

CYTODYN INC  
Form 10-K  
August 29, 2013  
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, 2013

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)

Edgar Filing: CYTODYN INC - Form 10-K

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

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

**5 Centerpointe Drive, Suite 400, Lake Oswego, Oregon**  
(Address of principal executive offices)

**97035**  
(Zip Code)

**Registrant's Telephone Number, including area code: (971) 204-0382**

**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

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: \$43,356,952 (as of November 30, 2012).

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of July 31, 2013, the registrant had 30,798,150 shares of common stock outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

<b>Document</b>	<b>Parts Into Which Incorporated Part III</b>
Portions of Proxy Statement for the 2013 Annual Meeting of Shareholders ( Proxy Statement )	

**Table of Contents**

CYTODYN INC.

FORM 10-K FOR THE YEAR ENDED MAY 31, 2013

**Table of Contents**

	<b>Page</b>
<b>PART I</b>	2
<b>ITEM 1.</b> <u>BUSINESS</u>	2
<b>ITEM 1A.</b> <u>RISK FACTORS</u>	9
<b>ITEM 1B.</b> <u>UNRESOLVED STAFF COMMENTS</u>	21
<b>ITEM 2.</b> <u>PROPERTIES</u>	21
<b>ITEM 3.</b> <u>LEGAL PROCEEDINGS</u>	21
<b>ITEM 4.</b> <u>MINE SAFETY DISCLOSURES</u>	21
<b>PART II</b>	21
<b>ITEM 5.</b> <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	21
<b>ITEM 6.</b> <u>SELECTED FINANCIAL DATA</u>	22
<b>ITEM 7.</b> <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	22
<b>ITEM 7A.</b> <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	26
<b>ITEM 8.</b> <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	27
<b>ITEM 9.</b> <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	62
<b>ITEM 9A.</b> <u>CONTROLS AND PROCEDURES</u>	62
<b>ITEM 9B.</b> <u>OTHER INFORMATION</u>	63
<b>PART III</b>	64
<b>ITEM 10.</b> <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	64
<b>ITEM 11.</b> <u>EXECUTIVE COMPENSATION</u>	64
<b>ITEM 12.</b> <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	64
<b>ITEM 13.</b> <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE</u>	64
<b>ITEM 14.</b> <u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	64
<b>PART IV</b>	64
<b>ITEM 15.</b> <u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	64

---

**Table of Contents**

THROUGHOUT THIS FILING, WE MAKE FORWARD-LOOKING STATEMENTS. THE WORDS ANTICIPATE, BELIEVE, EXPECT, INTEND, PREDICT, PLAN, SEEK, ESTIMATE, PROJECT, WILL, CONTINUE, COULD, MAY, AND SIMILAR TERMS AND EXPRESSIONS WILL FREQUENTLY IDENTIFY FORWARD-LOOKING STATEMENTS. THESE STATEMENTS INCLUDE, AMONG OTHERS, INFORMATION REGARDING FUTURE OPERATIONS, FUTURE CAPITAL NEEDS, EXPENDITURES AND ADEQUACY, AND FUTURE NET CASH FLOWS. SUCH STATEMENTS REFLECT THE COMPANY'S CURRENT VIEWS WITH RESPECT TO FUTURE EVENTS AND FINANCIAL PERFORMANCE AND INVOLVE RISKS AND UNCERTAINTIES, INCLUDING, WITHOUT LIMITATION, RISKS AND UNCERTAINTIES RELATING TO (i) GENERAL ECONOMIC AND BUSINESS CONDITIONS, (ii) CHANGES IN FOREIGN, POLITICAL, AND SOCIAL CONDITIONS, (iii) REGULATORY INITIATIVES, COMPLIANCE WITH GOVERNMENTAL REGULATIONS AND THE REGULATORY APPROVAL PROCESS, (iv) OUR ABILITY TO DEVELOP AND ACHIEVE APPROVAL OF A MARKETABLE PRODUCT, (v) DESIGN, IMPLEMENTATION AND CONDUCT OF CLINICAL TRIALS, (vi) THE POSSIBILITY OF UNFAVORABLE CLINICAL TRIAL RESULTS, (vii) THE SPECIFIC RISK FACTORS DISCUSSED IN ITEM 1A. BELOW, AND (viii) VARIOUS OTHER MATTERS, MANY OF WHICH ARE BEYOND THE COMPANY'S CONTROL. SHOULD ONE OR MORE OF THESE RISKS OR UNCERTAINTIES DEVELOP, OR SHOULD UNDERLYING ASSUMPTIONS PROVE TO BE INCORRECT, ACTUAL RESULTS MAY VARY MATERIALLY AND ADVERSELY FROM THOSE ANTICIPATED, BELIEVED, ESTIMATED, OR OTHERWISE INDICATED BY OUR FORWARD-LOOKING STATEMENTS.

**PART I**

**Item 1. Business.**

**Overview / Corporate History**

CytoDyn Inc. (the Company) is a Colorado corporation, with its principal business office at 5 Centerpointe Drive, Suite 400, Lake Oswego, Oregon 97035; telephone: (971) 204-0382, and website address: www.cytodyn.com. Unless the context otherwise requires, references in this report to CytoDyn, our, we, us, or the Company are to CytoDyn Inc. and its subsidiaries.

We are a publicly traded development stage biotechnology company focused on developing and potentially marketing a class of therapeutic 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 potentially block HIV from entering into and infecting certain cells. Although CytoDyn intends to focus its efforts on PRO 140, the Company also holds certain rights in two proprietary platform technologies: Cytolin<sup>®</sup>, a 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 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 drug, which means fewer side effects 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 receptor protein to which HIV attaches as part of HIV's entry into a cell.

PRO 140 is an antibody and not a 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 receptor. 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.

---

**Table of Contents**

PRO 140 was originally developed by Progenics Pharmaceuticals, Inc. ( Progenics ). Progenics led, and contributed to funding of, PRO 140 development and trials through 2011. We acquired the asset from Progenics in October 2012. Current collaborative research relating to PRO 140 planned for late 2013 is being conducted by Jeffrey M. Jacobson, M.D., Professor of Medicine, Microbiology and Immunology, Chief, Drexel University College of Medicine ( Drexel ), and is partially funded through two grants awarded to Drexel and Dr. Jacobson by the National Institutes of Health ( NIH ).

To date, PRO 140 has only been tested and administered to test subjects either intravenously or as a subcutaneous injection. We believe, however, that, if PRO 140 is approved for use as an injectible by the U.S. Food and Drug Administration (the FDA ), it may be an attractive and marketable therapeutic option (for patients with healthy CCR5) particularly in the following scenarios:

Patients with multi-drug resistant viruses;

Patients with difficulty adhering to daily drug regimens;

Patients who poorly tolerate existing therapies;

Patients with compromised organ function, such as HCV co-infection; and

Patients with complex concomitant medical requirements.

We believe PRO 140 has demonstrated potent, long-lived (as compared to existing treatments) antiretroviral activity and an encouraging safety profile in initial 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 may inhibit CCR5-tropic HIV while preserving CCR5's natural activity. PRO 140 also appears to broadly inhibit drug-resistant CCR5-tropic HIV viruses, including those resistant to small-molecule anti-CCR5 HIV therapies. It has no effect on strains of HIV that enter through the CXCR4 cell portal. 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 developing resistance to other therapies.

The Company 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 III trial or non-U.S. equivalent; (ii) \$5,000,000 at the time of FDA approval of the first U.S. new drug application 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 commercial sale of PRO 140, in each case determined on a country-by-country basis.

In connection with the Progenics Agreement, the Company assumed Progenics' rights and obligations under an additional license agreement (the PDL License ) with Protein Design Labs, Inc. (now AbbVie, Inc.), pursuant to which CytoDyn is required to pay the following milestone payments and royalties: (i) \$1,000,000 upon initiation of a Phase III clinical trial of a licensed product; (ii) \$500,000 at filing a new drug application for PRO 140 in the U.S. or non-U.S. equivalent; (iii) \$500,000 at the time of FDA approval of the first U.S. new drug application or other approval for sale by certain non-U.S. regulatory bodies; and (iv) royalties of up to seven and one-half percent (7.5%) of net sales payable to licensors or sublicensees 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 licensed and (b) 10 years following the first commercial sale of PRO 140. The PDL License also provides for an annual maintenance fee of \$150,000 until royalties exceed that amount.

As an integral part of CytoDyn's acquisition of PRO 140, we entered into a collaboration agreement with Drexel, whereby CytoDyn will provide Drexel with the necessary quantity of PRO 140 to conduct the clinical trials and CytoDyn will have access to all clinical trial data and the right to use such data to maintain the IND (Investigational New Drug application) for PRO 140 and to support its application to the FDA.



---

## **Table of Contents**

### **Other Product Candidates**

A second product candidate, Cytolin, is also a monoclonal antibody. 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 expires on the original expiration date of the patent in July 2014. On September 23, 2011, the Company filed a provisional patent application (Serial No. 61/534,942) in the United States for its humanized version of Cytolin, a monoclonal antibody for the treatment of HIV infection. 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.

In May 2011, we formed CytoDyn Veterinary Medicine LLC ( CVM ) to explore the possible application of feline reactive monoclonal antibodies for the treatment of FIV. On June 17, 2011, the Company 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, the Company filed an international patent application (Serial No. PCT/US2012/042693) claiming priority to this provisional patent application.

Until the clinical trials for PRO 140 commence, we plan to devote only a modest amount of resources towards the approval or commercialization of Cytolin or CytoFeline.

### **Product Development and Research Status of PRO 140**

Phase I and IIa clinical trials of PRO 140 were completed by Dr. Jacobson of Drexel prior to our acquisition of PRO 140. A total of 113 subjects were treated for a period of up to three weeks with as much as a 324 mg dose of PRO 140 administered weekly subcutaneously and 10mg/kg intravenously. Clinical results indicated a reduction of circulating HIV RNA an index of circulating virus of up to 2.17 logs intravenously and 1.77 logs subcutaneously (nearly a factor of a hundred) that persists for at least two weeks between injections at the 324 mg dose level. This response is similar in magnitude to that seen with any other single anti-HIV therapeutic agent. With respect to subcutaneously-administered trials, no significant safety signals were observed, with only minor irritation at the injection site in some subjects. While all protein therapeutic products are likely to have some immunogenicity that is, to cause the recipient to make antibodies against the protein therapeutic product only mild immunogenic responses were seen in a small number of subjects, and none of the immune response was associated with adverse effects or with an interference in the ability of PRO 140 to bind to its intended CCR5 target. Further trials are needed to determine the exposure time required for immunogenic responses to become significant.

Information regarding past and current study design, objectives and results are available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). To review these records, enter PRO 140 as the search term.

As clinical protocols are finalized for planned clinical trials expected to commence in late 2013, management, its clinical advisors, and Dr. Jacobson intend to meet with the FDA to ensure that the final clinical protocols are fully aligned with the FDA's prior guidance to Progenics, wherein the FDA designated PRO 140 as a candidate for fast track approval, and to independently confirm that such protocols are fully aligned with what is believed to be the most important clinical evaluation criteria supporting the highest commercial opportunities for PRO 140.

### **Research History of Cytolin Compound**

In 1993, six HIV-infected patients were treated with murine Cytolin. Blood and skin tests of these patients suggested that the antibody might be producing improvements in the immune function of each patient.



---

## Table of Contents

Based on the results of this pilot study, a compassionate use trial was initiated. In this study a relatively small number of physicians in the United States administered Cytolin to their HIV-infected patients over two years. As results from this initial use became available, other physicians obtained and administered Cytolin to their patients as well. Four of the doctors using Cytolin allowed the Company's predecessor to send in an independent Institutional Review Board to inspect the medical records of approximately 200 patients treated with Cytolin once or twice a month over 18 months. Data were recorded and summarized and formed part of the material presented to the FDA as an early indication of the safety and potential efficacy of Cytolin.

To date, only the murine version of Cytolin has been tested in clinical, research and development studies. The Company understands that registrational studies will require similar testing and confirmation of activity with its proprietary humanized version of Cytolin should it want to pursue this product.

The Company may explore the initiation of a study of Cytolin and PRO 140 used in combination to evaluate the possibility of collaborating with other companies in an effort to develop a course of treatment similar to the current standard known as HAART Highly Active Antiretroviral Therapy based on antibodies. Current business plans, however, are focused on PRO 140.

Under a Clinical Trial Agreement dated September 28, 2009 and as amended to date (the Clinical Trial Agreement), in exchange for a research grant by the Company, Massachusetts General Hospital (MGH) in Boston, Massachusetts conducted an ex-vivo study of murine Cytolin in accordance with a study protocol entitled An observational study to determine the in-vitro immunologic and virology activity of Cytolin (the Study). In addition to providing financial support for the Study, the Company agreed to provide MGH with supplies of Cytolin needed for the Study. Under the Clinical Trial Agreement, Eric S. Rosenberg, M.D. was designated as the Principal Investigator for the Study.

Ten adults with early HIV infection and 10 healthy adults were enrolled in the Study, all of whom were required to participate for six months. Each patient enrolled in the study donated blood to allow the study of the effects of Cytolin when it was added in the test tube to their peripheral blood mononuclear cells. The Study design and objectives are available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), ID NCT01048372. To review public records for the Study on the government's website, enter Cytolin as the search term (case sensitive).

The Study was completed in December 2012. Dr. Rosenberg submitted a manuscript detailing his results, which can be found at Rychert J, Jones L, McGrath G, et al. A monoclonal antibody against lymphocyte function-associated antigen-1 decreases HIV-1 replication by inducing the secretion of an antiviral soluble factor. *J Virol.* 2013; 10:120. The release of this or any data from the Study is entirely dependent on Dr. Rosenberg.

The Study was a science-intensive research study and was not intended to function as a registrational study (see Registrational Clinical Trials Process below). A clinical trial would be necessary to continue to explore Cytolin and none is currently planned. The Company will determine if clinical trials with the humanized version of Cytolin are warranted based on results from studies with the murine molecule and available resources.

## Patents and Proprietary Technology

Protection of our intellectual property rights is important to our business. We may file patent applications in the U.S., Canada, 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, subject to a five-year extension in certain instances. The duration of foreign patents varies in accordance with the provisions of applicable local law, although most countries provide for patent terms of 20 years from the earliest asserted filing date and allow patent extensions similar to those permitted in the U.S.

Patents may not enable us to preclude competitors from commercializing drugs in direct competition with our products, and consequently may not provide us with any meaningful competitive advantage. See Item 1A below. We

**Table of Contents**

may also rely on trade secrets and proprietary know-how to develop and attempt to achieve a competitive position in our product areas. 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.

Information with respect to our current patent portfolio 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	15	18	2015-2031	6	17
Cytolin <sup>(2)</sup>	1		2014	1	1
CytoFeline <sup>(2)</sup>					1

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

<sup>(2)</sup> Our former patent counsel has filed liens against two applications relating to humanized Cytolin (PCT/US2012/055132) and to CytoFeline (PCT/US2012/042693) based on related unpaid legal fees.

Additional detail regarding our patents and patent applications is available upon request. 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 drug 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. The validity of issued patents, patentability of claimed inventions in pending applications and applicability of any of our development programs are uncertain and subject to change, and patent rights asserted against us could adversely affect our ability to commercialize or collaborate with others on specific products. See Item 1A below.

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.

**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



---

## **Table of Contents**

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.

### *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. Under the Company s current business plan, most of this initial work may be sponsored and conducted by Drexel, or a different clinical trial research facility, as determined at some point in the future. After these trials have been initiated, the Company could enter into a strategic alliance with a larger pharmaceutical company after development has progressed to a certain point.

### *Phase I*

Phase I 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 I, sufficient information about the investigational product s pharmacokinetics and pharmacological effects are obtained to permit the design of well-controlled, scientifically valid, Phase II studies.



---

## Table of Contents

### *Phase II*

Phase II 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 II studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving several hundred people. In some cases, depending upon the need for a new drug, it may be licensed for sale in interstate commerce after a pivotal Phase II trial.

Phase II is often broken into Phase IIa, which can be used to refer to pilot trials, or more limited trials evaluating exposure response in patients, and Phase IIb trials that are designed to evaluate dosing efficacy and ranges. We believe trials to be commenced in late 2013 under the direction of Dr. Jacobson at Drexel will collectively constitute a Phase IIb trial.

### *Phase III*

Phase III studies are expanded controlled clinical studies. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase II, 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 III studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase III studies usually include several hundred to several thousand people.

As described above, we are currently working with Dr. Jacobson to begin two additional clinical trials of PRO 140, which we believe will satisfy requirements for Phase IIb study of the product candidate. Dr. Jacobson has received two NIH grants to fund these clinical trials. It is critical to our business strategy and estimated capital requirements that the current clinical trials by Dr. Jacobson both be fully funded by the existing NIH grants and achieve results that enable us to proceed further along the regulatory approval process and maintain PRO 140's status as a candidate for fast track consideration by the FDA.

## Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. We compete with other more established biotechnology companies that have greater financial and managerial resources than we do.

Our current focus is on developing PRO 140 and, to a lesser extent, Cytolin, which are both monoclonal antibodies that have been shown to act as HIV entry inhibitors in preliminary testing. 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 have significant side effects. For these reasons, we believe that our monoclonal antibody products may prove to be useful in patients that cannot tolerate existing HIV 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.

---

## Table of Contents

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 drugs. Worldwide, there are many antiviral drugs for treating HIV. In seeking to manufacture, distribute and market the various potential drugs we intend to develop, we face competition from established pharmaceutical companies. All of our potential competitors in this field 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 our potential drugs.

### Research and Development Costs

Our sponsored research and development expenses were \$619,838, \$530,027 and \$3,379,333 in fiscal 2013, 2012 and for the period October 28, 2003 through May 31, 2013, 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 two full-time employees, our CEO and CFO, as well as several independent consultants assisting us with preparations for our Phase IIb clinical trials of PRO 140. There can be no assurance 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. The risk factors are not intended to be an all-inclusive discussion of all of the potential risks relating to CytoDyn. 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.

***We are a development-stage 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 or licensing to date. Since our inception, we have incurred operating losses in each year due to costs incurred in connection with our collaborative research and development activities and general and administrative expenses associated with our operations. Our drug candidates are in the early stages of testing, and we or our current and future partners must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our products. We expect to incur losses for at least several more years as we continue development of, and seek regulatory approvals for, our drug candidates and commercialize any approved products. If our drug candidates fail or do not gain regulatory approval, or if our products do not achieve market acceptance, we will not be profitable, nor be able to explore other opportunities to enhance shareholder value. If we fail to 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, which may not be available or, if it is available, such financing may substantially dilute our existing shareholders.***

The discovery, development, and commercialization of new treatments, such as our PRO 140 product candidate, is costly. As a result, to the extent continued review of our product candidate by us or our partners is promising and we elect to fund the development or commercialization of a product, we will need to raise 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;

develop, test, and market our product candidates;

implement additional internal systems and infrastructure; and



---

**Table of Contents**

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 than it is now or was at the time shares were acquired. 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 the sources for the additional financing that we will require, and we do not have commitments from any third parties to provide this 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 stays flat or declines, would serve as a disincentive to holders of the Company's convertible promissory notes, totaling approximately \$7.2 million at July 31, 2013, to exercise their conversion rights, thereby prolonging our interest expense burden and increasing the probability that repayment of principal of \$1.8 million will be required in fiscal 2014, none in fiscal 2015, and \$5.4 million in fiscal 2016;

the rate of progress and costs borne by us related to clinical trials of PRO 140 being conducted at Drexel and other development activities;

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 related milestone payments due to Progenics and other third parties;

the costs of filing, prosecuting, maintaining and enforcing patents and other intellectual property rights and defending against potential claims of infringement;

whether or not we decide to hire additional scientific or administrative personnel or consultants; and

the presence or absence of adverse developments in our collaborative 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.***

We recognize that we will need to raise a significant amount of capital now and in the future in order to pursue our business plans. Our cash requirements may differ significantly from our estimates from time to time, depending on a number of factors, including:

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

The ability to maintain and benefit from our Clinical Research Collaboration Agreement with Drexel;

the results of clinical trials to be performed with PRO 140;

the time and costs involved in obtaining regulatory approvals, if any are sought;

---

**Table of Contents**

whether or not we receive additional cash upon the exercise of our outstanding common stock warrants;

whether or not we are required to pay our debt obligations, including repayment of our outstanding promissory notes totaling approximately \$7.7 million at July 31, 2013, in cash, which will depend on whether noteholders exercise rights to convert their notes into other securities;

the ability to obtain funding under future licensing agreements, strategic partnerships, or other collaborative relationships, if any;

the costs involved in obtaining and maintaining patents or pursuing or defending litigation regarding intellectual property rights;

the costs of compliance with laws, regulations, or judicial decisions applicable to us, including federal and state securities laws; and

the costs of general and administrative infrastructure required to manage our business and protect shareholder assets.

If we cannot raise the funds we need to pursue our business strategies and operate our business, we will need to scale back our business plans or may even be forced to discontinue our operations. Our business, financial condition, and stock price would be negatively affected by any of these outcomes.

***We have significant debt as a result of prior financings, all of which is scheduled to mature at various dates over the next three 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 \$7.2 million and other promissory notes in the amount of \$0.5 million at July 31, 2013, could have significant consequences on 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, debt repayment, and working capital, particularly if we are required to repay notes in the amounts of (i) \$1.1 million, at maturities scheduled to occur before the close of fiscal 2014, and (ii) \$1.2 million on February 1, 2014, or earlier certain rights to require repayment are triggered and exercised;

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

placing us at a disadvantage compared to our competitors that have less debt or are less leveraged.

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.

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

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 noteholders' willingness to convert their notes to common shares, which will likely depend on our stock price from time to time. If noteholders 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. Additional funds or alternative financing may not be available to us. 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**

*The Progenics Agreement and related license agreements assumed in the PRO 140 acquisition 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, we must pay to Progenics and third party licensors significant milestone payments and royalties as described in Item 1 above. For more information, please see the Progenics Agreement, which is attached as an exhibit to the Company's Current Report on Form 8-K filed with the SEC on July 30, 2012, and PDL License, which is filed as an exhibit to this report. In order to make the various milestone payments that are required, we will need to raise additional funds. In addition, our royalty obligations will reduce the economic benefits to us of future sales if we do receive regulatory approval and seek to commercialize PRO 140.

*Our proposed clinical trials of PRO 140 depend on funding from the NIH grants awarded to Drexel and its principal investigator, Dr. Jacobson.*

Prior to our acquisition of PRO 140, Progenics and Drexel and its principal investigator, Dr. Jacobson, were awarded various grants from the NIH to fund clinical trials of PRO 140, including two grants that remain open. In order to benefit from this continued funding, we are dependent on Dr. Jacobson's cooperation in structuring the protocols for the NIH-funded clinical trials in a manner that facilitates efforts to maintain PRO 140's fast track drug candidate designation by the FDA and obtain regulatory approval of commercially viable uses of PRO 140 in HIV-infected patients. We believe these clinical trials will constitute a Phase IIb 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 awarded, withdrawn, or proves insufficient, we will need significant additional financing to self-fund our trials, and our expected costs and time to completion would increase significantly.

*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 the clinical trials of our current drug candidate and any other drug candidates we decide to pursue will require several years to complete. Specifically, we estimate that it will take at least three 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. 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 our clinical trials could be delayed or prevented by many factors, including, but not limited to:

our ability to obtain regulatory or other approvals to commence and conduct clinical trials in the manner we or our partners consider appropriate for timely development;

our ability to identify and reach agreement on acceptable terms with prospective clinical trial sites and entities involved in the conduct of our clinical trials;

---

**Table of Contents**

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;

delays in reaching agreement with our partners, such as Drexel, as to appropriate clinical development strategies or funding requirements;

delays in paying third-party vendors of biopharmaceutical services;

lack of effectiveness of our drug candidates during clinical trials;

unforeseen safety issues; or

inadequate supply of clinical trial materials.

***Testing of our primary product candidate, PRO 140, is in early stages 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 early test results are positive, the process of obtaining approval of a drug product for use in humans is extremely lengthy and time-consuming, and numerous factors may prevent our successful development of PRO 140, including negative results in future clinical trials, the development of other products with equal or better results by competitors, or inability to obtain sufficient additional funding to continue to pursue development. In addition, although PRO 140 has not demonstrated significant immunogenic response in trials conducted to date, these trials have been quite short (up to three weeks) and further trials are needed to determine whether the length of time until development of immunogenic response in humans is long enough for PRO 140 to be a viable treatment regimen. 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. Any 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. Currently, we have only two employees, our President and Chief Executive Officer and our Chief Financial Officer. 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.



---

## **Table of Contents**

***We do not have a chief medical officer, internal research and development operations, or a sales and marketing staff, which will increase our dependence on consulting relationships and strategic alliances with industry partners.***

We currently have no chief medical officer, research and development staff or coordinators, or internal sales, marketing or distribution capabilities. We rely and intend to continue to rely on third parties for many of these functions. 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 are unable to successfully manage our relationships with third parties, we may not be able to successfully manage development and approval of our PRO 140 drug candidate or other products or commercialize any products that are approved.

***We may not be able to identify, negotiate and maintain the strategic alliances necessary to develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.***

We may seek to enter into a strategic alliance with a pharmaceutical company for the further development and approval of one or more of our product candidates. Strategic alliances potentially provide us with additional funds, expertise, access, and other resources in exchange for exclusive or non-exclusive licenses or other rights to the technologies and products that we are currently developing or may explore in the future. We cannot give any assurance that we will be able to enter into additional strategic relationships with a pharmaceutical company or others in the near future or at all, or maintain our current relationships. In addition, we cannot assure you that any agreements we do reach will achieve our goals or be on terms that prove to be economically beneficial to us. When we do enter into strategic or contractual relationships, we become dependent on the successful performance of our partners or counter-parties. If they fail to perform as expected, such failure could adversely affect our financial condition, lead to increases in our capital needs, or hinder or delay our development efforts.

***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, such as Drexel, 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 candidates. 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. In addition, we are dependent on clinical trials to be conducted by Dr. Jacobson at Drexel for completion of Phase IIb clinical trials that may enable us to proceed further in the regulatory approval process. 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.

***Clinical trials may fail to demonstrate the desired safety and efficacy of our drug 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 drug candidates, we must adequately demonstrate to the FDA and any foreign regulatory authorities in jurisdiction 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 the filing of an Investigational New Drug application with respect to our potential drug candidates 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.



---

## **Table of Contents**

Our drug candidates are subject to the risks of failure inherent in drug-related product development. Preclinical studies may not yield results that adequately support an IND application. Even if these applications are filed with respect to our drug 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 drug 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.

*Even if we obtain regulatory approvals, our products will be subject to ongoing regulatory review.*

Following any initial regulatory approval of any products we may develop, we will also be subject to continuing regulatory review, including the review of adverse drug experiences and clinical results that are reported after our products are made commercially available. This would include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our products will also be subject to periodic review and inspection by the FDA. The discovery of any previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product from the market. Reliance on third-party manufacturers entails risks, including the continuation of a contractual or other relationship with the third-party manufacturer, and reliance on the third-party manufacturer for regulatory compliance. Our product promotion and advertising also will be subject to regulatory requirements and continuing FDA review.

*Our competitors may develop drugs that are more effective, safer and less expensive than ours, which may diminish or eliminate the commercial success of any drug candidates that we may commercialize.*

We are engaged in the HIV treatment sector of the biopharmaceutical industry, which is intensely competitive and changes rapidly. 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 drug candidates may be competing with existing and future antiviral treatments for HIV.

Our competitors may:

develop drug candidates and market drugs that are less expensive or more effective than our drugs;

commercialize competing drugs before we or our partners can launch any products developed from our drug candidates;

hold or obtain proprietary rights that could prevent us from commercializing our products;

develop drug candidates and market drugs that increase the levels of safety or efficacy that our drug candidates will need to show in order to obtain regulatory approval; or

introduce therapies or market drugs that render our potential drugs obsolete.

We will 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 and have substantially greater financial resources than we do. Our competitors also have significantly greater experience in:

developing drug candidates;

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

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 our competitors market drugs that are less expensive, safer or more efficacious than our potential drugs, or that reach the market sooner or gain or maintain greater market acceptance, we may not achieve commercial success. In addition, if we fail to achieve technical superiority over other treatments, we may be unable to compete effectively.

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

Our primary drug 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 one of our contract manufacturers fails to maintain ongoing compliance at any time, the production of our drug candidates could be interrupted, resulting in delays or discontinuance of our clinical trials, additional costs and loss of potential revenues. In addition, failure of any third-party manufacturers, or us, to comply with applicable regulations could result in sanctions. These sanctions could include fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, product seizures or recalls, operational restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

*We may not be able to successfully scale-up manufacturing of our drug candidates in sufficient quality and quantity, which would delay or prevent us from developing our drug candidates and commercializing resulting approved drugs, if any.*

To date, our drug candidates have been manufactured in small quantities for preclinical studies and early-stage clinical trials. In order to conduct larger-scale or late-stage clinical trials for a drug candidate and for commercialization of the resulting product, if that drug 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 drug candidates, whether in collaboration with third-party manufacturers or on our own, in a timely or cost-effective manner or at all. In addition, quality issues may arise during those scale-up activities. If we are unable to successfully scale up the manufacture of any of our drug candidates in sufficient quality and quantity, the development and testing of that drug candidate and regulatory approval or commercial launch of any resulting drugs may be delayed, which could significantly harm our business.

*There is uncertainty relating to our drug 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 at this time 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. The use of our drug candidates in clinical trials may result in adverse effects. We cannot predict all the possible harms or adverse effects that may result. We do not maintain product liability insurance, but plan to obtain product liability insurance prior to the commencement of further clinical trials of PRO 140. We may

---

**Table of Contents**

not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim, even if we do later become insured. In addition to the possibility of direct claims, we may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which would increase our liability exposure. If third parties that have agreed to indemnify us fail to do so, we may be held responsible for those damages and other liabilities as well.

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

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

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

Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal year. Management determined that as of both May 31, 2012, and May 31, 2013, 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 drug 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 drug 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 U.S. without repeating the extensive testing required of us or our partners to obtain FDA approval.

---

## **Table of Contents**

***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 drug 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. 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. The relevant patent expires before we expect to commercially introduce that drug candidate. 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 drug 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 drug candidates and seeking new potential drug candidates. There may be existing patents, unknown to us, on which our activities with our drug candidates could infringe.

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

infringement and other intellectual property claims that, even if meritless, can be costly and time-consuming, delay the regulatory approval process and divert management's attention from our core business operations;

substantial damages for infringement, if a court determines that our drugs 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.

---

**Table of Contents**

***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.

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

Conversion of outstanding notes into common shares and the sale of such shares into the trading market of common shares or exercise of our warrants could depress the market price of our common shares.

***Our auditors have issued a going concern opinion and it is likely we will not be able to achieve our objectives and will have to cease operations unless our future attempts to raise capital are successful.***

Our auditors issued a going concern opinion in connection with the audit of our annual financial statements for the fiscal year ended May 31, 2013. A going concern opinion means that there is doubt that the company can continue as an ongoing business for the next 12 months. We will need to raise additional funds within the next three to six months in order to continue our business operations. There is no assurance that we will be able to adequately fund our operations.

***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. The market price of stock in a development stage biotech company may often be driven by investor sentiment, expectation and perception, all of which are 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 and thus, the economic incentive for noteholders to convert into common shares and our ability to raise additional capital. The stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks.

---

**Table of Contents**

*You may experience dilution of your ownership because of the future issuance of additional common shares or other securities.*

We may conduct sales of our securities at prices per share below the current market price for our common stock, resulting in dilution to shareholders at the time. 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.

*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, nor can we assure 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.

*Our common shares are classified as penny stock and trading of our shares may be restricted by the SEC's penny stock regulations.*

Rules 15c-1 through 15c-9 promulgated under 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.

*We may continue to have potential liability with respect to the rights of some shareholders to rescind their investment in our securities.*

In March 2011, we disclosed that certain of our shares sold between 2008 and the date of disclosure may have been sold in violation of the federal securities laws of the United States. For further information on the sale of securities in violation of federal and state securities laws, please see Note 3 to our Consolidated Financial Statements included in Item 8 of this report. Management's analysis, based upon various statutes of limitations,

**Table of Contents**

among other issues, indicates that the Company's estimated rescission liability as of May 31, 2013, has declined to a total of \$536,500. Since the issue of potential rescission liability was first disclosed by the Company in early 2011, no investor has asserted rescission rights.

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

None.

**Item 2. Properties.**

On October 25, 2012, the Board approved relocating the Company's principal offices to Lake Oswego, Oregon, a suburb of Portland. We presently lease approximately 617 square feet in a full service office suite pursuant to a lease that expires on October 31, 2013 at a cost of \$4,149 per month, plus voice and data line expenses.

**Item 3. Legal Proceedings.**

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

**Item 4. Mine Safety Disclosures.**

Not applicable.

**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.****Market Information**

Our common stock is presently quoted on the OTCQB of the OTC Markets marketplace under the trading symbol CYDY. Historically, trading in our stock has been very limited and the trades that have occurred cannot be characterized as amounting to an established public trading market. As a result, the trading prices of our common stock may not reflect the price that would result if our stock was actively traded.

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

	High	Low
<b>Fiscal Year Ended May 31, 2013</b>		
First quarter ended August 31, 2012	\$ 1.55	\$ 0.62
Second quarter ended November 30, 2012	\$ 2.10	\$ 0.67
Third quarter ended February 28, 2013	\$ 1.60	\$ 0.76
Fourth quarter ended May 31, 2013	\$ 0.96	\$ 0.41
<b>Fiscal Year Ended May 31, 2012</b>		
First quarter ended August 31, 2011	\$ 2.75	\$ 1.70
Second quarter ended November 30, 2011	\$ 3.00	\$ 1.85
Third quarter ended February 29, 2012	\$ 4.40	\$ 2.52
Fourth quarter ended May 31, 2012	\$ 2.80	\$ 1.46



Holders

The number of record holders of our common stock on May 31, 2013, was approximately 200.

**Table of Contents****Dividends**

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

**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, 2013.

**Item 6. Selected Financial Data.**

Not applicable.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the other sections of this Annual Report, including our consolidated financial statements and related notes set forth in Item 8. This discussion and analysis contains forward-looking statements, including information about possible or assumed results of our financial condition, operations, plans, objectives and performance that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated and set forth in such forward-looking statements.

**Results of Operations**

Results of operations for the year ended May 31, 2013, compared to May 31, 2012 are as follows:

For the years ended May 31, 2013 and 2012, we had no activities that produced revenues from operations.

For the years ended May 31, 2013 and 2012, we had net losses of approximately \$9.6 million and \$7.5 million, respectively. The increase in net loss of approximately \$2.1 million for fiscal 2013 over fiscal 2012 was primarily attributable to increased amortization of discount on convertible debt, which is reported as interest expense, coupled with higher general and administrative expenses.

The operating expenses for the years ended May 31, 2013 and 2012, are as follows:

	<b>2013</b>	<b>2012</b>
Accounting and consulting	\$ 421,000	\$ 524,000
Stock-based compensation	3,262,000	2,858,000
Legal	946,000	1,469,000
Salaries and other compensation	1,411,000	1,623,000
Research and development	620,000	530,000
Depreciation and amortization	223,000	2,000
Other	1,110,000	450,000
<b>Total</b>	<b>\$ 7,993,000</b>	<b>\$ 7,456,000</b>

The increase in fiscal 2013 operating expenses of approximately \$537,000 over fiscal 2012 was primarily related to higher stock-based compensation, patent amortization, which was attributable to our recently acquired PRO 140 patent portfolio, and increased research and development expenditures. These comparably higher expenses for fiscal 2013 were offset, in part, by lower legal expenses, salaries, accounting and consulting as compared to fiscal 2012.

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

Accounting and consulting expenses decreased approximately \$103,000 from \$524,000 in fiscal year 2012 to approximately \$421,000 for the year ended May 31, 2013. The decrease in accounting and consulting expenses for fiscal 2013 as compared to fiscal 2012 reflects a more efficient utilization of third party resources.

Stock-based compensation increased approximately \$404,000 from approximately \$2,858,000 for the year ended May 31, 2012, to \$3,262,000 for the year ended May 31, 2013. The increase relates to the acceleration of

**Table of Contents**

vesting of certain options granted to the Company's former CEO in connection with his Transition Agreement, and option grants made to other Company executives, as well as warrants granted to certain consultants with immediate vesting rights. Additionally, as disclosed in Notes 9 and 11 to the consolidated financial statements in Item 8, the Company granted warrants and common stock pursuant to the Settlement Agreement during fiscal 2012.

Legal expenses decreased approximately \$523,000 from approximately \$1,469,000 for the year ended May 31, 2012, to \$946,000 for the year ended May 31, 2013. The trend in the Company's legal expenses will depend on the Company's future capital raising efforts, complexity of certain regulatory filings, effective management of intellectual property, and continued strengthening of the internal staff.

Salaries and other compensation decreased approximately \$212,000 from approximately \$1,623,000 in fiscal year 2012, to \$1,411,000 for the year ended May 31, 2013. The decrease in fiscal 2013 from fiscal 2012 is directly attributable to significant reductions in staffing levels and incentive compensation. Incentive compensation accrued in fiscal 2013 for executives was based upon achievement of certain corporate performance goals, in addition to specific individual performance goals for each executive. The performance evaluations of each executive against their respective annual goals were approved by the compensation committee of the board of directors.

Research and development expenses for fiscal 2013 increased approximately \$90,000 over fiscal 2012. While the advancement of PRO 140 is the Company's highest priority, increased expenditures to further the preparation of PRO 140 for clinical trials were nearly offset by a significant reduction of expenditures in fiscal 2013 for Cytolin, as compared to fiscal 2012.

Other operating expenses of \$1,110,000 for fiscal 2013 were approximately \$660,000 higher than fiscal 2012 owing to increased expense levels for travel, investor relations, insurance and corporate governance, among others, as compared to fiscal 2012.

For fiscal 2013, the Company realized a gain of approximately \$373,000 in connection with the negotiated settlements of previously accrued expenses, for which approximately \$322,000 was related to legal fees and \$50,000 for consulting services.

The increase in interest expense of approximately \$1.9 million in fiscal 2013 over fiscal 2012 was primarily attributable to the Company's private placement of convertible promissory notes totaling approximately \$6.6 million. In addition to the stated rate of interest, which ranges from 5% to 10% per annum, generally accepted accounting principles require the recognition of a debt discount, which must be amortized over the term of the note. The debt discount is defined by the sum of the intrinsic value of the beneficial conversion feature of the notes and the fair value of the attached warrants, for which the amortization of both elements is reported as a component of interest expense.

The future trends in all of our expenses will be driven, in part, by the future outcomes of the 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.

---

## Table of Contents

### Liquidity and Capital Resources

We had cash and cash equivalents of approximately \$0.6 million as of May 31, 2013, compared with \$0.3 million as of May 31, 2012. The net increase in our cash and cash equivalents over a year ago was attributable primarily to proceeds from the issuance of promissory notes totaling approximately \$7.1 million, which was reduced by our payment of \$3.5 million to acquire PRO 140, along with cash used by operating activities of approximately \$3.4 million.

As of May 31, 2013, the Company had negative working capital of approximately \$2.4 million, which compares to negative working capital a year ago of \$4.0 million.

### Cash Flows

Net cash used in operating activities was approximately \$3.4 million during fiscal year 2013, which represents a decrease of approximately \$1.0 million from net cash used in operating activities of approximately \$4.4 million in fiscal 2012. The decrease in the net cash used in operating activities for fiscal 2013 as compared to fiscal 2012 was primarily attributable to higher amortization of discount on convertible debt and stock-based compensation, together with increases in accounts payable and accrued interest, offset in part by a higher net loss.

The increase in cash used in investing activities for fiscal 2013 over fiscal 2012 represents the purchase of PRO 140 in October 2012.

Cash flows provided by financing activities of approximately \$7.2 million during fiscal 2013 increased approximately \$3.6 million over fiscal 2012. The increase in cash provided by financing activities was attributable primarily to the proceeds from the sale of approximately \$6.6 million of convertible notes payable, \$0.5 million of one note payable to a related party, offset by an approximate \$3.4 million reduction in proceeds from the sale of common stock, which only occurred in fiscal 2012.

As shown in the accompanying consolidated financial statements in Item 8, for the years ended May 31, 2013 and 2012, and since October 28, 2003 through May 31, 2013, we incurred net losses of approximately \$9,568,000 and \$7,474,000 and \$32,401,000, respectively. As of May 31, 2013, we have not emerged from the development stage. In view of these matters, our ability to continue as a going concern is dependent upon our ability to begin operations and to achieve a level of profitability. Since inception, we have financed our activities principally from the sale of public and private equity securities and proceeds from notes payable. We intend to finance our future development activities and our working capital needs largely from the sale of equity securities with some additional funding from other traditional financing sources.

As previously mentioned, since October 28, 2003, we have financed our operations largely from the sale of common stock and preferred stock and proceeds from notes payable. From October 28, 2003 through May 31, 2013 we raised cash of approximately \$10,504,000 (net of offering costs) through private placements of common stock and preferred stock financings, and \$8,165,000 through the issuance of related party notes payable and convertible notes. The Company has raised approximately \$612,000 from the issuance of common stock and preferred stock in conjunction with certain acquisitions in prior years. Additionally, the Company raised approximately \$556,000 from the exercise of common stock options and warrants. We intend to continue to finance our operations through the sale of our shares.

Since October 28, 2003 through May 31, 2013, we have incurred approximately \$3,379,000 of research and development costs and approximately \$30,288,000 in operating expenses. We have incurred significant net losses and negative cash flows from operations since our inception. As of May 31, 2013, we had an accumulated deficit of approximately \$34,003,000 and negative working capital of approximately \$2,388,000.

---

## Table of Contents

### Recent Sales of Convertible and Other Notes

During the period from October 1, 2012, to November 30, 2012, we raised a total of \$5,648,250 through the sale of unsecured convertible promissory notes in a private placement. These notes bear interest at an annual rate ranging from 5% to 10% payable semi-annually, are convertible into common shares at a price of \$0.75 per share, and mature three years from the date of issuance. A portion of the proceeds from the sale of the notes was used to pay the purchase price due under the Progenics Agreement. Of these notes, notes with a total principal amount of \$567,000 were converted into common shares in December 2012. In connection with sale of the notes, we issued two-year warrants to purchase a total of 7,530,676 common shares. Of these warrants, 3,000,000 are exercisable at a price of \$1.50 per share and 4,530,676 are exercisable at a price of \$2.00 per share. Holders must pay cash to exercise the warrants.

Between December 1, 2012, and March 31, 2013, we raised a total of \$560,000 through the sale of additional convertible promissory notes on similar terms, except that one note in the amount of \$250,000 matures one year from the date of issuance. We issued two-year warrants to purchase a total of 705,001 common shares in these transactions exercisable at a price of \$2.00 per share.

On April 11, 2013, Jordan Naydenov, a director, purchased an unsecured promissory note in the principal amount of \$500,000. The principal of the note is due on April 11, 2014, and bears interest at the annual rate of 15%. Accrued interest is payable semi-annually in common shares at a rate of \$0.50 per share, up to a total of 150,000 shares.

Effective May 31, 2013, we raised a total of \$380,000 through the sale of additional unsecured convertible promissory notes bearing interest at an annual rate of 5%, with a conversion price of \$0.65 per share, and maturing six months from the date of issuance. In connection with these note sales, we issued two-year warrants to purchase a total of 292,307 common shares exercisable at a price of \$0.75 per share.

On July 31, 2013, we completed a financing transaction, in connection with which we raised an additional \$1,200,000 through the sale of unsecured convertible promissory notes with an annual interest rate of 5%, a conversion price of \$0.65 per share, and a maturity date of February 1, 2014. In the event of default in repayment, the conversion price will decrease by \$0.10 per share, to a minimum of \$0.35 per share, for each month that the default continues. Until October 1, 2013, holders of the notes have the right to convert the principal amount of the notes plus accrued but unpaid interest into Units consisting of two shares of common stock plus a warrant to purchase one share of common stock. Each Unit is valued at \$1.30 for purposes of this conversion right. Each Unit warrant, if any, issued upon conversion will have an exercise price of \$0.75 per share and a five-year term. If we raise \$3,000,000 on or after August 1, 2013, holders of notes may, within 15 days of announcement, require payment in full of their notes. The notes were placed by a placement agent, who received a cash fee equal to 10% of the amount raised. In connection with these note sales, we issued three-year warrants to purchase a total of 923,072 common shares exercisable at a price of \$0.50 per share.

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 July 31, 2013, the Company had a total of approximately \$7.7 million outstanding in promissory notes; of these, \$7.2 million is convertible into shares of common stock, and \$0.5 million is not convertible into common stock and matures in the fourth quarter of fiscal 2014. In the event our promissory notes, which mature as early as November 30, 2013, do not convert 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. If the Company is unsuccessful in raising additional capital in the future, it may be required to cease its operations.

We have not generated revenue to date, and will not generate product revenue in the foreseeable future. We may incur increased operating losses as we proceed with our collaborative research efforts 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 costs to increase, as we add personnel and other administrative expenses associated with our current efforts.

### Going Concern

We will require additional funding in order to continue with research and development efforts.

---

## Table of Contents

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. As shown in the accompanying consolidated financial statements, the Company is currently in the development stage with losses for all periods presented. As of May 31, 2013, 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 to fund its business plan. There is no assurance that the Company will be successful in these endeavors.

### Off-Balance Sheet Arrangements

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

### Critical Accounting Policies and Estimates

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

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

We 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 issue common stock 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 issue 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 warrants to record the debt discount requires the use of certain assumptions inherent in the Black-Scholes option pricing model, which requires judgments and estimates.

We estimated an amount that is a probable indicator of our rescission liability and recorded rescission liabilities for May 31, 2013 and May 31, 2012 of \$536,500 and \$3,749,000, respectively. These amounts represent the believed potential rescission liability as of the dates presented, including any contingent interest payable to investors who accept the rescission right, 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. Although the Company has assumed that affirmative defenses based upon the expiration 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. See Note 3 to our consolidated financial statements in Item 8 for further information.

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

This item is not required for smaller reporting companies.





---

**Table of Contents**

**Item 8. Financial Statements and Supplementary Data.**

CYTODYN INC.

(A DEVELOPMENT STAGE COMPANY)

CONTENTS	PAGE
<u>REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	28
<u>CONSOLIDATED BALANCE SHEETS AS OF MAY 31, 2013 AND MAY 31, 2012</u>	30
<u>CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEARS ENDED MAY 31, 2013 AND 2012, AND FOR THE PERIOD FROM OCTOBER 28, 2003 THROUGH MAY 31, 2013</u>	31
<u>CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS (DEFICIT) FOR THE PERIOD FROM OCTOBER 28, 2003 THROUGH MAY 31, 2013</u>	32
<u>CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED MAY 31, 2013 AND 2012, AND FOR THE PERIOD FROM OCTOBER 28, 2003 THROUGH MAY 31, 2013</u>	50
<u>NOTES TO CONSOLIDATED FINANCIAL STATEMENTS</u>	52

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders

CytoDyn Inc. (A Development Stage Company)

Lake Oswego, Oregon

We have audited the accompanying consolidated balance sheet of CytoDyn Inc. (a development stage company) as of May 31, 2013, and the related consolidated statements of operations, changes in stockholders' (deficit), and cash flows for the year then ended and the period from October 28, 2003 through May 31, 2013. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required at this time, to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provides 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, 2013 and the results of its operations and its cash flows for the year then ended and the period from October 28, 2003 through May 31, 2013 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 \$9,568,301 for the year ended May 31, 2013, has a working capital deficit of \$2,388,138, and has an accumulated deficit of \$34,002,819 through May 31, 2013, 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

August 29, 2013

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders

CytoDyn Inc. (A Development Stage Company)

Lutz, Florida

We have audited the accompanying consolidated balance sheet of CytoDyn Inc. (a development stage company) as of May 31, 2012 and the related consolidated statements of operations, changes in stockholders' (deficit), and cash flows for the year 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required at this time, to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provides 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, 2012 and the results of its operations and its cash flows for the years then ended and the period from October 28, 2003 through May 31, 2012 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 \$7,474,224 for the year ended May 31, 2012, has a working capital deficit of \$4,015,969, 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/ Pender Newkirk & Company LLP  
Pender Newkirk & Company LLP

Certified Public Accountants

Tampa, Florida

August 21, 2012

**Table of Contents**

## CytoDyn Inc.

(A Development Stage Company)

## Consolidated Balance Sheets

	2013	May 31, 2012
<b>Assets</b>		
Current Assets:		
Cash	\$ 603,681	\$ 284,991
Prepaid expenses	139,849	65,982
Deferred offering costs	96,930	677,327
Total current assets	840,460	1,028,300
Intangible assets, net	3,317,239	38,610
Furniture and equipment, net		800
Other assets		3,125
	\$ 4,157,699	\$ 1,070,835
<b>Liabilities and Shareholders (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,111,285	\$ 831,336
Accrued liabilities	321,884	150,573
Accrued salaries and severance	364,698	189,249
Indebtedness to related parties	509,000	83,493
Accrued interest payable	56,884	40,618
Convertible notes payable, net	328,347	
Stock rescission liability	536,500	3,749,000
Total current liabilities	3,228,598	5,044,269
Long-term liabilities		
Convertible notes payable, net	1,153,017	
Total liabilities	4,381,615	5,044,269
Shareholders (deficit):		
Series B Convertible Preferred Stock, no par value; 400,000 shares authorized, 95,100 and 98,900 shares issued and outstanding at May 31, 2013 and 2012, respectively	274,091	451,993
Common stock, no par value; 100,000,000 shares authorized, 30,798,150 and 28,636,530 outstanding at May 31, 2013 and 2012, respectively; 30,998,150 and 28,836,530 issued at May 31, 2013 and May 31, 2012, respectively	16,244,673	15,150,261
Common stock payable	117,778	388,000
Additional paid-in capital	17,523,796	8,020,533
Common and Preferred Stock subject to rescission	(536,500)	(3,749,000)
Treasury stock, at cost, 200,000 and 200,000 shares held at May 31, 2013 and 2012, respectively	(100,000)	(100,000)
Additional paid-in capital - treasury stock	255,065	299,297
Accumulated deficit on unrelated dormant operations	(1,601,912)	(1,601,912)
Deficit accumulated during development stage	(32,400,907)	(22,832,606)
Total shareholders (deficit)	(223,916)	(3,973,434)
	\$ 4,157,699	\$ 1,070,835

See accompanying notes to consolidated financial statements.

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Operations

	Year ended May 31,		October 28,
	2013	2012	2003 through May 31, 2013
Operating expenses:			
General and administrative	\$ 6,204,865	\$ 5,454,477	\$ 22,666,757
Amortization / depreciation	222,684	2,013	405,546
Research and development	619,838	530,027	3,379,333
Legal fees	946,030	1,469,129	3,836,661
Total operating expenses	7,993,417	7,455,646	30,288,297
Operating loss	(7,993,417)	(7,455,646)	(30,288,297)
Interest income	1,167		2,794
Gain on settlement of accounts payable	372,759		710,101
Interest expense:			
Amortization of discount on convertible debt	(1,703,616)	(2,063)	(2,440,542)
Interest on notes payable	(245,194)	(16,515)	(384,963)
Loss before income taxes	(9,568,301)	(7,474,224)	(32,400,907)
Income tax provision			
Net loss	\$ (9,568,301)	\$ (7,474,224)	\$ (32,400,907)
Constructive preferred stock dividends	\$	\$	\$ (6,000,000)
Convertible preferred stock dividends	\$ (2,190)	\$ (88,743)	\$ (99,483)
Net loss applicable to common shareholders	\$ (9,570,491)	\$ (7,562,967)	\$ (38,500,390)
Basic and diluted loss per share	\$ (0.32)	\$ (0.31)	\$ (2.43)
Basic and diluted weighted average common shares outstanding	29,942,393	24,618,812	15,843,957

See accompanying notes to consolidated financial statements.

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock		Common Stock		Additional Paid-In Capital	Subject to Rescission
	Shares	Amount	Shares	Amount		
Balance at October 28, 2003, following recapitalization		\$	6,252,640	\$ 1,425,334	\$ 23,502	\$
February through April 2004, sale of common stock less offering costs of \$54,000 (\$.30/share)			1,800,000	486,000		
February 2004, shares issued to former officer as payment for working capital advance (\$.30/share)			16,667	5,000		
Net loss for year ended May 31, 2004						
Balance at May 31, 2004			8,069,307	1,916,334	23,502	
July 2004, capital contribution by an officer					512	
November 2004, common stock warrants granted					11,928	
February 2005, capital contribution by an officer					5,000	
Net loss for year ended May 31, 2005						
Balance at May 31, 2005			8,069,307	1,916,334	40,942	

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Deficit Accumulated During Development Stage	Total
Balance at October 28, 2003, following recapitalization	\$		\$ (1,594,042)	\$	\$ (145,206)
February through April 2004, sale of common stock less offering costs of \$54,000 (\$.30/share)					486,000
February 2004, shares issued to former officer as payment for working capital advance (\$.30/share)					5,000
Net loss for year ended May 31, 2004			(7,870)	(338,044)	(345,914)
Balance at May 31, 2004			(1,601,912)	(338,044)	(120)
July 2004, capital contribution by an officer					512
November 2004, common stock warrants granted					11,928
February 2005, capital contribution by an officer					5,000
Net loss for year ended May 31, 2005				(777,083)	(777,083)
Balance at May 31, 2005			(1,601,912)	(1,115,127)	(759,763)
See accompanying notes to consolidated financial statements.					



**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock		Common Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
June through July 2005, sale of common stock less offering costs of \$27,867 (\$0.75/share)			289,890	189,550	
August 2005, common shares issued to extinguish promissory notes payable and related interest (\$0.75/share)			160,110	120,082	
May 2006, common shares issued to extinguish convertible debt			350,000	437,500	
November 2005, 94,500 warrants exercised (\$0.30/share)			94,500	28,350	
January through April 2006, common shares issued for prepaid services			183,857	370,750	
Amortization of prepaid stock services					
January through May 2006, warrants issued with convertible debt					274,950
January through May 2006, beneficial conversion feature of convertible debt					234,550
March through May 2006, stock options granted to consultants					687,726

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Deficit Accumulated During Development Stage	Total
June through July 2005, sale of common stock less offering costs of \$27,867 (\$.75/share)					189,550
August 2005, common shares issued to extinguish promissory notes payable and related interest (\$.75/share)					120,082
May 2006, common shares issued to extinguish convertible debt					437,500
November 2005, 94,500 warrants exercised (\$.30/share)					28,350
January through April 2006, common shares issued for prepaid services		(370,750)			
Amortization of prepaid stock services		103,690			103,690
January through May 2006, warrants issued with convertible debt					274,950
January through May 2006, beneficial conversion feature of convertible debt					234,550
March through May 2006, stock options granted to consultants					687,726
See accompanying notes to consolidated financial statements.					

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock		Common Stock		Additional
	Shares	Amount	Shares	Amount	Paid-In Capital
March 2006, stock options issued to extinguish debt					86,341
Net loss for year ended May 31, 2006					
Balance at May 31, 2006			9,147,664	3,062,566	1,324,509
Common stock issued to extinguish convertible debt			119,600	149,500	
Common stock issued for AITI acquisition			2,000,000	934,399	
Amortization of prepaid stock services					
Common stock payable for prepaid services					120,000
Stock-based compensation					535,984
Warrants issued with convertible debt					92,500
Common stock issued for services			30,000	26,400	
Preferred shares issued to AGTI	100,000	167,500			
Net loss for year ended May 31, 2007					
Balance at May 31, 2007	100,000	167,500	11,297,264	4,172,865	2,072,993

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Deficit Accumulated During Development Stage	Total
March 2006, stock options issued to extinguish debt					86,341
Net loss for year ended May 31, 2006				(2,053,944)	(2,053,944)
Balance at May 31, 2006		(267,060)	(1,601,912)	(3,169,071)	(650,968)
Common stock issued to extinguish convertible debt					149,500
Common stock issued for AITI acquisition					934,399
Amortization of prepaid stock services		267,060			267,060
Common stock payable for prepaid services		(106,521)			13,479
Stock-based compensation					535,984
Warrants issued with convertible debt					92,500
Common stock issued for services					26,400
Preferred shares issued to AGTI					167,500
Net loss for year ended May 31, 2007				(2,610,070)	(2,610,070)
Balance at May 31, 2007		(106,521)	(1,601,912)	(5,779,141)	(1,074,216)

See accompanying notes to consolidated financial statements.

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Subject to Rescission
Amortization of prepaid stock for services						
Stock-based compensation					461,602	
Common stock issued to extinguish convertible debt			750,000	75,000		
Rescission of common stock issued for services			(142,857)	(100,000)		
Original issue discount convertible debt with warrants					3,662	
Original issue discount convertible debt with beneficial conversion feature					75,000	
Stock issued for cash (\$.50/share)			642,000	321,000		(321,000)
Net loss for year ended May 31, 2008						
Balance at May 31, 2008	100,000	167,500	12,546,407	4,468,865	2,613,257	(321,000)

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Deficit Accumulated During Development Stage	Total
Amortization of prepaid stock for services		106,521			106,521
Stock-based compensation					461,602
Common stock issued to extinguish convertible debt					75,000
Rescission of common stock issued for services					(100,000)
Original issue discount convertible debt with warrants					3,662
Original issue discount convertible debt with beneficial conversion feature					75,000
Stock issued for cash (\$.50/share)					
Net loss for year ended May 31, 2008				(1,193,684)	(1,193,684)
Balance at May 31, 2008			(1,601,912)	(6,972,825)	(1,646,115)

See accompanying notes to consolidated financial statements.

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock		Common Stock		Additional Paid-In Capital	Subject to Rescission
	Shares	Amount	Shares	Amount		
Stock issued for cash (\$.50/share)			3,023,308	1,511,654		(1,494,000)
Stock issued for services (\$.50/share)			388,200	194,100		
Stock issued for services (\$.37/share)			150,000	55,500		
Stock-based compensation					371,996	
Stock issued in payment of accounts payable (\$.50/share)			98,000	49,000		
Stock issued for services (\$.42/share)			15,400	6,468		
Capital contribution					8,900	
Net loss for year ended May 31, 2009						
Balance at May 31, 2009	100,000	167,500	16,221,315	6,285,587	2,994,153	(1,815,000)
Stock issued for cash (\$.50/share)			236,400	118,200		(118,200)
Stock issued for cash (\$.50/share)			632,000	290,500		(290,500)
Stock issued for cash (\$.50/share)			304,580	137,061		(137,061)
Conversion of debt to common stock (\$.45/share)			325,458	146,456		

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock		Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Deficit Accumulated During Development Stage	Total
	Shares	Amount					
Stock issued for cash (\$.50/share)							17,654
Stock issued for services (\$.50/share)							194,100
Stock issued for services (\$.37/share)							55,500
Stock-based compensation							371,996
Stock issued in payment of accounts payable (\$.50/share)							49,000
Stock issued for services (\$.42/share)							6,468
Capital contribution							8,900
Net loss for year ended May 31, 2009						(1,306,004)	(1,306,004)
Balance at May 31, 2009					(1,601,912)	(8,278,829)	(2,248,501)
Stock issued for cash (\$.50/share)							
Stock issued for cash (\$.50/share)							
Stock issued for cash (\$.50/share)							
Conversion of debt to common stock (\$.45/share)							146,456

See accompanying notes to consolidated financial statements.



**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock		Common Stock		Additional Paid-In Capital	Subject to Rescission
	Shares	Amount	Shares	Amount		
Conversion of preferred stock to common stock	(100,000)	(167,500)	2,356,142	167,500		
Stock-based compensation					1,671,118	
Original issue discount convertible debt with beneficial conversion feature					38,604	
Expiration of rescission liabilities						903,550
Repurchase of common stock (\$.28/share)						
Repurchase of common stock (\$.50/share)						
Stock issued for cash (\$.50/share)						(277,000)
Stock issued for services (\$1.45/share)						
Stock issued for cash (\$.50/share)						(253,789)

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock		Treasury Stock APIC	Stock for Prepaid Services	Accumulated Development Deficit	Deficit Accumulated During Development Stage	Total
	Shares	Amount					
Conversion of preferred stock to common stock							
Stock-based compensation							1,671,118
Original issue discount convertible debt with beneficial conversion feature							38,604
Expiration of rescission liabilities							903,550
Repurchase of common stock (\$.28/share)	(1,200,000)	(336,000)					(336,000)
Repurchase of common stock (\$.50/share)	(200,000)	(100,000)					(100,000)
Stock issued for cash (\$.50/share)	550,000	154,000	123,000				
Stock issued for services (\$1.45/share)	81,580	22,842	95,449	(118,291)			
Stock issued for cash (\$.50/per share)	568,420	159,158	94,631				

See accompanying notes to consolidated financial statements.

**Table of Contents**

Cytodyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock		Common Stock		Additional Paid-In Capital	Subject to Rescission Amount
	Shares	Amount	Shares	Amount		
Amortization of prepaid stock for services						
Series B Convertible Preferred Stock issued for cash (\$5.00/share)	400,000	2,009,000				(2,009,000)
Net loss for year ended May 31, 2010						
Balance at May 31, 2010	400,000	2,009,000	20,075,895	7,145,304	4,703,875	(3,997,000)
Conversion of Series B Convertible Preferred Stock to Common Stock	(88,200)	(442,984)	882,000	442,984		
Stock issued for services (\$1.23/share)			150,000	184,500		
Capital contribution					229,500	
Stock issued for cash (\$1.00/share)			1,365,987	1,365,987		(1,365,987)
Series B Convertible Preferred Stock dividends			17,100	8,550	(8,550)	
Stock-based compensation					952,316	
Rescission expirations and exclusions						511,987
Amortization of prepaid stock for services						
Net loss for year ended May 31, 2011						
Balance at May 31, 2011	311,800	1,566,016	22,490,982	9,147,325	5,877,141	(4,851,000)

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock		Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Deficit Accumulated During Development Stage	Total
	Shares	Amount					
Amortization of prepaid stock for services				69,003			69,003
Series B Convertible Preferred stock issued for cash (\$5.00/share)							
Net loss for year ended May 31, 2010						(3,359,865)	(3,359,865)
Balance at May 31, 2010	(200,000)	(100,000)	313,080	(49,288)	(1,601,912)	(11,638,694)	(3,215,635)
Conversion of Series B Convertible Preferred Stock to Common Stock							
Stock issued for services (\$1.23/share)							184,500
Capital contribution							229,500
Stock issued for cash (\$1.00/share)							
Series B Convertible Preferred Stock dividends							
Stock-based compensation							952,316
Rescission expirations and exclusions							511,987
Amortization of prepaid stock for services				49,288			49,288
Net loss for year ended May 31, 2011						(3,719,688)	(3,719,688)
Balance at May 31, 2011	(200,000)	(100,000)	313,080		(1,601,912)	(15,358,382)	(5,007,732)
See accompanying notes to consolidated financial statements.							

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock		Common Stock		Common Stock Payable	Additional Paid-In Capital	Subject to Rescission Amount
	Shares	Amount	Shares	Amount			
Rescission expirations and exclusions							1,102,000
Conversion of Series B Convertible Preferred Stock to Common Stock	(212,900)	(1,064,500)	2,129,000	1,064,500			
Series B Convertible Preferred Stock Dividends			177,485	88,743		(88,743)	
Series B Convertible Preferred Stock Cash Dividends						(1,500)	
Common Stock issued to consultants for services (\$2.55-\$2.80/share)			72,500	203,000			
Common Stock issued to directors for services (\$2.07/share)			16,675	34,560			
Common Stock issued for cash (\$1.50/share)			1,997,388	2,996,024			
Exercise of Common Stock options (\$.30-\$1.00/share)			527,500	326,900			
Common shares issued from escrow liability (\$1.00/share)			1,425,000	1,425,000			
Common stock to be issued related to legal settlement (\$0.97/share)					388,000		
Amortization of deferred offering costs related to rescission liability		(49,523)		(135,791)			
Capital Contribution						1,336	
Stock-based compensation						1,692,290	
Warrants to be issued related to legal settlement						540,009	
Net loss for year ended May 31, 2012							
Balance at May 31, 2012	98,900	\$ 451,993	28,836,530	\$ 15,150,261	\$ 388,000	\$ 8,020,533	\$ (3,749,000)

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock		Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Deficit Accumulated During Development Stage	Total
	Shares	Amount					
Rescission expirations and exclusions							1,102,000
Conversion of Series B Convertible Preferred Stock to Common Stock							
Series B Convertible Preferred Stock Dividends							
Series B Convertible Preferred Stock Cash Dividends							(1,500)
Common Stock issued to consultants for services (\$2.55-\$2.80/share)							203,000
Common Stock issued to directors for services (\$2.07/share)							34,560
Common Stock issued for cash (\$1.50/share)							2,996,024
Exercise of Common Stock options (\$.30-1.00/share)							326,900
Common shares issued from escrow liability (\$1.00/share)							1,425,000
Common stock to be issued related to legal settlement (\$0.97/share)							388,000
Amortization of deferred offering costs related to rescission liability			(13,783)				(199,097)
Capital Contribution							1,336
Stock based compensation							1,692,290
Warrants to be issued related to legal settlement							540,009
Net loss for year ended May 31, 2012						(7,474,224)	(7,474,224)
Balance at May 31, 2012	(200,000)	\$ (100,000)	\$ 299,297		\$ (1,601,912)	\$ (22,832,606)	\$ (3,973,434)

See accompanying notes to consolidated financial statements.

**Table of Contents**

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Preferred Stock		Common Stock		Common Stock Payable	Additional Paid-In Capital	Rescission Amount
	Shares	Amount	Shares	Amount			
Rescission expirations and exclusions							3,212,500
Amortization of deferred offering costs related to rescission liability		(158,902)		(377,258)			
Conversion of Series B Convertible Preferred Stock to Common Stock	(3,800)	(19,000)	38,000	19,000			
Series B Convertible Preferred Stock Dividends			4,380	2,190		(2,190)	
Common Stock issued related to legal settlement (\$.97/share)			400,000	388,000	(388,000)		
Common Stock issued to consultants for services (\$2.68/share)			60,000	160,800			
Amortization of prepaid stock service							
Common Stock issued to directors for services (\$1.60/share)			7,810	12,496			
Common Stock issued to directors for services (\$.77/share)			16,230	12,497			
Common Stock issued to directors for services (\$1.00/share)			12,500	12,500			
Common Stock issued to directors for services (\$.80/share)			14,980	11,984			
Exercise of Common Stock warrants (\$.25/share)			750,000	187,500			
Exercise of Common Stock warrants (\$1.00/share)			5,000	5,000			
Exercise of Common Stock options (\$.34/share)			25,000	8,500			
Conversion of convertible debt to common stock (\$.75/share)			756,000	567,000			
Conversion of accrued interest on convertible debt to common stock (\$.75/share)			5,604	4,203			
Issuance of common stock for accounts payable (\$1.21/share)			66,116	80,000			
Common stock issuable for accrued interest					10,278		
Common stock issuable for bonuses					107,500		
Stock-based compensation						3,261,951	
Debt discount related to warrants and beneficial conversion feature associated with convertible debt						6,243,502	
Net Loss for year ended May 31, 2013							

Edgar Filing: CYTODYN INC - Form 10-K

Balance at May 31, 2013	95,100	\$ 274,091	30,998,150	\$ 16,244,673	\$ 117,778	\$ 17,523,796	\$ (536,500)
-------------------------	--------	------------	------------	---------------	------------	---------------	--------------

See accompanying notes to consolidated financial statements.



**Table of Contents**

Cytodyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders (Deficit)

Period October 28, 2003 through May 31, 2013

	Treasury Stock		Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Deficit Accumulated During Development Stage	Total
	Shares	Amount					
Rescission expirations and exclusions							3,212,500
Amortization of deferred offering costs related to rescission liability			(44,232)				(580,392)
Conversion of Series B Convertible Preferred Stock to Common Stock							
Series B Convertible Preferred Stock Dividends							
Common Stock issued related to legal settlement (\$.97/share)							
Common Stock issued to consultants for services (\$2.68/share)				(160,800)			
Amortization of prepaid stock service				160,800			160,800
Common Stock issued to directors for services (\$1.60/share)							12,496
Common Stock issued to directors for services (\$.77/share)							12,497
Common Stock issued to directors for services (\$1.00/share)							12,500
Common Stock issued to directors for services (\$.80/share)							11,984
Exercise of Common Stock warrants (\$.25/share)							187,500
Exercise of Common Stock warrants (\$1.00/share)							5,000
Exercise of Common Stock options (\$.34/share)							8,500
Conversion of convertible debt to common stock (\$.75/share)							567,000
Conversion of accrued interest on convertible debt to common stock (\$.75/share)							4,203
Issuance of common stock for accounts payable (\$1.21/share)							80,000
Common stock issuable for accrued interest							10,278
Common stock issuable for bonuses							107,500
Stock-based compensation							3,261,951
Debt discount related to warrants and beneficial conversion feature associated with convertible debt							6,243,502
Net Loss for the year ended May 31, 2013						(9,568,301)	(9,568,301)

Edgar Filing: CYTODYN INC - Form 10-K

Balance at May 31, 2013	(200,000)	\$ (100,000)	\$ 255,065	\$ (1,601,912)	\$ (32,400,907)	\$ (223,916)
-------------------------	-----------	--------------	------------	----------------	-----------------	--------------

See accompanying notes to consolidated financial statements.

**Table of Contents**

## Cytodyn Inc.

(A Development Stage Company)

## Consolidated Statements of Cash Flows

	Year Ended May 31, 2013	Year Ended May 31, 2012	October 28, 2003 through May 31, 2013
<b>Cash flows from operating activities</b>			
Net loss	\$ (9,568,301)	\$ (7,474,224)	\$ (32,400,907)
Adjustments to reconcile net loss to net cash used by operating activities:			
Amortization / depreciation	222,684	2,013	405,546
Loss on disposal of furniture and equipment		2,560	2,560
Amortization of discount on convertible debt	1,703,616	2,063	2,422,881
Gain on settlement of accounts payable	(372,759)		(710,101)
Purchased in process research and development			274,399
Stock-based compensation	3,590,011	2,857,859	12,167,995
Changes in current assets and liabilities:			
Increase in accrued salaries	175,449	189,249	364,698
Increase in prepaid expenses	(73,867)	(6,707)	(139,849)
(Increase) decrease in other assets	5,744	(25,987)	
Increase in accounts payable, accrued interest and accrued liabilities	924,490	62,079	2,210,482
<b>Net cash used in operating activities</b>	<b>(3,392,933)</b>	<b>(4,391,095)</b>	<b>(15,402,296)</b>
<b>Cash flows from investing activities:</b>			
Asset acquisition of intangibles	(3,500,000)		(3,500,000)
Furniture and equipment purchases	(3,135)		(24,218)
<b>Net cash used in investing activities</b>	<b>(3,503,135)</b>		<b>(3,524,218)</b>
<b>Cash flows from financing activities:</b>			
Capital contributions by executive		1,336	15,748
Preferred stock dividends		(1,500)	(1,500)
Proceeds from notes payable to related parties	500,000		1,205,649
Payments on notes payable to related parties	(74,492)	(74,492)	(314,482)
Proceeds from notes payable issued to individuals			145,000
Payments on notes payable issued to individuals			(34,500)
Proceeds from convertible notes payable	6,588,250		7,274,250
Proceeds from sale of common stock		3,386,024	8,966,072
Proceeds from Series B preferred stock			2,009,000
Purchase of treasury stock			(436,000)
Proceeds from sale of treasury stock			559,210
Deferred offering costs			(1,029,940)
Proceeds from issuance of stock in AITI acquisition			512,200
Proceeds from issuance of stock in AGTI acquisition			100,000
Proceeds from exercise of warrants and options	201,000	326,900	556,250
<b>Net cash provided by financing activities</b>	<b>7,214,758</b>	<b>3,638,268</b>	<b>19,526,957</b>
<b>Net change in cash</b>	<b>318,690</b>	<b>(752,827)</b>	<b>600,443</b>
Cash, beginning of period	284,991	1,037,818	3,238
<b>Cash, end of period</b>	<b>\$ 603,681</b>	<b>\$ 284,991</b>	<b>\$ 603,681</b>

Edgar Filing: CYTODYN INC - Form 10-K

Supplemental disclosure of cash flow information:

Cash paid during the period for:

Income taxes	\$	\$	\$
Interest	\$ 224,724	\$ 2,593	\$ 251,481

**Table of Contents**

## CytoDyn Inc.

(A Development Stage Company)

## Consolidated Statements of Cash Flows

	Year Ended May 31,		October 28, 2003
	2013	2012	through May 31, 2013
<b>Non-cash investing and financing transactions:</b>			
Net assets acquired in exchange for common stock in CytoDyn/Rexray business combination	\$	\$	\$ 7,542
Common stock issued to former officer to repay working capital advance	\$	\$	\$ 5,000
Common stock issued for convertible debt	\$ 567,000	\$	\$ 1,229,000
Common stock issued for debt	\$	\$	\$ 245,582
Common stock issued for accrued interest payable	\$ 4,205	\$	\$ 25,161
Options to purchase common stock issued for debt	\$	\$	\$ 62,341
Original issue discount and intrinsic value of beneficial conversion feature related to convertible debt issued with warrants	\$ 6,243,502	\$	\$ 6,962,768
Common stock issued for preferred stock	\$	\$	\$ 167,500
Treasury stock issued for prepaid services	\$	\$	\$ 118,291
Common stock issued on settlement of accounts payable	\$ 80,000	\$	\$ 129,000
Preferred and common stock subject to rescission	\$ 3,212,500	\$ 1,102,000	\$ 536,500
Accrued stock incentive and deferred offering costs	\$	\$	\$ 1,717,000
Common stock issued for Series B preferred stock	\$ 19,000	\$ 1,064,500	\$ 1,526,484
Series B preferred stock dividends	\$ 2,190	\$ 88,743	\$ 99,483
Accrued salaries related party contributed as capital	\$	\$	\$ 229,500
Reversal of accrued stock incentive and deferred offering costs	\$	\$	\$ 1,717,000
Constructive dividend	\$	\$	\$ 6,000,000
Amortization of deferred offering costs related to rescission liability	\$ 580,398	\$ 199,097	\$ 779,495
Common shares issued from escrow liability	\$	\$ 1,425,000	\$ 1,425,000

See accompanying notes to consolidated financial statements.



---

**Table of Contents**

CYTODYN INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF MAY 31, 2013

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.

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

The Company entered the development stage effective October 28, 2003 upon the reverse merger and recapitalization of the Company and follows Financial Standard Accounting Codification No. 915, Development Stage Entities.

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 2013 presentation. These reclassifications did not have any effect on total current assets, total assets, total current liabilities, total liabilities, total shareholders (deficit), 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 is currently in the development stage with losses for all periods presented. The Company incurred a net loss of \$9,568,301 for the period ended May 31, 2013, has an accumulated deficit of \$34,002,819, and a working capital deficit of \$2,388,138 as of May 31, 2013. 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 attain profitability. The Company intends to seek additional

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

funding through equity and debt offerings to fund its business plan. There can be no assurance, however, that the Company will be successful in these endeavors.



---

## **Table of Contents**

### 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.

### Cash

The Company considers all highly liquid debt instruments with original maturities of three months or less when acquired to be cash equivalents. The Company had no cash equivalents as of May 31, 2013 or May 31, 2012. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances.

### 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 11 for acquisition of patents). There were no impairment charges for the years ended May 31, 2013 and 2012, or for the period October 28, 2003 through May 31, 2013. The value of the Company's patents would be significantly impaired by any adverse developments as they relate to the clinical trials pursuant to the patents acquired as discussed in Notes 9 and 11.

### Research and Development

Research and development costs are expensed as incurred.

### 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 granted 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 graded 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% as of May 31, 2013 and May 31, 2012.

### Preferred Stock

As of May 31, 2013, 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, 2013, the Company has authorized the issuance of 400,000 shares of Series B convertible preferred stock (see Note 4). The remaining preferred shares authorized have no specified rights other than the shares are non-voting and no par value.



**Table of Contents**

## Deferred Offering Costs

In connection with a stock rescission liability as discussed at Note 3, the Company has recorded approximately \$97,000 and \$677,000 in deferred offering costs as of May 31, 2013 and May 31, 2012, respectively. These deferred offering costs have been recorded as a current asset for the respective periods. The asset is amortized and reduces equity on a pro rata basis with the decreases in the rescission liability. If investors exercise their rescission rights and forfeit their shares, the deferred offering costs would be expensed at that time.

## Stock for Services

The Company issues common stock, warrants and common stock options 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 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 18,146,938, 10,327,664 and 18,146,938 shares of common stock were not included in the computation of diluted weighted average common shares outstanding for the periods ended May 31, 2013 and 2012 and for the period October 28, 2003 to May 31, 2013, respectively, as inclusion would be anti-dilutive for these periods. Additionally, as of May 31, 2013, 95,100 shares of Series B convertible stock can potentially convert into 951,000 shares of common stock, and \$6,021,250 of convertible debt can potentially convert into 8,106,282 shares of common stock based on fixed conversion prices ranging from \$.65 to \$.75 per share.

## 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 carryforwards are recognized to the extent that realization of these benefits is considered more likely than not. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all 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 at May 31, 2013 or 2012 and since the date of adoption. 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. The Company is subject to examination by the Internal Revenue Service and state tax authorities for tax years ending after 2008.

## 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, originally estimated to total approximately \$6.4 million, is now being properly 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). On July 21, 2011, the Company filed a Current Report on Form 8-K disclosing its receipt of an SEC letter of inquiry and request for voluntary assistance in discovering information



**Table of Contents**

related to the Liability Disclosure. By letter dated January 3, 2012, the Division of Enforcement of the Securities and Exchange Commission notified the Company that the SEC had completed its informal investigation of the Company and had recommended no enforcement action be taken against the Company, or its officers, directors, or employees.

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' deficiency in the Company's balance sheet. As the statutory periods for pursuing such rights expire in the respective states, such amounts for those shares are reclassified to shareholders' deficiency. 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 estimates an amount that is a probable indicator of the rescission liability and recorded rescission liabilities for May 31, 2013 and May 31, 2012 of \$537,000 and \$3,749,000, respectively. These amounts represent the believed remaining potential rescission liability as of the dates presented, including any contingent interest payable 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 various states. 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.

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 entered into a seven-year Personal Services Agreement on August 4, 2008 (the "Contract") with Nader Pourhassan, now the Company's President and Chief Executive Officer. It was subsequently determined that the compensation provided for under the Contract may have violated applicable securities laws. Such violations gave rise to the Company's rescission liability described above. It was unclear whether the Company had any defenses to payment, whether the Company had any rights to recover payments made to Dr. Pourhassan or others at his direction or as contemplated in the Contract (including payments in the form of securities), or whether, even if the Company did have such rights, Dr. Pourhassan (and perhaps others) would have certain equitable remedies that would entitle Dr. Pourhassan (and perhaps others) to set off against the Company's rights or would obligate the Company to make compensatory payments for services performed by Dr. Pourhassan (and others under his direction).

The Contract provided for compensation to Dr. Pourhassan at an annual salary of \$200,000. Additionally, as incentive compensation, Dr. Pourhassan's personal assistant and one additional person were each to receive 50,000 common shares for every \$500,000 in capital received by the Company through Dr. Pourhassan's efforts. On October 11, 2011, Dr. Pourhassan and the Company entered into a Mutual Release and Personal Services Termination Agreement (the "MRPSTA") which relieved the Company of liability for any claims of compensation under the Contract. Simultaneously with the signing of the MRPSTA, Dr. Pourhassan and the Company entered into a new Employment and Non-Compete Agreement whereby Dr. Pourhassan was appointed Managing Director of Business Development with an annual salary of \$200,000. Upon the signing of the MRPSTA, the Company at May 31, 2011 reversed all accrued stock compensation and deferred offering costs, as the Company had no further obligations under the Contract.

**4 - Convertible Instruments**

During fiscal 2010, the Company authorized the issuance of 400,000 shares of Series B Convertible Preferred Stock (Series B) at \$5.00 per share. During the year ended May 31, 2013, 3,800 shares of the Series B were converted into 38,000 shares of common stock. The Series B is convertible into ten shares of the Company's common stock including any accrued dividends, with an effective fixed conversion price of \$0.50 per share. The holders of the Series B are able to convert their shares to common shares only if the Company has sufficient authorized common shares at the time of conversion. Accordingly, the conversion option was contingent upon the Company increasing

**Table of Contents**

its authorized common shares, which occurred in April 2010 when the Company's shareholders approved an increase in the authorized common shares. At the commitment date, which occurred upon the shareholders approving the increase in the authorized shares, 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 the same amount. The Series B has liquidation preferences over the common shares at \$5.00 per share plus any accrued dividends. Dividends are payable to the Series B holders when declared by the board of directors at the rate of \$0.25 per share per annum. The Series B holders have no voting rights.

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 \$.75 per share, and \$380,000 is convertible at \$.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 \$.75 to \$2.00 per share were issued to the investors. The warrants are currently exercisable in full and will expire between October 1, 2014 and May 31, 2015. 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 the Notes, and a corresponding increase to additional paid-in capital. The debt discounts are being 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. During the year ended May 31, 2013, activity related to the Notes was as follows:

Face amount of convertible notes	\$ 6,588,250
Debt discounts	(6,243,502)
Amortization of debt discount	1,703,616
Conversions	(567,000)
Total carrying value of convertible notes	1,481,364
Short-term portion of convertible notes	(328,347)
Long-term portion of convertible notes	\$ 1,153,017

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

Expected dividend yield	-0%
Stock price volatility	70 - 94%
Expected term	2 years
Risk-free interest rate	.28%
Grant-date fair value	\$.11 - \$1.10

#### 5 - Stock Options and Warrants

The Company has one stock-based equity plan at May 31, 2013. Pursuant to the 2004 Stock Incentive Plan, as amended, which was originally adopted by the Company's shareholders in 2005, the Company was authorized to

**Table of Contents**

issue options to purchase up to 7,600,000 shares of the Company's common stock. On December 12, 2012, the Company's shareholders approved the CytoDyn Inc. 2012 Equity Incentive Plan (the 2012 Plan), which replaced the 2004 Stock Incentive Plan and provides for the issuance of up to 3,000,000 shares of common stock pursuant to various forms of incentive awards allowed under the 2012 Plan. As of May 31, 2013, the Company had 1,976,710 shares available for future stock-based grants under the 2012 Plan.

During the year ended May 31, 2013, the Company granted a total of 148,290 common stock options to directors with exercise prices ranging from \$1.40 to \$1.55 per share, which vest in quarterly increments over one year and have an expiration date of five years from the date of grant. The average grant date fair value related to these options was \$.89 per share.

During the year ended May 31, 2013, the Company granted a total of 1,225,000 common stock options to employees with exercise prices ranging from \$.80 to \$1.80 per share. Of the options, 112,500 vested immediately, and 112,500 vest in October 2013. The remaining options vest annually over three years, beginning one year following the grant date. The options have expiration dates that range from three to five years from the date of grant. The average grant date fair value related to these options was \$.60 per share.

During the year ended May 31, 2013, the Company granted a total of 515,000 common stock warrants to consultants with exercise prices ranging from \$1.00 to \$5.00 per share. The warrants have varying vesting terms, but were fully vested in April 2013. The expiration dates for the warrants range from September 2014 to October 2015. The average grant date fair value related to these warrants was \$.56 per share.

On July 27, 2012, the Company entered into a Settlement Agreement and Mutual Release (the Settlement Agreement) with William Carmichael and Mojdeh Javadi (the Plaintiffs) with respect to a complaint filed in December 2011 alleging breach of contract for failure to issue warrants to purchase shares of the Company's common stock to the Plaintiffs pursuant to a contract entered into between the Company and the Plaintiffs in November 2007, as well as failure to pay compensation to which the Plaintiffs were allegedly entitled pursuant to the Contract described in Note 3 above. In the Settlement, the Company granted warrants to purchase a total of 750,000 common shares to the Plaintiffs at an exercise price of \$.25 per share. All compensation expense associated with the warrants was recognized at May 31, 2012, totaling approximately \$540,000. All the warrants were exercised during the year ended May 31, 2013. Ms. Javadi is the spouse of the Company's chief executive officer.

As discussed in Note 4, the Company issued warrants to purchase a total of 8,527,984 common shares to investors. The grant date fair value of the warrants was \$.72 per share.

Net cash proceeds from the exercise of common stock warrants and options were \$201,000 for the year ended May 31, 2013.

Compensation expense related to stock options and warrants was approximately \$3,262,000 and \$1,692,000 for the year ended May 31, 2013, and 2012, respectively. The grant date fair value of options and warrants vested during the year ended May 31, 2013 and 2012 was approximately \$8,889,000 and \$1,562,000, respectively. As of May 31, 2013 there was approximately \$1,748,000 of unrecognized compensation costs related to share-based payments for unvested options, which is expected to be recognized over a weighted average period of 1.57 years.

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, 2013 and 2012:

	2013	2012
Risk free rate	0.12% - 0.70%	0.12% - .87%
Dividend yield		
Volatility	87% - 102%	93% - 102%
Expected term	1 - 4 years	1 - 4 years

**Table of Contents**

The following table represents stock option and warrants activity for the periods ended May 31, 2013 and 2012:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Options and warrants outstanding - May 31, 2011	7,473,576	\$ 1.34	3.84	\$ 10,495,913
Granted	3,456,088	\$ 2.04		
Exercised	(527,500)	\$ .62		
Forfeited/expired/cancelled	(74,500)	\$ 2.49		
Options and warrants outstanding - May 31, 2012	10,327,664	\$ 1.60	3.20	\$ 2,308,279
Granted	11,166,274	\$ 1.61		
Exercised	(780,000)	\$ 0.26		
Forfeited/expired/cancelled	(2,567,000)	\$ 1.73		
Options and warrants outstanding - May 31, 2013	18,146,938	\$ 1.65	1.86	\$ 140,321
Exercisable - May 31, 2013	16,253,188	\$ 1.68	1.65	\$ 140,321

#### 6 - Common Stock and common stock payable issued for services

During the year ended May 31, 2013, the Company issued 51,520 fully vested shares of common stock at prices ranging from \$.80 to \$1.60 per share, and recognized approximately \$49,000 in compensation expense to directors for past services. Compensation expense to directors related to common stock issuances was approximately \$35,000 for the year ended May 31, 2012.

During the year ended May 31, 2013, the Company issued 60,000 shares of common stock to a consultant at \$2.68 per share, which was the fair value at the commitment date, which was amortized over the requisite service period. During the year ended May 31, 2013 the Company recognized approximately \$161,000 in stock-based compensation related to this grant. During the year ended May 31, 2012, compensation expense related to common stock issuances to consultants was approximately \$203,000.

Effective December 28, 2012, the Company settled trade payable balances of approximately \$447,000 owed to its previous principal law firm in exchange for a cash payment of \$45,000 and 66,116 shares of Company common stock with a value of \$80,000 as determined by the closing price of the stock on December 24, 2012. The Company recorded a gain on the satisfaction of the payables of approximately \$322,000 for the year ended May 31, 2013.

At May 31, 2013, the Company is committed, subject to satisfaction of certain conditions, to issue approximately \$108,000 of common stock to two executives of the Company for past services. This amount is included in common stock payable as of May 31, 2013. At May 31, 2013, the Company is committed to issue approximately \$10,000 of common stock to a director of the Company related to accrued interest on a note payable (see Note 10). This amount is included in common stock payable. Pursuant to the Settlement Agreement described in Note 5, the Company issued 400,000 shares of common stock, which was recorded as common stock payable at May 31, 2012. The Company recognized approximately \$388,000 in stock compensation expense during the year ended May 31, 2012 related to the issuance of this common stock.

#### 7 - Recent Accounting Pronouncements

Recent accounting pronouncements 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.

#### 8 - Income Taxes



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

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, 2013 and 2012, or for the period ended October 28, 2003 through May 31, 2013.

**Table of Contents**

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

	2013	2012
Income tax provision at statutory rate	34.0%	34.0%
State income taxes, net	5.1	5.1
Rate change	0.0	0.0
Other	0.0	0.0
Valuation allowance	(39.1)	(39.1)
	0.0%	0.0%

Net deferred tax assets and liabilities are comprised of the following as of May 31, 2013 and 2012:

	2013	2012
Deferred tax asset (liability) current:		
Accrued salary and expenses	\$ 291,100	\$ 49,100
Debt discount amortization	(118,100)	
Valuation allowance	(173,000)	(49,100)
Deferred tax asset (liability) non-current	\$	\$
Net operating loss	\$ 8,256,000	\$ 6,317,000
Debt discount	(1,659,300)	
Expense on non-qualified stock options	2,928,000	2,093,100
Other	155,500	96,500
Valuation allowance	(9,680,200)	(8,506,600)
	\$	\$

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, 2013, the Company had available net operating loss carryforwards of approximately \$21,000,000 which expire beginning in 2022.

#### 9 - Commitments and Contingencies

On July 25, 2012, the Company and Kenneth J. Van Ness entered into a Transition Agreement (the "Transition Agreement"). Pursuant to the Transition Agreement, Mr. Van Ness stepped down as the Chairman of the Board, effective immediately. In addition, Mr. Van Ness agreed to step down as the President and CEO of the Company. Mr. Van Ness ceased to be a director on December 12, 2012.

The Transition Agreement provided that, in lieu of any compensation otherwise payable to Mr. Van Ness under the Executive Employment Agreement, dated April 16, 2012, but effective as of August 9, 2011 (the "Employment Agreement"), by and between the Company and Mr. Van Ness, during the period beginning on July 18, 2012 through October 16, 2012 (the "Transition Period") Mr. Van Ness would be paid a salary equal to \$13,890 per month and continue to receive, during the Transition Period, the fringe benefits, indemnification and miscellaneous business expense benefits provided for in the Employment Agreement. Mr. Van Ness is also entitled to (i) receive a cash severance payment equal to \$13,890 per month for 33 months following the Transition Period, (ii) the opportunity to elect the timing of distribution of his account balance in the Company's 401(k) Plan, and (iii) reimbursement for continuing health care insurance coverage under COBRA for nine months.

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

The Transition Agreement also amended (A) the CytoDyn Inc. Stock Option Award Agreement, dated December 6, 2010, with Mr. Van Ness to provide for immediate vesting of all of the 500,000 options granted at \$1.19 per share, and (B) the CytoDyn Inc. Stock Option Award Agreement, dated April 16, 2012, but effective as of August 9, 2011,

## Table of Contents

with Mr. Van Ness to provide for (i) immediate vesting of 750,000 of the 1,500,000 options granted at \$2.00 per share, and (ii) forfeiture of the remaining 750,000 options. In addition, the expiration date of the 25,000 options granted to Mr. Van Ness on September 22, 2010, as well as the options described above, will be August 8, 2016.

Pursuant to the terms of the Transition Agreement described above, during the year ended May 31, 2013, the Company recognized approximately \$479,000 in severance expense and has an accrued liability of approximately \$365,000, which is included in accrued salaries and severance on the consolidated balance sheet as of May 31, 2013. The Company accrued for the severance to be paid to Mr. Van Ness, as Mr. Van Ness has no significant continuing service obligation to the Company. Additionally, related to the modification of the above stock option awards to Mr. Van Ness, the Company recognized approximately \$1,128,000 of stock-based compensation expense during the year ended May 31, 2013. This amount was determined based on the provisions of the above Transition Agreement, including the impact of the accelerated vesting and forfeitures.

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 U.S. Phase III 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 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 III 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. Such amount remains due for calendar year 2013 and the failure to pay such amount gives rise to a termination right after notice and an opportunity to cure.

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 resolving any such claims against the Company will not have a material adverse effect on the Company's business, financial condition or results of operations.

### 10 - Related Party Transactions

During the year ended May 31, 2013, the Company issued a note payable to a director of the Company for \$500,000. The note is included in Indebtedness to related parties on the consolidated balance sheet as of May 31, 2013. The note bears interest at an annual rate of 15%, and principal and interest are payable in full at the April 11, 2014 maturity date. At the election of the Company, interest may be paid in the form of shares of common stock not to exceed 150,000 shares at a fixed price of \$.50 per share.

During the year ended May 31, 2013, the Company issued a convertible note (see Note 4) to the above director. The note has a face value of \$1,000,000, and interest is payable at a rate of 5% in cash semi-annually in arrears beginning on April 1, 2013. The principal of the note is payable in full at the October 16, 2015 maturity date. The note is convertible into common shares at a fixed conversion price of \$.75 per share at any time at the election of the holder of the note. In conjunction with the note, the Company issued 1,333,333 detachable common stock warrants at an exercise price of \$2.00 per share. The warrants expire on October 16, 2014. The Company recorded debt discounts related to the fair value of the warrants and the intrinsic value of the beneficial conversion feature at the commitment date of the note. As of May 31, 2013, the carrying value of this convertible note was approximately \$207,000, which is included in convertible notes payable, net in long-term liabilities on the consolidated balance sheet. During the year ended May 31, 2013, the Company recognized approximately \$207,000 in interest expense related to the amortization of the above discounts.

**Table of Contents**

See also the description of the Settlement Agreement with the spouse of the Company's chief executive officer and an unrelated party in Note 5 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.

**11 - Acquisition of patents**

As discussed in Note 9 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 product. 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, 2013, the Company has recorded \$3,500,000 of intangible assets in the form of patents. The Company estimates the patents have an estimated life of ten years. As of the date of this filing, management cannot reasonably estimate the likelihood of paying the milestone payments and royalties described in Note 9 and, accordingly, as of May 31, 2013, the Company has not accrued any liabilities related to these contingent payments, as more fully described above in Note 9.

The following presents intangible assets as of May 31, 2013:

Gross carrying amounts	\$ 3,500,000
Accumulated amortization	(218,750)
<b>Total amortizable intangible assets, net</b>	<b>3,281,250</b>
Patents currently not amortized	35,989
<b>Carrying value of intangibles, net</b>	<b>\$ 3,317,239</b>

Amortization expense related to intangible patents was approximately \$219,000 for the year ended May 31, 2013. 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.

**12 - Subsequent Events**

Subsequent to year-end and effective July 31, 2013, the Company issued \$1,200,000 in unsecured convertible promissory notes (the Six-Month Notes) to investors. The Six-Month Notes bear simple interest at the annual rate of 5% payable on the maturity date of February 1, 2014, or earlier date of repayment. Each investor has the right to demand earlier repayment if the Company raises \$3,000,000 or more in gross cash proceeds from the sale of equity securities after August 1, 2013. Each Six-Month Note is convertible at the election of the holder into shares of common stock at a price of \$0.65 per share; provided that upon a default in repayment of a Six-Month Note, the conversion price will decrease by \$0.10 per share, to a minimum of \$0.35 per share, for each month that the default continues. In connection with the sale of the Six-Month Notes, the Company issued common stock warrants exercisable for three years to the investors to purchase a total of 923,072 shares at a price of \$0.50 per share. Until October 1, 2013, each holder of a Note has the right to convert the principal amount of the Note plus accrued but unpaid interest into Units consisting of two shares of common stock plus a warrant to purchase one share of common stock. Each Unit is valued at \$1.30 for purposes of this conversion right. Each Unit warrant, if any, issued upon conversion will have an exercise price of \$0.75 per share and a five-year term. The Company paid a cash fee of \$120,000 to a registered broker-dealer who acted as placement agent with respect to the Six-Month Notes and related warrants.

Subsequent to year-end and effective August 1, 2013, holders of \$920,000 in principal amount of Notes (see Note 4) converted the aggregate principal amount, plus accrued but unpaid interest totaling \$12,071, into common stock at a conversion price of \$.75 per share, resulting in the issuance of a total of 1,242,762 shares.

---

## **Table of Contents**

### **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.** **Previous Independent Auditors**

The Company was previously advised that, effective January 1, 2013, Pender Newkirk & Company LLP ( Pender Newkirk ) discontinued its audit practice and the partners and employees of Pender Newkirk joined the firm of Warren Averett, LLC. Warren Averett has served as the Company's principal independent auditing firm since that time. The decision to retain Warren Averett as the Company's principal independent auditing firm was approved by the Company's Audit Committee of the Board of Directors.

### **Item 9A. Controls and Procedures.**

#### **Disclosure Controls and Procedures**

As of May 31, 2013, 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, 2013 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, 2013 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, 2013 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, 2013, 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, 2013, management has, however, implemented improved controls and procedures over cash disbursements and monthly internal financing reporting.



**Table of Contents**

**Item 9B. Other Information.**

None.



**Table of Contents**

**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 2013 Annual Meeting of Shareholders, to be filed with the SEC within 120 days of May 31, 2013.

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 definitive proxy statement for the 2013 Annual Meeting of Shareholders, to be filed with the SEC within 120 days of May 31, 2013.

**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 definitive proxy statement for the 2013 Annual Meeting of Shareholders, to be filed with the SEC within 120 days of May 31, 2013.

**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 definitive proxy statement for the 2013 Annual Meeting of Shareholders, to be filed with the SEC within 120 days of May 31, 2013.

**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 definitive proxy statement for the 2013 Annual Meeting of Shareholders, to be filed with the SEC within 120 days of May 31, 2013.

**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, 2013 and 2012 are included in Item 8 of this report starting on page 27.

**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: August 29, 2013

CYTODYN INC.  
(Registrant)

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on August 29, 2013.

**Principal Executive Officer and Director:**

/s/ Nader Z. Pourhassan  
Nader Z. Pourhassan

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 Naydenov

\* Michael Nobel

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

**Table of Contents**

EXHIBIT INDEX

Exhibit 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	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).
	<u>Material Contracts</u>
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.
10.6*	Form of Stock Option Award for Non-Employee Directors under the 2004 Plan.
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).
10.8*	Form of Stock Option Award Agreement for Employees under the 2012 Plan.
10.9*	Form of Stock Option Award Agreement for Non-Employee Directors under the 2012 Plan.
10.10*	Form of Stock Option Award Agreement for Employees granted under an arrangement not approved by the Registrant's shareholders.

**Table of Contents**

Exhibit Number	Description
10.11*	Form of Stock Option Award Agreement for Non-Employee Directors granted under an arrangement not approved by the Registrant's shareholders.
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.
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.
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.
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.
10.20*	Consulting Agreement between CytoDyn Inc. and Michael Nobel dated March 28, 2013.
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.
10.22	Clinical Research Collaboration Agreement between CytoDyn Inc. and Philadelphia Health and Education Corporation dba Drexel University College of Medicine effective November 15, 2012.
	<u>Other</u>
21	Subsidiaries of the Registrant
23.1	Consent of Warren Averett LLP
23.2	Consent of Pender Newkirk & Company LLP
24	Power of Attorney of executive officers and directors
	<u>Certifications</u>
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 pursuant to 18 U.S.C. Section 1350
	<u>XBRL</u>
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

Edgar Filing: CYTODYN INC - Form 10-K

\* Management contract or compensatory plan or arrangement

\*\* These interactive data files shall not be deemed filed for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under those sections.

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