CYTODYN INC
Form 10-K
November 03, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended May 31, 2011

or

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

For the transition period from to

Commission file number 000-49908

CYTODYN INC.

(Exact name of registrant as specified in its charter)

Colorado	**75-3056237**
(State or other jurisdiction of	**(I.R.S. Employer**

incorporation or organization)	Identification No.)
110 Crenshaw Lake Road, Lutz, Florida	**33548**
(Address of principal executive offices)	**(Zip Code)**

Registrant s Telephone Number, including area code: (813) 527-6969

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 x No

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

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

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

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter: $15,834,556 (as of November 30, 2010).

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date. As of October 1, 2011, the registrant had 22,290,982 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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CYTODYN INC

FORM 10-K FOR THE YEAR ENDED MAY 31, 2011

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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 TERM EXPRESSIONS ARE INTENDED TO IDENTIFY FORWARD-LOOKING STATEMENTS. THESE STATEMENTS INCLUDE, AMONG OTHERS, INFORMATION REGARDING FUTURE OPERATIONS, FUTURE CAPITAL EXPENDITURES, 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, GENERAL ECONOMIC AND BUSINESS CONDITIONS, CHANGES IN FOREIGN, POLITICAL, SOCIAL, AND ECONOMIC CONDITIONS, REGULATORY INITIATIVES AND COMPLIANCE WITH GOVERNMENTAL REGULATIONS, THE ABILITY TO ACHIEVE MARKET PENETRATION AND ATTRACT CUSTOMERS, AND VARIOUS OTHER MATTERS, MANY OF WHICH ARE BEYOND THE COMPANY S CONTROL. SHOULD ONE OR MORE OF THESE RISKS OR UNCERTAINTIES OCCUR, OR SHOULD UNDERLYING ASSUMPTIONS PROVE TO BE INCORRECT, ACTUAL RESULTS MAY VARY MATERIALLY AND ADVERSELY FROM THOSE ANTICIPATED, BELIEVED, ESTIMATED, OR OTHERWISE INDICATED. CONSEQUENTLY, ALL OF THE FORWARD-LOOKING STATEMENTS MADE IN THIS FILING ARE QUALIFIED BY THESE CAUTIONARY STATEMENTS AND THERE CAN BE NO ASSURANCE OF THE ACTUAL RESULTS OR DEVELOPMENTS.

PART I

Item 1. Business.

Overview / Corporate History

CytoDyn Inc. (the Company), is a Colorado corporation, with its principal business office at 110 Crenshaw Lake Road, Lutz, Florida 33548; telephone: (813) 527-6969, facsimile: (813) 527-6970, and website address: www.cytodyn.com. We are a development stage biotechnology company (concept company) focused on discovering and developing a class of therapeutic monoclonal antibodies to treat Human Immunodeficiency Virus (HIV) infection. In addition, we formed a wholly owned subsidiary, CytoDyn Veterinary Medicine LLC (CVM), which will explore the possible application of our existing proprietary monoclonal antibody technology to the treatment of Feline Immunodeficiency Virus (FIV).

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, we acquired assets related to our leading 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 HIV disease with the use of monoclonal antibodies. This includes issued U.S. Patent Nos. 5,424,066; 5,651,970 and 6,534,057, as well as European Patent Nos. 0690725 and 1438970. In addition, Hong Kong Patent No. 1067958, Australian Patent No. 684074 and Canadian Patent No. 2156495 have been obtained as well. We

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also acquired the federally registered trademarks, CYTODYN (U.S. Registration No. 2095498) and CYTOLIN (U.S. Registration No. 2095497), and a related trademark symbol. The license acquired gives the Company the worldwide, exclusive right to develop, market and sell compounds disclosed by the patent claims, practice methods taught by the patent claims, and exploit specified technology related to the patents. The term of the license agreement is for the life of the patents of which the first will expire in 2013. The original expiration dates on the issued U.S. Patent Nos. 5,424,066; 5,651,970 and 6,534,057 are 2013, 2014 and 2013, respectively.

Until recently, our Cytolin-related patents were for a murine (mouse) version of the drug. In addition, all of our research on Cytolin to date has utilized the current murine (mouse) version of the drug. However, on September 23, 2011, the Company filed a provisional patent application in the United States for its humanized version of its lead product Cytolin®, a monoclonal antibody for the treatment of HIV Infection.

The Company is also exploring other antibodies as potential therapeutics for FIV. On June 17, 2011 the Company filed for a provisional patent in the United States for the use of these antibodies as well as selected small molecule antagonists and agonists for the treatment of FIV, a retroviral infection in cats. The Company anticipates it will apply to trademark this product under the name CytoFeline.

Research History of Cytolin(R) Compound

Allen D. Allen, the former Chairman of our Board of Directors, has been researching treatments for HIV and Acquired Immune Deficiency Syndrome (AIDS) since 1987. He received the three United States patents along with foreign counterpart patents described above, now licensed to the Company, which cover the use of certain antibodies for treating patients with HIV. Our leading drug candidate, Cytolin, is part of a class of drugs called monoclonal antibodies or targeted therapies , which target specific antigens on a cell or pathogen. Cytolin is based on a monoclonal antibody that binds to the cellular adhesion molecule LFA-1.

In 1993, six HIV-infected patients were treated with Cytolin. Blood and skin tests of these patients suggested that the antibody might be producing improvements in the immune function of each patient. 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 CytoDyn 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 U.S. Food & Drug Administration (the FDA) as an early indication of the safety and potential efficacy of Cytolin.

In 1996, the FDA approved a drug master file, designated BB-DMF#6836, for the manufacture of Cytolin at Vista Biologicals Corporation. CytoDyn of New Mexico, Inc. (a predecessor to the Company) and Vista Biologicals Corporation worked cooperatively to develop the drug master file. In accordance with the practice of the FDA, the drug master file was issued to and became the property of the entity with the capacity to manufacture the drug, in

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this case Vista Biologicals Corporation. By contract with Vista Biologicals Corporation, CytoDyn of New Mexico, Inc. had the exclusive right to reference the drug master file, that is, to authorize Vista Biologicals Corporation to manufacture Cytolin in accordance with the terms of the drug master file.

In 1996, the FDA also designated our investigational new drug application for Cytolin as BB-IND #6845, and subsequently approved a clinical trial. In 2002, Symbion Research International, a contract research organization, completed a Phase I a/b clinical trial of Cytolin (a Phase I trial includes the initial introduction of an investigational new drug or biologic into humans). The trial was sponsored by Amerimmune, Inc., the previous licensee of CytoDyn of New Mexico, Inc. but Symbion was never paid for its work. As a result, its work product became Symbion s. We entered into a buy-sell agreement with Symbion to purchase the Phase Ia study data in 2004. The Phase Ia study, conducted in 13 subjects suffering from HIV/AIDS, found Cytolin to be safe and well tolerated. The initial safety study supported the safety and tolerability of the drug in these dose groups. Some of the data were presented as an abstract and poster session, entitled Phase I Study of Anti-LFA-1 Monoclonal Antibody (Cytolin in Adults with HIV Infection) at the 9th Conference on Retroviruses and Opportunistic Infections held in Seattle, Washington on February 24-28 2002 as well as the 16th International AIDS Conference held August 2006 in Toronto, Canada. The Company then went through a period of years where legal issues delayed the progress of this treatment.

Cytolin - Current Research

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 CytoDyn, Massachusetts General Hospital (MGH) in Boston, Massachusetts agreed to conduct an ex-vivo study of 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, CytoDyn agreed to provide MGH with supplies of Cytolin needed for the Study. Under the Clinical Trial Agreement, Eric S. Rosenberg, M.D. is designated as the Principal Investigator for the Study.

Human subjects have been recruited for the Study from Dr. Rosenberg s clinic. The Study has enrolled 10 adults with early HIV infection and 10 healthy adults as the control arm, all of whom will be required to participate for six months. None of the patients enrolled in the study will receive injections of Cytolin; rather they will donate blood to allow one to examine the effects of Cytolin when it is added in the test tube to their peripheral blood mononuclear cells. In July, 2010, the enrollment closed and the Study began. The Study design and objectives are available to view at the government s website at www.clinicaltrials.gov, ID NCT01048372. The public has online access to this federal database, which describes elements of clinical trials and their status. To review public records for the Study on the government s website, enter Cytolin as the search term (case sensitive).

The Second amendment to the Clinical Trial Agreement provided that our research grant commitment for the Study would total $316,755. In March 2010, we agreed in a third amendment to the Clinical Trial Agreement to provide an additional $233,815 for the Study to enable the Principal Investigator to engage additional personnel. In December 2010, we further agreed in a fourth amendment to the Clinical Trial Agreement to provide an additional $25,000

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for the Study. On May 20, 2011, we entered into a fifth amendment of the Clinical Trial Agreement with The General Hospital Corporation, d/b/a/ MGH to extend the Study enabling MGH Principal Investigator Eric Rosenberg, M.D., to further explore his initial findings regarding the potential mechanism of action of Cytolin to treat HIV-positive adults. Under the fifth amendment we agreed to pay MGH the remaining unpaid balance of $291,590 of the total research grant of $865,375 over the six month period beginning on May 20, 2011 and ending on November 20, 2011. While there are many factors that can delay clinical trial benchmarks, we anticipate that the Study may be completed by the end of 2011, although there is not a contractual obligation to do so in that timeframe.

The Study is a science-intensive research study and is not intended to function as a registrational study (see Registrational Clinical Trials Process below). CytoDyn contemplates that the Study will be followed by a clinical trial that may or may not be conducted at MGH or with Dr. Rosenberg as the Principal Investigator. The Company s intention is to either fund additional clinical trials and/or attempt to enter into a strategic alliance with a third party concerning its Cytolin(R) brand of S6F1 monoclonal antibodies. There is no assurance that the results of the Study will warrant further clinical trials, or that a strategic alliance for Cytolin will be available.

The Clinical Trial Agreement governs intellectual property rights that may result from the Study. Specifically, under the Clinical Trial Agreement, inventions and other patentable subject matter conceived or reduced to practice in the performance of the Study by Dr. Rosenberg, as Principal Investigator, or others acting at his direction (collectively, MGH Investigators) belong to MGH; patentable subject matter that is jointly invented by MGH Investigators and Company personnel is jointly owned. The Clinical Trial Agreement provides that, upon conception and reduction to practice, MGH Investigators will report and assign their inventions to MGH. MGH is then obligated to advise the Company of the reported invention and to discuss with the Company whether and where patent applications should be filed to protect the invention. Under the Clinical Trial Agreement, MGH controls the prosecution of patent applications. The Company is obligated to bear all costs (including attorney s fees) associated with patent filings, including patent maintenance costs. If the Company does not provide such funding, MGH obtains the right to file and prosecute the invention at its own expense, and the right to license associated rights to other parties without obligation to the Company.

If the Company pays patent application filing costs, the Company obtains a three month period, commencing on the application filing date, to exercise an option to negotiate an exclusive license to all of MGH s rights in the invention. If the Company exercises this option, the parties are provided a further three month period to negotiate a license agreement (the Negotiation Period). Under the Clinical Trial Agreement, the license agreement must contain terms that are standard for agreements between universities and industry, including reasonable royalties, time-limited due diligence provisions, and indemnification and insurance requirements. If, upon expiration of the Negotiation Period, the parties have failed to agree upon license terms as specified, then MGH obtains the right to license to others all of MGH s rights in the invention, to the exclusion of the Company. In all instances, MGH reserves the right to use any invention for research, clinical and educational purposes.

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The Clinical Trial Agreement also governs the parties rights in Study data and the results of the Study (Study Data and Results). MGH retains ownership of all Study Data and Results, and is obligated to provide the Company with a copy of such Study Data and Results. The Clinical Trial Agreement places limits on the Company s ability to use Study Data and Results. Specifically, the Company is permitted to use Study Data and Results that disclose individually identifiable health information only for purposes of the Study or related studies that concern Cytolin or medical conditions / disease area that are the subject of the Study, however, the Company is permitted to use information that is not identifiable for any research and development purposes. These uses are further limited by the requirements that any such use comply with applicable law (including the Health Insurance Portability and Accountability Act of 1996 (HIPAA)); and that the use is permitted by the informed consent form used with subjects in connection with the Study.

Why Cytolin May Be a Unique Treatment for Early HIV Infection

During the past decade, significant improvements in the antiviral cocktails used to treat HIV/AIDS have transformed this once fatal disease into a chronic, manageable condition. These drugs are the ingredients of Highly Active Antiretroviral Therapy (HAART), which has saved countless lives and is well tolerated by most patients, although all drugs have side effects.

The current standard of treatment allows for withholding antiviral drugs until the disease has progressed to the point where the drugs are required to maintain a patient s health, typically a period of about five years from initial infection. A chief reason for withholding treatment during the early years of HIV infection is that antiviral drugs attack the virus directly. As a result, natural selection promotes the evolution of HIV into species that are resistant to those drugs. If antiviral drugs were prescribed too early, then the virus might become resistant to those drugs, rendering them ineffective, by the time they were necessary to maintain a patient s health. Additionally, other treatment regimens call for intermittent drug use to minimize toxicities from the anti-retroviral drugs. These treatment interruptions also can contribute to the generation of resistant viruses.

Because Cytolin is a monoclonal antibody, Cytolin can be administered either by intravenous infusion or subcutaneous injection. Cytolin binds to a normal cellular antigen called CD11a. This antigen is highly expressed on killer cells called cytotoxic T cells or CTLs. As first shown by Zarling, et al in 1990 (Journal of Immunology, vol. 144, page 2992), the ability of these killer T cells to indiscriminately destroy CD4 T cells was a trait thought to be unique to humans. It has been known since the beginning of the AIDS pandemic that a wholesale loss of CD4 T cells is the reason why individuals infected with HIV become susceptible to the opportunistic infections and cancers that characterize AIDS. Up until the 1990s when three independent studies proposed that the killer T cells might be contributing to the wholesale loss of CD4 T cells, the actual decline remained a mystery because the virus infects relatively few CD4 T cells. Cytolin was originally thought to act to prevent the wholesale destruction of helpful CD4 T cells by blocking the unwanted activity of an HIV-infected person s own killer T cells. In compassionate use involving hundreds of patients treated for about two years, who were also simultaneously given access to antiretroviral drugs, Cytolin appeared to be well tolerated. Subsequent uncontrolled clinical trials showed that treatment also was associated with favorable results in selected markers of disease progression. Subsequent studies and analysis of the activity of Cytolin has shown that this antibody does not block Cytotoxic T cells. However, in addition to

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being expressed on CTLs, the CD11a protein has also been reported to be present on the surface of the HIV virion, presumably to assist in the infectious cycle of the virus. This opens the possibility that Cytolin may bind and neutralize HIV, providing a direct action against the virus in the bloodstream. The exact mechanism of action through which this antibody may exhibit antiviral activity is still under investigation.

With respect to the decline of CD4 cells after HIV infection, researchers have provided an alternate theory for the decline in CD4 T cells through a process of cellular suicide or cellular self-destruction called apoptosis. This process is initiated when the virus enters the target cells but does not complete its infectious cycle. In addition to CTLs, Cytolin also recognizes and binds to dendritic cells (DCs). These two types of immune cells are critical to the control of viral burden in HIV infected individuals. By binding to these cells, Cytolin appears to induce an antiviral activity that can impede infection of new cells and presumably lead to a reduction in viral burden. Since Cytolin targets a cellular protein, it potentially should not induce the expansion of resistant virus because its target protein is not under the genetic control of the virus. This is in contrast to the antiviral drugs that target viral proteins and thus allow for the generation of drug-resistant viruses. Research is currently underway to understand exactly how this antibody can disrupt HIV infection.

Monoclonal Antibodies

Cytolin is part of a class of drugs called monoclonal antibodies or targeted therapies . Monoclonal antibodies target specific antigens on a cell or pathogen. Advances in antibody production technologies, such as high productivity cell culture has enabled manufacturers to produce antibody products more cost-effectively than 20 years ago. Many monoclonal antibodies have been approved for marketing as therapeutics by the FDA, and a large number of monoclonal antibodies are currently under investigation in clinical trials. Other companies have monoclonal antibodies in clinical research to prevent or treat HIV/AIDS that are targeted towards the virus. Our monoclonal antibody is intended to treat HIV disease by targeting a cellular protein. The fact that this protein is highly expressed in killer T cells and DCs may allow Cytolin to act through some as yet to be discovered mechanism and indirectly or directly result in the suppression of viral replication, ultimately resulting in the sparing of CD4 T cells in humans infected with HIV.

Acquisition of Advanced Genetic Technologies, Inc.

On January 30, 2007, we acquired, from Utek Corp., our subsidiary Advanced Genetic Technologies, Inc., which holds the exclusive right to develop alternative antibodies that bind to the same cellular target as Cytolin. These two monoclonal antibodies were invented at Harvard University Medical School s CBR Institute for Biomedical Research. The Company has not used these two antibodies in our research and development efforts to date but we intend to use these in future research and development efforts.

Formation of CytoDyn Veterinary Medicine LLC

On May 16, 2011, we formed a wholly owned subsidiary, CVM, which will explore the possible application of our existing proprietary monoclonal antibody technology to the treatment of FIV. We view the formation of CVM and the exploration of the application of our existing proprietary monoclonal antibody technology to FIV as an effort to strategically diversify the use of our proprietary monoclonal antibody technology.

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Manufacturing and Source for Raw Materials

We negotiated with a contract manufacturer, Vista Biologicals Corporation (Vista), to manufacture Cytolin suitable for use in our current ex vivo clinical trial of Cytolin at a cost of $565,000, all of which was paid by September 2008. In February 2010, we entered into a statement of work for the development of a humanized form of Cytolin® at a cost of $229,500. Vista entered into an assignment agreement with us to transfer all rights and title to certain inventions and applications to us in consideration for our forgiveness of certain disputed amounts under the contractual arrangements between the parties. There are ongoing negotiations related to the ultimate obligations of the Company and Vista under both the 2008 and 2010 contractual arrangements. Although a murine (mouse) version of Cytolin was used for previous human experience that included approximately 200 patients treated for up to two years, as well as an encouraging uncontrolled Phase I(b)/II(a) study, and our current ex-vivo clinical trial, the Company understands that a fully-humanized version is necessary for the controlled clinical trials that are expected to follow the previous ones. The Company expects to begin discussions with a contract lab to manufacture the proprietary version of the humanized antibody.

Patents and Trademarks

We have a License Agreement with Allen D. Allen, our former Chief Executive Officer and former Chairman of our Board of Directors that gives us the exclusive right to develop, market, and profit from his technology worldwide. This includes issued U.S. Patent Nos. 5,424,066; 5,651,970 and 6,534,057, as well as European Patent Nos. 0690725 and 1438970. In addition, Hong Kong Patent No. 1067958, Australian Patent No. 684074 and Canadian Patent No. 2156495 have been obtained as well. We also acquired the federally registered trademarks, CYTODYN (U.S. Registration No. 2095498) and CYTOLIN (U.S. Registration No. 2095497), and a related trademark symbol. The license acquired gives the Company the worldwide, exclusive right to develop, market and sell compounds disclosed by the patent claims, practice methods taught by the patent claims, and exploit specified technology related to the patents. The term of the license agreement is for the life of the patents of which the first will expire in 2013. The original expiration dates on the issued U.S. Patent Nos. 5,424,066; 5,651,970 and 6,534,057 are 2013, 2014 and 2013, respectively. We estimate the costs associated with these issued patents to be approximately $100,000 per year. On June 17, 2011 we filed for a provisional patent in the United States for the treatment of FIV, a retroviral infection in cats. We anticipate that we will apply to trademark this product under the name CytoFeline. On September 23, 2011, we filed a provisional patent application in the United States for our humanized version of its lead product Cytolin®, a monoclonal antibody for the treatment of HIV Infection.

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

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state health care laws and regulations that apply to the operation of clinical laboratories, the business relationships between health care providers and suppliers, the privacy and security of health information and the conduct of clinical research.

Regulation of Products

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

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

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

Regulation of Laboratory Operations

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

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.

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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, much of this initial work may be sponsored and conducted by MGH, or a different clinical trial research facility, as determined by us at some point in the future and different studies may also be explored. 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. The Company is exploring all options available to determine the most cost effective implementation of the clinical trial process.

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.

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.

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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.

CytoDyn may fund clinical trials using venture capital or through the sale of our common stock or other equity securities, or, at that time, may enter into a strategic alliance for completion of research and the subsequent marketing of Cytolin if approved. In the former case, and while the cost will be to some extent determined by the trial size, we currently estimate that we will need to provide additional humanized product, which we estimate will cost approximately $500,000. The Company intends to conduct one or more private placement offerings of common shares to secure the needed capital. We cannot estimate the cost of any potential follow up study or whether any of the planned private placement offerings will be successful.

While there are many factors that can delay clinical trial benchmarks, we anticipate that the Study may be completed by the end of 2011, although there is not a contractual obligation to do so in that timeframe.

Benchmark	**Some Factors That Can Cause Delays+**
Patient Outreach	Manufacturing Delays
	Documentation Delays
	IRB Delays
	Delays in Regulatory Review or Approval
	Force Majeure
Dose First Patient	Fill and Finish Delays
	Slower Than Expected Patient Enrollment
	Force Majeure
Lock Database - Begin Statistical Analysis	Slower Than Expected Patient Enrollment
	Clinical Hold
	Laboratory Error
	Protocol Deviation
	Force Majeure
Release Final Report	Additional Stratification Required
	Computer Hardware or Software Malfunction
	Force Majeure

+ There are other factors, known and unknown, such as unexpected financial hardships, that can cause delays.

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Competition

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

Our potential competitors include entities that develop and produce therapeutic agents for treatment of human and animal disease. 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. Almost all of these potential competitors have substantially greater capital resources, research and development capabilities, manufacturing and marketing resources and experience than we have. 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 and AIDS. 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 personnel 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 $480,765, $328,775, and $2,229,468 in fiscal 2011, 2010 and for the period October 28, 2003 through May 31, 2011, respectively. We expect that research and development expenses will increase as we seek to expand development of our current and future product pipeline.

Employees

We have four full time employees, one part time employee, and a varying number of consultants engaged in management and product development. We are severely understaffed and will expand our employee force if we complete further financings. There can be no assurance we will be able to locate or secure suitable employees upon acceptable terms in the future.

Item 1A. Risk Factors.
This item is not required for smaller reporting companies.

Item 2. Properties.
Our principal offices were located at 1511 Third Street, Santa Fe, New Mexico 87505 for the fiscal year 2010. We leased approximately 1,200 square feet under a lease from September 1, 2010 until August 31, 2011 at $1,650 per month.

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On June 7, 2011, the Board of Directors of the Company approved the relocation of the Company s principal office to Lutz, Florida. Effective as of June 15, 2011, the principal office of the Company is now located at 110 Crenshaw Lake Road, Lutz, Florida 33548. We use approximately 1,600 square feet on a month-to-month basis which has been accruing at a cost of $1,650 per month since September 1, 2011. The building related to this lease is owned by Kenneth Van Ness, our President, Chief Executive Officer (CEO) and Chairman of the Board of Directors.

Item 3. Legal Proceedings.
None.

Item 4. [Removed and Reserved.]

PART II

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

Our common stock trades on the OTC Pink Sheets under the ticker symbol CYDY.

The table below provides the high and low sales prices of our common stock for the periods indicated, as reported by the Pink Sheets quotations system:

Price Range of Outstanding Common Stock

	$1.40	$1.40
Year Ended May 31, 2011	**High**	**Low**
First Quarter Ended August 31, 2010	$ 1.54	$ 0.75
Second Quarter Ended November 30, 2010	$ 1.40	$ 0.95
Third Quarter Ended February 28, 2011	$ 2.29	$ 1.15
Fourth Quarter Ended May 31, 2011	$ 4.40	$ 1.70
Year Ended May 31, 2010	**High**	**Low**
First Quarter Ended August 31, 2009	$ 0.74	$ 0.11
Second Quarter Ended November 30, 2009	$ 2.00	$ 0.50
Third Quarter Ended February 28, 2010	$ 2.07	$ 1.40
Fourth Quarter Ended May 31, 2010	$ 2.08	$ 0.60

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Holders

The approximate number of record holders of our common stock on May 31, 2011 was approximately 1,036. This number includes shareholders that hold the shares in street name with Broker/Dealers. There have been no shares issued by the Company after May 31, 2011.

Dividends

Holders of our common stock are entitled to receive dividends as may be declared from time to time by our Board of Directors. 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.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding outstanding options and rights and shares reserved for future issuance under our existing equity compensation plans as of May 31, 2011.

	3,976,500	3,976,500	3,976,500

Equity Compensation Plan Information

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	3,976,500	$ 1.40	3,625,500
Equity compensation plans not approved by security holders (1)	3,497,076	$ 1.27	0
Total	7,473,576	$ 1.34	3,625,500

(1) Represents warrants issued by the Company (i) in connection with previous issuances of debt and previous private placements of the Company s securities, and (ii) as consideration for certain consulting services provided to the Company, and also includes the issuance of options prior to the adoption of the 2004 Incentive Plan.

Recent Sales of Unregistered Securities

There were no sales of any of our equity securities during the three months ended May 31, 2011.

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Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of any of our equity securities during the three months ended May 31, 2011.

Item 6. Selected Financial Data.
This item is not required for smaller reporting companies.

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations
The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the other sections of this Annual Report, including our financial statements and related notes appearing elsewhere herein. This discussion and analysis contains forward-looking statements including information about possible or assumed results of our financial conditions, operations, plans, objectives and performance that involve risk, 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, 2011 compared to May 31, 2010 are as follows:

For the years ended May 31, 2011 and 2010, we had no activities that produced revenues from operations.

For the year ended May 31, 2011, we had a net loss of approximately $(3,720,000) compared to a net loss of approximately $(3,359,000) for the corresponding period in 2010. For the year ended May 31, 2011 and 2010, we incurred operating expenses consisting primarily of stock-based compensation, accounting and consulting, research and development, salary, legal expenses, and various other expenses.

The operating expenses for the years ended May 31, 2011 and 2010 are as follows:

	2011	2010
Accounting and consulting	$ 274,000	$ 218,000
Stock-based compensation	1,186,000	1,740,000
Legal and accounting	689,000	42,000
Salaries	700,000	602,000
Research and development	481,000	329,000
Depreciation and amortization	3,000	2,000
Other	365,000	363,000
Total	**$ 3,698,000**	**$ 3,296,000**

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Legal expenses increased approximately $647,000 related to fees incurred to understand the scope of the Company s potential liability for common stock issued potentially in violation of federal and state securities laws, to determine the Company s liability under certain employment contracts entered into by the Company, to amend and restate certain of the Company s past financial statements, to amend and restate certain of the Company s prior filings with the Securities and Exchange Commission (SEC) and to prepare and file numerous current required securities filings with the SEC to bring the Company up to date with its SEC filing obligations. Stock-based compensation decreased approximately $554,000 from $1,740,000 in 2010 to $1,186,000 in 2011 due to the Company s significant stock option grants during 2010 that included a significant number of option grants with immediate vesting at the date of grant. The stock option grants with immediate vesting during 2010 increased stock-based compensation approximately $1.3 million in 2010. Additionally, during 2011 the Company granted common stock as well as common stock options that resulted in significant stock-based compensation during 2011. The Company expects to grant significant stock option grants in the future, and accordingly, the Company expects stock-based compensation to increase in the future. Salary expenses increased approximately $98,000 from $602,000 in 2010 to $700,000 in 2011 with the hiring of the Company s CEO, chief financial officer (CFO), and controller in 2011. The increase was offset by the termination of the predecessor CEO and CFO during 2011. Accounting and consulting expenses increased with the Company s restatements and additional SEC filings. The Company expects accounting and consulting expenses to stabilize when the Company becomes current on their SEC filings. The research and development expenses increased approximately $152,000 from fiscal year 2011 to 2010 in connection with our extension of our agreement with MGH for continuing research activities with respect to Cytolin. We expect research and development expenses to increase as our clinical trials progress.

Interest expense in 2011 related to convertible debt decreased to zero ($0) relative to 2010, which was $38,604, due to having previously fully amortized our beneficial conversion feature associated with the conversion option related to this debt. There was no beneficial conversion features associated with convertible debt during 2011. Interest expense related to interest on notes payable decreased approximately $3,400 from fiscal year 2011 to 2010, as we paid down certain notes during 2011.

Rescission Liability

The Company has recorded rescission liabilities for May 31, 2011 and May 31, 2010 of $4,851,000 and $3,997,000, 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 based upon a literal interpretation of the applicable statute. 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

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defenses are ruled upon by judge 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 Footnote 3 of our Financial Statements on page 47 for further information regarding these rescission liabilities.

Accrued Incentive Stock Compensation

On August 4, 2008, the Company entered into a seven year Personal Services Agreement with Nader Pourhassan (the Contract). The Contract provides 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 are to receive 50,000 common shares each of Company stock for every $500,000 in capital received by the Company through Dr. Pourhassan s efforts. As of May 31, 2010, the Company accrued $1,180,000 related to the Contract. Subsequent to the fiscal year ended May 31, 2011, Dr. Pourhassan and the Company entered into a Mutual Release and Personal Services Termination Agreement (the MRPSTA) which relieves 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 will serve as Managing Director of Business Development at an annual salary of $200,000. See Footnote 3 of our Financial Statements on page 47 for further information.

The Company had been accruing stock compensation and deferred offering costs related to the Contract as described at Note 3. Upon the signing of the MRPSTA, the Company at May 31, 2011 reversed all accrued stock compensation and deferring offering costs, as the Company currently has no further obligations under the Contract.

Liquidity and Capital Resources.

On May 31, 2011, we had negative working capital of $(5,022,000) as compared to a negative working capital of approximately $(3,007,000) on May 31, 2010.

Cash Flows

Net cash used in operating activities was approximately $1,821,000 during fiscal year 2011, which reflects an increase of approximately $52,000 from net cash used in operating activities of approximately $1,769,000 in 2010. The increase in the net cash used in operating activities for the above periods was primarily attributable to the following:

Net loss increased approximately $360,000.

The above increases were partially offset by the following:

Stock-based compensation decreased approximately $554,000 from 2010 to 2011; and

Accounts payable, accrued interest payable, and accrued liabilities increased approximately $900,000.

There were no other significant changes in cash used in operating activities from 2010 to 2011.

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There were no material changes in cash flows from investing activities from 2010 to 2011.

Cash flows provided by financing activities of approximately $1,128,000 during fiscal year 2011 decreased approximately $1,080,000 from approximately $2,208,000 during 2010. The decrease in cash provided by financing activities for the above periods was attributable primarily to the decrease in proceeds from the preferred stock and treasury stock, offset partially by the increase in proceeds from the sale of common stock.

There were no other significant changes in cash provided by financing activities from 2010 to 2011.

As shown in the accompanying Financial Statements, for the year ended May 31, 2011 and 2010, and since October 28, 2003 through May 31, 2011 we incurred net losses of approximately $(3,720,000) and $(3,360,000) and $(15,358,000), respectively. As of May 31, 2011, 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, 2011 we raised cash of approximately $6,083,000 (net of offering costs) through private placements of common and preferred stock financings and $1,537,000 through the issuance related party notes payable and convertible notes. Additionally, the Company has raised approximately $612,000 from the issuance of common stock and preferred stock in conjunction with certain acquisitions in prior years. In April 2010, our shareholders voted to amend our Articles of Incorporation to increase the number of authorized shares of common stock to 100,000,000 shares; accordingly, we intend to continue to finance our operations through the sale of our shares.

Since October 28, 2003 through May 31, 2011, we have incurred approximately $2,230,000 of research and development costs and approximately $14,839,000 in operating expenses. We have incurred significant net losses and negative cash flows from operations since our inception. As of May 31, 2011, we had an accumulated deficit of approximately $(16,960,000) and negative working capital of approximately $(5,022,000).

We anticipate that cash used in product development and operations, especially in the marketing, production and sale of our products will increase significantly in the future. We currently do not have any significant material commitments related to capital expenditures. As described above, we do have material commitments related to our current Study (as defined above) of our product with MGH, and have potential obligations under our contracts with Vista.

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Going Concern

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

The 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 financial statements, the Company is currently in the development stage with losses for all periods presented. As of May 31, 2011 these factors, among others, raise substantial doubt about the Company s ability to continue as a going concern.

The 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 medical treatments, obtain FDA approval, outsource manufacturing of the treatments, 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 revenues and 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 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 estimated an amount that is a probable indicator of our rescission liability and will record rescission liabilities for May 31, 2011 and May 31, 2010 of $4,851,000 and $3,997,000,

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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 based upon a literal interpretation of the applicable statute. 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 by judge 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 Footnote 3 of our Financial Statements on page 47 for further information.

The Company entered into the Contract, with Nader Pourhassan pursuant to which compensation was paid or accrued in view of a subsequent determination that these payments violated applicable securities laws. Such violations gave rise to the Company s rescission obligation reflected in the Financial Statements. It was unclear whether the Company had any defenses to payment, whether the Company had any rights to recover payments made to Mr. 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 does have such rights, Mr. Pourhassan (and perhaps others) would have certain equitable remedies that would entitle Mr. 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 Mr. 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 to receive 50,000 common shares each of Company stock for every $500,000 in capital received by the Company through Dr. Pourhassan s efforts. As of May 31, 2010, the Company accrued $1,180,000 related to this agreement.

Subsequent to the fiscal year ended May 31, 2011, Dr. Pourhassan and the Company entered into the MRPSTA which relieves 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 will serve as Managing Director of Business Development at an annual salary of $200,000. See Footnote 3 of our Financial Statements on page 47 for further information.

The Company had been accruing stock compensation and deferred offering costs related to the Contract as described at Note 3. Upon the signing of the MRPSTA, the Company at May 31, 2011 reversed all accrued stock compensation and deferring offering costs, as the Company currently has no further obligations under the Contract.

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

This item is not required for smaller reporting companies.

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Item 8. Financial Statements and Supplementary Data.

CYTODYN INC.

(A DEVELOPMENT STAGE COMPANY)

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

CytoDyn Inc. (A Development Stage Company)

Lutz, Florida

We have audited the accompanying consolidated balance sheets of CytoDyn Inc. (a development stage company) as of May 31, 2011 and 2010 and the related consolidated statements of operations, changes in stockholders equity (deficit), and cash flows for the years then ended and the period from October 28, 2003 through May 31, 2011. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the 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 audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CytoDyn Inc. as of May 31, 2011 and 2010 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, 2011 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 $(3,719,688) for the year ended May 31, 2011, has a working capital deficit of 5,021,917, and has an accumulated deficit of $(16,960,294) from the date of inception through May 31, 2011, 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

November 3, 2011

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CytoDyn Inc.

(A Development Stage Company)

Condensed Consolidated Balance Sheets

	May 31, 2011	2010
Assets		
Current Assets:		
Cash	$ 2,818	$ 700,497
Restricted cash	1,035,000	
Prepaid expenses	59,275	12,127
Deferred Offering Costs	876,423	1,823,879
Prepaid license fees		7,500
Total current assets	1,973,516	2,544,003
Furniture and equipment, net	5,374	3,549
Other Assets	15,748	23,975
	$ 1,994,638	$ 2,571,527
Liabilities and Shareholders (deficit)		
Current liabilities:		
Accounts payable	$ 932,996	$ 178,956
Accrued liabilities	756	15,209
Accrued stock incentive compensation		1,180,000
Indebtedness to related parties - short-term portion	148,985	153,985
Accrued interest payable	26,696	25,575
Deposits on stock purchases	1,035,000	
Stock rescission liability	4,851,000	3,997,000
Total current liabilities	6,995,433	5,550,725
Long-Term Liabilities		
Accrued salaries - related party		229,500
Convertible notes payable, net	6,937	6,937
Total Liabilities	7,002,370	5,787,162
Shareholders (deficit):		
Series B Convertible stock preferred stock, no par value; 400,000 shares authorized, 311,800 and 400,000 shares issued and outstanding at May 31, 2011 and 2010, respectively	1,566,016	2,009,000
Common stock, no par value; 100,000,000 shares authorized, 22,290,982 and 19,875,895 outstanding at May 31, 2011 and 2010, respectively; 22,490,982 and 20,075,895 issued at May 31, 2011 and May 31, 2010, respectively	9,147,325	7,145,304
Additional paid-in capital	5,877,141	4,703,875
Common and Preferred stock subject to rescission	(4,851,000)	(3,997,000)
Treasury stock, at cost, 200,000 shares held at May 31, 2011 and 2010, respectively	(100,000)	(100,000)
Additional paid-in capital - treasury stock	313,080	313,080
Prepaid stock for services		(49,288)
Accumulated deficit on unrelated dormant operations	(1,601,912)	(1,601,912)
Deficit accumulated during development stage	(15,358,382)	(11,638,694)

Total shareholders (deficit)	(5,007,732)	(3,215,635)
	$ 1,994,638	$ 2,571,527

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

(A Development Stage Company)

Condensed Consolidated Statements of Operations

	Year ended May 31,		October 28, 2003 through May 31, 2011
	2011	2010	
Operating expenses:			
General and administrative	$ 2,525,661	$ 2,923,736	$ 11,007,415
Amortization / depreciation	2,880	2,077	180,849
Research and development	480,765	328,775	2,229,468
Legal fees	688,933	41,795	1,421,502
Total operating expenses	3,698,239	3,296,383	14,839,234
Operating loss	(3,698,239)	(3,296,383)	(14,839,234)
Interest income			1,627
Extinguishment of debt			337,342
Interest expense:			
Interest on convertible debt		(38,604)	(734,863)
Interest on notes payable	(21,449)	(24,878)	(123,254)
Loss before income taxes	(3,719,688)	(3,359,865)	(15,358,382)
Income tax provision			
Net loss	$ (3,719,688)	$ (3,359,865)	$ (15,358,382)
Constructive preferred stock dividends	$	(6,000,000)	(6,000,000)
Convertible preferred stock dividends	$ (8,550)	$	$ (8,550)
Net loss applicable to common shareholders	$ (3,728,238)	$ (9,359,865)	$ (21,366,932)
Basic and diluted loss per share	$ (0.18)	$ (0.49)	$ (1.67)
Basic and diluted weighted average common shares outstanding	21,076,430	18,999,234	12,829,828

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders Equity (Deficit)

Period October 28, 2003 through May 31, 2011

	Preferred Stock		Common Stock		Additional	Subject to
	Shares	Amount	Shares	Amount	Paid-In Capital	Recession
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 at 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 at year ended May 31, 2005						
Balance at May 31, 2005			8,069,307	1,916,334	40,942	

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CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders Equity (Deficit)

Period October 28, 2003 through May 31, 2011

	Treasury Stock APIC	Stock for Prepaid Services	Accumulated 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 at 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 at 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.

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CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders Equity (Deficit)

Period October 28, 2003 through May 31, 2011

	Preferred Stock		Common Stock		Additional
	Shares	Amount	Shares	Amount	Paid-In Capital
June through July 2005, sale of common stock less offering costs of $27,867($.75/share)			289,890	189,550	
August 2005, common shares issued to extinguish promissory notes payable and related interest ($.75/share)			160,110	120,082	
May 2006, common shares issued to extinguish convertible debt			350,000	437,500	
November 2005, 94,500 warrants exercised ($.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

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CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders Equity (Deficit)

Period October 28, 2003 through May 31, 2011

	Treasury Stock APIC	Stock for Prepaid Services	Accumulated 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.

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CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders Equity (Deficit)

Period October 28, 2003 through May 31, 2011

	Preferred Stock		Common Stock		Additional Paid-In Capital	Subject to Rescission
	Shares	Amount	Shares	Amount		
March 2006, stock options issued to extinguish debt					86,341	
Net loss at 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 AGTI	100,000	167,500				
Net loss, May 31, 2007						
Balance at May 31, 2007	100,000	167,500	11,297,264	4,172,865	2,072,993	

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CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders Equity (Deficit)

Period October 28, 2003 through May 31, 2011

	Treasury Stock APIC	Stock for Prepaid Services	Accumulated Deficit	Accumulated During Development Stage	Total
March 2006, stock options issued to extinguish debt					86,341
Net loss at 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					