CYTODYN INC
Form 10KSB
September 14, 2004

CytoDyn, Inc.
200 West De Vargas Street
Suite 1
Santa Fe, New Mexico 87501

Securities and Exchange Commission
450 Fifth Street NW
Washington, DC 20549

Re: CytoDyn, Inc.

Ladies and Gentlemen:

We enclose our annual report on Form 10KSB for filing. The financial statements in this report do not reflect a change from the preceding year in any accounting principles or practices or in the methods of application of those principles or practices.

Very truly yours,

/s/ Allen D. Allen
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Allen D. Allen

U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-KSB

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

For the fiscal year ended May 31, 2004

[ ]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.
(Name of small business issuer in its charter)

| Colorado | 75-3056237 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer or Identification No.) |
| 200 West DeVargas Street, Suite 1<br>Santa Fe, New Mexico | 87501 |
| (Address of principal executive offices) | (Zip Code) |

Telephone Number: 505-988-5520

Securities Registered under Section 12(b) of the Exchange Act: None

Securities Registered under Section 12(g) of the Exchange Act:
Common Stock, no par value

Check whether the issuer (i) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for which shorter period that the was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No ...

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation SB contained in this form and no disclosure will 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-KSB or any amendment to this Form 10-KSB. [ ]

Revenues for the most recent fiscal year $0

Aggregate market value of the voting and non-voting common stock held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of common stock as of a specified within the past 60 days. $1,264,337

Number of shares of common stock outstanding as of August 10, 2004: 8,069,307.

CYTODYN, INC
FORM 10-KSB FOR THE YEAR ENDED MAY 31, 2004
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Item 1. Description of Business

We are a development stage biotechnology research company, incorporated in Colorado on May 2, 2002 as Rexray Corporation. Until October 28, 2003, we were a blank check company. On that date, we entered into an acquisition agreement with CytoDyn of New Mexico, Inc., the purpose of which was to acquire the license to three United States patents and foreign counterpart patents, trademarks, and related technology. These patents cover the use of monoclonal antibodies to treat patients with Human Immunodeficiency Virus (HIV) by protecting crucial cells of the body's immune system that are otherwise killed by the disease, permitting the immune system to inhibit the disease and protect against the collateral illnesses that commonly accompany the disease. A phase I/a/b clinical trial using this treatment method, sponsored by a former licensee of CytoDyn of New Mexico, was completed in 2002. We are continuing the research and development of a treatment for HIV, using the licensed technology, and may either repeat the Phase I trials, if necessary for non-clinical reasons, or, with FDA approval conduct a Phase II/III pivotal study. Neither CytoDyn of New Mexico nor we have derived revenues from it, but we are planning to pursue further clinical trials. Our principal executive offices are located at 200 West DeVargas Street, Suite 1, Santa Fe, New Mexico 87501; telephone: (505) 988-5520, facsimile: (800) 417-7252, and website address; www.cytodyn.com. CytoDyn(R) and Cytolin(R) are our registered trademarks.

Our service trademark symbol is: [GRAPHIC OMITTED]

The Acquisition Agreement with CytoDyn of New Mexico. Under the October 28, 2003 acquisition agreement with CytoDyn of New Mexico, we:

- Effected a one-for-two reverse split of our common stock,
- Issued to CytoDyn of New Mexico 5,362,640 post-split shares, and
- Amended our articles of incorporation to change our name to CytoDyn, Inc.
- Assumed liabilities in the amount of $161,578 related to the assigned assets

As consideration for the issuance of our shares to it, CytoDyn of New Mexico:

- Assigned a Patent License Agreement dated July 1, 1994 between CytoDyn of New Mexico and Allen D. Allen, covering United States patent numbers 5424066, 5651970, and 6534057, and related foreign patents and patents pending, for a method of treating HIV disease with the use of monoclonal antibodies,
- Assigned its trademarks, CytoDyn and Cytolin, and related trademark symbol, and
- Paid $10,000 in cash.

CytoDyn of New Mexico has been, since its incorporation in New Mexico in June 1994, a research and development company and has never been profitable. It is in the process of dissolving and has distributed the 5,362,640 shares of common stock that it received from us in the acquisition to its shareholders, pro rata. It entered into the acquisition agreement with us because, based upon its experience, it believed that finding financing for clinical trials without having publicly traded stock was difficult and Rexray Corporation offered the public vehicle that CytoDyn of New Mexico sought. Please see the sections

entitled "Management's Discussion and Analysis" and "Legal Proceedings," for a further description of the history of CytoDyn of New Mexico and of the patented technology.



The Biotechnology Industry

We estimate that approximately 4,000 biotech companies are operating around the world today, about 1,500 of which are in the United States. The biotech industry is growing. Revenues of U.S. biotech companies increased from about $8 billion in 1992 to about $34.8 billion in 2001. In 1990, the market capitalization of public companies in the biotechnology industry was less than $50 billion. By April of 2003, the market capitalization was estimated to be $206 billion. More than 370 biotechnology drug products and vaccines are currently in human trials in the U.S., and we estimate that there are hundreds more in development. The number of U.S. patents issues annually to biotech companies has climbed from about 2,500 in 1992 to about 7,760 in 2002. Because of FDA expedited approval procedures that reduced clinical testing periods from 15 years to 5 years, and also because of the increasing attention being directed to biotechnologies, 134 biotech drugs and vaccines were approved, during the 5 years from 1988 through 1992 as compared to 69 in the years 1993 to 1997.. Biotechnology Industry Organization: Biotechnology Industry Statistics, 2003

Background on HIV and AIDS

UNAIDS, the Joint United Nations Programme on HIV/AIDS, estimates that 40 million people were living with HIV/AIDS in 2003, reflecting a steady increase since 1999, especially in sub-Saharan Africa, as well as in Asia and the Pacific, Eastern Europe and Central Asia. In 2003, about 3 million people died from HIV/AIDS, and another 5 million contracted the disease. AIDS epidemic update, December 2003. In the United States, the Centers for Disease Control and Prevention estimates that as of the end of 2002, about 530,000 people were living with HIV, of whom about 384,900 were living with AIDS, the full-blown Acquired Immune Deficiency Syndrome that develops from HIV. During 2002, over 35,000 new cases of HIV were reported in the United States. No cure is currently known for HIV.

The human immune system is the body's primary defense against disease. It consists of a vast number of specialized cells and proteins that assist in detecting and destroying foreign organisms and eliminating disease cells. Normally, the body's immune system can distinguish between normal cells and those that appear to be foreign by recognizing proteins, or antigens. CD4 "watch dog" cells identify foreign cells, and the immune system launches an antibody response against the foreign organisms or cells.

HIV triggers a flaw in the human immune system that leads to its destruction. Patients with HIV proliferate CD8 "killer" cells, which kill off CD4 watch dog cells, whether healthy or not, leading to the loss of immune function. But for this flaw, HIV infection in humans might be similar in character to the infection in other primates, which can be infected with HIV without the destruction of their immune systems because their killer cells do not destroy their CD4 cells. The destruction of CD4 cells in humans leaves those persons susceptible to certain cancers and other infections that would normally not be fatal to a person with a normal number of CD4 cells.



Sources: Zarling JM, Ledbetter JA, Sias J, et al: HIV-infected humans, but not chimpanzees, have circulating cytotoxic T-Lymphocytes that lyse uninfected CD4+

cells. J Immunol 1990;144;2992-98; Adelman L. Woofsy D: T-cell homeostasis; implications in HIV infection. J Acquir Immune Defic Syndr 1993; 6:144-152; Allen AD, Mathisen, GE, Glover N, Au J: Immunization against the HIV-associated anti-self, anti-CD4 cytotoxic T lymphocyte. AIDS 1993;7:1130; Allen AD, Mathisen GE, Leader W, et al: T-cell homeostasis in HIV infection: new evidence. J Acquir Immune Defic Syndr 1994;7:627-32; National Institute of Allergies and Infectious Diseases (www.niaid.nih.gov/factsheets/hivinf.htm).

When AIDS first surfaced in the United States, no medicines were available to combat the underlying immune deficiency, and few treatments were available to combat the diseases that resulted. Since then, the FDA has approved a number of drugs in two groups, both antivirals, for treating HIV infection. These groups are:

- Drugs that interrupt an early stage of the virus making copies of itself; and
- Drugs that treat HIV infection by interrupting virus replication at a later step in the virus' life cycle.

Frequently, these two groups of drugs are used in combinations for treatment. Treatment with these drugs, whether alone or in combination, has two primary drawbacks: the virus can mutate to avoid the attack, rendering the drugs ineffective, and the side effects can be severe. Some of the first group of drugs can cause a decrease of red or white blood cells, especially when taken in later stages of the disease. Some may also cause inflammation of the pancreas and painful nerve damage, in addition to other severe reactions. The most common side effects in the second group of drugs include nausea, diarrhea, and other gastrointestinal symptoms. This second group can also interact with other drugs to produce severe side effects. Current research and development for HIV is focused on therapies to reduce the side effects of the antiviral drugs so as to enhance the efficacy of existing treatments and delay the progression of the HIV virus.

Sources: National Institute of Allergy and Infectious Diseases

Cytolin(R)

We own the license to a number of unique, patented methods for the use of drugs that have been studied as a treatment for the disease associated with HIV. Our president, Mr. Allen, has been researching treatments for HIV and AIDS since 1987. He identified a family of monoclonal antibodies that protect the CD4 watchdog cells from the CD8 killer cells of the immune systems of people infected with HIV. He received three U.S. patents and additional foreign counterpart patents, now licensed to us, covering the use of these antibodies for treating patients with HIV. Our leading drug candidate, Cytolin, is based on a monoclonal antibody that protects CD4 cells from CD8 cells, thus preventing the weakening of the immune system.



The Cytolin treatment we are now developing is based on a body of literature that was published by Mr. Allen and others in peer journals from 1987 to 1996. We believe, based on tests conducted to date, that Cytolin may offer some solutions to the problems encountered with antiviral therapies. First, it functions independently of the virus and the virus' mutations, concentrating instead on the body's flawed immune response and enabling the immune system itself to handle the virus more effectively. Because it does not attack the virus, the virus is not stimulated to mutate to become resistant to the antibodies. Second, the antibody, unlike the antiviral medications, is not by its very nature a toxic substance and, we believe, based on tests to date, that it does not appear to produce the side effects associated with other therapies.

Like all proteins, however, it can produce a serious allergic reaction, which has been seen in fewer than 4% of all patients who have been treated with Cytolin. See, for instance, the report by Mr. Allen and others entitled "Leukocyte Adhesion Molecules as a Cofactor in AIDS: Basic science and pilot study," published in 45 Medical Hypotheses164 (1995).

Experiments and Trials

In 1993, a small group of scientists and doctors treated six HIV-infected patients with the antibody Cytolin and later published the results of their study. Blood and skin tests of these patients demonstrated that the antibody was producing improvements in the immune function of each patient. Allen AD, Hart DN, Hechinger MJ, Slattery MJ, Chesson CV, Vidikan P: Leukocyte adhesion molecules as a cofactor in AIDS: Basic science and pilot study, 45 Medical Hypotheses 164 (1995).

Cytolin was tested in toxicology studies, where it was found safe to administer to humans. A 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 188 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 of Cytolin. In 1996, the FDA approved a drug master file for Cytolin and assigned to it the designation "BB-DMF#6836." Also in 1996, the FDA approved the clinical trials based on an investigational new drug application, designated "BB-IND#6845," related to Cytolin. FDA approval made clinical trials of Cytolin possible.

In 2002, Symbion Research International, a contract research organization, completed a Phase I a/b clinical trial of Cytolin. The trial was sponsored by Amerimmune, Inc., the former licensee of CytoDyn of New Mexico. The Phase Ia study, conducted in 13 subjects suffering from HIV/AIDS, found Cytolin to be safe and well tolerated across a narrow dose range. The initial safety study, which consisted of two single escalating doses of 0.05mg and 0.1mg/kg body weight, affirmed the safety and tolerability of the drug in these lower dose groups, as well as preliminary efficacy in lowering the concentration of HIV and increasing T-cell counts in the study's patient population with no serious or sever adverse events reported. The data were presented as an abstract and poster session, entitled `Phase I Study of Anti-LFA-1 Monoclonal Antibody (Cytolin(R)) in Adults with HIV Infection" at the 9th Conference on Retroviruses and Opportunistic Infections held in Seattle, Washington on February 24-28, 2002.



In January 2002, following the completion with favorable early results of the Phase Ia clinical trial, a Phase Ib clinical trial was conducted to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and activity of escalating doses of Cytolin in adults with HIV infection.

We hope, based upon the favorable results of the Phase Ia/b studies, to obtain FDA approval to conduct a Phase II/III pivotal study to determine if Cytolin is effective for a wide range of patients and what side effects, if any, may exist. Additional studies may be required, that involve more patients at more sites, to add data about Cytolin's effectiveness, side effects, and appropriate use.

We are planning to continue the research and development efforts conducted under the auspices of Amerimmune, Inc. as CytoDyn of New Mexico's then licensee. During the last two fiscal years, we have not expended funds for research and

development, having directed our expenditures to patent issuance and protection and general and administrative expenses.

Overview of the FDA Approval Process

General. The production and marketing of therapeutic products for use in humans, and related research and development, are subject to regulation by numerous governmental authorities in the United States and other countries. In the United States, these products and research are subject to FDA review for safety and efficacy. The Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations govern or influence the testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drugs. Noncompliance with applicable requirements can result in criminal prosecution and fines, recall or seizure of potential drugs, total or partial suspension of production, refusal of the government to approve a New Drug Application ("NDA") or a Biologic License Applications ("BLA") or refusal to allow us to enter into supply contracts. The FDA also has authority to revoke product licenses and establishment licenses previously granted.

Approval Process. In order to obtain FDA approval to market a new biological or pharmaceutical product, we must submit proof of product safety, purity, potency and efficacy, and reliable manufacturing capability, which will require us to conduct extensive laboratory, preclinical and clinical tests. This testing, as well as preparation and processing of necessary applications, is expensive, time-consuming, and often takes several years to complete. There is no assurance that the FDA will act favorably in making these reviews. We may encounter significant difficulties or costs in our efforts to obtain FDA approvals, which could delay or preclude us from marketing any drugs that we may develop. The FDA may also require post marketing testing and surveillance to monitor the effects of marketed products, or place conditions on approvals that could restrict the commercial applications of products. Product approvals may be withdrawn if problems occur following initial marketing, such as noncompliance with regulatory standards. With respect to patented drugs or technologies, delays imposed by governmental marketing approval processes may materially reduce the period during which we will have the exclusive right to exploit patented potential drugs or technologies. Refusals or delays in the regulatory process in one country may make it more difficult and time consuming for us to obtain marketing approvals in other countries.



The FDA approval process for a new pharmaceutical product involves completion of preclinical studies and the submission of the results of these studies to the FDA in an Initial New Drug Application, which must be approved before human clinical trials may be conducted. The results of preclinical and clinical studies on pharmaceutical products that are biologics, like Cytolin, are submitted to the FDA in the form of a BLA for approval to commence commercial sales. In responding to one of these applications, the FDA may require additional testing or information, or may deny the application. In addition to obtaining FDA approval for each biological or chemical product, an Establishment License Application ("ELA") must be filed and the FDA must inspect and license the manufacturing facilities for each product. Product sales may commence only when both the BLA and the ELA are approved. The FDA does offer an accelerated drug approval program for new drugs which treat serious or life-threatening illnesses. See "Accelerated Drug Approval," below. We hope to take advantage of this accelerated approval.

Pre-clinical Testing. A compound is subjected to extensive laboratory and animal testing to determine if it is safe and has the functionality for which its therapeutic use is intended. All animal safety studies must be performed under current good laboratory practices. Cytolin was tested through a contract with

Vista Biologicals Corporation. This testing took approximately one year and cost approximately $900,000.

Investigational New Drug ("IND"). Before human tests can begin, a drug sponsor must file an IND application with the FDA, showing how the drug and drug products are made, the results of animal testing and a protocol describing the initial study in human beings. If the FDA does not reject or place an application "on hold" within 30 days, the drug receives IND status, which permits a sponsor to undertake studies in human volunteer subjects. The IND application for Cytolin was submitted in September 1996 by CytoDyn of New Mexico, and approval was received in October 1996.

Human Testing: Clinical. Under an IND, the human clinical testing program involves three phases. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety, the efficacy criteria to be evaluated, and the type of statistical analysis that will be done. Each protocol is submitted to the FDA as part of an IND filing or amendment. Each clinical study is conducted under the auspices of an independent Institutional Review Board ("IRB") for each institution at which a study will be conducted. The IRB considers, among other things, information on the product, ethical factors, informed consent documents, the risk to human subjects, and the potential benefits of therapy relative to risk.

Phase I clinical trials are the initial introduction of the drug into human patients. The product is generally tested for safely, dosage tolerance, absorption, metabolism, distribution, and excretion. Phase Ia/b trials of Cytolin were completed in 2002, as reported above. Because the trials were sponsored by Amerimmune, we do not know their cost.



Phase II/III pivotal studies combine the Phase II trials that typically involve studies in a limited patient population to (i) determine the biological or clinical activity of the product for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage; and (iii) identify possible adverse effects and safety risks, and the Phase III trials that are large-scale studies on patients with the disease in order to evaluate the clinical efficacy of the drug. Phase II trials on Cytolin have not yet been scheduled, pending resolution of legal disputes. Please see "Legal Proceedings," below. If, as a result of the pending litigation, we can use the Phase I data, we plan to conduct a Phase II/III pivotal study. We expect that these trials will take approximately 29 to 42 months and will cost approximately $2,050,000 to $3,350,000. plus estimated manufacturing and supply costs of $350,000 to $400,000. If we cannot use the Phase I data, we will need to repeat the Phase I study. In either case, we will need to raise funding to support this effort. Please see the section entitled "Management's Plan of Operation."

Biologic License Application. Upon completion of the Phase II/III pivotal study, we may file a BLA containing clinical, pharmacology, toxicology and clinical trial data, and chemistry, manufacturing and control information that has been gathered, as well as all other information that is known from any other sources. The information must include essentially all the data collected during the IND phase (e.g., characterization of the drug, formula and manufacturing process, stability in the proposed packaging, animal and laboratory studies, results of all human tests, etc.) and proposed labeling.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing a BLA and supplements to it, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. The BLA review fee alone can exceed $500,000, although certain

limited deferrals, waivers, and reductions may be available.

Under applicable laws and FDA regulations, each BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If the application is deemed complete, the FDA will "file" the BLA, triggering substantive review of the application. The FDA can refuse to file any BLA that it deems incomplete or not properly reviewable. If the FDA refuses to file an application, the FDA will retain 25% of the user fee as a penalty. The FDA has established performance goals for the review of BLA's--six months for priority applications, and ten months for regular applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an "action letter" that describes additional work that must be done before the application can be approved. The FDA's review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval.



Approval. Once a BLA is approved, the manufacturer is required to keep the FDA informed at all times regarding any adverse reactions to the product. Moreover, contract manufacturers that we may use must adhere at all times to current Good Manufacturing Practices ("GMP") regulations enforced by the FDA through its facilities inspection program. These facilities must pass a pre-approval plant inspection before the FDA will issue a pre-market approval of the product. After FDA approval is obtained for the initial indication, further clinical trials are necessary to gain approval for the use of the product for additional indications.

The FDA may also require post-marketing testing (Phase IV) to support a conclusion of efficacy and safety of a product, or answer specific questions that arose during IND studies. Phase IV can involve significant expense and time.

Side effect or adverse events that are reported during clinical studies can delay, impede, or prevent marketing authorization. Adverse events that are reported after marketing authorization can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market.

The testing and approval process is likely to require substantial time and effort, and we cannot assure that any FDA approval of Cytolin will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the adverse effects of a drug, or its safety, and its therapeutic benefits, or efficacy. Additional preclinical or clinical trials of Cytolin may be required during the FDA review period and may delay marketing approval, if any.

The FDA may propose significant changes in the design, analysis and reporting of clinical studies conducted under IND's in response to the results of clinical studies by other companies. If significant changes are implemented, the costs associated with obtaining market approval of Cytolin by the FDA are likely to be increased.

Accelerated Drug Approval. The FDA allows patients with serious and life-threatening diseases, such as HIV, to benefit from earlier access to important new drugs through an "accelerated drug approval" program. To be eligible for this program, products must treat serious or life-threatening illnesses and provide meaningful therapeutic benefits beyond existing treatments. Under this program, a significant new therapy could be approved for marketing at the earliest possible point at which its safety and effectiveness are reasonably established under existing law. For example, the approval of a drug could be accelerated by demonstrating a favorable effect on a well-documented surrogate endpoint to predict clinical benefit, instead of requiring that the drug demonstrate actual clinical benefit, which may take many months or years. Approval would be granted only if a sponsor agrees to conduct additional post-marketing studies to confirm the product's effectiveness and/or agrees to restrict distribution of the product. In addition, if further clinical trials do not bear out the product's effectiveness or if restricted distribution is inadequate to assure safe use, approval of the product would be withdrawn.



Orphan Drug Status. In certain circumstances in which a treatment for a rare disease or condition is concerned, the manufacturer may request the FDA to grant the drug product Orphan Drug status for a particular use. In this case, the developer of the drug may request grants from the government to defray the costs of certain expenses related to the clinical testing of the drug and also be entitled to marketing exclusivity and specified tax credits. We may seek Orphan Drug designation in the future for drugs, not including Cytolin, that we may try to develop. If these are the first such drugs approved, we may be entitled to seven-year marketing exclusivity in the U.S. for them. The seven-year exclusivity applies only to the particular drug for the rare disease or condition for which the FDA has designated the drug an Orphan Drug. Therefore, another manufacturer could obtain approval of the same drug for a disease or condition other than the one for which we have approval, or could seek Orphan Drug status for a different drug for the same disease or condition.

Regulation in Addition to the FDA. In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of the Inspector General), and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We may become subject to additional federal, state and local laws, regulations and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Sales outside of the United States of products we develop will also be subject to regulatory requirements governing human clinical studies and marketing for

drugs and biological products and devices. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources. In most cases, if the FDA has not approved a product for sale in the United states, the product may be exported to any country if it complies with the laws of that country and has valid marketing authorization by the appropriate authority (i) in Canada, Australia, New Zealand, Japan, Israel, Switzerland or South Africa, or (ii) in the European Union or a country in the European Economic Area if the drug is marketed in that country or the drug is authorized for general marketing in the European Economic Area. The FDA has specific regulations that govern this process.



Our ability to earn any returns on products we may develop and have approved may depend in part on the extent to which government health administration authorities, private health coverage insurers, and other organizations will provide reimbursement for the costs of those products and related treatments. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and we cannot assure that adequate third-party coverage will be available if and when Cytolin or any other products we may develop become marketable.

Manufacturing Process

The antibodies used in Cytolin are produced from FDA-approved cell banks, which in turn are produced from clones, or "seeds." Cells harvested from the cell bank are fermented or otherwise processed to make raw antibodies. These are then purified and put in vials using an FDA-approved method.

We do not own or license the clones we use to produce antibodies. In order to commercialize any product using cell banks from the clones, we must license the clones from their owners. We have not yet begun discussions to obtain those licenses. If we cannot obtain a license, we will be limited to research use only, or we must purchase a clone on the open market, which we may not be able to do or at a price we can afford.

We expect, when and if we can begin production of our pharmaceutical products, to enter into strategic alliances with pharmaceutical companies that have in place the structures and organizations that can produce Cytolin for us. Currently, we plan to license independent manufacturers to make the Cytolin necessary for our clinical trials.

Production Facilities

We will outsource all of the manufacturing of Cytolin to plants which meet Good Manufacturing Practice standards. GMP is a pre-requisite for all drugs, regardless of their classification. In order to be certain that we are in compliance throughout all the levels of the manufacturing process, we will have periodic reviews of the manufacturing facilities performed.

Patents

Patents which have been licensed to us are as follows:

- U.S. Patent No. 5,424,066 ("Method for increasing CD$+ cell numbers through the use of monoclonal antibodies directed against self-reactive, CD4 specific cytotoxic T-cells"),
- U.S. Patent No. 5,651,970 ("Method for inhibiting disease associated with the Human Immunodeficiency Virus through the use of monoclonal antibodies directed against anti-self cytotoxic T-lymphocytes or their

lytics"),
- U.S. Patent No. 6,534,057 ("Method for increasing the delayed-type hypersensitivity response by infusing LFA-1-specific antibodies"), and
- Issued and pending foreign counterpart patents.



CytoDyn owns the registered trademarks, CytoDyn(R) and Cytolin(R), and a related service mark symbol.

We acquired the license to these patents and the trademarks pursuant to our 2003 acquisition agreement with CytoDyn of New Mexico. CytoDyn of New Mexico entered into a Patent License Agreement with Allen D. Allen, the owner of the patents and our current president, on July 1, 1994. This agreement was assigned to us, and amended and confirmed by an amendment between us and Mr. Allen dated August 23, 2004. Under the agreement, Mr. Allen licensed the technology, now covered by the patents, for inhibiting HIV through the use of monoclonal antibodies, in exchange for 25,000 shares of CytoDyn of New Mexico common stock in 1994. This license is an exclusive, world-wide license to manufacture, use, and sell the monoclonal antibodies for use in treating or inhibiting diseases associated with HIV and AIDS, together with other products, devices or processes described in the patents, and applications and patents for any improvements. Mr. Allen has the responsibility for obtaining patents, and we have the responsibility to pay the costs of them. If we want to assign the agreement or sublicense the inventions covered by the agreement, we need Mr. Allen's permission. In order to keep our exclusive license in each country, we also must defend the patents against infringement in that country.

Other Potential Drugs

We may pursue opportunities to develop other kinds of drugs, by ourselves or jointly with others. We cannot assure that we will ever successfully develop other drugs, alone or with others, that patents for any drugs we might develop would be issued, that FDA approval will be obtained for the drugs, or that any drugs would be commercially viable and marketable.

Product Liability Insurance

The testing, marketing and sale of therapeutic products for use in humans entail an inherent risk of allegations of product liability. We cannot assure that product liability claims will not be asserted against us. We do not have product liability insurance. We may not be able to get product liability insurance in the future on acceptable terms. Even if we are able to get product liability insurance, claims could exceed the amount of our coverage.

Competition

Competition in the biopharmaceutical industry is intense and based on scientific, technological, and other factors. These factors include:

- Availability of patent and other protection for technology and products,
- Ability to commercialize technological developments,
- Ability to obtain governmental approval for testing, manufacturing, and marketing,
- Availability of funding for research and development, testing, the approval process, and marketing.

Our potential competitors include entities that develop and produce therapeutic agents for treatment of human and animal disease. These entities range from small, dedicated companies that are research and development intensive, to large, diversified companies that have significant in-house resources and well-established production and distribution systems. They 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 our potential competitors have substantially greater capital resources, research and development capabilities, manufacturing and marketing resources, and experience, than we do. Some of these include Schering AG, Biogen, and Elan, among others. They may succeed in developing drugs or processes that are more effective or less costly than any that we may develop, or they may gain regulatory approval for their drugs before we do for ours.

Worldwide, many antiviral drugs are available for treating HIV and AIDS. We will, if Cytolin is approved, compete with already existing treatments such as these, and with treatments that are developed and made available before ours. We know, for example, that Johns Hopkins Medical School owns patents on specific antibodies which are believed to prevent the clumping of white blood cells, a problem for patients with HIV that causes the patients to lose CD4 cells. Johns Hopkins could license these antibodies for marketing in competition with Cytolin.

We expect that the number of our competitors will increase as more drugs receive marketing approvals from the FDA or analogous foreign regulatory agencies. Any of these competitors may be more successful than we in manufacturing, marketing and distributing their drugs.

Employees

We have two full-time employees and one part-time employee, engaged in management and product development. We are severely understaffed, and we will need to expand our employee force in order to accomplish our objectives. However, we may not be able to locate or retain suitable employees on acceptable terms.

RISK FACTORS

An investment in our shares is very risky. You should only invest if you can afford to lose your entire investment. Before you invest, carefully consider the risks we discuss in this section, as well as the information elsewhere in these materials. You should also consider the information we incorporate by reference, and information that we file with the Securities and Exchange Commission from time to time.



Risks Related to Our Financial Condition

Our accountant has expressed substantial doubt that we can continue as a going concern.

WE HAVE INCURRED LOSSES SINCE OUR INCEPTION AND MAY NEVER BE PROFITABLE. We have expended capital to make an acquisition and to create an infrastructure to support our business, but we have never had operating revenues or profits. The company from which we acquired our proprietary technology in October 2003 also never had revenues or profits from it. We cannot assure you that we will be able to use our technology to generate revenues and profits and to remain in business.

WE NEED ADDITIONAL FINANCING AND MAY NOT BE ABLE TO FINISH DEVELOPMENT OF OUR PROPOSED PRODUCTS, OR, IF THEY ARE APPROVED, TO BEGIN MARKETING THEM WITHOUT IT. We need to raise substantial additional funds in order to continue our operations. If we are unable to obtain debt or equity financing on a continuing basis, we may be required to suspend or discontinue our operations and will not be able to produce our proposed products.

Risks Related to Our Business

OUR ONLY POTENTIAL PRODUCTS, PROPOSED ANTIBODY THERAPIES TO TREAT HIV INFECTION AND AIDS, ARE IN THE RESEARCH AND DEVELOPMENT STAGE AND MAY NEVER BECOME APPROVED, AVAILABLE, EFFECTIVE TREATMENTS. IF THEY DO NOT, OUR BUSINESS IS LIKELY TO FAIL. The only potential products we currently have are proposed antibody treatments for HIV and AIDS for which only limited human trials have been conducted. We cannot assure that these treatments will ever

- be successfully developed;
- prove to be safe and effective in clinical trials for treatment of HIV and AIDS;
- meet applicable regulatory standards;
- be capable of being manufactured in commercial quantities at a reasonable cost;
- be marketed successfully; or
- achieve marketplace acceptance.

If these do not happen, we will have no products with which to build our business and our business is likely to fail.

WE MAY BE REQUIRED TO REPEAT PHASE I CLINICAL TRIALS. Pending litigation may affect our access to the results obtained in the Phase I clinical trial of Cytolin. Should the litigation produce an unfavorable outcome with respect to this issue, we may be obliged to repeat the Phase I clinical trials. A repeated trial would result in significant additional costs and delays, and could result in additional complications in the drug approval process.

WE NEED, FOR ANY PURPOSE OTHER THAN RESEARCH, TO OWN OR LICENSE THE CLONES THAT ARE NECESSARY TO PRODUCE ANTIBODIES, BUT WE DO NOT NOW OWN OR LICENSE THEM. The source for the FDA-approved cell bank used to produce antibodies is called a clone. In order to produce the antibodies we will need for our potential products, we must either license a clone from the owners of the clones we now



use, or we must buy a clone in the public domain. If we buy a clone, we must conduct an "equivalency study" Phase I trial before we can use it to produce antibodies. We do not know if or when we will be able to license or buy a clone at all, whether we can afford the cost, or whether any Phase I trial would produce results that would enable us to use a purchased clone.

THE U.S. PATENTS THAT WE LICENSE ARE SCHEDULED TO EXPIRE IN 2013 AND 2014. We currently license three U.S. patents. So long as required maintenance fees are paid, two of the patents will expire on March 19, 2013 and the other will expire on July 29, 2014. Upon expiration of each patent, the exclusivity and other protections afforded by that patent will no longer be available to us.

WE MAY NOT BE ABLE TO ENFORCE OUR PATENT RIGHTS OR OTHERWISE PROTECT OUR INTELLECTUAL PROPERTY. DISPUTES AND DISPUTE RESOLUTION COULD BE EXPENSIVE. Our success will depend, in part, on our ability to develop and protect our intellectual property. In addition to three issued U.S. patents and foreign counterparts, we also license one foreign patent pending. Patents have the

following risks:

- We cannot guarantee that pending patents will be issued, or that issued patents will be enforced in a court of law if challenged. Currently, no consistent policy regarding the breadth of claims in biotechnology patents, like ours, has emerged.
- Patent applications in the U.S. are not publicly disclosed until the patents are issued. Therefore, undisclosed U.S. patent applications that relate to our proposed products and technology may have been filed.
- We cannot be certain that foreign patents have not been or will not be issued that would harm our ability to commercialize our proposed products.
- Even as we obtain patent protection for our intellectual property, third parties could independently develop and patent equivalent or superior products or technology, in which case we may be required to obtain licenses to that technology from those parties, increasing our cost of doing business.

IN ADDITION TO PATENT RIGHTS, WE RELY UPON TRADE SECRET LAWS, INDUSTRIAL KNOW-HOW, AND EMPLOYEE CONFIDENTIALITY AGREEMENTS TO PROTECT OUR INTELLECTUAL PROPERTY. These may raise concerns such as the following:

- Third parties or employees may breach our agreements with them or otherwise attempt to disclose, obtain or use our products and technologies.
- If consultants, employees, or other parties apply technological information developed independently, by them or others, to our projects, disputes may arise as the proprietary rights to that information. Those disputes may not be resolved in our favor.
- We may not be able to obtain court enforcement of our agreements, which would leave us with inadequate remedies to protect our intellectual property rights. This is particularly true in foreign countries, where laws or law enforcement practices often do not protect intellectual property as fully as in the U.S.



WE MAY HAVE TO LITIGATE TO ENFORCE OR DEFEND OUR INTELLECTUAL PROPERTY RIGHTS. In addition, companies frequently sue other companies as a means of delaying the introduction of a competitor's products or technologies. Any litigation, regardless of outcome, including any interference proceeding to determine priority of inventions, oppositions to patents in foreign countries, or litigation against us, may be costly and time consuming. Further, if it were ultimately determined that our claimed intellectual property rights are unenforceable, or that our products infringe on the rights of others, we may be required to pay past royalties or obtain licenses to use technologies. We may not be able to obtain licenses for these technologies on commercially reasonable terms, or at all.

Management's responsibility is to protect the patents, trademarks and technology. This includes legal expenses to oppose attempts to steal, convert or misappropriate the company's property. The company has been targeted in the past and has had to spend significant legal fees to recover its property. The company is currently incurring legal fees for this purpose. Please see disclosures under "Company History" and "Legal Proceedings." If the company is unsuccessful in opposing efforts to steal, convert or misappropriate the company's property, this could have a materially adverse effect on our business.

SALES OF OUR PROPRIETARY PRODUCTS WILL DEPEND ON THE MEDICAL COMMUNITY'S ACCEPTANCE OF OUR PRODUCTS AND ON OUR ABILITY TO OBTAIN ADEQUATE THIRD PARTY

REIMBURSEMENT FOR THEM. Our HIV/AIDS treatment, if it becomes marketable, will be available to patients only through licensed medical professionals. We must persuade these professionals to prescribe our treatment. Successful commercialization of our products will also depend in large part on whether patients using them will be reimbursed for the expense by government agencies and other third-party payors. Government agencies and other third-party payors continue efforts to contain or reduce the costs of health care by various methods, including limitations on coverage and the level of reimbursement. We do not know if our proprietary pharmaceuticals, should they become available for prescription and sale, will be eligible for reimbursement, or at what level they would be reimbursed. If they are not, their use could be severely limited and our business could be harmed.

WE DO NOT HAVE, AND DO NOT PLAN TO HAVE, OUR OWN MANUFACTURING FACILITIES, SO WE WILL DEPEND UPON OTHERS TO MANUFACTURE OUR PRODUCTS AND CONDUCT THE TRIALS NECESSARY FOR REGULATORY APPROVAL. Manufacturing of pharmaceuticals for clinical trials and commercial marketing is subject to the FDA's Good Manufacturing Practices. Because we do not have manufacturing facilities, we must contract with others to manufacture our products in compliance with the GMP. If the manufacturing facilities we use should become unable to manufacture our products in a timely manner, at a price we can afford, and in compliance with GMP, our program to complete trials, obtain FDA approval, and commercialize our pharmaceuticals could be slowed significantly and our business prospects harmed.

COMPETITION IN THE PHARMACEUTICAL INDUSTRY IS INTENSE, AND THIS COULD ADVERSELY AFFECT OUR ABILITY TO COMMERCIALIZE OUR PRODUCTS AND TO GENERATE REVENUES AND MARKET SHARE. Our industry is characterized by intense competition. Our competition includes pharmaceutical companies, academic institutions, public and private research institutions, and others. In almost every case, our competitors, some of whom are Fortune 500 companies, have substantially greater resources, research and development staffs, and facilities than we do, as well as greater experience in developing products. Our competitors may succeed in developing products that are more effective or less costly than our products would be. If competitors' products are developed, we may not be able to commercialize our products at all, or we may not be able to sell them at a price that will give us an adequate return.



Many of our competitors have more established sales and customer support organizations than we do. In addition, many of these competitors have established name recognition, extensive customer bases, developed distribution channels, and broad product offerings, which we do not have. These companies can also develop competing treatments that may render our proprietary products, if approved, less competitive and marketable, which would harm our business prospects.

WE PLAN TO MARKET THROUGH ALLIANCES WITH OTHERS. IF WE CAN ESTABLISH THOSE ALLIANCES, WE WILL BE DEPENDENT UPON THEM FOR OUR SUCCESS. We plan to license our marketing rights to our anticipated proprietary products to others. We cannot assure you that we will be able to enter into marketing arrangements acceptable to us. If we are able to establish acceptable marketing arrangements, we nevertheless will be dependent upon the efforts of others whose actual performance we will not control. If we are not able to establish or maintain acceptable marketing arrangements, we will be required to delay or withdraw our marketing plans while we seek other partners willing to contract with us on terms acceptable to us. The delay could harm our business.

WE COULD BE SUBJECT TO PRODUCT LIABILITY CLAIMS FROM THE USE OF OUR PRODUCTS, OR PRODUCT RECALLS, BUT WE HAVE NO INSURANCE COVERAGE TO HELP US PAY THE COSTS OF DEFENSE OR ANY AWARD AGAINST US. Product liability claims arising out of the use

of our pharmaceuticals, including during clinical trials, could be asserted against us by consumers, pharmaceutical companies, and others. Recalls of our products also could be required. We do not have product liability insurance, which is becoming increasingly expensive. We may not be able to obtain that insurance at all or at a commercially reasonable cost, and what we obtain may not cover all of the liabilities to which we could be subject. If costs and damages for successful product liability claims are significant, or exceed any liability insurance we may be able to obtain, or if any claim results in product recall or significant adverse publicity, our reputation, our ability to conduct our business, and our financial condition could be severely harmed.

WE NEED TO RETAIN OUR CURRENT MANAGEMENT TO EFFECTIVELY CONTINUE OUR PRODUCT DEVELOPMENT EFFORTS. We are dependent upon our current officers and directors, especially, but not limited to, Mr. Allen, to continue development and commercialization of our HIV/AIDS pharmaceuticals. If we lose their services, or they are unable for any reason to devote to our business the time necessary to accomplish our plans, our operations and our ability to pursue our business plan could be harmed. We do not have keyman insurance on any of our officers and directors.

LEGAL PROCEEDINGS INVOLVING THE OWNERSHIP AND USE OF INTELLECTUAL PROPERTY CRITICAL TO OUR BUSINESS ARE PENDING. THE OUTCOMES AND COSTS OF THESE PROCEEDINGS ARE UNCERTAIN. Litigation currently is pending which relates, among other things, to the ownership and use of intellectual property upon which our business is based and the right to make use of the Phase I FDA clinical trial results. This litigation is more fully described under "Legal Proceedings", Part I, Item 3. We cannot predict with certainty the eventual outcomes of the litigation. If outcomes are unfavorable, we may be required to suspend or discontinue our operations, or to incur substantial additional costs and delays. We expect to devote significant effort and incur substantial expense in connection with the proceedings to which we are parties.



Risks Related to the Pharmaceutical Industry

THE PHARMACEUTICAL INDUSTRY IS HEAVILY REGULATED, AND STRINGENT, ONGOING, REGULATION, INSPECTION, AND APPROVAL OF OUR POTENTIAL PRODUCTS COULD LEAD TO DELAYS IN OR LIMIT OR PREVENT DEVELOPMENT, MANUFACTURE, MARKETING AND SALE OF ANY PRODUCTS, CAUSING OUR BUSINESS TO BE HARMED. Our research, preclinical development, clinical trials, product manufacturing, labeling, distribution, and marketing are regulated by the Food and Drug Administration and other government and public health agencies and similar authorities in foreign countries. Regulatory approval:

- may never be granted, or not granted on the schedule we need to meet;
- may take many years and is subject to significant delays;
- may require us to expend substantial resources, both financial and otherwise;
- may be subject to limits on use that reduce or eliminate any return we might make on a product; and
- is subject to changes in regulations that could delay or prevent approval of products already under development.

If we were to violate any regulatory requirements, we could be subject to severe regulatory consequences, including:

- the FDA's delay in approving or refusing to approve a new product;
- required withdrawal of an approved product from the market; or
- criminal penalties.

We may also be subject to manufacturing or marketing restrictions on an approved product or be required to withdraw it from the market if problems are discovered with the product after its approval or marketing, which could also harm our business.

THE PHARMACEUTICAL INDUSTRY IS SUBJECT TO UNCERTAINTY AND CHANGE. Even if we are able successfully to develop and obtain approvals for our potential products, as participants in the pharmaceutical industry, we may face the possibility of additional obstacles, including:

- Uncertain and increasing research and development costs;
- Decisions made in the approval process may have a substantial, later impact on marketing;
- Competition from "generic" or "follow on" versions of our potential products;
- Competition from new products and therapies, or new uses or applications of existing products and therapies;
- Pressure to lower prices exerted by government agencies, political representatives, and threatened or actual changes in law or regulations; and
- Opening of domestic markets to competing products from Canada or elsewhere.

Risks Related to Our Securities

TWO OFFICERS EFFECTIVELY CONTROL THE COMPANY BY VIRTUE OF THEIR OWNERSHIP OF A LARGE BLOCK OF SHARES. Our president, Allen D. Allen, and our Secretary and Vice President, Corrine Allen, have beneficial ownership of 2,118,515 and 1,736,335 shares of our common stock, respectively, which constitute approximately 26.25% and 21.51% of our voting securities. Allen D. Allen is the father of Corrine Allen. Collectively, our Directors and Officers, including Mr. Allen and Ms. Allen, have beneficial ownership of 3,863,326 shares of our common stock, which constitute approximately 47.9% of our voting securities. Based on Form 3 and 4 filed with the SEC, no other person or organized group holds more than 10% of our common stock. Therefore, as a practical matter, Mr. Allen and Ms. Allen have and will continue to have the power to elect our Board of Directors and effectively control all substantial corporate actions and decisions.



WE MAY CONTINUE TO SELL STOCK OR OTHER SECURITIES TO RAISE MONEY. IF WE DO, THESE SALES COULD SUBSTANTIALLY DILUTE YOUR INVESTMENT. We have the authority to issue up to 25,000,000 shares of common stock and 5,000,000 shares of nonvoting preferred stock and to issue options and warrants to purchase shares of our common stock without shareholder approval. 8,069,307 shares of common stock and no shares of our preferred stock were issued and outstanding as of May 31, 2004. If we issue additional stock, the holdings of current shareholders will be diluted, perhaps significantly.

OUR COMMON STOCK CURRENTLY HAS NO ESTABLISHED PUBLIC MARKET, AND WE CANNOT ASSURE YOU THAT ANY MARKET WILL DEVELOP, OR THAT IT WILL NOT BE VOLATILE. If a market does not develop in our common stock, your ability to sell your shares will be very limited, even if their offer and sale is registered. If a market does develop, trading could still be very sporadic, and the market price would be likely to be highly volatile and subject to wide fluctuations.

OUR QUARTERLY OPERATING RESULTS MAY FLUCTUATE, WHICH COULD CAUSE THE TRADING PRICE OF OUR STOCK TO FLUCTUATE OR DECLINE. Our operating results may fluctuate significantly from quarter to quarter in the future. If our quarterly revenues

and operating results fail to meet or exceed the expectations of securities analysts and investors, the market price of our common stock could decline substantially. Operating results vary depending upon a number of factors, many of which are out of our control, including:

- the successful development and approval of our products,
- our ability to get our products to market,
- demand for our products,
- the announcement and introduction of competing products,
- changes in our pricing policies or those of competitors,
- changes in the regulatory approval process, and
- changes in third party reimbursement policies.

Our results of operations for any one quarter should not be viewed as indicative of what the results of operations for any other future quarter will be.

OUR COMMON STOCK IS A "PENNY STOCK" AND, THEREFORE, ITS LIQUIDITY MAY BE ADVERSELY AFFECTED. If a market in our common stock develops, it will be subject to Rule 15g-9 under the Securities Exchange Act of 1934 for non-NASDAQ and non-exchange listed securities. Under that rule, broker-dealers who recommend those securities to persons other than established customers and accredited investors must make a special written suitability determination for the purchaser and receive the purchaser's written agreement to a transaction before the sale. The Securities and Exchange Commission defines a penny stock as an equity security, like our common stock, that has a market price or an exercise price of less than $5.00 per share. Unless specified exceptions which do not now apply to us are available, the broker-dealer must deliver to a customer, before a transaction, a risk disclosure schedule that explains the penny stock market and the risks associated with it. Because our stock is a penny stock, the ability of broker-dealers to sell our common stock and your ability to sell your shares in the secondary market will be limited by the penny stock regulations.



WE HAVE NEVER PAID, AND DO NOT EXPECT TO PAY, DIVIDENDS. We have had no operating revenues, have never had earnings, and have never paid dividends. We do not expect to be able to pay dividends for the foreseeable future. We expect to use any earnings we may have to develop and finance our operations.

## Item 2. Description of Property

Our principal offices are located at 200 West De Vargas Street, Suite 1, Santa Fe, New Mexico 87501. We lease this 169 square foot office space on a 1-year lease at a rent of $495 per month. The lease expires on November 30, 2004, but may be renewed.

## Item 3. Legal Proceedings

We currently are a party to two legal proceedings. Property important to us is the subject of a third proceeding, to which we are not a party.

CytoDyn of New Mexico, Inc. et al., v. Amerimmune Pharmaceuticals, Inc. et al., Case number BC 290154, California Superior Court in and for the County of Los Angeles. The original Complaint was filed on February 11, 2003. A First Amended and Supplemental Complaint was filed on March 23, 2004. Further refinement of the pleadings has occurred since then. Currently we are the sole plaintiff, and the defendants are Rex H. Lewis, Pamela Kapustay, Kimberly Cerrone, O.B. Parris and Michael Davis, Maya, LLC, and unknown others designated as "Does 2 through 10". Others named in the original Complaint, most notably Amerimmune Pharmaceuticals, Inc., as a defendant, are no longer parties.

The First Amended and Supplemental Complaint alleges causes of action for unfair business competition, inducement of breach of contract, fraud and unjust enrichment, and declaratory and equitable relief. Three of the causes of action have been dismissed, but the claim related to unjust enrichment and the requests for declaratory and equitable relief survive.

The facts most salient to the current posture of the case concern a purported transfer of patents, other intellectual property rights and good will related to Cytolin made to Maya, LLC, a Nevada entity controlled by Rex Lewis, the former Chief Executive Officer of Amerimmune Pharmaceuticals, Inc. This transfer purportedly occurred by means of a foreclosure of a security interest given by Amerimmune Pharmaceuticals, Inc. to Maya, LLC, to secure a promissory note in the original principal amount of $120,000. At the time the note and security interest were given and foreclosed, Amerimmune Pharmaceuticals, Inc. had been administratively dissolved by corporate authorities in Colorado. We contend that Amerimmune Pharmaceuticals, Inc. had no ownership interest, and no right or capacity to grant a security interest, in the patents, intellectual property or good will, and that Maya, LLC took nothing by virtue of its purported foreclosure.



The relief requested includes a declaration that would establish our rights in and to the patents, other intellectual property and good will, and would determine the current breach or invalidity of certain agreements, most notably the Conditional License Agreement of February 2000 and an alleged security agreement given by Amerimmune Pharmaceuticals, Inc. to Maya, LLC. In addition, an injunction is sought that would compel Maya, LLC to surrender to us any right it may have in and to the patents, other intellectual property and good will. Compensatory damages in the amount of $898,543 also are sought, as are exemplary damages in twice that amount, costs, attorney's fees, and "other and further" relief.

Rex H. Lewis, a Defendant and former director and C.E.O. of Amerimmune Pharmaceuticals, Inc. has filed a First Amended Cross-Complaint against CytoDyn of New Mexico, Inc., Allen D. Allen, Corinne E. Allen, Ronald J. Tropp, Brian J. McMahon , Daniel M. Stickland, M.D. and unknown others designated as "Does 101-150".

Mr. Lewis alleges, among other things, misrepresentations or failure to make disclosures related to Cytolin and its development, approval and marketing; interference with Amerimmune's attempt to complete clinical research related to Cytolin and Mr. Lewis' actual or prospective business relationships; and libel and slander of Mr. Lewis.

Currently the Cross-Complaint asserts causes of action for fraud, interference with prospective business interests, libel and slander. The requested relief includes damages (alleged to range from $3 million to $20 million or more), punitive damages, costs and other "just and proper" relief.

The outcome of litigation is uncertain. Management believes that an unfavorable result is unlikely with respect to the claims raised by the Complaint, and that the claims raised by the Cross-Complaint are without merit. We are providing a defense for all of the Cross-Defendants.

Discovery is continuing. Trial is scheduled for November 3, 2004.

CytoDyn, Inc., et al. v. Amerimmune, Inc. et al., Case number SC039250, California Superior Court in and for the County of Ventura. The action was filed on April 21, 2004. We and Allen D. Allen are the plaintiffs. The defendants are

Amerimmune Inc., its parent Amerimmune Pharmaceuticals, Inc., and unknown others designated as "Does 1-100".

The action concerns a Conditional License Agreement, dated February 24, 2000, between Allen D. Allen and CytoDyn of New Mexico, Inc., on one hand, and Amerimmune, Inc., on the other. The complaint alleges that the Conditional License Agreement licensed to the defendants technology and patents related to Cytolin and assigned to defendants an FDA approved investigational new drug application related to Cytolin. Further, it alleges that the defendants breached the Conditional License Agreement, resulting in its termination.



The principal relief sought is a declaration that the license granted and the assignment of the technology, patents and drug application made pursuant to the Conditional License Agreement were terminated no later than September 12, 2001, and that Allen and we are the owners of the technology, patents and investigational new drug application, free of any claims of the defendants. Costs, attorney's fees, and other "just and proper" relief also are sought.

The defendants have not yet answered or filed a responsive pleading, although the time for filing an answer or responsive pleading has passed.

The outcome of litigation is uncertain. Management believes an unfavorable outcome is unlikely

Symbion Research International, Inc., v. Amerimmune, Inc. et al., Case number SC035668, California Superior Court in and for the County of Ventura. The Complaint was filed on March 14, 2003. Symbion Research International, Inc is the plaintiff. Amerimmune, Inc. is the remaining defendant. We are not a party to this action, however the action affects intellectual property which is important to us.

The action concerns intellectual property generated in connection with services provided by Symbion with respect to early phase FDA clinical trials of Cytolin, including research data and a patent application filed in 2002. The Complaint alleges that Symbion performed early phase FDA trials (designated in the Complaint as "Phase Ia" and "Phase Ib/II", on behalf of Amerimmune pursuant to an oral agreement, and that Amerimmune failed to pay Symbion for its services, and otherwise breached its obligations under the agreement.

The Complaint asserts causes of action for breach of oral contract, account stated, work and labor done, fraud, and declaratory and injunctive relief. The relief sought includes damages in an amount in excess of $361,771 and a declaration that Symbion is the owner of the intellectual property resulting from the services provided by Symbion.

A default was entered against Amerimmune, Inc. on December 18, 2003. A hearing to "prove up" the default is scheduled for September 20, 2004. The hearing will afford Symbion an opportunity to establish its claim against Amerimmune, Inc. and its damages.

The intellectual property generated in the early phase FDA clinical trials is necessary to obtain approval for, and to conduct, further FDA clinical tests of Cytolin. If a satisfactory result is obtained in this action, we anticipate negotiating an agreement with Symbion that will allow the use in subsequent phases of clinical test of Cytolin of the research data generated in the early phases. If a satisfactory result is not obtained and we otherwise are unable to obtain the right to use the early phase research data, it will be necessary to repeat the early phase clinical trials.

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Item 4. Submission of Matters to a Vote of Security Holders

None.

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

We do not have a public trading market for our common stock. Our common stock does not have a trading symbol. As of August 10, 2004, we have approximately 133 holders of record of our common stock.

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 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 CytoDyn's operations and for expansion of the business.

Securities Authorized for Issuance under Equity Compensation Plans.

The following table sets forth, as of May 31, 2004, all compensation plans under which equity securities of CytoDyn, Inc. are authorized for issuance:

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted average exercise price of outstanding options, warrants and rights (b) | Number of Securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders | None | None | None |
| Equity compensation plans not approved by security holders | 150,000* | $1.00 per share | -0- |
| Total | 150,000 | | |

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*This plan is an individual plan pursuant to an employment agreement between us and Wellington A. Ewen. The plan states he is eligible to receive an option for 50,000 shares that will become exercisable at the end of his first year of employment, exercisable at $0.50 a share, additional options for 50,000 shares

that will become exercisable at the end of his second year of employment, exercisable at $1.00 a share, and options for 50,000 shares that will become exercisable at the end of his third year of employment, exercisable at $1.50 a share. We have adopted no other option plans.

Recent Sales of Unregistered Securities

During the last fiscal quarter of our fiscal year ended May 31, 2004, we issued, in a private offering begun in the third quarter of the fiscal year, an additional 290,000 shares of common stock to 10 individuals bringing the total number of shares issued in the offering to 1,800,000. We relied upon exemptions from registration pursuant to Regulation D, Rule 505 of the Securities Act of 1933. All purchasers were accredited investors as that term is defined in Regulation D and all gave representations that they were purchasing with an investment intent and with no intent to distribute their shares. All share certificates bear restrictive legends.

Also in connection with the private offering, we granted to J.P. Turner & Company LLC, the financial representative in the private offering and an accredited investor, rights to warrants to purchase 426,000 shares of common stock, exercisable over a five year period beginning upon the issuance of the Warrant Agreement, at an exercise price of $0.30 a share. The warrants will be issued pursuant to exemptions from registration pursuant to Section 4(2) of the Securities Act. The warrants provide for, among other things, (1) anti-dilution rights with respect to mergers, dividends, splits, and sale of substantially all assets of the company; (2) a cashless exercise provision; (3) unlimited piggy-back registration rights.

Purchases of Equity Securities

We did not repurchase any of our common stock during the fiscal year ended May 31, 2004.

Item 6. Management's Discussion and Analysis or Plan of Operation

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This annual report and other written and oral statements that we make from time to time contain forward-looking statements that set out anticipated results based on management's plans and assumptions. We have tried, wherever possible, to identify these statements by using words such as "anticipate," "estimate", "expect," "project," "intend," "plan," "believe," "will," and similar expressions in connection with any discussion of future operations or financial performance. In particular, these include statements relating to future actions, prospective products, or product approvals, future performance or results of anticipated products, sales efforts, expenses, interest rates, the outcome of contingencies, such as legal proceedings, and financial results. Among the factors that could cause actual results to differ materially are the following:



- The success of research and development activities and the speed with which regulatory authorizations, pricing approvals, and product launches may be achieved
- Competitive developments affecting our prospective products
- The ability to market successfully prospective products domestically and internationally
- Difficulties or delays in manufacturing
- Trade buying patterns

- The ability to meet generic and branded competition after the loss of patent protection for our prospective products
- Trends toward managed care and health insurance cost containment
- Possible U.S. legislation or regulatory action affecting, among other things, pharmaceutical pricing and reimbursement, including Medicare and Medicaid
- The potential impact of the Medicare Prescription Drug Improvement and Modernization Act of 2003
- Legal defense costs, insurance expense, settlement costs, and the risk of an adverse decision or settlement related to product liability, patent protection, government investigations, and other legal proceedings
- Our ability to protect our patents and other intellectual property, both domestically and internationally
- Interest rate and currency exchange rate fluctuations
- Governmental laws and regulations affecting our operations, including tax obligations
- Changes in generally accepted accounting principles
- Any changes in business, political and economic conditions due to the threat of future terrorist activity in the U.S. and other parts of the world, and related U.S. military action overseas
- Growth in costs and expense

We cannot guarantee that any forward-looking statement will be realized, although we believe we have been prudent in our plans and assumptions. Achievement of future results is subject to risks, uncertainties, and potentially inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors should bear this in mind as they consider forward-looking statements.

We undertake no obligation to update publicly forward-looking statements, whether as a result of new information, future events, or otherwise.

Certain risks, uncertainties, and assumptions are discussed here and under the heading "Risk Factors" in Item1. Business of this report.



This discussion of potential risks and uncertainties is by no means complete, but is designed to highlight important factors that may have an impact on our outlook.

Summary of Significant Accounting Policies

Going Concern
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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. 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 treatment, obtain FDA approval,

outsource manufacturing of the treatment, and ultimately to attain profitability. The Company intends to seek additional funding through equity offerings to fund its business plan. There is no assurance that the Company will be successful.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments with original maturities of three months or less when acquired, to be cash equivalents. The Company had no cash equivalents at May 31, 2004.

Furniture, Equipment and Depreciation

Furniture and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, generally 3 to 7 years. Maintenance and repairs are charged to expense as incurred and major improvements or betterments are capitalized. Gains or losses on sales or retirements are included in the statement of operations in the year of disposition.

Impairment of Long-Lived Assets

The Company evaluates the carrying value of any long-lived assets under the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". SFAS 144 requires impairment losses to be recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted future cash flows estimated to be generated by those assets are less than the assets' carrying amount. If such assets are impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying value or fair value, less costs to sell.



Income Taxes

The Company accounts for income taxes under the provisions of SFAS No. 109, Accounting for Income Taxes (SFAS 109). SFAS 109 requires recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

Earnings (Loss) per Common Share

Basic earnings per share is computed by dividing income available to common shareholders (the numerator) by the weighted-average number of common shares (the denominator) for the period. The computation of diluted earnings per share is similar to basic earnings per share, except that the denominator is increased

to include the number of additional common shares that would have been outstanding if potentially dilutive common shares had been issued.

At May 31, 2004, there was no variance between basic and diluted loss per share as there were no potentially dilutive common shares outstanding.

Overview

CytoDyn, Inc. was incorporated as Rexray Corporation in Colorado in May 2002. We were originally a blank check company created to target companies for merger or acquisition. We issued to our founder, James B. Wiegand 800,000 shares of our common stock in exchange for services valued at $8,000, and thereafter $3,400 for administrative purposes through a private placement equity offering of 340,000 shares in 2002.

In October 2003, we entered into an acquisition agreement with CytoDyn of New Mexico, Inc., the purpose of which was to acquire the license to three patents and foreign counterpart patents. These patents cover the use of monoclonal antibodies to treat patients with Human Immunodeficiency Virus (HIV) by protecting crucial cells of the body's immune system that are otherwise killed by the disease, permitting the immune system to inhibit the disease and protect against the collateral illnesses that commonly accompany the disease.



We are a development stage company. We have not commenced any significant product commercialization and, until we do, we will not generate any significant product revenues. Most of our efforts and resources have been directed to research and development of Cytolin and related technologies. Since inception, we have incurred research and development expenses of $1.3 million. As a result of these research and development costs, we have, since inception, incurred operating losses generating an accumulated deficit of approximately $1.5 million as of May 31, 2004, our fiscal year end. Since October 2003, when we entered into the acquisition agreement with RexRay Corporation, our accumulated net losses have been approximately $362,000. We have had not research and development expenses during the last two fiscal years, as we seek to be able to conduct further trials. We expect to continue to incur operating losses and we expect the accumulated deficit to increase until we are able to market a product and have sales sufficient to support our operations.

The Acquisition Agreement with CytoDyn of New Mexico. Under the October 28, 2003 acquisition agreement with CytoDyn of New Mexico, we:

- Effected a one-for-two reverse split of our common stock,
- Issued to CytoDyn of New Mexico 5,362,640 post-split shares, and
- Amended our articles of incorporation to change our name to CytoDyn, Inc.
- Assumed $161,578 in liabilities related to the assigned assets

As consideration for the issuance of our shares to it, CytoDyn of New Mexico:

- Assigned a Patent License Agreement dated July 1, 1994 between CytoDyn of New Mexico and Allen D. Allen, covering United States patent numbers 5424066, 5651970, and 6534057, and related foreign patents and patents pending, for a method of treating HIV disease with the use of monoclonal antibodies,
- Assigned its trademarks, CytoDyn and Cytolin, and related trademark symbol, and
- Paid $10,000 in cash.

We accounted for the acquisition as a recapitalization of CytoDyn of New Mexico, with Rexray Corporation as the legal surviving entity. For accounting purposes, the acquisition has been treated as a recapitalization of CytoDyn NM, with

Rexray the legal surviving entity. Since Rexray had minimal assets and no operations, the recapitalization has been accounted for as the sale of 890,000 shares of CytoDyn NM common stock for the net assets of Rexray. Therefore, the historical financial information prior to the date of the reverse business acquisition is the financial information of CytoDyn NM.

History of CytoDyn of New Mexico, Inc. CytoDyn of New Mexico has been, since its incorporation in New Mexico in 1994, a research and development company focused on developing a treatment for diseases associated with HIV/AIDS. It has never had operating revenues and has never been profitable. It is in the process of dissolving and has distributed the 5,362,640 shares of common stock that it received from us in the acquisition to its shareholders, pro rata.

COMPANY HISTORY

Our history is of continuing attempts to develop Cytolin and obtain its approval by the FDA, and, as part of that effort, the conveyance, re-conveyance and legal proceedings involving rights related to Cytolin. A chronology follows.



Invention by Allen D. Allen of HIV Treatment. Our president, Allen D. Allen, has been researching treatments for HIV and AIDS since 1987. He identified a family of monoclonal antibodies that protect the CD4 watchdog cells from the CD8 killer cells of the immune systems of people infected with HIV. He received three U.S. patents and additional foreign counterpart patents, now licensed to us, covering the use of these antibodies for treating patients with HIV. Our leading drug candidate, Cytolin, is based on a monoclonal antibody that protects CD4 cells from CD8 cells, thus preventing the weakening of the immune system.

Early study of Cytolin and Patents. In 1993, a small group of scientists and doctors treated six HIV-infected patients with Cytolin. Blood and skin tests of these patients demonstrated that the antibody was producing improvements in the immune function of each patient.

Formation of CytoDyn of New Mexico, Inc. In 1994, CytoDyn of New Mexico, Inc. was incorporated under the laws of New Mexico. CytoDyn of New Mexico developed a commercial method of manufacturing Cytolin and designed a clinical trial. Allen D. Allen and CytoDyn of New Mexico entered into a Patent License Agreement by which Allen granted to CytoDyn of New Mexico an exclusive, worldwide license to use patents, technology and know how related to Cytolin. In 1995, CytoDyn of New Mexico registered in the United States a trademark in the name "Cytolin".

Further Preliminary Studies of Cytolin. In 1995, subacute and acute toxicology studies found Cytolin safe to administer to humans. From 1995 through 1997, a relatively small number of physicians in the United States administered Cytolin to their HIV-infected patients. Four of these physicians permitted an independent Institutional Review Board to inspect the medical records of 188 patients treated with Cytolin once or twice a month over 18 months. Data were recorded and summarized and formed part of an investigational new drug application later submitted by CytoDyn to the FDA.

FDA Approval of Drug Master File for 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 and Vista Biologicals Corporation worked cooperatively to develop the drug master file. In accord 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 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.

FDA Designation of Investigational New Drug Application for Cytolin. In 1996, the FDA also designated our investigational new drug application for Cytolin as BB-IND #6845, and subsequently approved a clinical trial.

Transfer of Cytolin Rights to Three R. In August, 1998, Allen D. Allen and CytoDyn of New Mexico transferred patents, technology, and other rights related to Cytolin to Three R Associates, Inc., a California corporation. The transfer was made pursuant to a "Termination, Sale and Shareholder Agreement" by which:



- CytoDyn of New Mexico relinquished to Three R its exclusive license with respect to Cytolin;
- Allen sold to Three R his U.S. and foreign patent rights, technology and know how related to Cytolin;
- Three R agreed to pay Allen the sum of $1,350,000, subject to increase, in monthly installments over 15 years;
- Three R formed Amerimmune Pharmaceuticals, Inc.; and
- CytoDyn of New Mexico received 4,280,387 shares of the common stock of Amerimmune Pharmaceuticals, Inc.

Contemporaneously, Allen and Three R entered into a letter agreement, by the terms of which Allen was to provide consulting services and Three R was to pay Allen an annual fee initially set at ten thousand dollars ($10,000.00) and increasing 5% per annum thereafter. The term of the agreement was fifteen years, subject to the right of Three R, after the first year, to terminate it upon one year's written notice.

Transfer of Cytolin Rights to Amerimmune, Inc. A few months later, in October, 1998, the technology, patents and other rights in Cytolin were transferred again, this time to Amerimmune, Inc., a wholly owned subsidiary of Amerimmune Pharmaceuticals, Inc., which in turn was an affiliate of Three R. The transfer was made pursuant to a "Patent and Trademark License Agreement" by which:

- Three R licensed to Amerimmune, Inc. the Cytolin related rights recently acquired from Allen D. Allen and CytoDyn of New Mexico;
- Three R licensed to Amerimmune Pharmaceuticals, Inc. the trademarked name "Cytolin";
- Amerimmune Pharmaceuticals, Inc. issued to Three R 21,936,981 shares of the common stock of Amerimmune Pharmaceuticals Inc.; and
- Amerimmune Pharmaceuticals, Inc. assumed Three R's obligations to Allen.

Conditional Transfer of Cytolin Rights. In February, 2000, Allen D. Allen and CytoDyn of New Mexico conditionally transferred Cytolin rights to Amerimmune, Inc. under a "Conditional License Agreement", by which:

- Allen and CytoDyn of New Mexico granted to Amerimmune, Inc. a deemed, exclusive, worldwide license of Technology and Marks, effective if the August 1998 transfer to Three R were or became ineffective or inoperative;
- Amerimmune, Inc. agreed to protect patent and trademark rights;
- Amerimmune, Inc. agreed to pay to Allen certain sums owed to him by Three R;
- Allen and CytoDyn of New Mexico agreed to surrender certain common

stock in Amerimmune, Inc. or Amerimmune Pharmaceuticals, Inc. that they might recover from Three R;

- Amerimmune, Inc. agreed to maintain quality standards related to products involving the Technology or Marks; and
- Amerimmune, Inc. granted Allen and CytoDyn of New Mexico inspection rights related to quality standards.



Transfer of Cytolin Rights to Three R Effectively Rescinded. In 2000, disputes arose regarding the validity and enforceability of the 1998 Termination, Sale and Shareholder Agreement. In March 2000, CytoDyn of New Mexico and Allen D. Allen commenced an arbitration and in August 2000, Three R filed a lawsuit to address matters in dispute. In May 2001, CytoDyn of New Mexico, Allen and Three R settled their disputes, including those being arbitrated or litigated. The settlement was embodied in a "Settlement and Release Agreement", by which:

- Three R assigned to Allen and CytoDyn of New Mexico its rights in the August 1998 Termination, Sale and Shareholders Agreement;
- Three R agreed that all rights in the Technology and Marks which were the subject of the August 1998 Termination, Sale and Shareholders Agreement reverted to and were acquired by Allen and CytoDyn of New Mexico;
- Three R assigned to Allen and CytoDyn of New Mexico its rights in the October 1998 Patent and Trademark License Agreement with Amerimmune; and
- The parties mutually released one another.

Three R principal Lois Rezler has been indicted by a federal grand jury in San Francisco on six counts of using the mails to defraud Mr. Allen and Amerimmune. The trial was originally scheduled for September 27, 2004 but has been rescheduled until March 2005.

Phase Ia Clinical Trial of Cytolin. In 2001, a Phase Ia clinical trial of Cytolin was completed by Symbion Research International, Inc., under contract with Amerimmune Pharmaceuticals, Inc., pursuant to the FDA approved investigational new drug application, BB-IND #6845. The Phase Ia study, conducted in 13 subjects suffering from HIV/AIDS, found Cytolin to be safe and well tolerated across a narrow dose range. The initial safety study, which consisted of two single escalating doses of 0.05mg and 0.1mg/kg body weight, affirmed the safety and tolerability of the drug in these lower dose groups, as well as preliminary efficacy in lowering the concentration of HIV and increasing T-cell counts in the study's patient population with no serious or severe adverse events reported.

Phase Ib Clinical Trial of Cytolin. In 2002, following the completion with favorable early results of the Phase Ia clinical trial, a Phase Ib clinical trial was completed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and activity of escalating doses of Cytolin in adults with HIV infection.

Conditional Transfer of Cytolin Rights to Amerimmune Claimed to be Void. In August 2001, Allen D. Allen and CytoDyn of New Mexico gave notice of alleged breaches by Amerimmune, Inc. of its obligations under the February 2000 Conditional License Agreement and thereafter asserted that the agreement had terminated. The alleged breaches by Amerimmune, Inc. included refusal to permit inspection of the manufacturing processes used to produce the product used in the Phase I clinical trials, failure to make required payments to Allen, failure to maintain U.S. and foreign patents and failure to recover the remaining stock held by Three R. CytoDyn of New Mexico also claimed to be entitled to recover damages resulting from various acts, omissions and contractual breaches by

Amerimmune, Inc. and its officers and directors. Litigation ensued and is continuing in two actions in the California Superior Court, one in Los Angeles County in a case originally captioned CytoDyn of New Mexico, Inc., v. Amerimmune Pharmaceuticals, Inc. et al., Case number BC290154 and the other in Ventura County, in a case captioned CytoDyn, Inc., et al. v. Amerimmune, Inc. ., Case number SC039250. Please see the discussion entitled "Legal Proceedings" at Part I, Item 3.

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Formation of Rexray Corporation. In May 2002, Rexray Corporation was organized under the laws of Colorado as a blank check company.

Litigation Concerning Ownership of Results of Early Phase Clinical Trials of Cytolin. In March 2003, Symbion Research International, Inc. sued Amerimmune, Inc. and Rex Lewis, seeking, among other things, a declaration that Symbion is the owner of the intellectual property resulting from the services provided by Symbion in the early phase FDA clinical trials, designated in the lawsuit as "Phase Ia" and "Phase Ib/II". The intellectual property is alleged to include a patent application filed in 2002. The suit was filed in the California Superior Court in and for Ventura County, and is captioned Symbion Research International, Inc. v. Amerimmune Inc., et al., Case No. SC035668. We are not a party to the suit, but its results could affect our ability to proceed with clinical trials of Cytolin. Please see "Legal Proceedings" at Part I, Item 3.

Purported Transfer of Cytolin Rights by Amerimmune to Maya, LLC. We have been informed that in April 2003, a purported transfer of Cytolin rights was made to Maya, LLC, a Nevada entity controlled by Rex Lewis, the former Chief Executive Officer of Amerimmune, Pharmaceuticals, Inc.. The purported transfer reportedly occurred by means of a foreclosure of a security interest given by Amerimmune Pharmaceuticals, Inc. to Maya, LLC, to secure a promissory note in the original principal amount of $120,000. At the time the security interest was given and foreclosed, Amerimmune Pharmaceuticals, Inc. had been administratively dissolved by corporate authorities in Colorado: to date, it has not been reinstated. We are challenging the validity of this purported transfer in a legal action pending in the California Superior Court in and for the County of Los Angeles, originally captioned CytoDyn of New Mexico, Inc., v. Amerimmune Pharmaceuticals, Inc. et al., Case number BC290154. Please see the discussion entitled "Legal Proceedings" at Part I, Item 3.

Acquisition by Rexray of Assets of CytoDyn of New Mexico; Name Change. In October, 2003, Rexray and CytoDyn of New Mexico entered into an acquisition agreement, by which:

- Rexray effected a one-for-two reverse split of its common stock;
- Rexray issued to CytoDyn of New Mexico 5,362,640 post split shares of its common stock;
- Rexray assumed $161,578 in liabilities related to assigned assets
- CytoDyn of New Mexico assigned to Rexray its rights under the 1994 Patent License Agreement with Allen D. Allen,
- CytoDyn of New Mexico assigned to Rexray its trademarks CytoDyn and Cytolin and related trademark symbol; and
- CytoDyn of New Mexico paid to Rexray $10,000 in cash.

In addition, Rexray amended its articles of incorporation to change its name to CytoDyn, Inc. Please see "Description of Business" at Part I, Item 1.

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Plan of Operation

During the next 12 months, our objectives are:

- To continue our clinical trials of Cytolin,
- To continue our efforts to protect our technology by obtaining additional patents in The United Kingdom and the European Union,
- To conclude pending litigation with respect to the rights to our technology,
- To develop an established market for our shares, and raise funds to support our research and development efforts, the clinical trials relating to Cytolin, and our general and administrative expenses, and
- To explore joint venture arrangements for other possible pharmaceutical products.

Continuing Clinical Trials. As we discuss in Item 1, Business, Phase I clinical trials were conducted by Symbion Research International under the sponsorship of Amerimmune, Inc. during 2002. We believe that the data from these trials support approval by the FDA of Phase II trials, and we intend to seek approval for the Phase II trials. As we have discussed in the section entitled "Legal Proceedings," we cannot make application for the Phase II trials until litigation concerning the right to the data collected during the Symbion Phase I trials is concluded. If we have the right to those data, we will proceed with our application for Phase II trials; if we do not, we will need to repeat the Phase I trials. We expect a decision on our right to use the Phase I data in the next four months, but cannot be sure that we will have one within our time frame. Please see our discussion of the litigation below. If the litigation is concluded in our favor, we plan to submit our application for approval of Phase II/III pivotal studies. If the Phase II/III study is approved, we expect it, together with the pre-Phase II/III efforts, to cost an estimated $2,050,000 to $3,350,000, plus estimated manufacturing and supply costs of $350,000 to $400,000. These trials can take anywhere from 29 to 42 months. Until we have met with the FDA, which we plan to do within the next 6 months, we cannot be certain what additional studies, assuming that Phase II/III study supports the efficacy and safety of Cytolin, will be required to receive marketing approval. If we have to repeat the Phase I trials, we expect that our new trials will take from six months to one year and cost an estimated $750,000 to $1,000,000, adding significant time and expense to our proposed timeline for marketability of Cytolin.

If we are unable to complete clinical trials on a timely basis, with favorable results, our costs will increase significantly and we may not have enough capital to support further research and development and continue in business. Also, if we incur significant delays in being able to market our product, even if we are ultimately able to do so, we will be delayed in earning revenues and probably will require additional financing to continue in business. Please see the section entitled "Risk Factors" under Item 1. Business.

Patents

During fiscal year 2004, several European patents were granted with respect to our technology. The new patents are covered by our License Agreement with Allen D. Allen, our president. These patents are designated European Patent No. 94



912826.8, for the United Kingdom, Germany, France, Switzerland, Italy, the Netherlands, Portugal, Spain, and Sweden, and are the counterparts to our United States Patent No. 5424066. Patents are pending in those same countries which, if granted, will be the equivalent of our United States Patent No. 5651970. We estimate the costs associated with these pending patents to be approximately $65,000, including amounts we have already spent. We may file additional patents

during the current fiscal year if our research and development efforts warrant them, but we do not have any such potential patents identified at this time.

Litigation

For a thorough discussion of our pending litigation, please see the section entitled "Legal Proceedings."

We are a plaintiff in two pending cases, and intellectual property significant to us is the subject of a third case to which we are not a party. As we have discussed earlier, the timing and outcome of these cases will have a significant impact on our ability to continue clinical trials of Cytolin in the time frame we estimate and in line with our estimated costs. We are a plaintiff in each of CytoDyn of New Mexico, Inc. et al., v. Amerimmune Pharmaceuticals, Inc. et al., Case number BC 290154, California Superior Court in and for the County of Los Angeles and CytoDyn, Inc., et al. v. Amerimmune, Inc. et al., Case number SC039250, California Superior Court in and for the County of Ventura. These cases involve our rights to the patented technology underlying Cytolin and any other products we might wish to develop. If the timing or outcomes of these cases are unfavorable, we may be required to suspend or discontinue our operations, or to incur substantial additional costs and delays. The third case, Symbion Research International, Inc., v. Amerimmune, Inc. et al., Case number SC035668, California Superior Court in and for the County of Ventura, affects research data and other intellectual property generated in connection with early phase clinical trials of Cytolin. If a favorable result is obtained, we will be required to negotiate an agreement permitting use of the research data in later phase clinical tests of Cytolin. If the outcome of this case is unfavorable, and we otherwise are unable to obtain the right to use the research data, it will be necessary to repeat the early phase clinical trials. We expect to devote significant effort and incur substantial expense in connection with the two cases to which we are parties, and to monitor the third case.

Establishing a Market and Obtaining Funding

We will require funding during the 2005 fiscal year in order to continue our research and development efforts and to stay in business. The amount of that funding is directly related to the clinical trials we are able to conduct and the amounts we will need for our company operations.

We filed a registration statement on Form SB-2 on June 1, 2004, covering the sale of 250,000 shares of common stock at $0.75 per share, for total proceeds of $187,500, to be used primarily for general and administrative expense, SEC compliance costs, and legal and accounting fees. This registration statement has not yet gone effective, and we cannot assure that it will or that the shares that would be offered would sell. We intend, if this offering does go effective and if the shares sell, to seek an established market for our securities on an established quotation system, such as the NASD over-the-counter bulletin board, which we hope would give us a wider base of investors. We may not, however, be able to achieve our goals.



In connection with our private placement of securities in late 2003 and early 2004, we granted certain registration rights to the purchasers of our common stock and to our financial representative. The holders of these shares may demand that we register their shares for sale. We estimate that such a registration could cost us approximately $30,000, for which we would have to find funding.

In addition to operating funds, we will need from approximately $750,000 to $3,750,000 for research and development, including clinical trials, and

manufacturing and supply costs, depending upon whether we are approved by the FDA to conduct a Phase II/III pivotal study, or must repeat the Phase I clinical trial.

We do not have any of this funding arranged or secured, and we do not yet have plans for raising the funding we require. We anticipate that we will seek the funding through further equity offerings, either by private placement or by registered offering, or by possible joint venture arrangements with other parties. If we are unable to secure the necessary funding, we will not be able to conduct our research and development activities or to continue in business.

Exploring Joint Ventures

While we continue to pursue FDA approval of our Cytolin product, we are also considering entering into joint ventures to develop other types of products. We have, for instance, entered into a nondisclosure agreement with another development stage biotech company to discuss the possibility of the joint development of drugs to treat neuropsychiatric diseases or disorders. These discussions are in the early stages and we do not know if we will enter into a joint venture or other arrangement with this company or if any products might ensue from our efforts.

We may also pursue joint ventures or other arrangements to obtain funding for our Cytolin-related endeavors, but we have not pursued this possibility and do not have any prospects at this time.

Other Matters

We do not expect, in the next 12 months, to make any significant expenditures for equipment, nor do we expect to make any significant changes in the number of employees that we have. We have no off-balance sheet arrangements.

During the fiscal year ended May 31, 2004, we expended $235,455 in professional fees, consisting of $45,000 in consulting fees paid to our former president and founder, $190,747 in legal fees and professional fees incurred in connection with our private placement of 1,800,000 common shares, our additional patent protection filings, and litigating our pending lawsuits, and $5,208 in accounting and auditing fees. For the year ended May 31, 2004, $61,285 in legal fees was owed to our director, Ronald Tropp. We expect to incur similar fees in the current fiscal year, based on our research and development efforts, our need for additional capital, and continuing litigation.



Item 7. Financial Statements

CYTODYN, INC.
(A Development Stage Company)
Index to Financial Statements

## Report of Independent Auditors

To the Board of Directors and Shareholders
CytoDyn, Inc.:

We have audited the accompanying balance sheet of CytoDyn, Inc. (a development stage company) as of May 31, 2004, and the related statements of operations, changes in shareholders' deficit, and cash flows for the years ended May 31, 2004 and 2003, and the period from October 28, 2003 through May 31, 2004 (development stage). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of CytoDyn, Inc. as of May 31, 2004, and the results of its operations and its cash flows for the years ended May 31, 2004 and 2003, and the period from October 28, 2003 through May 31, 2004 (development stage) in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered significant operating losses since inception, which raises a substantial doubt about its ability to continue as a going concern. Management's plans in regard to this matter are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Cordovano and Honeck, P.C.
Denver, Colorado
August 20, 2004



CYTODYN, INC.
(A Development Stage Company)
Balance Sheet

May 31, 2004

Assets

| | |
|---|---|
| Current Assets: | |
| Cash | $ 186,964 |
| Prepaid expenses | 16,302 |
| Total current assets | 203,266 |
| Furniture and equipment, less accumulated depreciation of $204 | 3,131 |
| Deposit | 495 |
| | $ 206,892 |

Liabilities and Shareholders' Deficit

| | |
|---|---|
| Liabilities: | |
| Accounts payable | $ 118,686 |
| Accrued liabilities | 16,632 |
| Indebtedness to related parties (Note 2) | 71,694 |
| Total liabilities | 207,012 |
| Commitments and contingencies (Note 6) | -- |
| Shareholders' deficit (Note 4): | |
| Preferred stock, no par value; 5,000,000 shares authorized, -0- shares issued and outstanding | -- |
| Common stock, no par value; 25,000,000 shares authorized, 8,069,307 shares issued and outstanding | 1,916,334 |
| Additional paid-in capital | 23,502 |
| Accumulated deficit | (1,601,912) |
| Deficit accumulated during development stage | (338,044) |
| Total shareholders' deficit | (120) |
| | $ 206,892 |

See accompanying notes to financial statements.



CYTODYN, INC.
(A Development Stage Company)
Statements of Operations

| | For the Year Ended May 31, | | October 28, 2003 Through May 31, |
|---|---|---|---|
| | 2004 | 2003 | 2004 |
| Operating expenses: | | | |
| General and administrative (Note 8) .... | $ 357,246 | $ 30,229 | $ 337,730 |
| Depreciation ..... | 204 | -- | 204 |
| Total operating expenses | 357,450 | 30,229 | 337,934 |
| Operating loss ..... | (357,450) | (30,229) | (337,934) |
| Interest income ..... | 343 | -- | 343 |
| Interest expense ..... | (453) | -- | (453) |
| Loss before income taxes | (357,560) | (30,229) | (338,044) |
| Income tax provision (Note 5) ..... | -- | -- | -- |
| Net loss ..... | $ (357,560) | $ (30,229) | $ (338,044) |
| Basic and diluted loss per share ..... | $ (0.05) | $ (0.01) | |
| Basic and diluted weighted average common shares outstanding ..... | 6,557,362 | 5,362,640 | |

See accompanying notes to financial statements.



CYTODYN, INC.
(A Development Stage Company)
Statement of Changes in Shareholders' Deficit Deficit

| | Preferred Stock | Common Stock |
|---|---|---|

| | Shares | Amount | Shares | Amo |
|---|---|---|---|---|
| Balance at June 1, 2002 | -- | $ -- | 5,362,640 | $ 1,41 |
| Capital contributions by president (Note 2) | -- | -- | -- | |
| Net loss, year ended May 31, 2003 | -- | -- | -- | |
| Balance at May 31, 2003 | -- | -- | 5,362,640 | 1,41 |
| October 2004, stock issued to acquire the net assets of Rexray Corporation (Note 1) | -- | -- | 890,000 | |
| Balance at October 28, 2003, following reverse business combination | -- | -- | 6,252,640 | 1,42 |
| February through April 2004, sale of common stock less offering costs of $54,000 ($.30/share) (Note 4) | -- | -- | 1,800,000 | 48 |
| February 2004, shares issued to former officer as payment for working capital advance ($.30/share) (Note 2) | -- | -- | 16,667 | |
| Net loss, year ended May 31, 2004 | -- | -- | -- | |
| Balance at May 31, 2004 | -- | $ -- | 8,069,307 | $ 1,91 |

| | Accumulated During Development Stage | Total |
|---|---|---|
| Balance at June 1, 2002 | -- | $ (125,373) |
| Capital contributions by president (Note 2) | -- | 14,500 |
| Net loss, year ended May 31, 2003 | -- | (30,229) |
| Balance at May 31, 2003 | -- | (141,102) |
| October 2004, stock issued to acquire the net assets of Rexray Corporation (Note 1) | -- | 7,542 |
| Balance at October 28, 2003, following reverse business combination | -- | (133,560) |
| February through April 2004, sale of common stock less offering costs of $54,000 ($.30/share) (Note 4) | -- | 486,000 |
| February 2004, shares issued to former officer as payment for working capital advance ($.30/share) (Note 2) | -- | 5,000 |
| Net loss, year ended May 31, 2004 | (338,044) | (357,560) |

| | | |
|---|---|---|
| Balance at May 31, 2004 ..... | (338,044) | $ (120) |

See accompanying notes to financial statements.



CYTODYN, INC.
(A Development Stage Company)
Statement of Cash Flows

| | For the Year Ended May 31, | | October 28, 2003 Through May 31, |
|---|---|---|---|
| | 2004 | 2003 | 2004 |
| Cash flows from operating activities: | | | |
| Net loss ..... | $ (357,560) | $ (30,229) | $ (338,044) |
| Adjustments to reconcile net loss to net cash used by operating activities: | | | |
| Depreciation ..... | 204 | -- | 204 |
| Changes in current assets and liabilities: | | | |
| Increase in prepaid expenses ..... | (16,302) | -- | (16,302) |
| Increase in deposits ..... | (495) | -- | (495) |
| Increase in accounts payable and accrued liabilities ..... | 14,020 | -- | (2,258) |
| Net cash used in operating activities ..... | (360,133) | (30,229) | (356,895) |
| Cash flows from investing activities: | | | |
| Equipment purchases ..... | (3,335) | -- | (3,335) |
| Net cash used in investing activities ..... | (3,335) | -- | (3,335) |
| Cash flows from financing activities: | | | |
| Capital contributions by president (Note 2) ... | -- | 14,500 | -- |
| Proceeds from notes payable issued to related parties (Note 2) ..... | 111,194 | 10,500 | 111,194 |
| Repayment of notes payable to related parties (Note 2) ..... | (50,000) | -- | (50,000) |
| Proceeds from the sale of common stock (Note 4) | 540,000 | -- | 540,000 |
| Payment of offering costs (Note 4) ..... | (54,000) | -- | (54,000) |
| Net cash provided by financing activities ..... | 547,194 | 25,000 | 547,194 |
| Net change in cash ..... | 183,726 | (5,229) | 186,964 |

| | | | |
|---|---|---|---|
| Cash, beginning of period ..... | 3,238 | 8,467 | -- |
| Cash, end of period ..... | $ 186,964 | $ 3,238 | $ 186,964 |
| Supplemental disclosure of cash flow information: | | | |
| Income taxes ..... | $ -- | $ -- | $ -- |
| Interest ..... | $ 453 | $ -- | $ 453 |
| Non-cash investing and financing transactions: | | | |
| Net assets acquired in exchange for common stock in CytoDyn/Rexray business combination (Note 1) ..... | $ 7,542 | $ -- | $ 7,542 |
| Common stock issued to former officer to repay working capital advance (Note 2) ... | $ 5,000 | $ -- | $ 5,000 |

See accompanying notes to financial statements.



CYTODYN, INC.
(A Development Stage Company)
Notes to Financial Statements

(1) Summary of Significant Accounting Policies

Organization and Basis of Presentation

CytoDyn, Inc. (the "Company") was incorporated under the laws of Colorado on May 2, 2002 under the name Rexray Corporation ("Rexray"). The Company entered the development stage effective October 28, 2003 and follows Statements of Financial Accounting Standards ("SFAS") No. 7 "Accounting and Reporting by Development Stage Enterprises".

The Company plans to develop therapeutic agents for use against the disease associated with Human Immunodeficiency Virus ("HIV"). The Company intends to develop and obtain FDA approval for the use of monoclonal antibodies to treat patients with HIV by protecting the cells of the body's immune system that are otherwise killed by the disease. The Company is continuing the research and development of a treatment for HIV, using technology licensed to it by the Company's president, and may either repeat Phase I trials, if necessary for non-clinical reasons, or with FDA approval, conduct a Phase II/III pivotal study. The Company has not derived any revenues from the licensed technology, but the Company is planning to pursue further clinical trials.

On October 27, 2003, Rexray changed its name to CytoDyn, Inc.

Acquisition Agreement

On October 28, 2003, Rexray, the former Securities and Exchange Commission ("SEC") Registrant, entered into an Acquisition Agreement (the "Agreement") with CytoDyn of New Mexico, Inc. ("CytoDyn NM"), a New Mexico corporation. Under the terms of the Agreement, Rexray agreed to acquire some of the assets of CytoDyn NM in exchange for 5,362,640 shares of its common stock. Following the acquisition, CytoDyn NM held approximately 85.8 percent of the Company's

outstanding common stock, resulting in a change in control. However, for accounting purposes, the acquisition has been treated as a recapitalization of CytoDyn NM, with Rexray the legal surviving entity. Since Rexray had minimal assets and no operations, the recapitalization has been accounted for as the sale of 890,000 shares of CytoDyn NM common stock for the net assets of Rexray. Therefore, the historical financial information prior to the date of the reverse business acquisition is the financial information of CytoDyn NM.

Under the terms of the Agreement, CytoDyn NM:

- Assigned the patent license agreement between CytoDyn NM and Allen D. Allen covering United States patent numbers 5424066, 5651970, and 6534057, and related foreign patents and patents pending, for a method of treating HIV disease with the use of monoclonal antibodies;
- Assigned its trademarks, CytoDyn and Cytolin, and related trademark symbol; and
- Paid $10,000 in cash

In consideration for the above, the Registrant:

- Effected a one-for-two reverse split of its common stock;
- Issued 5,362,640 shares of its common stock to of CytoDyn NM;
- Amended its Articles of Incorporation to change its name to CytoDyn, Inc.; and
- Accepted $161,578 in liabilities related to the assigned assets



CYTODYN, INC.
(A Development Stage Company)
Notes to Financial Statements

Going Concern
---

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. 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 treatment, obtain FDA approval, outsource manufacturing of the treatment, and ultimately to attain profitability. The Company intends to seek additional funding through equity offerings to fund its business plan. There is no assurance that the Company will be successful.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments with original maturities of three months or less when acquired, to be cash equivalents. The Company had no cash equivalents at May 31, 2004.

Furniture, Equipment and Depreciation

Furniture and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, generally 3 to 7 years. Maintenance and repairs are charged to expense as incurred and major improvements or betterments are capitalized. Gains or losses on sales or retirements are included in the statement of operations in the year of disposition.

Impairment of Long-Lived Assets

The Company evaluates the carrying value of any long-lived assets under the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". SFAS 144 requires impairment losses to be recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted future cash flows estimated to be generated by those assets are less than the assets' carrying amount. If such assets are impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying value or fair value, less costs to sell.

Income Taxes

The Company accounts for income taxes under the provisions of SFAS No. 109, Accounting for Income Taxes (SFAS 109). SFAS 109 requires recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.





Earnings (Loss) per Common Share

Basic earnings per share is computed by dividing income available to common shareholders (the numerator) by the weighted-average number of common shares (the denominator) for the period. The computation of diluted earnings per share is similar to basic earnings per share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if potentially dilutive common shares had been issued.

At May 31, 2004, there was no variance between basic and diluted loss per share as there were no potentially dilutive common shares outstanding.

Financial Instruments

At March 31, 2004, the fair value of the Company's financial instruments approximate fair value due to the short-term maturity of the instruments.

(2) Related Party Transactions

During February 2004, the Company issued 16,667 shares of its common stock as payment for a $5,000 advance from a former officer ($.30 per share).

During the year ended May 31, 2003, the Company's president contributed $14,500 for working capital. This amount is included in the accompanying financial statements as Additional paid-in capital.

During the years ended May 31, 2004 and 2003, two officers advanced the Company a total of $111,194 and 10,500, respectively. During January 2004, the Company issued the officers promissory notes for the balances owed. The notes are due on demand and carry no interest rate. During February 2004, the Company repaid one officer $50,000. The remaining balance due of $71,694 is included in the accompanying financial statements as Indebtedness to related parties.

(3) Note Payable

On October 28, 2003, the Company issued a $30,000 promissory note to its former president as payment for services related to the CytoDyn NM Acquisition Agreement. The note carried a five percent interest rate and was due on January 27, 2004. The Company repaid the $30,000 note, and $442 in accrued interest, in February 2004.

(4) Shareholders' Equity

Preferred Stock

The Board of Directors is authorized to issue shares of preferred stock in series and to fix the number of shares in such series as well as the designation, relative rights, powers, preferences, restrictions, and limitations of all such series. The Company had no preferred shares issued and outstanding at May 31, 2004.





Common Stock Sales

From February 2004 through April 2004, the Company sold 1,800,000 shares of its common stock at $.30 per share for net proceeds totaling $486,000, after deducting offering costs of $54,000. The Company relied upon exemptions from registration believed by it to be available under federal and state securities laws in connection with the sales.

The Company has filed a Registration Statement on Form SB-2 with the SEC to offer for sale 250,000 common shares at a price of $.75 per share. To date, the SEC has not declared the Form SB-2 effective.

Stock Options - Employees

During May 2004, the Company granted 150,000 common stock options to an officer with exercise prices ranging form $.50 to $1.50 per share. The Company's common stock had no traded market value on the date of grant. The market value of the

stock was determined to be $.30 per share base on contemporaneous sales of common stock to unrelated third party investors. The weighted average exercise price and weighted average fair value of these options as of May 31, 2004 were $1.00 and $.-0-, respectively. 50,000 options vest on May 10, 2005, an additional 50,000 options vest on May 1, 2006, and the final 50,000 options vest on May 1, 2007.

Pro forma information regarding net income and earnings per share is required by SFAS 123 as if the Company had accounted for its granted stock options under the fair value method of that Statement. The fair value for the options granted during the fiscal year ended May 31, 2004 was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

| | |
|---|---|
| Risk-free interest rate..... | 3.00% |
| Dividend yield..... | 0.00% |
| Volatilitv factor..... | 0.00% |
| Weighted average expected life..... | 3 years |

The Black-Scholes options valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock options. Although the above options were determined to have $-0- fair value, the Company has presented the pro forma net loss and pro forma basic and diluted loss per common share using the assumptions noted above.



CYTODYN, INC.
(A Development Stage Company)
Notes to Financial Statements

| | For the Years Ended May 31, | |
|---|---|---|
| | 2004 | 2003 |
| Net loss, as reported ..... | $(357,560) | $ (30,229) |
| Pro forma net loss ..... | $(357,560) | $ (30,229) |
| Basic and diluted net loss per common share, as reported ..... | $ (0.05) | $ (0.01) |
| Pro forma basic and diluted net loss per common share ..... | $ (0.05) | $ (0.01) |

The following schedule summarizes the changes in the Company's outstanding stock options:

Options Outstanding and Exercisable

| | Number of Shares | Exercise Price Per Share | Weighted Average Exercise Price Per Share |
|---|---|---|---|
| Balance at May 31, 2002 | - | $0.00 | $ - |
| Options granted | - | $0.00 | $ - |
| Options exercised | - | $0.00 | $ - |
| Options expired | - | $0.00 | $ - |
| Balance at May 31, 2003 | - | $0.00 | $ - |
| Options granted | 150,000 | $0.50 to $1.50 | $ 1.00 |
| Options exercised | - | $0.00 | $ - |
| Options expired | - | $0.00 | $ - |
| Balance at May 31, 2004 | 150,000 | $0.50.to $1.50 | $ 1.00 |

(5) Income Taxes

A reconciliation of the U.S. statutory federal income tax rate to the effective tax rate is as follows:

| | For the Year Ended May 31, | |
|---|---|---|
| | 2004 | 2003 |
| U.S. Federal statutory graduated rate | 34.00% | 15.00% |
| State income tax rate, net of federal benefit | 3.17% | 4.08% |
| Net operating loss for which no tax benefit is currently available | 37.17% | 19.08% |
| | 0.00% | 0.00% |





At May 31, 2004, federal and state deferred tax assets consisted of a net tax asset of $140,338, which was fully allowed for in the valuation allowance of $140,338. The valuation allowance offsets the net deferred tax asset for which there is no assurance of recovery. The change in the valuation allowance for the years ended May 31, 2004 and 2003 totaled $134,570 and $5,768, respectively. The current tax benefit also totaled $134,570 and $5,768 for the years ended May 31, 2004 and 2003, respectively. The net operating loss carryforward expires through the year 2024.

The valuation allowance will be evaluated at the end of each year, considering positive and negative evidence about whether the deferred tax asset will be realized. At that time, the allowance will either be increased or reduced; reduction could result in the complete elimination of the allowance if positive evidence indicates that the value of the deferred tax assets is no longer impaired and the allowance is no longer required.

At October 28, 2003, the date of the Acquisition Agreement, Rexray had an accumulated deficit of $18,639 and CytoDyn NM had an accumulated deficit of $1,601,912. As a result of the reverse business combination accounting required for the acquisition, the accumulated deficit of CytoDyn NM is the historical information reported in the financial statements. However, because of the ownership change, the Company's tax net operating loss carryforwards generated prior to the ownership change may be subject to an annual limitation, which could reduce or defer the utilization of these losses.

(6) Commitments and Contingencies

The Company entered into a noncancellable operating lease for office space that commenced November 14, 2003 and expires November 30, 2004. Payments required under the operating lease are $495 per month.

The Company has committed to grant a financial representative warrants to purchase 426,000 shares of the Company's common stock . The warrants will carry an exercise price of $.30 per share and will expire after five years from the date of grant. To date, the warrants have not been exercised.

The Company has signed Personal Service Agreements with three officers that cover the two years ended May 31, 2005 and 2006. Under the terms of the agreements, if an officer is terminated by the Company without cause or terminates service for good cause within six months of a change in control, the Company is required to pay the officer the balance of the base salary for the term of the agreement and for an additional 12 months after the expiration of the term.

(7) Concentrations of Credit Risk

The Company has concentrated its credit risk for cash by maintaining deposits in financial institutions, which may at times exceed the amounts covered by insurance provided by the United States Federal Deposit Insurance Corporation ("FDIC"). The loss that would have resulted from that risk totaled $85,954 at May 31, 2004, for the excess of the deposit liabilities reported by the financial institutions over the amount that would have been covered by FDIC. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk to cash.

(8) General and Administrative Expenses

General and administrative expenses consist of the following:





| | For the Year Ended May 31, | | October 28, 2003 Through May 31, |
|---|---|---|---|
| | 2004 | 2003 | 2004 |
| Salaries and payroll taxes... | $ 96,102 | $ -- | $ 96,102 |
| Legal ..... | 163,477 | 13,213 | 157,472 |
| Consulting ..... | 35,000 | -- | 25,000 |

| | | | |
|---|---|---|---|
| Other professional fees ..... | 11,559 | -- | 16,059 |
| Patent fees ..... | 20,919 | 1,204 | 20,919 |
| Office, travel, and other.... | 30,189 | 15,812 | 26,992 |
| | $ 357,246 | $ 30,229 | $ 342,544 |

(9) Litigation

CytoDyn NM (predecessor in interest to CytoDyn, Inc.) filed a lawsuit against Amerimmune Pharmaceuticals, Inc. ("Amerimmune") and its former officers and directors in California Superior Court in Los Angeles County. CytoDyn NM filed the action claiming unjust enrichment. A trial date of November 3, 2004 has been set. The former CEO of Amerimmune, Rex Lewis filed a counter claim against the former officers and directors of CytoDyn of NM. Some of these officers and directors are also officers and directors of the Company. The Company's management believes the chance of an unfavorable outcome is remote.

CytoDyn, Inc., et al. v. Amerimmune, Inc. et al., Case number SC039250, California Superior Court in and for the County of Ventura. The action was filed on April 21, 2004. The Company is seeking declaratory relief that the February 2000 Conditional License Agreement with CytoDyn NM was breached and terminated no later than September 2001. The company's management believes the chance of an unfavorable outcome is remote.



Item 8. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 8A. Controls and Procedures.

Annual Controls Evaluation and Related CEO and CFO Certifications

As of the end of the period covered by this Annual Report on Form 10-KSB, we evaluated the effectiveness of the design and operation of "disclosure controls and procedures" (Disclosure Controls). The controls evaluation was done under the supervision and with the participation of management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective in alerting them in a timely manner to material information required to be disclosed in our periodic reports filed with the SEC.

Attached as Exhibits to this Annual Report on Form 10-KSB are certifications of the CEO (Exhibit 31.1) and the CFO (Exhibit 31.2), which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934 (the Exchange Act). This Controls and Procedures section includes the information concerning the controls evaluation referred to in the certifications and it should be read in conjunction with the certifications for a more complete understanding of the topics presented.

Disclosure Controls and Internal Controls

Disclosure Controls are procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, such as this Annual Report, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms. Disclosure Controls are also designed to ensure that the information is accumulated and communicated to our management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

Internal controls over financial reporting (Internal Controls) are procedures which are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of CytoDyn; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of CytoDyn are being made only in accordance with authorizations of management and directors of CytoDyn; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the CytoDyn assets that could have a material effect on the financial statements. To the extent that components of our Internal Controls are included in our Disclosure Controls, they are included in the scope of our annual controls evaluation.



Conclusions

We reviewed our internal controls and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of their most recent evaluation.

Item 8B. Other Information

None.

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance With Section 10(a) of the Exchange Act.

| Name | Age | Positions Held * |
|---|---|---|
| Allen D. Allen | 68 | President, Chief Executive Officer, Director |
| Wellington A. Ewen | 64 | Chief Financial Officer |
| Corinne E. Allen | 36 | Vice President Business Development, Secretary, Treasurer, Director |
| Daniel M. Strickland, MD | 59 | Director |
| Peggy J. Pence, Ph.D. | 54 | Director |
| Ronald J. Tropp, Esq. | 61 | Director |

* Each officer and Director holds office until his/her successor has been elected and qualified.

Allen D. Allen. Mr. Allen has been our chairman of our board and our president and chief executive officer since October, 2003. Before joining CytoDyn, he was the chairman of the board of directors and chief executive officer of CytoDyn of New Mexico, Inc., since its inception in 1994. From 1990 to 1994 he was a research associate with Olive View-UCLA Medical Center where he collaborated and published with various medical professors original research on HIV, dermatology and general immunology and was the co-investigator on an autologous vaccine study. From 1986 to 1990 Mr. Allen was director of scientific affairs, Center for Viral Diseases, Northridge, California, where he conducted and published original research on a large cohort of patients with complex constellations of neuroimmunologic complaints. From 1971 to 1986 he was president of Algorithms, Incorporated where he conducted and published original research in the areas of artificial intelligence, perception, man and machine systems and societal engineering. Over the past thirty years, he has published numerous papers in the



peer review science and medical journals. He has also served as an investigator on clinical research sponsored by major pharmaceutical companies, such as Ortho Biotech, Johnson & Johnson, and Sanofi-Winthrop. Mr. Allen invented and patented the family of HIV/AIDS therapies licensed to CytoDyn. He is a member of the American Physical Society and the American Federation of Scientists, a life member of the Institute of Electrical and Electronics Engineers, and a founding member of the Editorial Board of Physics Essays. Mr. Allen received an Associates of Arts degree from the University of California at Berkeley in 1957 and attended the University of California at Los Angeles from 1957 to 1959. In 1953 he received a national ARS Student Award in aeronautics from the American Rocket Society (now the Institute of Aeronautics and Astronautics). Mr. Allen is the father of Corinne E. Allen, our Vice President of Business Development.

Wellington A. Ewen, CPA, MBA. Mr. Ewen, has been our chief financial officer since May 6, 2004. From 1988 until 2000, Mr. Ewen was owner of Wellington Ewen & Associates in Malibu, California, which represented many clients as financial and accounting consultants. He also served as financial and accounting officer for several development stage pharmaceutical companies, including Entropin, Inc. from April 1998 to June, 2000. From February, 1999 until his resignation in 2000, he was the chief financial officer of Amerimmune, Inc. From January, 2000 to July, 2000, he also served as a manager at PriceWaterHouseCoopers in Los Angeles, California. Mr. Ewen is currently licensed as a CPA in Oregon. He received his Bachelor of Science in 1963 and Master of Business Administration from Cornell University in 1964.

Corinne E. Allen, CPA. Ms. Allen has been a director and our secretary and treasurer since October 2003, and was until May 2004, our chief financial officer. In May 2004, Ms. Allen became the vice president of business development. From April 1995 to October 2003, she served as secretary and treasurer of CytoDyn of New Mexico, Inc. where she was also a director from June, 1994 to October 2003. Ms. Allen is a licensed Certified Public Accountant. From 1999 to 2003, Ms. Allen was employed as a senior manager at Deloitte & Touche, and, from 1992 to 1998 was a CPA at Hallquist Jones P.C. She has over 17 years experience in the accounting industry. Ms. Allen received a B.S. in Business Administration from California State University Northridge with a specialty in Accounting Theory and Practice in 1992. She has been a Certified Public Accountant since January 1997. Ms.Allen is the daughter of Allen D. Allen.

Ronald J. Tropp, Esq. Mr. Tropp has been a director of CytoDyn, Inc. since October 2003. Mr. Tropp was a director of CytoDyn of New Mexico, Inc. from

February 2000 to October 2003. He is an attorney admitted to practice of law in New York, California and Wisconsin. He has practiced entertainment and transactional law for over 25 years and has been representing CytoDyn of New Mexico, Inc. since the Fall of 1999. From 1994-1997, he was counsel, legal and business affairs for The Kushner-Locke Company. From 1992 to 1994, Mr. Tropp was a consultant and attorney at law for the Data Group, Playboy Video Enterprises, and the Sinclair Institute. From 1985-1992, he was vice president, legal and business affairs and director legal and business affairs for Playboy Video Enterprises, Los Angeles. From 1980 to 1984, Mr. Tropp was Vice President, Legal Affairs, associate general counsel and as director of legal affairs for Embassy Pictures, Los Angeles. From 1973 to 1980, he served as corporate counsel for Pacific Coast Medical Enterprises; General Counsel for Pacific Medical Enterprises, which owned five acute care hospitals in Southern California. He received a Bachelor of Arts in political science from Swarthmore College in 1965 and a Juris Doctorate degree from University of Wisconsin at Madison in 1968.

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Daniel M. Strickland, MD. Dr. Strickland has been a director of CytoDyn, Inc. since October, 2003. He served as a director of CytoDyn of New Mexico, Inc. from 1999 to October 2003. From 1995 to 1998 he practiced with Reproductive Endocrinologists, PC, Augusta, Georgia. From 1998 to the present he has practiced with the Women's Health Clinic in West Jefferson, North Carolina. From 1989 to 1995, Dr. Strickland was Chief, Reproductive Endocrinology, Ob-Gyn Services Division, Saudi Aramco Medical Services Organization in Dhahran, Saudi Arabia. From 1986 to 1989, Dr. Strickland served as Clinical Associate Professor at the University of Texas Health Science Center in San Antonio, Texas. Dr. Strickland served as a nuclear engineer for the U.S. Air Force before he became a physician. Dr. Strickland is board certified by the National Board of Medical Examiners. He received training designations from the American College of Surgeons, and the American Heart Association for Advanced Trauma Life Support and Advanced Cardiac Life Support. He holds U.S. patent No. 3,909,624 for a Split-Ring Marx Generator Grading. Dr. Strickland received a Bachelor of Science in Physics from the University of Georgia in 1966, and a Master of Science in Nuclear Engineering from the Air Force Institute of Technology in 1969. Dr. Strickland received his Doctorate of Medicine from Medical College of Georgia in 1977.

Peggy C. Pence, PhD. Dr. Pence has been a Director since October, 2003. In 1995, Dr. Pence founded Symbion Research International, the CRO (Contract Research Organization) that conducted the successful Phase 1 study of Cytolin, and from then to the present has been its president and chief executive officer. From 1988 to 1992, Dr. Pence was manager of clinical operations and manager of clinical studies for Amgen. From 1986 to 1988, she was manager of therapeutic products for Berlex Laboratories (then known as Triton Biosciences). from 1983 to 1986, she was a pharmaceutical research manager for Serono, Inc. Dr. Pence was employed from 1970 to 1983 by Eli Lilly and Company where, from 1982 to1983, she was a medical information administrator, regulatory affairs and from 1970 to 1974, she was an associate microbiologist for Eli Lilly's Immunology Research Laboratory. Dr. Pence has 30 years of experience in the research and development of traditional pharmaceutical and biotechnology-derived potential drugs and medical devices, including 13 years at Eli Lilly and Company. Dr. Pence received a bachelor of Science degree, magna cum laude, in microbiology from Louisiana Polytechnic Institute in 1969, and a doctor of Philosophy in toxicology in 1983 from Indiana University.

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We have no other significant employees whom we expect to contribute

significantly to our business.

Currently, we do not have an audit committee. Our Board of Directors acts as our audit committee. Similarly, the Board of Directors has determined that we do not have an audit committee financial expert as defined under the Exchange Act rules. We have been seeking, and continue to seek, an independent person to fill this role.

Compliance with Section 16(a) of the Exchange Act.

Section 16(a) of the Exchange Act requires our Officers and Directors, and persons who beneficially own more than 10% of our common stock, to file reports of ownership and changes in ownership with the Securities and Exchange Commission and to provide copies of those filings to us. Based solely on our review of the copies of those forms furnished to us during the fiscal year ended May 31, 2004, we are aware of the following untimely filings:

| Name | Position Held | Report | Number of Late Reports |
|---|---|---|---|
| Brian J. McMahon1 | Executive Vice President | Form 3 | 1 |
| Daniel M. Strickland, MD | Director | Form 3 | 1 |
| Peggy C. Pence, Ph.D | Director | Form 3 | 1 |
| Ronald J. Tropp, Esq. | Director | Form 3 | 1 |

1 Mr. McMahon served as our executive vice president until May 6, 2004.

Code of Ethics.

We have adopted a Code of Ethics for our president, vice president of business development and our chief financial officer. This Code of Ethics can be found on our website at www.cytodyn.com and is attached as an exhibit to this Form10-KSB.



Item 10. Executive Compensation

The following table provides an overview of compensation that CytoDyn, Inc. paid to the Named Executive Officers for the fiscal years ended May 31, 2004, 2003 and 2002.

Summary Compensation Table

| | | Annual Compensation | Long Term Compensation Awards | |
|---|---|---|---|---|
| Name and Principal Position | Year | Salary | Securities Underlying Options(# shares) | All Other Compensation |
| Allen D. Allen, | 2004 | 98,0001 | 0 | 0 |
| President, Chief | 2003 | 0 | 0 | 0 |
| Executive Officer | 2002 | 0 | 0 | 0 |

| | | | | |
|---|---|---|---|---|
| James E. Wiegand, President2 | 2004 | 45,0003 | 0 | 0 |
| | 2003 | 0 | 0 | 0 |
| | 2002 | 8,0004 | 0 | 0 |

1 Mr. Allen's employment agreement with CytoDyn provides for a salary of $98,000. He was paid a total of $32,667 as of the end of the fiscal year, and the remainder of his salary was accrued.
2 Mr. Wiegand resigned as president following the acquisition of certain assets of CytoDyn of New Mexico dated October 28, 2003.
3 Paid for services to CytoDyn in connection with the acquisition.
4 Paid in the form of 400,000 shares of common stock of CytoDyn, valued at $8,000 for his services in connection with the incorporation and organization of CytoDyn.

Director Compensation

Our directors did not receive any compensation for their services as directors, nor did any director receive reimbursement for attendance at meetings of the Board of Directors.

Personal Service Agreements

All of our named executive officers have personal service agreements with us. Among other things, each agreement:

- Is effective for two years after its effective date;
- May be terminated by us:
  - Without cause, immediately upon written notice,
  - With "cause", immediately upon notice specifying the cause, or
  - Upon the death or disability of the executive;
- May be terminated by the executive:
  - Voluntarily, upon 4 weeks notice,
  - Within a specified period after a "change in control", upon two weeks notice, and
  - For "good reason", if we do not cure the reason within 30 days of notice;



- Entitles the executive, upon termination by him or her within the specified period after a "change of control" and with "good reason", to:
  - Base salary for the remainder of the term and 12 additional months,
  - Immediate vesting of all stock options,
  - 4 month period in which to exercise options thereby vested,
  - Payment of our portion of premiums under our health plan for the shorter of 12 months or the executive's eligibility for coverage under a health plan offered by the executive's new employer, and
  - Payment of our portion of premiums under our life insurance plan or an equivalent amount for 12 months;
  - Entitles the executive, upon termination by him or her without cause or for "good reason", to:
  - Base salary for the remainder of the term and 12 additional months, and
  - Payment of our portion of premiums under our health plan for the shorter of 12 months or the executive's eligibility for

coverage under a health plan offered by the executive's new employer;
- Restricts the solicitation of persons who were our officers, directors, executives, consultants or employees;
- Restricts the disclosure of confidential information during or after the term of the Agreement; and
- Requires the disclosure and assignment to us of all "Innovations" developed by the executive individually or jointly during the period of employment and that relate in any way to our business.

Proprietary Information And Inventions Agreement

Wellington E. Ewen, our chief financial officer, and Corinne E. Allen, our vice president for business development, have signed and delivered to us a Proprietary Information and Inventions Agreement For Employees. Among other things, each agreement provides that:

- It is effective from the first date of employment until five years from the date of termination of employment. Employment is defined to include any time retained as a consultant or on contract.
- The employee will refrain from any activity that is hostile, adverse or competitive, or otherwise interferes with the executive's service, to us;
- We are the sole owner of the "Proprietary Information" and all patents and other rights related to it
- Any rights that the employee has or may acquire in the "Proprietary Information" are assigned to us
- The "Proprietary Information" will be kept in confidence and trust during and after employment



- All works made by the employee during employment that fall within our scope of our business are Works for Hire, and we will have the sole and exclusive copyrights in them.
- All "Inventions" made by the employee (either alone or jointly) during the period of employment, will be disclosed to us and we will be the sole owner of them, and any related patents and rights.

Change Of Control Agreement

Allen D. Allen, our president and chief executive officer, and Corinne E. Allen, our vice president for business development, have signed and delivered to us a Change of Control Agreement. Among other things, each agreement provides that:

- The Agreement will terminate at the time the executive's employment with us terminates or is terminated;
- Upon termination of the executive's employment by us without "cause" or by him or her with "good reason", in either case within 6 months after a "change of control", the executive will be entitled to:
  - Base salary for the remainder of the term and 12 additional months
  - Immediate vesting of all stock options,
  - 4 month period in which to exercise options thereby vested,
  - Payment of our portion of premiums under our health plan for the shorter of 12 months or the executive's eligibility for coverage under a health plan offered by the executive's new employer, and
  - Payment of our portion of premiums under our life insurance

plan or an equivalent amount for 12 months.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth as of August 17, 2004 the beneficial ownership of common stock by each person who is known by CytoDyn to own beneficially more than 5% of the outstanding shares of common stock.

| Name and Address of Beneficial Owner | Amount and Nature of Beneficial Ownership* | Percent of Class Beneficially Owned |
|---|---|---|
| Allen D. Allen2 | 2,118,515 | 26.25% |
| Corinne E. Allen2 | 1,736,335 | 21.51% |
| J.P. Turner & Company, LLC 1,3 | 426,0001 | 5.01% |

*To CytoDyn's knowledge, all persons have sole voting power of the shares.



1 J.P. Turner is eligible to receive 426,000 warrants to purchase shares of common stock. Although the warrants have not yet been issued, J.P. Turner was entitled to receive them as of November, 2003, and upon issuance they are immediately exercisable at $0.30 per share.

2 The address for these shareholders is in care of the corporation at 200 West De Vargas Street, Suite 1, Santa Fe, New Mexico 87501.

3 The address of the shareholder is 3060 Peachtree Road, Floor 1100, Atlanta, Georgia 30305

The following table sets forth as of August 17, 2004, the number of common stock beneficially owned by all directors and executive officers.

| Name and Address of Beneficial Owner | Amount and Nature of Beneficial Owner1 | Percent of Class* |
|---|---|---|
| Allen D. Allen2 | 2,118,515 | 26.25% |
| Wellington A. Ewen2,3 | -0- | * |
| Corinne E. Allen2 | 1,736,335 | 21.51% |
| Ronald J. Tropp2 | -0- | * |
| Daniel M. Strickland2 | 8,476 | * |
| Peggy J. Pence2 | -0- | * |
| All Officers and Directors as a Group | 3,863,326 | 47.9% |

*Less than 1% of outstanding common stock

1 Each shareholder has sole voting and investment power for the shares.

2 The address for the shareholders is in care of the corporation at 200 West De Vargas Street, Suite 1, Santa Fe, New Mexico 87501

3 Mr. Ewen has options to purchase 150,000 shares of common stock in connection with an employment agreement. No options are currently exercisable.

We know of no arrangements concerning anyone's ownership of stock, which may, at a subsequent date, result in a change of control.

Item 12. Certain Relationships and Related Transactions

Related Party Transactions, Actual or Proposed, In Last 2 Years. We propose to be, or during the last two years were, party to certain transactions involving amounts in excess of $60,000, in which our directors, executive officers, others hold more than 5% of any class of our securities, or their immediate family members, had or will have a material interest. The interested parties and transactions are described below.

Common Stock, Options and Compensation. For a discussion of transactions within the past two years having aggregate values in excess of $60,000 and involving compensation paid or securities issued to our directors or executive officers, please see the discussions entitled "Executive Compensation" in Part III, Item 10 and "Security Ownership of Certain Beneficial Owners and Management And Related Stockholder Matters" in Part III, Item 11.



Agreement to Issue Warrants to J.P. Turner & Company, LLC. J.P. Turner & Company, LLC, is a beneficial owner of 5.01% of our common stock, by virtue of common stock warrants which it is entitled to receive pursuant to a "Financial Representative Agreement" dated November 25, 2003. Pursuant to the terms of that agreement:

- J.P. Turner acted as our agent in connection with a private offering of our securities;
- We paid the sum of $54,000 to J.P. Turner;
- We are to issue to J.P. Turner warrants for the purchase of 426,000 shares of our common stock, at an exercise price of $0.30 per share;
- When issued, the warrants will:
  - Vest immediately in favor of J.P. Turner;
  - Be exercisable immediately and thereafter for 5 years;
  - Contain customary anti-dilution provisions for stock dividends, splits, mergers and sales of substantially all assets;
  - Contain a "cashless exercise" provision;
- We have granted J.P. Turner "piggyback" registration rights, at our expense, with respect to the shares underlying the warrants;
- We are to indemnify J.P. Turner and others against certain losses arising in connection with our material misrepresentations or omissions, the performance by J.P. Turner of the agreement, or breach of representations or warranties by an investor; and
- The term of the agreement is 12 months, subject to termination upon 45 days written notice.

Agreement with Symbion Research International, Inc. Our director, Peggy C. Pence, PhD., is the President and Chief Executive Officer of Symbion Research International, Inc. On October 1, 2003, we entered into a "Master Agreement for Professional Services" with Symbion. The agreement describes general terms and conditions intended to apply to services which Symbion may provide for us, most likely in connection with the conduct of future FDA clinical trials of Cytolin. That agreement requires an advance payment of $25,000 to Symbion, of which $5,000 is to serve as a retainer and the remaining $20,000 is to be applied against billing for services that may be rendered. We have made the advance payment. We also have had discussions with Symbion regarding the possible

conduct of Phase II and III trials, and these discussions have resulted in Symbion providing us with a cost estimate:

- based on the assumption that the Phase I trials will not have to be repeated and that the FDA will approve the currently designed Phase II/III study;
- that services related to the end of Phase I and the Pre-Phase II meeting will cost between $50,000 and $100,000;
- that services related to the Phase II/Phase III pivotal study will cost between $1,250,000 and $1,750,000; and
- that the cost to the Investigators will be between $750,000 and $1,500,000, plus the costs of materials, investigational product manufacturing or supplies.



Acquisition of the Assets of CytoDyn of New Mexico. Allen D. Allen, our president, chief executive officer and the chairman of the board of directors, Corinne E. Allen, our vice president of business development, secretary, treasurer and director, Ronald J. Tropp and Daniel M. Strickland, M.D., our directors, and Brian J. McMahon, our former executive vice president, formerly also served as executive officers or directors of CytoDyn of New Mexico, Inc. In October 2003, we acquired the assets of CytoDyn of New Mexico, Inc. and changed our name to CytoDyn, Inc. Please see "The Acquisition Agreement with CytoDyn of New Mexico" under "Description of Business" at Part I, Item 1. In connection with that transaction:

- we issued to CytoDyn of New Mexico 5,362,640 post reverse- split shares of our common stock;
- Allen D. Allen, who is our president, chief executive officer and the chairman of our board of directors, ultimately received 2,118,515 shares of our post reverse-split common stock 1 and indirectly benefited from our assumption of debts in the amount of $71,694 owed to him and Corinne E. Allen by CytoDyn of New Mexico;
- Corinne E. Allen, who is our vice president of business development, secretary and treasurer, ultimately received 1,736,335 shares of our post reverse-split common stock 1 and indirectly benefited from our assumption of debts in the amount of $71,694 owed to her and Allen D. Allen by CytoDyn of New Mexico;
- Daniel M. Strickland, MD, who is a member of our board of directors, ultimately received 8,476 shares of our post reverse-split common stock 1; and
- James B. Wiegand, who until this transaction had been our president, retained 400,000 shares of our post reverse-split common stock.

Services Provided by Ronald J. Tropp. Our director, Ronald J. Tropp, Esq., has provided legal services to us, and to CytoDyn of New Mexico, for a number of years. Currently, we owe him the sum of $61,285 for these services. No arrangements have been made for the payment of this obligation. We anticipate that Mr. Tropp will provide additional legal services to us in the future.

Indemnification, Legal Costs and Fees Incurred by Directors and Officers. Allen D. Allen, our president, chief executive officer and the chairman of the board of directors, Corinne E. Allen, our vice president of business development, secretary, treasurer and director, Ronald J. Tropp and Daniel M. Strickland, M.D., our directors, and Brian J. McMahon, our former executive vice president, are named as Cross-Defendants in a Cross-Complaint filed in the California Superior Court in and for Los Angeles County in an action originally captioned CytoDyn of New Mexico, Inc. et al., v. Amerimmune Pharmaceuticals, Inc. et al., Case number BC 290154. The Cross-Complaint is based upon alleged acts and omissions of these individuals occurring before we

entered into the Acquisition Agreement with CytoDyn of New Mexico. In a separate proceeding, in Ventura County, California, captioned CytoDyn, Inc., et al. v. Amerimmune, Inc. et al., Case number SC039250, Allen D. Allen is our co-plaintiff. Please see the discussion entitled "Legal Proceedings" in Part I, Item 3. Our Articles of Incorporation and by-laws provide that we will indemnify directors, officers, and enumerated others against certain liabilities and expenses arising because of the indemnitee's corporate status or relationship. We have not determined whether we have an obligation to indemnify Messrs. Allen, McMahon, Tropp and Strickland and Ms. Allen with respect to any liability that may arise under the Cross-Complaint. We have, however, assumed responsibility for the payment of the legal fees and costs of counsel who jointly represent us and any of Messrs. Allen, McMahon, Tropp and Strickland and Ms. Allen in the Los



Angeles County proceeding. Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to directors, officers and controlling persons, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

Note Given and Debt Owed to Allen D. Allen. In January 2004 we issued to Allen D. Allen, our president, chief executive officer and the chairman of our board of directors, a non interest bearing promissory note, payable on demand, in the original principal amount of $22,788. The note reflects advances made to us by Mr. Allen during the years ending on May 31, 2003 and May 31, 2004. In addition, we owe the sum of $10,000 to Mr. Allen, who advanced that amount to CytoDyn of New Mexico for further payment to Rexray Corporation in connection with the acquisition of the assets of CytoDyn of New Mexico. The sum owed does not bear interest and is payable on demand.

Notes Given to Corinne Allen. In January 2004, we issued to Corinne E. Allen, our vice president of business development, secretary, treasurer and director, two non interest bearing promissory notes, each payable on demand, in the original principal amounts of $50,000 and $38,906. The notes reflected advances made to us by Ms. Allen during the years ending on May 31, 2003 and May 31, 2004. The $50,000 note was paid in full in February, 2004. The $38,906 note remains outstanding and does not bear interest.

Transactions With Promoters. James B. Wiegand was the promoter of Rexray Corporation and served as its president from the time of incorporation until its acquisition of the assets of CytoDyn of New Mexico. Rexray was incorporated on May 2, 2002, under the laws of Colorado as a "blank check" company. 800,000 shares of its common stock were issued to Mr. Wiegand in exchange for organizational services provided and valued by him at $8,000. By virtue of a one-for-two reverse stock split effected in October, 2003, Mr. Wiegand's common stock ownership was reduced to 400,000 shares. We were party to the following additional direct or indirect transactions with Mr. Wiegand:

- Compensation for Services. In October 2003, we paid $15,000 and gave a promissory note in the original principal amount of $30,000 to Mr. Wiegand. Interest accrued on the unpaid principal amount of the note at the rate of 5% per annum. The note was paid in full in February 2004. The cash payment and note were given in consideration of services provided to us by Mr. Wiegand, principally in connection with the acquisition of the assets of CytoDyn of New Mexico. Mr. Wiegand determined the value of his services.

- Rent of Office Space. From May 2, 2002 through September 30, 2002, we rented office space located in Mr. Wiegand's home from Amery Coast Corporation at the rate of $100.00 per month. The rental rate was based, according to him, upon then current comparable rents. Amery Coast Corporation was controlled by Mr.Wiegand.

- Contributions of Office Space. From October 1, 2002 through May 31, 2003, Amery Coast Corporation contributed office space to us. The rental value of the office space was deemed to be $100 per month, based on the previous rental rate determined by Mr. Wiegand.

- Contributions of Time, Fee and Cash. Mr. Wiegand contributed services during the year ended May 31, 2003, which he valued at $2,970. In addition, during the year ended May 31, 2003, he paid, on our behalf, $1,645 for professional services rendered to us, and during the 6 month period ending November 30, 2003, he contributed $2,500 to us. The contribution of services and the payments were treated as contributions to capital.

Item 13. Exhibits

Index to Exhibits

| | Incorporated By Reference | | | | | |
|---|---|---|---|---|---|---|
| Exhibit Number | Exhibit Description | Form | File Number | Exhibit Number | Filing Date | Filed Herewith |
| 3.i | Articles of Incorporation | 10SB | 000-49908 | 3.1 | 7/11/2002 | |
| 3.i.2 | Amendment to Articles of Incorporation | 8K | 000-49908 | 3.i.2 | 11/12/2003 | |
| 3.ii | Bylaws | 10SB | 000-49908 | 3.2 | 7/11/2002 | |
| 10.i | Acquisition Agreement between Rexray Corporation and CytoDyn of NM, Inc. dated October 28, 2003 | 8K/A | 000-49908 | 10.i | 01/12/2004 | |
| 10.ii | Patent License Agreement between CytoDyn of New Mexico, Inc and Allen D. Allen and Amendment to Patent License Agreement | | | | | X |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10.iii | Personal Services Agreement between Allen D. Allen and CytoDyn, Inc | | | | | X |
| 10.iv | Personal Services Agreement Between Wellington A. Ewen and CytoDyn, Inc. | | | | | X |
| 10.v | Personal Services Agreement between Corinne E. Allen and CytoDyn, Inc | | | | | X |
| 10.vi | Financial Representative Agreement between J.P. Turner & Company, LLC and CytoDyn, Inc | | | | | X |
| 10.vii | Change of Control Agreement between Allen D. Allen and CytoDyn, Inc. | | | | | X |
| 10.viii | Change of Control Agreement between Corinne E. Allen and CytoDyn, Inc. | | | | | X |
| 10.ix | Proprietary Information between Corinne E. Allen and CytoDyn | | | | | X |
| 10.x | Proprietary Information between Wellington A. Ewen and CytoDyn, Inc. | | | | | X |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10.xi | Proprietary Agreement between Allen D. Allen and CytoDyn, Inc. | | | | | X |
| 14 | Code of Ethics | | | | | X |
| 21 | Subsidiaries of the Company: None | | | | | |
| 31.1 | Section 302 Certification of Allen D. Allen | | | | | X |
| 31.2 | Section 302 Certification of Wellington A. Ewen | | | | | X |
| 32.1 | Section 906 Certification of Allen D. Allen | | | | | X |
| 32.2 | Section 906 Certification of Wellington A. Ewen | | | | | X |

Item 14. Principal Accountant Fees and Services

Approval of Services

The Board of Directors has resolved to establish an audit committee composed of our chief financial officer, Wellington Ewen, Corinne Allen, a director and our vice president of Business Development, and an independent member when that person is identified. The audit committee does not yet have a charter. Pending proper establishment of the audit committee, the Board of Directors pre-approves all engagements for audit and non-audit services provided by the Company's principal accounting firm, Cordovano and Honeck, P.C.

Audit Fees

The aggregate fees billed during the fiscal years ended May 31, 2004 and 2003 for professional services rendered by our principal accounting firm, Cordovano and Honeck, P.C., for the audit of the financial services included in Form 10-KSB, and for the review of the interim condensed financial statements included in Form 10-QSB, were approximately $2,500 and $3,000, respectively. Included here are fees associated with the review by Cordovano and Honeck, P.C. of a registration statement filed with the SEC and the related issuance of independent accountant consent letters.

Audit Related Fees

The aggregate fees billed during the fiscal years ended May 31, 2004 and 2003 for assurance and related services rendered by our principal accounting firm, Cordovano and Honeck, P.C., were approximately $0 and $0 respectively. Assurance and related service fees include the audit of employee benefit plan financial statements and audit-related due diligence assistance on potential acquisitions.

Tax Compliance/Preparation Fees

The aggregate fees billed during the fiscal years ended May 31, 2004 and 2003 for professional services rendered by our principal accounting firm, Cordovano and Honeck, P.C., for tax compliance, tax advice, and tax planning were approximately $0 and $750, respectively. Tax compliance services include the preparation of income tax returns filed with the Internal Revenue Service. Tax advice and planning services included assistance with implementation of tax planning strategies and consultation on other tax matters.

All Other Fees

The aggregate fees billed during the fiscal years ended May 31, 2004 and 2003 for all other professional services rendered by our principal accounting firm, Cordovano and Honeck, P.C., were approximately $0 and $0, respectively. Other services consisted of assistance with the interpretation of new accounting standards and other related services.

Chart of Fees Paid to Independent Auditing Firm For Past Two Fiscal Years

| | For fiscal years ended May 31, | | | |
|---|---|---|---|---|
| Type of Service | 2004 | % not pre-approved 1 | 2003 | % not pre-approved 1 |
| Audit fees | $ | N/A | $ | N/A |
| Audit-related fees | | | | |
| Tax fees | | | | |
| Tax compliance | 750 | | | |
| Tax advice & planning | | | | |
| Total tax fees | | | | |
| All other fees | | | | |
| Total fees | $750 | | $ 0 | |

1 These percentages reflect services for which the pre-approval requirement is waived under applicable accounting rules.



SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CytoDyn, Inc.

By: /s/ Allen D. Allen
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Allen D. Allen, Chief Executive Officer
Date: September 14, 2004

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Allen D. Allen — Date: September 14,2004
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Allen D. Allen, President, Chief Executive Officer, Director

/s/ Wellington A. Ewen — Date: September 14, 2004
---
Wellington A. Ewen, Chief Financial Officer

/s/ Corinne E. Allen — Date: September 14, 2004
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Corinne E. Allen, Vice President of Business Development, Secretary, Treasurer, Director

/s/ Peggy C. Pence — Date: September 14, 2004
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Peggy C. Pence, Director

/s/ Daniel M. Strickland — Date: September 14, 2004
---
Daniel M. Strickland, Director

/s/ Ronald J. Tropp — Date: September 14, 2004
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Ronald J. Tropp, Director