 31, 2015 and 2014:

	2015	2014
Risk-free rate	0.73% - 1.10%	0.52% - 1.85%
Dividend yield		
Volatility	74.36% - 81.16%	78.73% - 92.92%
Expected term	2.5-3.5 years	2.5-3.5 years
Grant date fair value	\$0.33 - \$0.60	\$.40- \$.67

The following table represents stock option and warrant activity for the periods ended May 31, 2015 and 2014:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options and warrants outstanding - May 31, 2013	18,146,838	\$ 1.65	1.86	\$ 140,321
Granted	18,414,244	0.74		
Exercised	(50,000)			
Forfeited/expired/cancelled	(5,704,721)	1.49		
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
Outstanding exercisable - May 31, 2015	29,898,494	\$ 0.89	2.91	\$ 5,334,919

**Note 7 License Agreements**

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 proprietary 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; (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. Payments to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the PDL License ), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the Asset Purchase Agreement, pursuant to which we must pay additional milestone payments and royalties as follows: (i) \$1,000,000 upon initiation of a Phase 3 clinical trial; (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. 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.

Subsequent to year end, the Company reached agreement in principle with a third-party licensor to enter into a licensing agreement 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 license will require payment of £600,000 (approximately US\$930,000) by December 31, 2015, and a contingent payment of up to an additional £600,000 (approximately US\$930,000) on June 30, 2016. The amount of the contingent payment depends on the outcome of pending litigation between the licensor and the company that sold PRO 140 to CytoDyn. The Company has accrued an expense for the payment of US\$930,000, as of May 31, 2015, for the amount due by December 31, 2015, but has not accrued the contingent payment due on June 30, 2016, as of May 31, 2015, as the amount and probability of payment cannot be reasonably estimated. Future annual license fees and royalty rate will vary depending on whether CytoDyn manufactures PRO 140 itself, utilizes the third-party licensor as a contract manufacturer, or utilizes an independent party as a contract manufacturer. The licensor does not charge an annual license fee of £300,000 when it serves as the manufacturer.

#### **Note 8 Commitments and Contingencies**

Upon the successful completion of our Phase 2b study and in anticipation for the upcoming U.S. Phase 3 clinical trial, the Company entered into a project work order with its current clinical research organization ( CRO ). The estimated cost for this study is approximately \$13 million to \$15 million, of which \$4.4 million represents direct service fees payable to the CRO. Under the terms of this agreement, the Company paid an execution fee of \$733,916 toward direct service fees. These fees are reflected as a current asset and has an unamortized balance of such amount at May 31, 2015. The balance of the estimated trial costs are provided by third parties, such as testing laboratories and patient clinics.

---

**Table of Contents**

In furtherance of our business strategy and subsequent to fiscal year-end 2014, the Company entered into a manufacturing agreement with a contract manufacturing organization to manufacture additional PRO 140. The remaining costs to be incurred under this agreement, are approximately \$3.6 million, of which approximately \$3.2 million represent a fixed contractual obligation pursuant to various termination provisions. The total future estimated costs of manufacturing may vary materially depending on future decisions by management and its technical consultants with respect to various scientific and regulatory requirements.

In addition, from time to time, the Company is involved in claims and suits that arise in the ordinary course of business. Management currently believes that the resolution of any such claims against the Company, if any, will not have a material adverse effect on the Company's business, financial condition or results of operations.

**Note 9 Private Securities Offering**

On October 23, 2013, the Company completed a private equity offering (the Equity Offering). Pursuant to the Equity Offering, the Company sold to investors a total of 11,153,850 Units at a price of \$1.30 per Unit, for total gross proceeds of approximately \$14.5 million. Each Unit consisted of two shares of common stock and one warrant to purchase common stock at an exercise price of \$.75 per share. During the fiscal year ended May 31, 2014, the Company issued a total of 20,989,494 shares of common stock. In conjunction with the Equity Offering, the Company also issued warrants to purchase 11,153,850 shares of common stock at the \$.75 per share exercise price (see Notes 2 and 5 for a description of the warrants and offering costs related to the Equity Offering).

During April and May 2015, the Company completed a private debt offering of convertible promissory notes in the aggregate principal amount of \$3,981,050. Each note is convertible into common stock at the rate of \$0.75 per share. Each note has 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 50% of the number of share into which the related note is convertible. Each warrants has an exercise price of \$0.75 per share and a five-year term.

**Note 10 Recent Accounting Pronouncements**

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

In April 2015, the FASB issued ASU 2015-03 Simplifying the Presentation of Debt Issuance Costs. 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 has evaluated this ASU and determined that it will early adopt beginning with the annual period ended May 31, 2015. The adoption of this guidance is not expected to have a material impact on our 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 special optional transitional guidance for awards with performance targets. 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 our Consolidated Financial Statements.

**Table of Contents****Note 11 Related Party Transactions**

During the year ended May 31, 2014, the Company paid in cash a note payable to a director of the Company for \$500,000 with accrued interest at 15%. The principal and accrued interest were paid in full at the April 11, 2014 maturity date. Interest was payable in the form of shares of common stock not to exceed 150,000 shares at a fixed price of \$.50 per share. For the years ended May 31, 2015 and May 31, 2014, the Company recorded approximately \$ 0 and \$64,700 in interest expense, respectively, and issued a total of 150,000 shares.

On September 26, 2014, the Company entered into a \$2 million convertible promissory note with AVCP, as more fully described in Note 4 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 4 above.

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 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 2014.

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

	2015	2014
Income tax provision at statutory rate	34.0%	34.0%
State income taxes, net	0.0	0.4
Rate change	(0.6)	(9.6)
Derivative gain/loss	(1.2)	
Valuation allowance	(32.2)	(24.8)
	0.0%	0.0%

Net deferred tax assets and liabilities are comprised of the following as of May 31, 2015 and 2014:

	2015	2014
Deferred tax asset (liability) current:		
Accrued expenses	\$ 219,100	\$ 159,300
Debt discount and amortization		
Valuation allowance	(219,100)	(159,300)
	\$	\$

Edgar Filing: CYTODYN INC - Form 10-K

Deferred tax asset (liability) non-current:		
Net operating loss	\$ 16,857,600	\$ 9,957,400
Debt discount	(902,700)	(663,700)
Expense on non-qualified stock options	3,073,500	2,893,300
Other	211,700	176,200
Valuation allowance	(19,240,100)	12,363,200
	\$	\$



**Table of Contents**

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, 2015, the Company had available net operating loss carry forwards of approximately \$49,581,217, which expire beginning in 2022.

The Company's income tax returns remain subject to examination by all tax jurisdictions for tax years May 31, 2012 through 2014.

**Note 13 Acquisition of Patents**

As discussed in Note 7 above, 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, 2015 and 2014, the Company has recorded \$3,500,000 of intangible assets in the form of patents. The Company estimates the acquired patents have an estimated life of eight 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.

The following presents intangible assets activity:

	May 31, 2015	May 31, 2014
Gross carrying amounts	\$ 3,500,000	\$ 3,500,000
Accumulated amortization	(918,750)	(568,750)
Total amortizable intangible assets, net	2,581,250	2,931,250
Patents currently not amortized	35,989	35,989
Carrying value of intangibles, net	\$ 2,617,239	\$ 2,967,239

Amortization expense related to intangible patents was approximately \$350,000 for the years ended May 31, 2015 and May 31, 2014. 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 14 Subsequent Events**

On June 1, 2015, the Company, pursuant to its non-employee director compensation program, granted annual awards of stock options to its non-employee directors covering a total of 350,000 shares, with an exercise price of \$0.975 per share and a five-year term. These options vest in equal quarterly installments over one year.

On June 11, 2015, the Company granted a stock option to the Chairman of the board of directors covering 250,000 shares with an exercise price of \$0.97 and a five-year term. This option award was fully vested on the date of grant.

Also on June 11, 2015, the Company approved the issuance of the following warrants with an exercise price of \$1.02 per share and a five-year term to: (i) a consultant covering 200,000 shares, as to which vest 50% in January of 2016 and January of 2017; (b) an advisor covering 10,000 shares and were fully vested upon issuance and (c) its clinical research organization covering 170,000 shares, as to which will be fully vested in February 2017, conditioned upon performance against numerous specific milestone dates.

Effective June 23, 2015, the Company, Alpha Venture Capital Management, LLC and Alpha Venture Capital Partners, LP ( AVCP ) entered into a Debt Conversion and Termination Agreement (the Conversion and Termination Agreement ) pursuant to which (i) AVCP agreed to convert the \$3,535,627.15 in aggregate indebtedness (the Note Debt ) owed to AVCP as of June 23, 2015 under its two convertible notes in exchange for 5,237,966 shares of the Company s common stock (the Note Shares ); (ii) subject to the conversion of the Note Debt, the Company agreed to issue AVCP an additional five-year warrant award to purchase 1,000,000 shares of Common Stock at an exercise price of \$0.675 per share (the Inducement Warrant ); and (iii) subject to the AVCP s receipt of the Note Shares and Inducement 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 convertible notes, the Note Debt and the subscription agreements.

On June 30, 2015, the Company granted annual awards of stock options to its two officers covering an aggregate of 350,000 shares with an exercise price of \$0.90 per share and a five-year term, which vest ratably over three years. The Company also granted a stock option to an employee covering 50,000 shares with an exercise price of \$0.90 per share and a five-year term, which vest ratably over three years.

---

**Table of Contents**

**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, 2015, 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, 2015 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, 2015 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, 2015 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 several 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. Due to the Company's limited resources and staffing, management has not developed a plan to mitigate the above material weaknesses. 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.

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, 2015, 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, 2015, management has, however, continued to strengthen internal controls and procedures through the implementation of entity-level controls.

**Table of Contents**

**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 2015 Annual Meeting of Shareholders, to be filed with the SEC within 120 days of the end of the Company's fiscal year, May 31, 2015 (the 2015 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](http://www.cytodyn.com).

**Item 11. Executive Compensation.**

The information required by Item 11 relating to executive compensation is incorporated herein by reference to our 2015 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 2015 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 2015 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 2015 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, 2015 and 2014 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.

**Table of Contents**

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 10, 2015

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 10, 2015.

**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:**

\* Anthony D. Caracciolo

\* Gregory A. Gould

\* Jordan G. Naydenov

\* A. Bruce Montgomery, M.D.

\* Denis R. Burger, Ph.D.

\* S. Michael Nobel, Ph.D.

\* Carl C. Dockery

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



**Table of Contents**

## EXHIBIT INDEX [II2]

Exhibit	Description
Number	Description
	<u>Plan of Acquisition</u>
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).
	<u>Articles of Incorporation and Bylaws</u>
3.1	Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10SB12G filed July 11, 2002).
3.2	Amendment to Articles of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed November 12, 2003).
3.3	Amendment to Articles of Incorporation (incorporated by reference to Exhibit 3.4 to the Registrant's Annual Report on Form 10-K filed March 12, 2010).
3.4	Amendment to Articles of Incorporation (incorporated by reference to Exhibit 3.5 to the Registrant's Current Report on Form 8-K filed April 29, 2010).
3.5	Amendment to Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed March 2, 2015)
3.6	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed November 10, 2011).
	<u>Instruments Defining Rights of Security Holders</u>
4.1	Form of Convertible Promissory Note bearing interest at 10% per annum with related common stock warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q filed April 12, 2013).
4.2	Form of Convertible Promissory Note bearing interest at 5% per annum with related common stock warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q filed April 12, 2013).
4.3	Form of Convertible Promissory Note bearing interest at 5% per annum (incorporated by reference to Exhibit 4.3 to the Registrant's Form S-1 Registration Statement filed November 15, 2013 (the Form S-1)).
4.4	Form of common stock warrant (incorporated by reference to Exhibit 4.4 to the Form S-1).
4.5	Form of purchase warrant issued to Paulson Investment Company, Inc. (incorporated by reference to Exhibit 4.5 to the Form S-1).
4.6	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).

## Edgar Filing: CYTODYN INC - Form 10-K

- 4.7 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).
- 4.8 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).
- 4.9 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).
- 4.10 Amendment dated April 30, 2015 to Convertible Promissory Note issued to Alpha Venture Capital Partners, L.P. dated February 6, 2015
- 4.11 Form of Convertible Promissory Note and Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed May 5, 2015).
- 4.12 Form of Placement Agent Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed May 18, 2015).

### 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).

**Table of Contents**

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*	Summary of Non-Employee Director Compensation Program Effective June 1, 2013 (incorporated by reference to Exhibit 10.13 to the 2013 10-K).
10.14*	Transition Agreement, dated as of July 25, 2012, between CytoDyn Inc. and Kenneth J. Van Ness (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 25, 2012).
10.15*	Separation Agreement and Release, dated as of May 31, 2013, between CytoDyn Inc. and Richard J. Trauger (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 10, 2013).
10.16*	Employment Agreement and Non-Compete Agreement between CytoDyn Inc. and Nader Pourhassan dated October 17, 2011 (incorporated by reference to Exhibit 10.16 to the 2013 10-K).
10.17*	Convertible Promissory Note dated October 16, 2012, in the principal amount of \$1,000,000 issued to Jordan Naydenov, together with a related common stock warrant to purchase 1,333,333 shares of the Registrant's common stock (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed April 12, 2013).
10.18*	Promissory Note dated April 11, 2013, in the principal amount of \$500,000 issued to Jordan Naydenov (incorporated by reference to Exhibit 10.18 to the 2013 10-K).
10.19*	Form of Common Stock Warrant Agreements for Jordan Naydenov covering a total of 303,200 shares of the Registrant's common stock and expiring March to May of 2014 (incorporated by reference to Exhibit 10.19 to the 2013 10-K).
10.20*	Consulting Agreement between CytoDyn Inc. and S. Michael Nobel dated March 28, 2013 (incorporated by reference to Exhibit 10.20 to the 2013 10-K).
10.21	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).
10.22	

Edgar Filing: CYTODYN INC - Form 10-K

Clinical Research Collaboration Agreement between CytoDyn Inc. and Philadelphia Health and Education Corporation dba Drexel University College of Medicine effective November 15, 2012 (incorporated by reference to Exhibit 10.22 to the 2013 10-K).

- 10.23 Amendment to Clinical Research Collaboration Agreement between CytoDyn Inc. and Philadelphia Health and Education Corporation dba Drexel University College of Medicine effective February 10, 2014 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed April 11, 2014).
- 10.24 Clinical Trial Agreement between CytoDyn Inc. and Philadelphia Health and Education Corporation dba Drexel University College of Medicine effective February 10, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed April 11, 2014).
- 10.25\* Amendment to Consulting Agreement between CytoDyn Inc. and Denis R. Burger dated November 3, 2014.
- 10.26 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).
- 10.27 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).

**Table of Contents**

## Exhibit

Number	Description
10.28*	Summary of Non-Employee Director Compensation Program Effective June 1, 2014 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed October 10, 2014).
10.29*	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).
10.30*	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).
10.31	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).
10.32	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).
10.33	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed May 5, 2015).
10.34	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).
10.35	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).

Other

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

Certifications

31.1	Certification of Chief Executive Officer under Rule 13a-14(a)
31.2	Certification of Chief Financial Officer under Rule 13a-14(a)
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350

XBRL

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

101.LAB XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

\* Management contract or compensatory plan or arrangement

Note: All exhibits have SEC File No. 000-49908.