CYTODYN INC
Form 10-K/A
August 05, 2011
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549**

# FORM 10-K/A

**(Amendment No. 1)**

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended May 31, 2010**

**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 incorporation or organization)** | **(I.R.S. Employer 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 (i) 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. x

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: $15,201,858 (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 November 30, 2010, the registrant had 20,942,296 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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CYTODYN INC

FORM 10-K/A FOR THE YEAR ENDED MAY 31, 2010

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THROUGHOUT THIS FILING, WE MAKE FORWARD-LOOKING STATEMENTS. THE WORDS ANTICIPATE, BELIEVE, EXPECT, INTEND, PREDICT, PLAN, INTEND, SEEK, ESTIMATE, PROJECT, WILL, CONTINUE, COULD, MAY, AND SIM 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. is a Colorado corporation, with its principal business office at 1511 Third Street, Santa Fe, New Mexico, 87505; telephone: (505) 988-5520, facsimile: (800) 417-7252, 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 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 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.

Our Cytolin-related patents are for a murine (mouse) version of the drug. However, as discussed below in Manufacturing and Source for Raw Materials , the Company has contracted to develop a humanized version, which we believe is necessary for any future clinical trials. All of our research on Cytolin to date has utilized the current murine (mouse) version of the drug.

Research History of Cytolin(R) Compound

Allen D. Allen, the 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.

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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 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 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 (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.

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Human subjects were recruited for the Study from Dr. Rosenberg s clinic. The Study enrolled 10 adults with early HIV infection and 10 healthy adults as the control arm, all of whom were required to participate for six months. None of the patients enrolled in the study received injections of Cytolin; rather they donated blood for examination of the effects of Cytolin on their peripheral blood mononuclear cells ( PBMCs ). In July, 2010, the enrollment is scheduled to close and the study is scheduled to begin. The Company expects the study to be completed by January 2011. 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 Clinical Trial Agreement originally provided that the Company s research grant commitment for the Study would total $316,755. In May 2010, the Company agreed to provide an additional $204,000 for the Study. The added funding is designed to enable the Principal Investigator to engage additional personnel for purposes of making Study data available by December 31, 2010. The Company accordingly expects that funding requirements for the Study will total approximately $550,000. The sum of $412,000 is due to be paid by November 30, 2010, with the remaining balance of $137,500 due in January 2011.

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.

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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.

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 is 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.

Cytolin is a monoclonal antibody administered by intravenous infusion and might expand the standard of treatment for HIV infection. In compassionate use involving hundreds of

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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.

Cytolin binds to a cellular protein 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.

Since that time, 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. This unique mechanism of action opens the possibility that Cytolin could be administered early in the infection in order to delay the natural progression of the disease and, therefore, the time when antiviral drugs become necessary. If so, healthcare providers could treat individuals infected with HIV more quickly, rather than spending years just watching and waiting.

*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.

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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.

In exchange for $100,000 and seven years of prepaid license fees, the Company issued 100,000 shares of our preferred stock to Utek Corp., in exchange for 1,000 shares or 100% of Advanced Genetic Technologies, Inc., common stock. On July 2009, the preferred shares were converted into 2,356,142 shares of our common stock.

Manufacturing and Source for Raw Materials

We negotiated with a contract manufacturer, Vista Biologicals Corporation, 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. We have also negotiated a contract with Vista Biologicals Corporation to manufacture a humanized version of Cytolin at a cost of $229,500, which the Company expects to be paid over the twelve (12) months beginning in March 2010. 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 have its proprietary, fully-humanized version of Cytolin ready for bulk manufacturing in the second quarter of 2011.

Patents and Trademarks

We have a License Agreement with Allen D. Allen, the 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

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$100,000 per year. The Company intends to file a new patent application covering its humanized version(s) of Cytolin during the next fiscal year if our research and development efforts warrant it.

Government Regulation

*Regulation of Health Care Industry*

The health care industry is highly regulated, and state and federal health care laws and regulations are applicable to certain aspects of our business. For example, there are federal and state health care laws and regulations that apply to the operation of clinical laboratories, the business relationships between health care providers and suppliers, the privacy and security of health information and the conduct of clinical research.

*Regulation of Products*

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

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

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*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, much of this initial work may be sponsored and conducted by the MGH at some point in the future. Once 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. While there can be no guarantee that this will occur in our case, if it does, then our larger partner would usually be responsible for dealing with the FDA.

*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.

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*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 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 attempt to enter into a strategic alliance with a pharmaceutical marketing company after completion of the current research or after completion of any subsequent clinical trials. There is no guarantee that a strategic alliance would be achieved after any of those trials.

Subsequently, CytoDyn may fund clinical trials using venture capital 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, CytoDyn Inc., will need to provide a new batch of humanized product, which we estimate will cost approximately $500,000. The Company is conducting a private placement of common shares to secure the capital needed for the follow-up study. We cannot yet estimate the cost of a follow up study at this time or whether or not the private placement will be successful.

There are many factors that can delay clinical trial benchmarks. However, the Company hopes to receive the results and analysis of the upcoming clinical trial during 2011.

| **Benchmark** | **Some Factors That Can Cause Delays +** |
|---|---|
| | Manufacturing Delays |
| | Documentation Delays |
| Patient Outreach | IRB Delays |
| | Delays in Regulatory Review or Approval |
| | Force Majeure |

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| | |
|---|---|
| | Fill and Finish Delays |
| Dose First Patient | Slower Than Expected Patient Enrollment |
| | Force Majeure |
| Lock Database - Begin Statistical Analysis | Slower Than Expected Patient Enrollment<br>Clinical Hold<br>Laboratory Error<br>Protocol Deviation<br>Force Majeure |
| | Additional Stratification Required |
| Release Final Report | Computer Hardware or Software Malfunction |
| | Force Majeure |

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

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 $328,775, $468,700, and $1,748,703 in fiscal 2010, fiscal 2009 and for the period October 28, 2003 through May 31, 2010, respectively. We expect that research and development expenses will increase as we seek to expand development of our current and future product pipeline.

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Employees

We have four full time employees 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 are located at 1511 Third Street, Santa Fe, New Mexico 87505. We leased approximately 1,200 square feet for two years under a lease from September 1, 2008 until August 31, 2010 at $1,750 per month.

**Item 3. Legal Proceedings.**
Pursuant to that certain amendment, dated April 27, 2009, to the second amended cross-complaint, the Company was added as a defendant to the lawsuit, styled Barry v. CytoDyn of New Mexico, Inc. (Case No. BC 362909), filed in the Superior Court of the State of California, Los Angeles County. The cross-complaint alleges that we breached an agreement for legal services and that we are indebted to its attorney in connection with such legal services. The cross-complaint seeks monetary damages in the amount of $16,318 or $21,318. We believe these claims are without merit and are responding appropriately to these claims and will continue to vigorously protect our interests.

As previously disclosed, the Company entered into a settlement agreement in December, 2008 with Rex H. Lewis, Maya LLC, and others, related to certain litigation with whereby the Company was both a defendant and a plaintiff. As part of the settlement agreement, the Company agreed to pay $50,000 in January 2009 and $25,000 on or before January 14, 2010 to the plaintiff. The Company paid the $50,000 in January 2009. The remaining $25,000 was unsecured and to accrue interest at 10.0 percent per annum. The Company paid $27,500 in January 2010. As of May 31, 2010, all amounts related to this litigation have been paid and settled.

**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.

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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**

| **Year Ended May 31, 2010** | **High** | **Low** |
|---|---|---|
| First Quarter Ended August 31, 2009 | $ 0.70 | $ 0.21 |
| Second Quarter Ended November 30, 2009 | $ 1.97 | $ 0.50 |
| Third Quarter Ended February 28, 2010 | $ 2.06 | $ 1.55 |
| Fourth Quarter Ended May 31, 2010 | $ 2.08 | $ 1.30 |
| **Year Ended May 31, 2009** | | |
| First Quarter Ended August 31, 2008 | $ 1.00 | $ 0.30 |
| Second Quarter Ended November 30, 2008 | $ 0.66 | $ 0.35 |
| Third Quarter Ended February 28, 2009 | $ 0.49 | $ 0.29 |
| Fourth Quarter Ended May 31, 2009 | $ 0.80 | $ 0.25 |

Holders

The approximate number of record holders of our common stock on November 30, 2010 was 750. This includes shareholders that hold the shares in street name with Broker/Dealers.

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 and for expansion of the business.

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, 2010.

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**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 | 4,201,122 | $ 1.58 | 3,398,878(1) |
| Equity compensation plans not approved by security holders (2) | 3,459,054 | $ 1.23 | 0 |
| **Total** | 7,660,176 | $ 1.42 | 3,398,878 |

(1) As of May 31, 2010 we had 19,875,895 shares of common stock issued and outstanding; 3,398,878 shares currently reserved and available for future option grants under our 2004 Stock Incentive Plan.

(2) 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

During the three months ended May 31, 2010, the Company issued 632,000 shares of common stock at $.50 per share, and realized cash proceeds of approximately $288,000. In connection with the sales, the Company relied on the exemption provided by Section 4(2) of the Securities Act of 1933, as amended (the Act ) and Rule 506 under the Act.

During the three months ended May 31, 2010 the Company issued 25,700 shares of Series B Convertible Preferred Stock ( Series B ) at $5.00 per share for cash proceeds totaling approximately $128,500. The Series B is convertible into ten shares of the Company s common stock, with an effective fixed conversion price of $.50 per share. In connection with the sales, the Company relied on the exemption provided by Section 4(2) of the Act and Rule 506 under the Act.

On June 25, 2009, the Company converted 100,000 shares of preferred stock held by UTEK Corp., into 2,356,142 shares of common stock, upon request by UTEK Corp. The Company originally issued 100,000 shares of preferred stock to UTEK Corp., in connection with the acquisition from UTEK Corp., of 100% of the common stock of Advanced Genetic Technologies, Inc. The preferred shares were convertible at the current average trading price for $1,300,000 worth of common shares, which was $0.62 per share. In connection with the issuance of the shares of common stock to UTEK Corp., the Company relied upon the exemption provided by Section 4(2) of the Act and Rule 506 under the Act. UTEK Corp., is an accredited investor , as such term is defined in Rule 501 of Regulation D.

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In July 2009, the Company amended certain promissory notes into convertible notes that can be converted into shares of common stock. The notes had a fixed conversion price of $0.45 per share. In July 2009, the Company converted $146,456 of the notes and accrued interest into 325,458 shares of common stock. In connection with the issuance of the shares of common stock, the Company relied upon the exemption provided in Section 4(2) of the Act and Rule 506 under the Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

| Period | (a) Total Number of Shares (or Units) Purchased | (b) Average Price Paid per Share (or Unit) | (c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs | (d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| March 1 to March 31 | 0 | 0 | 0 | 0 |
| April 1 to April 30 | 0 | 0 | 0 | 0 |
| May 1 to May 31 | 200,000 | $ 0.50 | 0 | 0 |

**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.

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Results of Operations

Results of operations for the year ended May 31, 2010 compared to May 31, 2009 are as follows:

For the years ended May 31, 2010 and 2009, we had no activities that produced revenues from operations.

For the year ended May 31, 2010, we had a net loss of approximately ($3,359,000) compared to a net loss of approximately $(1,306,000) for the corresponding period in 2009. For the year ended May 31, 2010 and 2009, we incurred operating expenses consisting primarily of stock-based compensation, consulting and salaries, research and development, and amortization.

The operating expenses for the years ended May 31, 2010 and 2009 are as follows:

| | 2010 | 2009 |
|---|---|---|
| Stock-based compensation | $ 1,740,000 | $ 628,000 |
| Legal and accounting | 209,000 | 123,000 |
| Salaries and consulting | 585,000 | 170,000 |
| Research and development | 329,000 | 469,000 |
| Amortization | 4,000 | 9,000 |
| Other | 429,000 | 203,000 |
| **Total** | **$ 3,296,000** | **$ 1,602,000** |

Stock-based compensation increased approximately $1,112,000 primarily due to a significant grant of options in the fourth quarter of fiscal year 2010. A significant amount of the grants had immediate vesting rights, which resulted in a significant increase in stock-based compensation in the fourth quarter of 2010. Legal and accounting expenses increased approximately $86,000 as we incurred increases in audit and accounting fees relative to our efforts to become current on our Exchange Act filings (e.g. the filings of our Form 10-Ks and 10-Qs),

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which was offset by a decrease in legal fees as our past litigation was settled in fiscal year 2009. Salary and consulting expenses increased approximately $415,000 in 2010 relative to 2009, as our operations increased with the our increases in cash proceeds from equity offerings, which allowed us to hire our Chief Operating Officer. Additionally, some of our employees converted from part time to full time during fiscal year 2010. The research and development expenses decreased approximately $140,000 from fiscal year 2010 to 2009. During 2009 we incurred significant expenditures related to the manufacturing of products used in our clinical trials that are currently in process. We expect research and development expenses to increase as our clinical trials progress.

Interest expense in 2010 related to convertible debt increased relative to 2009 due to fully amortizing our beneficial conversion feature associated with the conversion option related to this debt. There was no beneficial conversion features associated with convertible debt during 2009. Interest expense related to interest on notes payable decreased from fiscal year 2010 to 2009, as we paid down certain notes during 2010.

During 2009, we recognized approximately $337,000 in other income related to the extinguishment of certain debt. Given our current operating environment, we determined that the extinguishment was not extraordinary, but is not included in our operating income. The extinguishment was due to the statute of limitations expiring on a contract that created the debt.

Rescission Liability

The Company has recorded rescission liabilities for May 31, 2010 and May 31, 2009 of $3,997,000 and $1,815,000, respectively. These amounts represent the believed potential rescission liability as of the dates presented. With the filing of this Form 10-K/A, the Company is restating its previously issued financial statements for the above-mentioned periods to increase the Company s current liabilities based on the amounts of the above stated rescission liability and to correspondingly increase stockholders deficit for the same amount. See Footnote 3 of our Financial Statements on page 42 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 and May 31, 2009, respectively, the Company could potentially owe the two individuals referenced above common stock in the amount of 900,000 common shares and 300,000 common shares, respectively, the cost of which is reflected as Accrued Stock Incentive Compensation at a cost of $ 1,180,000 and $171,000, respectively. We are restating our previously issued financial statements for the above-mentioned periods in the above referenced amounts to increase our liabilities of Accrued Stock Incentive Compensation and to correspondingly decrease our Common Stock to reflect the associated placement offering costs. In addition, costs of $377,079 and $266,800, which were originally reflected as consulting fees and payroll costs during fiscal years 2010 and 2009, respectively, have been reclassified to

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Placement Offering Costs, offsetting Common Stock, and to correspondingly reduce our loss and deficit for those years. With the filing of this Form 10-K/A, the Company is restating its previously issued financial statements for the periods of fiscal years ended May 31, 2010 and May 31, 2009, to increase the Company s current liability to issue common stock based on the amounts provided in the Contract. However, the ultimate decision on issues relating to the Contract, as referenced above, is still being evaluated by the Company. See Footnote 3 of our Financial Statements on page 42 for further information.

Liquidity and Capital Resources.

On May 31, 2010, we had negative working capital of ($4,831,000) as compared to a negative working capital of approximately ($2,205,000) on May 31, 2009.

Cash Flows

Net cash used in operating activities was approximately $1,769,000 during fiscal year 2010, which reflects an increase of approximately $749,000 from net cash used in operating activities of approximately $1,020,000 in 2009. The increase in the net cash used in operating activities for the above periods was primarily attributable to the following:

- Our net cash flows used in operating activity losses increased approximately $749,000, with an increase in accounts payable, accrued interest payable, and accrued liabilities decreasing approximately $99,000.

The above increases were partially offset by the following:

- Stock-based compensation increased approximately $1,112,000 from 2009 to 2010.

- Debt extinguishment gain of approximately $337,000 in 2009.

There were no other significant changes in cash used in operating activities from 2009 to 2010.

There were no material changes in cash flows from investing activities from 2009 to 2010.

Cash flows provided by financing activities of approximately $2,208,000 during fiscal year 2010 increased approximately $1,006,000 from approximately $1,202,000 during 2009. The increase in cash provided by financing activities for the above periods was primarily attributable to the following:

- Cash proceeds from the sale of Series B Convertible Stock increased approximately $2,009,000.

- Proceeds from the sale of treasury stock increased approximately $559,000.

The above increases were partially offset by the following:

- Proceeds from the sale of common stock decreased approximately $923,000 from 2009 to 2010.

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Purchases of treasury stock increased approximately $436,000 from 2009 to 2010.

Payments related to equity offering costs increased approximately $182,000 from 2009 to 2010.
There were no other significant changes in cash provided by financing activities from 2009 to 2010.

As shown in the accompanying Financial Statements, for the year ended May 31, 2010 and 2009, and since October 28, 2003 through May 31, 2010 we incurred net losses of approximately $(3,360,000) and $(1,306,000) and $(11,639,000), respectively. As of May 31, 2010, 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 public 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, 2010 we raised cash of approximately $4,950,000 (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, 2010, we have incurred approximately $1,749,000 of research and development costs and approximately $11,141,000 in operating expenses. We have incurred significant net losses and negative cash flows from operations since our inception. As of May 31, 2010, we had an accumulated deficit of approximately $13,241,000 and negative working capital of approximately $4,831,000.

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 our contracts with Vista Biologicals Corporation.

Going Concern

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

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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, 2010 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, 2010 and May 31, 2009 of $3,997,000 and $1,815,000, respectively. These amounts represent the believed potential rescission liability as of the dates

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presented. With the filing of this Form 10-K/A, we are restating our previously issued financial statements for the above-mentioned periods to increase our current liabilities based on the amounts of the above stated rescission liability and to correspondingly increase stockholders deficit for the same amount. See Footnote 3 of our Financial Statements on page 42 for further information.

The Company is evaluating its obligations under a seven year Personal Services Agreement dated August 4, 2008 (the Contract ), with Nader Pourhassan pursuant to which compensation was paid or accrued in view of the 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 is unclear at this point whether the Company has any defenses to payment, whether the Company has 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 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 and May 31, 2009, respectively, the Company could potentially owe the two individuals referenced above common stock in the amount of 900,000 common shares and 300,000 common shares, respectively, the cost of which is reflected as Accrued Stock Incentive Compensation at a cost of $ 1,180,000 and $ 171,000, respectively. We are restating our previously issued financial statements for the above-mentioned periods in the above referenced amounts to increase our liabilities of Accrued Stock Incentive Compensation and to correspondingly decrease our Common Stock to reflect the associated placement offering costs. In addition, costs of $377,079 and $266,800, which were originally reflected as consulting fees and payroll costs during fiscal years 2010 and 2009, respectively, have been reclassified to Placement Offering Costs, offsetting Common Stock, and to correspondingly reduce our loss and deficit for those years. With the filing of this Form 10-K/A, the Company is restating its previously issued financial statements for the periods of fiscal years ended May 31, 2010 and May 31, 2009, to increase the Company s current liability to issue common stock based on the amounts provided in the Contract. However, the ultimate obligations or rights under the Contract is still being evaluated by the Company. See Footnote 3 of our Financial Statements on page 42 for further information.

**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, 2010 and 2009 and the related consolidated statements of operations, changes in stockholders equity, and cash flows for the years then ended and the period from October 28, 2003 through May 31, 2010. 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 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, 2010 and 2009 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, 2010 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 ($3,359,865) for the year ended May 31, 2010 and has an accumulated deficit of ($13,240,606) from the date of inception through May 31, 2010, 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.

As discussed in Note 3 to the consolidated financial statements, the Company has restated its financial statements as of May 31, 2010 and 2009 and for the periods then ended.

/s/ Pender Newkirk & Company LLP
Pender Newkirk & Company LLP

Certified Public Accountants

Tampa, Florida

December 3, 2010 except for Note 3 and Note 11,

for which the date is August 4, 2011

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CytoDyn Inc.

(A Development Stage Company)

Consolidated Balance Sheets

| | May 31, 2010 (Restated) | 2009 (Restated) |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash | $ 700,497 | $ 265,520 |
| Prepaid Insurance | 12,127 | |
| Prepaid License Fees | 7,500 | 7,500 |
| Total current assets | 720,124 | 273,020 |
| Furniture and equipment, net | 3,549 | 1,963 |
| Intangible assets, net | | 161 |
| Other assets | 23,975 | 29,600 |
| | $ 747,648 | $ 304,744 |
| Liabilities and Stockholders Deficit | | |
| Current Liabilities: | | |
| Accounts payable | $ 178,956 | $ 269,870 |
| Accrued liabilities | 15,209 | 49,424 |
| Accrued stock incentive compensation | 1,180,000 | 171,000 |
| Short-term portion of commitment and contingencies | | 25,000 |
| Indebtedness to related parties | 153,985 | |
| Short-term portion of accrued interest payable | 25,575 | 80,329 |
| Short-term portion of notes payable | | 67,500 |
| Stock rescission liability | 3,997,000 | 1,815,000 |
| Total current liabilities | 5,550,725 | 2,478,123 |
| Other liabilities: | | |
| Accrued salaries - related party | 229,500 | 229,500 |
| Notes payable - less current portion | | 70,500 |
| Convertible notes payable, net | 6,937 | 21,937 |
| Indebtedness to related parties | | 190,985 |
| Total liabilities | 5,787,162 | 2,991,045 |
| Shareholders (deficit): | | |
| Series A Convertible Preferred Stock; no par value; 5,000,000 shares authorized; -0- and 100,000 shares issued and outstanding at May 31, 2010 and 2009, respectively | | 167,500 |
| Series B Convertible Preferred stock; no par value; 400,000 shares authorized; 400,000 and -0- shares issued and outstanding at May 31, 2010 and 2009, respectively | 1,127,005 | |
| Common stock, no par value; 100,000,000 shares authorized; 20,075,895 and 16,221,315 shares issued and outstanding at May 31, 2010 and 2009, respectively | 6,448,925 | 5,847,787 |

| | | |
|---|---|---|
| Additional paid-in capital | 4,703,875 | 2,994,153 |
| Common and preferred stock subject to rescission | (3,997,000) | (1,815,000) |
| Treasury Stock at cost; 200,000 and -0- shares held at May 31, 2010 and 2009, respectively | (100,000) | |
| Additional paid-in capital - treasury stock | 67,575 | |
| Prepaid stock services | (49,288) | |
| Accumulated deficit on unrelated dormant Operations | (1,601,912) | (1,601,912) |
| Deficit accumulated during development stage | (11,638,694) | (8,278,829) |
| Total shareholders (deficit) | (5,039,514) | (2,686,301) |
| | $ 747,648 | $ 304,744 |

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Operations

| | Year Ended May 31, | | October 28, 2003 through May 31, 2010 |
|---|---|---|---|
| | 2010 (Restated) | 2009 (Restated) | (Restated) |
| Operating expenses: | | | |
| General and administrative | $ 2,923,736 | $ 1,024,973 | $ 8,481,754 |
| Amortization / depreciation | 2,077 | 9,392 | 177,969 |
| Research and development | 328,775 | 468,700 | 1,748,703 |
| Legal fees | 41,795 | 99,385 | 732,569 |
| Total operating expenses | 3,296,383 | 1,602,450 | 11,140,995 |
| Operating loss | (3,296,383) | (1,602,450) | (11,140,995) |
| Interest income | | | 1,627 |
| Extinguishment of debt | | 337,342 | 337,342 |
| Interest expense: | | | |
| Interest on convertible debt | (38,604) | | (734,863) |
| Interest on notes payable | (24,878) | (40,896) | (101,805) |
| Loss before income taxes | (3,359,865) | (1,306,004) | (11,638,694) |
| Income tax provision | | | |
| Net loss | $ (3,359,865) | $ (1,306,004) | $ (11,638,694) |
| Convertible preferred Stock dividends | (6,000,000) | | (6,000,000) |
| Net loss applicable to Common shareholders | $ (9,359,865) | $ (1,306,004) | $ (17,638,694) |
| Basic and diluted loss per share applicable to common shareholders | $ (0.49) | $ (0.09) | $ (1.52) |
| Basic and diluted weighted average common shares outstanding | 18,999,234 | 14,210,631 | 11,641,851 |

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, 2010

Restated

| | Preferred Stock | | Common Stock | | | Subject to |
|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | APIC | Rescission |
| 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 ($0.30 per share) | | | 1,800,000 | 486,000 | | |
| February 2004, shares issued to former officer as payment for working capital advance ($.30 per 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, 2010

Restated

| | Treasury Stock | | | Stock for Prepaid | | Deficit Accumulated During Development | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | APIC | Services | Accumulated Deficit | 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 ($0.30 per share) | | | | | | | 486,000 |
| February 2004, shares issued to former officer as payment for working capital advance ($.30 per 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, 2010

Restated

| | Preferred Stock | | Common Stock | | | Subject to |
|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | APIC | Rescission |
| 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 June 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, 2010

Restated

| | Treasury Stock | | | | | | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | 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 June 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, 2010

Restated

| | Preferred Stock | | Common Stock | | | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | APIC | Subject to Rescission |
| 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, 2010

Restated

| | Treasury Stock | | | | | | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | 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 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 | | | | | | | 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 AGTI | | | | | | | 167,500 |
| Net loss, 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.

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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, 2010

Restated

| | Preferred Stock | | Common Stock | | | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Amount | Subject to Rescission |
| Amortization of prepaid stock for service | | | | | | |
| 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 | | | | | | |
| Balance at May 31, 2008 | 100,000 | $ 167,500 | 12,546,407 | $ 4,468,865 | $ 2,613,257 | (321,000) |

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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, 2010

Restated

| | Treasury Stock | | | | | | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | APIC | Stock for Prepaid Services | Accumulated Deficit | Deficit Accumulated During Development Stage | Total |
| Amortization of prepaid stock for service | | | | 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 | | | | | | (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.

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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, 2010

Restated

| | Preferred Stock | | Common Stock | | | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | APIC | Subject to Rescission |
| Stock issued for cash ($.50/share) Less offering costs of $420,146 | | | 3,023,308 | $ 1,073,854 | | (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) | | | | | | |