

CYTODYN INC  
Form 10-K  
July 10, 2015  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For the fiscal year ended May 31, 2015**

**or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number 000-49908**

**CYTODYN INC.**

**(Exact name of registrant as specified in its charter)**

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

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

**1111 Main Street, Suite 660**

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

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

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

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

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

**Title of class**

**Common Stock, no par value**

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

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

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

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

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

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: \$64,183,157 (as of November 30, 2014).

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of June 30, 2015, the registrant had 70,142,332 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

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

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**FORWARD-LOOKING STATEMENTS**

This annual report contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as believes, hopes, intends, estimates, expects, projects, plans, anticipate, variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements we urge you to specifically consider various risk factors identified in this prospectus, including the matters set forth under the heading Risk Factors, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position, (ii) our ability to meet our debt obligations, (iii) our ability to achieve approval of a marketable product, (iv) design, implementation and conduct of clinical trials, (v) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (vi) the market for, and marketability of, any product that is approved, (vii) the existence or development of vaccines, drugs, or other treatments for infection with the Human Immunodeficiency Virus that are viewed by medical professionals or patients as superior to our products, (viii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (ix) general economic and business conditions, (x) changes in foreign, political, and social conditions, (xi) the specific risk factors discussed under the heading Risk Factors below, and (xii) various other matters, many of which are beyond our control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

We intend that all forward-looking statements made in this prospectus will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended, to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this prospectus. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

**PART I**

**Item 1. Business.**

Overview / Corporate History

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

We are a publicly traded biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies to treat Human Immunodeficiency Virus ( HIV ) infection. Our lead product candidate, PRO 140, belongs to a class of HIV therapies known as entry inhibitors. These therapies

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

***PRO 140***

We believe the PRO 140 antibody shows promise as a powerful anti-viral agent while not being a chemically synthesized drug, which means fewer side effects, lower toxicity and less frequent dosing requirements, as compared to daily drug therapies currently in use. The PRO 140 antibody belongs to a class of HIV therapies known as entry inhibitors that block HIV from entering into and infecting certain cells. PRO 140 blocks HIV from entering a cell by binding to a molecule called CCR5, a normal cell surface co-receptor protein to which HIV attaches as part of HIV s entry into a cell.

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PRO 140 is an antibody and not a chemically synthesized drug, and through preliminary, short-term trials it has demonstrated efficacy without issues relating to toxicity and autoimmune resistance. Moreover, these trials suggested that PRO 140 does not affect the normal function of the CCR5 co-receptor for HIV. Instead, PRO 140 binds to a precise site on CCR5 that HIV uses to enter the cell and, in doing so, inhibits the ability of HIV to infect the cell without affecting the cell's normal function.

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

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

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

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

Patients desiring a break from existing treatment regimens, whether due to side-effects or personal reasons;

Patients with difficulty adhering to daily drug regimens;

Patients who poorly tolerate existing therapies;

Patients with compromised organ function, such as HCV (hepatitis C) co-infection;

Patients with complex concomitant medical requirements; and

Patients who choose not to start their highly active antiretroviral therapy ( HAART ) regimen immediately after being infected with HIV.

We believe PRO 140 has demonstrated potent (as compared to existing treatments) antiretroviral activity and an encouraging safety profile in prior clinical testing, that PRO 140 has the potential to be the first long-acting (weekly or every other week), self-administered HIV therapy, and that PRO 140 inhibit CCR5-tropic HIV while preserving CCR5's natural activity. PRO 140 also appears to broadly inhibit drug-resistant CCR5-tropic HIV viruses, including



one resistant to small-molecule anti-CCR5 HIV therapies. PRO 140 has no effect on strains of HIV called X4 exclusive virus. Overall, we believe PRO 140 represents a distinct class of CCR5 inhibitors with unique virological and immunological properties and may provide another distinct tool to treat HIV-infected subjects.

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

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

Our ongoing treatment substitution extension study has two objectives: (1) to assess the efficacy of PRO 140 monotherapy for the maintenance of viral suppression after being used in substitution of a patient's HAART regimen and (2) to assess the clinical safety and tolerability parameters for PRO 140 following use in substitution of HAART. The study protocol requires patients to be stable on HAART with an undetectable viral load. The trial design provided that patients will be shifted from HAART regimen to PRO 140 monotherapy for 12 weeks. PRO 140 is being administered as a 350mg subcutaneous dosage weekly and participants are monitored for viral rebound on a weekly basis. Total treatment duration with PRO 140 in the initial study was up to 14 weeks with one week overlap of existing retroviral regimen and PRO 140 at the beginning of the study period and also one week of overlap at the end in subjects who did not experience virologic failure, which is defined as a viral load above 400 two weeks in a row. An independent Data Safety Monitoring Board ( DSMB ) is required to monitor the study to ensure patient safety and to assess efficacy. The DSMB operates in conformance with the FDA guidelines for its independence, management and oversight.

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

98% of the patients passed 4 weeks of monotherapy

91% of the patients passed 6 weeks of monotherapy

82% of the patients passed 8 weeks of monotherapy

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

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

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

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

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

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

The Company's first Phase 3 study is designed to allow PRO 140 as a component of a HAART regimen for treatment experienced patients. HAART is the current standard of medical care for individuals with HIV. Management believes the market size for a HAART therapy, which includes the PRO 140 antibody, along with other PRO 140 indications, could exceed a billion dollars. CytoDyn believes that its PRO 140 antibody has compelling advantages over Maraviroc, the only other CCR5 antagonist for HIV therapy (Maraviroc is a pill taken orally twice a day. PRO 140 is

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

***Other Product Candidates***

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

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

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

Until the clinical trials for PRO 140 have advanced further, we do not plan to devote any resources towards the development, research, testing, approval, or commercialization of Cytolin or CytoFeline.

### ***PRO 140 Acquisition***

We acquired PRO 140, as well as certain other related assets, including the existing inventory of PRO 140 bulk drug substance, intellectual property, and FDA regulatory filings, pursuant to an Asset Purchase Agreement, dated as of July 25, 2012 (the Progenics Agreement ), between CytoDyn and Progenics. The terms of the Progenics Agreement provided for an initial cash payment of \$3,500,000, which was paid at closing in October 2012, as well as the following milestone payments and royalties to be paid to Progenics in the future: (i) \$1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-US equivalent; (ii) \$5,000,000 at the time of the first U.S. new drug application approval by the FDA or other non-U.S. approval for the sale of PRO 140; and (iii) royalty payments of 5% of net sales during the period beginning on the date of the first commercial sale of PRO 140 until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years following the first commercialization sale of PRO 140, in each case determined on a country-by-country basis. The Progenics Agreement is filed as an exhibit to this annual report on Form 10-K.

Payments to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the PDL License ), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the PRO 140 transaction, pursuant to which we must pay additional milestone payments and royalties as follows: (i) \$1,000,000 upon initiation of a Phase 3 clinical trial; (ii) \$500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) \$500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iv) royalties of up to 7.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of \$150,000 until royalties paid exceed that amount. As of the date of this filing, management has reasonably estimated the likelihood of paying the first milestone payments, as probable, and accordingly, as of May 31, 2015, the Company has accrued \$2,500,000 for the initial milestone associated with the first dosing in a Phase 3 trial. See Note 7 to the financial statements included herein under Item 8.

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

### ***Patents, Proprietary Technology, and Data Exclusivity***

Protection of our intellectual property rights is important to our business. We may file patent applications in the U.S., Canada, China, Japan, European countries that are party to the European Patent Convention and other countries on a selective basis in order to protect inventions we consider to be important to the development of our business.

Generally, patents issued in the U.S. are effective for either (i) 20 years from the earliest asserted filing date, if the application was filed on or after June 8, 1995, or (ii) the longer of 17 years from the date of issue or 20 years from the earliest asserted filing date, if the application was filed prior to that date. A U.S. patent, to be selected by the company upon receipt of FDA regulatory approval, may be subject to up to a five-year patent term extension in certain instances. While the duration of foreign patents varies in accordance with the provisions of applicable local law, most countries provide for a patent term of 20 years measured from the application filing date and some may also allow for patent term extension to compensate for regulatory approval delay. We pursue opportunities for seeking new meaningful patent protection on an ongoing basis. We currently anticipate that, absent patent term extension, patent protection relating to the PRO 140 antibody itself will start to expire in 2023, certain methods of using PRO 140 will start to expire in 2026, and certain formulations comprising PRO 140 will start to expire in 2031.

Patents do not enable us to preclude competitors from commercializing drugs in direct competition with our products that are not covered by granted and enforceable patent claims. Consequently, patents may not provide us with any meaningful competitive advantage. See related risk factors under the heading **Risk Factors** above. We may also rely on data exclusivity, trade secrets and proprietary know-how to develop and attempt to achieve a competitive position with our product candidates. We generally require our employees, consultants and partners who have access to our proprietary information to sign confidentiality agreements in an effort to protect our intellectual property.

Separate from and in addition to the patent rights noted above, we expect that PRO 140 will be subject to at least a 12-year data exclusivity period measured from the first date of FDA licensure, during which period no other applications referencing PRO 140 will be approved by FDA. Further, no other applications referencing PRO 140 will be accepted by FDA for a 4-year period measured from the first date of FDA licensure. Accordingly, this period of data exclusivity is expected to provide at least a 12-year term of protection against competing products shown to be biosimilar or interchangeable with PRO 140. Similar data exclusivity or data protection periods of up to about 5-years or more are provided in at least Australia, Canada, Europe, Japan, and New Zealand.

We note that data exclusivity is not an extension of patent rights, and it does not prevent the introduction of generic versions of the innovative drug during the data exclusivity period, as long as the marketing approval of the generic version does not use or rely upon the innovator's test data. Patents and data exclusivity are different concepts, protect different subject matter, arise from different efforts, and have different legal effects over different time periods.

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

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

<sup>(1)</sup> Patent term extensions and pending patent applications may extend periods of patent protection. Research, development and commercialization of a biopharmaceutical product often require choosing between alternative development and optimization routes at various stages in the development process. Preferred routes depend upon current and may be affected by subsequent discoveries and test results, availability of financial resources, and other factors, and cannot be identified with certainty. There are numerous third-party patents in fields in which we work, and we may need to obtain licenses under patents of others in order to pursue a preferred development route of one or more of our product candidates. The need to obtain a license would decrease the ultimate value and profitability of an affected product. If we cannot negotiate such a license, we might have to pursue a less desirable development route or terminate the program altogether. See Risk Factors below.

**Government Regulation***Regulation of Health Care Industry*

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

*Regulation of Products*

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

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

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

*Regulation of Laboratory Operations*

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

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### *State Governments*

Most states in which we operate have regulations that parallel federal regulations. Most states conduct periodic unannounced inspections and require licensing under such state's procedures. Our research and development activities and the manufacture and marketing of our products are and will be subject to rigorous regulations relating to product safety and efficacy by numerous governmental authorities in the United States and other countries.

### *Other Laws and Regulations*

We are subject to various laws and regulations relating to safe working conditions, clinical, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of government regulation applying to our business that might result from any legislative or administrative action cannot be accurately predicted.

### *Environmental*

We are subject to a variety of federal, state and local environmental protection measures. We believe that our operations comply in all material respects with applicable environmental laws and regulations. Our compliance with these regulations did not have during the past year and is not expected to have a material effect upon our capital expenditures, cash flows, earnings or competitive position.

### ***Registrational Clinical Trials Process***

Described below is the traditional registrational drug development track. Our current business strategy is to focus primarily on the PRO 140 Phase 3 trial, seeking additional indications in Phase 3 trials, which we will sponsor and fund (subject to the availability of sufficient capital to pursue additional paths), and to continue to evaluate and leverage the clinical data from our recently completed Phase 2b treatment substitution trial. Additional clinical studies of our lead product candidate, PRO 140, are being sponsored by Drexel and funded at least in part by the NIH but are less critical to the viability of our business.

#### *Phase 1*

Phase 1 includes the initial introduction of an investigational new drug or biologic into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in a small number of healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the investigational product's pharmacokinetics and pharmacological effects are obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. Phase 1 studies of PRO 140 have been conducted and completed by or on behalf of Progenics by Dr. Jacobson and others prior to our acquisition of PRO 140.

#### *Phase 2*

Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, often involving several



hundred people. In some cases, depending upon the need for a new drug, a particular drug candidate may be licensed for sale in interstate commerce after a pivotal Phase 2 trial.

Phase 2 is often broken into Phase 2a, which can be used to refer to pilot trials, or more limited trials evaluating exposure response in patients, and Phase 2b trials that are designed to evaluate dosing efficacy and ranges. We believe studies conducted under the direction of Dr. Jacobson at Drexel will collectively constitute a Phase 2b trial. Our treatment substitution clinical trial is a Phase 2b trial.

### *Phase 3*

Phase 3 studies are expanded controlled clinical studies. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit/risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually involve significantly larger groups of patients, and considerable additional expense. We are required to pay significant fees to third parties upon the first patient dosing in a Phase 3 trial of PRO 140. See the discussion under the subheading PRO 140 Acquisition above.

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### ***Competition***

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

Advancing PRO 140 is our highest priority. PRO 140 blocks a cell receptor called CCR5, which is the entry point for most strains of HIV virus. Pfizer's maraviroc (Selzentry®) is the only currently approved CCR5 blocking agent. Another recent entry into the HIV treatment space is Truvada, an HIV drug produced by Gilead Sciences, Inc. Both of these drugs must be taken daily and are believed to have significant side effects. For these reasons, we believe that our lead product, PRO 140, a monoclonal antibody may prove to be useful in patients that cannot tolerate existing HIV therapies or desire a respite from those therapies. Nonetheless, manufacturers of current therapies, such as Pfizer and Gilead Sciences, are very large, multi-national corporations with significant resources. We expect that these companies will compete fiercely to defend and expand their market share.

Our potential competitors include entities that develop and produce therapeutic agents. These include numerous public and private academic and research organizations and pharmaceutical and biotechnology companies pursuing production of, among other things, biologics from cell cultures, genetically engineered drugs and natural and chemically synthesized drugs. All of these potential competitors have substantially greater capital resources, management expertise, research and development capabilities, manufacturing and marketing resources and experience than we do.

Our competitors may succeed in developing potential drugs or processes that are more effective or less costly than any that may be developed by us or that gain regulatory approval prior to our potential drug candidates. Worldwide, there are many antiviral drugs for treating HIV. In seeking to manufacture, distribute and market the potential drugs we hope to have approved, we face competition from established pharmaceutical companies. All of our potential competitors have considerably greater financial and management resources than we possess. We also expect that the number of our competitors and potential competitors will increase as more potential drugs receive commercial marketing approvals from the FDA or analogous foreign regulatory agencies. Any of these competitors may be more successful than us in manufacturing, marketing and distributing HIV treatments.

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

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

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

We have three full-time employees, our CEO, CFO and Director of Accounting, as well as several independent consultants assisting us with our clinical trials of PRO 140 and manufacturing activities. There can be no assurances, however, that we will be able to identify or hire and retain additional employees or consultants on acceptable terms in the future.

## **Item 1A. Risk Factors**

The risks enumerated below are not the only risks we face, and the listed risk factors are not intended to be an all-inclusive discussion of all of the potential risks relating to our business. Any of the risk factors described below could significantly and adversely affect our business, prospects, financial condition and results of operations. Additional risks and uncertainties not currently known or that are currently considered to be immaterial may also materially and adversely affect our business.

### **Risks Related to Our Business**

*We are a biotechnology company and have a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve or maintain profitability.*

We have not generated any revenue from product sales, licensing, or other potential sales to date. Since our inception, we have incurred operating losses in each year due to costs incurred in connection with research and development activities and general and administrative expenses associated with our operations. Our current drug candidate is in the later stages of clinical trials, and we expect to commence significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial

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sales. During the fiscal years ended May 31, 2015, 2014 and 2013, we have incurred net losses of approximately \$25.1 million, \$12.4 million and \$9.6 million and at May 31, 2015, we had an accumulated deficit of approximately \$71.5 million. We expect to incur losses for the foreseeable future as we continue development of, and seek regulatory approvals for, our drug candidate and commercialize any approved product usages. If our current drug candidate fails to gain regulatory approval, or if it or other candidates we own do not achieve approval and market acceptance, we will not be able to generate any revenue, or explore other opportunities to enhance shareholder value, such as through a sale. If we fail to generate revenue and eventually become and remain profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or part of their investments.

***We will need substantial additional funding to complete our Phase 3 clinical trial for PRO 140 and to operate our business and such funding may not be available or, if it is available, such financing is likely to substantially dilute our existing shareholders.***

The discovery, development, and commercialization of new treatments, such as our PRO 140 product candidate, entail significant costs. We expect the total estimated expenses for our first Phase 3 trial may range from approximately \$13 million to \$15 million. In addition, to the extent further development and clinical trials of PRO 140 and other products continue to appear promising and we elect to fund its development and commercialization, we will need to raise substantial additional capital, or enter into strategic partnerships, to enable us to:

fund clinical trials and seek regulatory approvals;

build or access manufacturing and commercialization capabilities;

pay required license fees, milestone payments, and maintenance fees to Progenics Pharmaceuticals, Inc. (from which we acquired our PRO 140 product candidate) ( Progenics ) and other third parties;

develop, test, and, if approved, market our product candidate;

acquire or license additional internal systems and other infrastructure; and

hire and support additional management and scientific personnel.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never achieve, we expect to finance our cash needs primarily through public or private equity offerings, debt financings or through strategic alliances. We cannot be certain that additional funding will be available on acceptable terms or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials, collaborative development programs or future commercialization initiatives. In addition, any additional funding that we do obtain will dilute the ownership held by our existing security holders. The amount of this dilution may be substantially increased if the trading price of our common stock is lower at the time of any financing. Regardless, the economic dilution to shareholders will be significant if our stock price does not increase significantly, or if the effective price of any sale is below the price paid by a particular shareholder. Any debt financing could involve substantial restrictions on activities and creditors could seek a pledge of some or all of our

assets. We have not identified potential sources for the additional financing that we will require, and we do not have commitments from any third parties to provide any future financing. If we fail to obtain additional funding as needed, we may be forced to cease or scale back operations, and our results, financial condition and stock price would be adversely affected.

***The amount of financing we require will depend on a number of factors, many of which are beyond our control. Our results of operations, financial condition and stock price are likely to be adversely affected if our funding requirements increase or are otherwise greater than we expect.***

Our future funding requirements will depend on many factors, including, but not limited to:

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

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

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

our ability to attract strategic partners to pay for or share costs related to our product development efforts;

the costs and timing of seeking and obtaining regulatory approvals and making related milestone payments due to Progenics and other third parties.

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

decisions to hire additional scientific or administrative personnel or consultants;

our ability to manage administrative and other costs of our operations; and

the presence or absence of adverse developments in our research program.

If any of these factors cause our funding needs to be greater than expected, our operations, financial condition, ability to continue operations and stock price may be adversely affected.

***Our future cash requirements may differ significantly from our current estimates.***

Our cash requirements may differ significantly from our estimates from time to time, depending on a number of factors, including:

the costs and results of our Phase 3 clinical trial and other clinical trials we are undertaking or may in the future pursue with PRO 140;

the time and costs involved in obtaining regulatory approvals;

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

whether we are able to obtain funding under future licensing agreements, strategic partnerships, or other collaborative relationships, if any;

the costs of compliance with laws, regulations, or judicial decisions applicable to us;

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

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

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

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

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

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

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

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

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

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

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

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***Certain agreements and related license agreements require us to make significant milestone, royalty, and other payments, which will require additional financing and, in the event we do commercialize our PRO 140 product, decrease the revenues we may ultimately receive on sales.***

Under the Progenics Agreement (see Our Business PRO 140 for a description), we must pay to Progenics and third-party licensors significant milestone payments, license fees for system know-how technology and royalties. For more information, see Business PRO 140 Acquisition and the Progenics Agreement, which is attached as Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission (the SEC) on July 30, 2012, and the PDL License Agreement, which is filed as Exhibit 10.21 to our Annual Report on Form 10-K for the fiscal year ended May 31, 2013, filed with the SEC on August 29, 2013.

In order to make the various milestone and license payments that are required, we will need to raise additional funds. In addition, our royalty obligations will reduce the economic benefits to us of any future sales if we do receive regulatory approval and seek to commercialize PRO 140.

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

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

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

***Clinical trials are expensive, time-consuming and subject to delay.***

Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design and implement. The length of time and number of trial sites and patients required for clinical trials vary substantially based on the type, complexity, novelty, intended use and any safety concerns relating to a drug candidate. We estimate that it may take at least two years to complete the necessary clinical trials, obtain regulatory approval from the FDA or other non-U.S. regulatory agency, and begin to commercialize PRO 140, even if trials are successful, of which there can be



no assurance. Clinical trials for our other drug candidates, including Cytolin, may take significantly longer to complete, if they are pursued at all.

The commencement and completion of clinical trials which we are undertaking ourselves or are being conducted by Drexel could be delayed or prevented by many factors, including, but not limited to:

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

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

slower than expected rates of patient recruitment and enrollment, including as a result of competition with other clinical trials for patients, limited numbers of patients that meet the enrollment criteria, or the introduction of alternative therapies or drugs by others;

unforeseen issues with our relationship with our contract clinical management services provider;

delays in paying third-party vendors of biopharmaceutical services;

lack of effectiveness of our drug candidates during clinical trials; or

unforeseen safety issues.

***Testing of our primary product candidate, PRO 140, is ongoing and our clinical trial results may not ultimately confirm initial positive indications, which would materially and adversely affect our business, financial condition and stock price.***

Our efforts to commercialize PRO 140 are dependent on obtaining FDA or other non-U.S. regulatory agency approval of its use in HIV-infected patients. Although test results have been positive thus far, the process of obtaining approval of a drug product for use

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in humans is extremely lengthy and time-consuming, and numerous factors may prevent our successful development of PRO 140, including negative results in future clinical trials, the development by competitors of other products with equal or better results, or inability to obtain sufficient additional funding to continue to pursue development. Failure to successfully develop PRO 140 would have a material and adverse effect on our business, financial condition and stock price, and would threaten our ability to continue to operate our business, particularly since PRO 140 is the only product candidate we are actively pursuing at this time.

***Although PRO 140 has been designated as a candidate for fast track approval by the FDA, our ability to obtain accelerated approval may be lost.***

The FDA designated PRO 140 as a candidate for fast track consideration in 2006. The letter ascribing this designation stated that, if the clinical development program pursued for PRO 140 did not continue to meet the criteria for fast track designation, the Investigational New Drug ( IND ) application would not be reviewed under the fast track program. There is no assurance that the FDA will ultimately consider PRO 140 for approval on an accelerated basis. Failure to maintain eligibility for fast track review will likely result in requirements for longer or additional clinical trials and a slower approval process, resulting in additional costs and further delay in the potential realization of revenues from commercialization of PRO 140.

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

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

***We do not have internal research and development personnel, making us dependent on consulting relationships and strategic alliances with industry partners.***

We currently have no research and development staff or coordinators. We rely and intend to continue to rely on third parties for many of these functions. We engaged Amarex Clinical Research, LLC ( Amarex ), a full service clinical research organization, to manage our clinical trials and chemistry and manufacturing control ( CMC ) endeavors. As a result, we will be dependent on consultants and strategic partners in our development and commercialization activities, and it may be administratively challenging to monitor and coordinate these relationships. If we do not appropriately manage our relationships with third parties, we may not be able to successfully manage development, testing, and approval of our PRO 140 drug candidate or other products or commercialize any products that are approved, which would have a material and adverse effect on our business, financial condition and stock price.

***We will need to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of product candidates, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.***

We are dependent on third parties for important aspects of our product development strategy. We do not have the required financial and human resources to carry out independently the pre-clinical and clinical development for our product candidate, and do not have the capability or resources to manufacture, market or sell our current product candidate. As a result, we contract with and rely on third parties for important functions, including testing, storing, and manufacturing our products and managing and conducting clinical trials from which we may obtain a benefit. We have recently entered into several agreements with third parties for such services. If problems develop in our relationships with third parties, or if such parties fail to perform as expected, it could lead to delays or lack of progress, significant cost increases, changes in our strategies, and even failure of our product initiatives.

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

We may seek to enter into a strategic alliance with a pharmaceutical company for the further development and approval of one or more of our product candidates. Strategic alliances potentially provide us with additional funds, expertise, access, and other resources in exchange for exclusive or non-exclusive licenses or other rights to the technologies and products that we are currently developing or may explore in the future. We cannot give any assurance that we will be able to enter into additional strategic relationships with a pharmaceutical company or others in the near future or at all, or maintain our current relationships. In addition, we

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cannot assure you that any agreements we do reach will achieve our goals or be on terms that prove to be economically beneficial to us. When we do enter into strategic or contractual relationships, we become dependent on the successful performance of our partners or counter-parties. If they fail to perform as expected, such failure could adversely affect our financial condition, lead to increases in our capital needs, or hinder or delay our development efforts.

***Clinical trials may fail to demonstrate the desired safety and efficacy of our product candidates, which could prevent or significantly delay completion of clinical development and regulatory approval.***

Prior to receiving approval to commercialize PRO 140 or any other product candidates, we must adequately demonstrate to the FDA and any foreign regulatory authorities in jurisdictions in which we seek approval that it or any other product candidate is sufficiently safe and effective with substantial evidence from well-controlled clinical trials. In clinical trials, we will need to demonstrate efficacy for the treatment of specific indications and monitor safety throughout the clinical development process and following approval. If clinical work by us or others leads to undesirable adverse effects in patients, it could delay or prevent us from furthering the regulatory approval process or cause us to cease clinical trials with respect to any drug candidate. If our current or future preclinical studies or clinical trials are unsuccessful, our business will be significantly harmed and our stock price would be negatively affected.

Our product candidates are subject to the risks of failure inherent in drug-related product development. Preclinical studies may not yield results that adequately support our regulatory applications. Even if these applications are filed with respect to our product candidates, the results of preclinical studies do not necessarily predict the results of clinical trials. In addition, even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercialize our products, and our business, results of operations and financial condition would be harmed.

***Our competitors may develop drugs that are more effective, safer and less expensive than ours.***

We are engaged in the HIV treatment sector of the biopharmaceutical industry, which is intensely competitive. There are current treatments that are quite effective at controlling the effects of HIV, and we expect that new developments by other companies and academic institutions in the areas of HIV treatment will continue. If approved for marketing by the FDA, depending on the approved clinical indication, our product candidates may be competing with existing and future antiviral treatments for HIV.

Our competitors may:

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

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

commercialize competing drugs before we or our partners can launch any products we are working to develop;

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

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

We expect to compete against large pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. These competitors, in nearly all cases, operate research and development programs that have substantially greater financial resources than we do. Our competitors also have significantly greater experience in:

developing drug and other product candidates;

undertaking preclinical testing and clinical trials;

building relationships with key customers and opinion-leading physicians;

obtaining and maintaining FDA and other regulatory approvals;

formulating and manufacturing drugs;

launching, marketing and selling drugs; and

providing management oversight for all of the above-listed operational functions.

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If we fail to achieve superiority over other existing or newly developed treatments, we may be unable to obtain regulatory approval. If our competitors market drugs that are less expensive, safer or more effective than our potential product candidates, or that gain or maintain greater market acceptance, we may not be able to compete effectively.

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

Our primary product candidate and potential drug candidates require precise, high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including failure to detect or control anticipated or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in patient injury or death, discontinuance or delay of ongoing or planned clinical trials, delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals and other problems that could seriously hurt our business. Contract drug manufacturers often encounter difficulties involving production yields, quality control and quality assurance and shortages of qualified personnel. These manufacturers are subject to stringent regulatory requirements, including the FDA's current good-manufacturing-practices regulations and similar foreign laws and standards. If our contract manufacturers fail to maintain ongoing compliance at any time, the production of our product candidates could be interrupted, resulting in delays or discontinuance of our clinical trials, additional costs and loss of potential revenues.

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

In order to conduct larger-scale or late-stage clinical trials and for commercialization of any resulting product, if that candidate is approved for sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development and testing of that product candidate and regulatory approval or commercial launch of any resulting product may be delayed, which could significantly harm our business.

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

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

***We may be subject to potential product liability and other claims that could materially impact our business and financial condition.***

The development and sale of medical products exposes us to the risk of significant damages from product liability and other claims, and the use of our product candidates in clinical trials may result in adverse effects. We cannot predict all the possible harms or adverse effects that may result. We maintain a modest amount of product liability insurance to provide some protections from claims. Nonetheless, we may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim, even if it is partially covered by insurance. In addition to the possibility of direct claims, we may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which would increase our liability exposure.

If third parties that have agreed to indemnify us fail to do so, we may be held responsible for those damages and other liabilities as well.

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

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

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

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Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal year. Management determined that as of both May 31, 2015, and May 31, 2014, our disclosure controls and procedures and internal control over financial reporting were not effective due to material weaknesses in our internal control over financial reporting related to inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions. Any failure to implement new or improved controls necessary to remedy the material weaknesses described above, or difficulties encountered in the implementation or operation of these controls, could harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

***Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our product candidates and research technologies.***

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the claim scope of patents, our ability to enforce our existing patents and to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and pharmaceutical patents. Thus, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competing products, or will afford us a commercial advantage over competitive products. If one or more products resulting from our product candidates is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate them for approval and sale in the United States without repeating the extensive testing required of us or our partners to obtain FDA approval.

***Known third party patent rights could delay or otherwise adversely affect our planned development and sale of PRO 140. We have identified but not exhaustively analyzed other patents that could relate to our proposed products.***

We are aware of patent rights held by a third party that may cover certain compositions within our PRO 140 candidate. The patent holder has the right to prevent others from making, using, or selling a drug that incorporates the patented compositions, while the patent remains in force. While we believe that the third party's patent rights will not affect our planned development, regulatory clearance, and eventual marketing, commercial production, and sale of PRO 140, there can be no assurance that this will be the case. The relevant patent expires before we expect to commercially introduce PRO 140. In addition, the Hatch-Waxman exemption to U.S. patent law permits all uses of compounds in clinical trials and for other purposes reasonably related to obtaining FDA clearance of drugs that will be sold only after patent expiration, so our use of PRO 140 in those FDA-related activities does not infringe the patent holder's rights. However, were the patent holder to assert its rights against us before expiration of the patent for activities unrelated to FDA clearance, the development and ultimate sale of a PRO 140 product could be significantly delayed, and we could incur the expense of defending a patent infringement suit and potential liability for damages for periods prior to the patent's expiration.

In connection with our acquisition of rights to PRO 140, our patent counsel conducted a freedom-to-operate search that identified other patents that could relate to our proposed PRO 140 candidate. Sufficient research and analysis was conducted to enable us to reach the conclusion that PRO 140 likely does not infringe those patent rights. However, we did not have an exhaustive analysis conducted as to the identified patent rights, because doing so would have been



more costly than appeared to be justified. If any of the holders of the identified patents were to assert patent rights against us, the development and sale of PRO 140 could be delayed, we could be required to spend time and money defending patent litigation, and we could incur liability for infringement or be enjoined from producing our products if the patent holders prevailed in an infringement suit.

***If we are sued for infringing on third-party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business.***

Our ability to commercialize our product candidates depends on our ability to use, manufacture and sell those products without infringing the patents or other proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the monoclonal antibody therapeutic area in which we are developing product candidates and seeking new potential product candidates. There may be existing patents, unknown to us, on which our activities with our product candidates could infringe.

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

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

substantial damages for infringement, if a court determines that our products or technologies infringe a third party's patent or other proprietary rights;

a court prohibiting us from selling or licensing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which it is not required to do; and

even if a license is available from a holder, we may have to pay substantial royalties or grant cross-licenses to our patents or other proprietary rights.

If any of these events occur, it could significantly harm our operations and financial condition and negatively affect our stock price.

***We may undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.***

We may come to believe that third parties are infringing on our patents or other proprietary rights. To prevent infringement or unauthorized use, we may need to file infringement and/or misappropriation suits, which are very expensive and time-consuming and would distract management's attention. Also, in an infringement or misappropriation proceeding a court may decide that one or more of our patents is invalid, unenforceable, or both, in which case third parties may be able to use our technology without paying license fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party's activities are not covered by our patents.

***We may become involved in disputes with our present or future contract partners over intellectual property ownership or other matters, which would have a significant effect on our business.***

Inventions discovered in the course of performance of contracts with third parties may become jointly owned by our strategic partners and us, in some cases, and the exclusive property of one of us, in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention or whether it is jointly owned, and disputes could arise regarding ownership or use of those inventions. Other disputes may also arise relating to the performance or alleged breach of our agreements with third parties. Any disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business.

***We are subject to the oversight of the SEC and other regulatory agencies. Investigations by those agencies could divert management's focus and could have a material adverse effect on our reputation and financial condition.***

We are subject to the regulation and oversight of the SEC and state regulatory agencies, in addition to the FDA. As a result, we may face legal or administrative proceedings by these agencies. We are unable to predict the effect of any

investigations on our business, financial condition or reputation. In addition, publicity surrounding any investigation, even if ultimately resolved in our favor, could have a material adverse effect on our business.

***Our auditors have issued a going concern opinion, and we will not be able to achieve our objectives and will have to cease operations if we cannot adequately fund our operations.***

Our auditors issued a going concern opinion in connection with the audit of our annual financial statements for the fiscal year ended May 31, 2015. A going concern opinion means that there is substantial doubt that the company can continue as an ongoing business for the next 12 months. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties. There is no assurance that we will be able to adequately fund our operations in the future.

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**Risks Relating to Our Common Stock**

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

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline significantly. In addition, we have 5,981,158 shares subject to outstanding options under our stock option plans, 1,754,930 shares reserved for future issuance under our equity compensation plan, 28,178,551 shares issuable upon exercise of outstanding warrants and 5,374,706 shares issuable upon conversion of our outstanding notes. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

***The market price for our common shares has been and is likely to continue to be volatile.***

The market price for our common shares has been and is likely to continue to be volatile. The volatile nature of our common share price may cause investment losses for our shareholders. In addition, the market price of stock in small capitalization biotech companies is often driven by investor sentiment, expectation and perception, all of which may be independent of fundamental valuation metrics or traditional financial performance metrics, thereby exacerbating volatility. In addition, our common shares are quoted on the OTCQB of the OTC Markets marketplace, which may increase price quotation volatility and could limit liquidity, all of which may adversely affect the market price of our shares.

***We do not expect any cash dividends to be paid on our shares in the foreseeable future.***

We have never declared or paid a cash dividend and we do not anticipate declaring or paying dividends for the foreseeable future. We expect to use future financing proceeds and earnings, if any, to fund operating expenses. Consequently, shareholders' only opportunity to achieve a return on their investment is if the price of our stock appreciates and they sell their shares at a profit. We cannot assure shareholders of a positive return on their investment when they sell their shares or that shareholders will not lose the entire amount of their investment.

***If the beneficial ownership of our stock continues to be highly concentrated, it may prevent you and other shareholders from influencing significant corporate decisions.***

Our significant shareholders may exercise substantial influence over the outcome of corporate actions requiring shareholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets, or any other significant corporate transactions. These shareholders may also vote against a change of control, even if such a change of control would benefit our other shareholders. See "Stock Ownership by Principal Shareholders and Management" below.

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

Rules 15g-1 through 15g-9 promulgated under the Securities Exchange Act of 1934 (the "Exchange Act") impose sales practice and disclosure requirements on certain brokers-dealers who engage in transactions involving a penny stock. The SEC has adopted regulations which generally define penny stock to be any equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. Our

common shares are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and accredited investors. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, prior to a transaction in a penny stock that is not otherwise exempt, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules may discourage investor interest in and limit the marketability of our common shares.

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*Future sales of our securities could adversely affect the market price of our common stock and our future capital-raising activities could involve the issuance of equity securities, which would dilute your investment and could result in a decline in the trading price of our common stock.*

We may sell securities in the public or private equity markets if and when conditions are favorable, or at prices per share below the current market price of our common stock, even if we do not have an immediate need for additional capital at that time. Sales of substantial amounts of shares of our common stock, or the perception that such sales could occur, could adversely affect the prevailing market price of our shares and our ability to raise capital. We may issue additional shares of common stock in future financing transactions or as incentive compensation for our executive management and other key personnel, consultants and advisors. Issuing any equity securities would be dilutive to the equity interests represented by our then-outstanding shares of common stock. Moreover, sales of substantial amounts of shares in the public market, or the perception that such sales could occur, may adversely affect the prevailing market price of our common stock and make it more difficult for us to raise additional capital.

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

None.

**Item 2. Properties.**

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

**Item 3. Legal Proceedings.**

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

**Item 4. Mine Safety Disclosures.**

Not applicable.

**PART II**

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

Market Information

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

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

	High	Low
<b>Fiscal Year Ended May 31, 2015:</b>		
First quarter ended August 31, 2014	\$ 0.85	\$ 0.72
Second quarter ended November 30, 2014	\$ 1.25	\$ 1.18
Third quarter ended February 28, 2015	\$ 0.84	\$ 0.78
Fourth quarter ended May 31, 2015	\$ 1.09	\$ 0.63
<b>Fiscal Year Ended May 31, 2014:</b>		
First quarter ended August 31, 2013	\$ 1.10	\$ 0.65
Second quarter ended November 30, 2013	\$ 1.50	\$ 0.70
Third quarter ended February 28, 2014	\$ 1.40	\$ 0.79
Fourth quarter ended May 31, 2014	\$ 1.00	\$ 0.54

 **Holders**

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

 **Dividends**

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

Holders of 95,100 shares of Series B Preferred Stock are entitled to receive, in preference to the common stock, annual cumulative dividends equal to \$0.25 per share per annum from the date of issuance, which shall accrue, whether or not declared. At the time shares of Series B Preferred Stock are converted into common shares, accrued and unpaid dividends will be paid in cash or with common shares. In the event we elect to pay dividends with common shares, the shares issued will be valued at \$0.50 per share. As of June 30, 2015, if the Company declared a dividend and elected to pay such dividend in the form of common stock, approximately 251,000 shares of common stock would be issued in the form of dividend.

 **Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

There were no repurchases of our equity securities during the three months ended May 31, 2015.

**Item 6. Selected Financial Data.**

This item is not required for smaller reporting companies.

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



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

*Business Highlights*

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

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

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

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

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

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

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

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

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

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

**Results of Operations**

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

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

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

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

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

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

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

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

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

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

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

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

We record research and development where directly identifiable as follows:

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

The Company s two convertible promissory notes held by Alpha Venture Capital Partners, L.P. and its affiliate ( AVCP ) in the principal amount of approximately \$3.5 million, which were issued during the fiscal year ended May 31, 2015, each contain a provision for potential adjustment of the conversion rate of the note, commonly known as an anti-dilution or round down provision. Carl C. Dockery, one of our directors, is the sole member of Alpha Advisors, LLC, the investment advisor for AVCP. Pursuant to U.S. GAAP, each of these notes require the recognition of a derivative liability. Accordingly, the Company incurred a non-cash net charge of approximately \$0.8 million during fiscal year ended May 31, 2015. In June 2015, the Company entered into a Debt Conversion and Termination Agreement, whereby AVCP converted its promissory notes into an aggregate of 5,237,966 shares of common stock and received warrants to purchase up to 1,000,000 shares of common stock at an exercise price of \$0.675 and agreed to terminate its rights under its purchase agreements, including future investment rights.

Interest expense for fiscal 2015 totaled approximately \$4.7 million, of which all but approximately \$0.4 million was non-cash. Interest expense for fiscal 2015 was comprised of approximately (i) \$2.7 million (non-cash) related to amortization of debt discounts, (ii) \$1.5 million (non-cash) arising from inducements to convert notes and the exercise of warrants, (iii) \$0.4 million payable on outstanding notes and (iv) \$0.1 million related to the amortization of previously paid debt issuance costs. U.S. GAAP requires the recognition of debt discounts when the conversion feature of a convertible note is beneficial at the commitment date. The debt discounts represent the sum of the intrinsic value of the conversion feature and the fair value of the detachable warrants issued with the notes. The combined discounts are limited to the note proceeds. The value of the debt discount is amortized over the term of the note as interest expense and the amortization is accelerated upon conversion prior to maturity date. Due to the timing of note

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

The future trends in all of our expenses will be driven, in part, by the future outcomes of our clinical trials and the correlative effect on general and administrative expenses, especially FDA regulatory requirements, in addition to the possibility that all or a portion of the holders of the Company's outstanding convertible notes may elect to convert their notes into common stock, which would reduce future interest expense. See, in particular, Item 1A Risk Factors above.

#### Liquidity and Capital Resources

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

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

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**Cash Flows**

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

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

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

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

The Company is current with its interest payment obligations to all note holders and is in compliance with all other terms of outstanding promissory notes. As of May 31, 2015, the Company had a total of approximately \$7.5 million outstanding in face amount of convertible promissory notes. In the event our promissory notes are not converted into shares of common stock, the Company's ability to continue as a going concern will be contingent upon its ability to raise additional capital to meet these obligations, or refinance. If the Company is unsuccessful in raising additional capital or refinancing in the future, it may be required to cease its operations. In June 2015, the Company entered into a Debt Conversion and Termination Agreement, whereby AVCP converted its promissory notes into an aggregate of 5,237,966 shares of common stock and received warrants to purchase up to 1,000,000 shares of common stock at an exercise price of \$0.675 and agreed to terminate its rights under its purchase agreements, including future investment rights. See Note 14 to the financial statements included herein under Item 8. As such, the total amount of outstanding convertible promissory notes as of the date of the filing has been reduced from approximately \$7.5 million down to approximately \$4 million and the earliest maturity date is October 2015 rather than August 2015.

We have not generated revenue to date, and will not generate product revenue in the foreseeable future. We expect to continue to incur sizable operating losses as we proceed with our clinical trials with respect to PRO 140 and continue to advance it through the product development and regulatory process. In addition to increasing research and development expenses, we expect general and administrative and manufacturing costs to increase, as we add personnel and other administrative expenses associated with our current efforts.

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

Under the Asset Purchase Agreement (the "Asset Purchase Agreement"), dated July 22, 2012, between the Company and Progenics Pharmaceuticals, Inc. ("Progenics"), the Company acquired from Progenics its proprietary HIV viral-entry inhibitor drug candidate PRO 140 ("PRO 140"), a humanized anti-CCR5 monoclonal antibody, as well as certain other related assets, including the existing inventory of bulk PRO 140 drug product, intellectual property, certain related licenses and sublicenses, and U.S. Food and Drug Administration ("FDA") regulatory filings. On October 16, 2012, the Company paid \$3,500,000 in cash to Progenics to close the acquisition transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) \$1,500,000 at the time of the first dosing in a Phase 3 trial or non-US equivalent; (ii) \$5,000,000 at the time of the first US new drug application approval by the FDA or other non-U.S. approval for the sale of PRO 140; and (iii) royalty payments of up to five percent (5%) on net sales during the period beginning on the date of the first commercial sale of PRO 140 until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years, in each case determined on a country-by-country basis. Payments to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the "PDL

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License ), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the PRO 140 transaction, pursuant to which we must pay additional milestone payments and royalties as follows: (i) \$1,000,000 upon initiation of a Phase 3 clinical trial; (ii) \$500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) \$500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iv) royalties of up to 7.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of \$150,000 until royalties paid exceed that amount. As noted above and in the financial statements included herein under Item 8, the Company accrued milestone payments totaling \$2.5 million as of May 31, 2015 in connection with its Phase 3 clinical trial.

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

## Going Concern

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

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses for all periods presented and has a substantial accumulated deficit. As of May 31, 2015, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent upon its ability to obtain additional operating capital, complete development of its product candidates, obtain FDA approval, outsource manufacturing of its products, and ultimately to attain profitability. The Company intends to seek additional funding through equity offerings or licensing agreements or strategic alliances to implement its business plan. There are no assurances, however, that the Company will be successful in these endeavors.

## Off-Balance Sheet Arrangements

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

## Critical Accounting Policies and Estimates



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

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

The Company may scale-up and make commercial quantities of its product candidate prior to the date it anticipates that such product will receive final FDA approval. The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever. This risk notwithstanding, the Company may scale-up and build pre-launch inventories of product that have not yet received final governmental approval when the Company believes that such action is appropriate in relation to the commercial value of the product launch opportunity. The determination to capitalize is made once the Company (or its third party development partners) has filed a New Drug Application (an NDA ) that has been acknowledged by the FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely

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manner and management is reasonably certain that all regulatory and legal hurdles will be cleared. This determination is based on the particular facts and circumstances relating to the expected FDA approval of the drug product being considered. As of May 31, 2014 and 2015 the Company did not have pre-launch inventory.

We use the Black-Scholes option pricing model to estimate the fair value of stock-based awards on the date of grant utilizing certain assumptions that require judgments and estimates. These assumptions include estimates for volatility, expected term, and risk-free interest rates in determining the fair value of the stock-based awards.

We follow the provisions of FASB ASC 815 Derivatives and Hedging ( ASC 815 ), as instruments are recorded as a derivative liability, at fair value, with changes in fair value reflected in income. Derivative financial instruments consist of financial instruments that contain a notional amount and one or more underlying variables (e.g., interest rate, security price, variable conversion rate or other variables), require no initial net investment and permit net settlement. Derivative financial instruments may be free-standing or embedded in other financial instruments.

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

We have issued convertible promissory notes with detachable warrants to purchase common stock. The conversion options are fixed, but beneficial to the note holders at the respective commitment dates. The valuation of the beneficial conversion feature of the notes and of the warrants gives rise to the recognition of a debt discount, which requires the use of certain assumptions inherent in the Black-Scholes option pricing model, including various judgments and estimates.

As discussed in Notes 7 and 8 to the consolidated financial statements, we have significant contingent potential milestone and royalty liabilities. We must estimate the likelihood of paying these contingent liabilities periodically based on the progress of our clinical trials.

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

This item is not required for smaller reporting companies.

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

CYTODYN INC.

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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders

CytoDyn Inc.

Vancouver, Washington

We have audited the accompanying consolidated balance sheets of CytoDyn Inc. as of May 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required at this time, to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CytoDyn Inc. as of May 31, 2015 and 2014 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company incurred a net loss of \$25,088,070 for the year ended May 31, 2015, and has an accumulated deficit of \$71,522,302 through May 31, 2015, which raises a substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Warren Averett, LLC

Warren Averett, LLC  
Certified Public Accountants  
Tampa, Florida  
July 10, 2015

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CytoDyn Inc.

Consolidated Balance Sheets

May 31,  
2014





Schedule of Income (Loss) Per Share



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	Three Months Ended		September 30, 2012	September 30, 2011	September 30, 2012
	September 30, 2012	September 30, 2011			
Income (loss) per share - basic	\$	(28,650)	\$	24,971	\$ (123,117)
Weighted average shares outstanding - basic		9,118,161		8,235,697	9,077,566
Weighted average shares outstanding - assuming dilution		9,382,745		8,445,895	9,166,888
Income (loss) per share - diluted	\$	(.00)	\$	.00	\$ (.01)
Income (loss) per share - diluted	\$	(.00)	\$	.00	\$ (.01)

	Three Months Ended		September 30, 2012	September 30, 2011	September 30, 2012
	September 30, 2012	September 30, 2011			
Stock options		1,187,116		1,519,788	1,187,116
Warrants and non-employee stock options		140,000		371,000	140,000
Convertible promissory note		107,843		107,843	107,843
		1,434,959		1,998,631	1,434,959

		September 30, 2012	
Accounts receivable	\$	267,502	\$
Less allowance for doubtful accounts		(212,134)	
	\$	55,368	\$



	September 30, 2012		
Computers and equipment	\$	1,524,949	\$
Leasehold improvements		991,749	
Software		57,337	
Furniture and fixtures		28,521	
		2,602,556	
Less accumulated depreciation		(2,540,266)	
	\$	62,290	\$

	September 30, 2012	
Accrued interest	\$ 2,363	\$
Accrued deferred compensation	839,102	
Accrued unused vacation and sick leave	114,871	
Accrued other liabilities	126,543	
	1,082,879	
Less current portion	1,060,374	
	\$ 22,505	\$



	Three Months Ended		Weighted Average	Nine Months Ended
	September 30, 2012			September 30, 2012
Options outstanding, beginning of the period	1,292,116	\$	.038	1,462,783
Options granted during the period	195,000		.003	338,000
Options exercised during the period	-		-	(140,000)
Options expired during the period	-		-	(173,667)
Options outstanding, end of the period	1,487,116	\$	.033	1,487,116





	Three Months Ended September 30, 2012	Weighted Average Exercise Price	Nine Months Ended September 30, 2012	We Av Exerc
Warrants and non-employee stock options outstanding, beginning of the period	579,000	\$ .022	591,000	\$
Warrants and non-employee stock options expired during the period	(14,000)	.080	(26,000)	
Warrants and non-employee stock options outstanding, end of the period	565,000	.020	565,000	





se. In September 2007, the lessor agreed to cease the monthly lease payments effective January 1, 2007 which generated a total of \$54,7



business at the state and federal levels. These include proceedings before both the Federal Communications Commission and the Oklaho



*lectively referred to as the Disclosure Documents ). Certain forward-looking statements contained in this Report and in the Disclosu*

















	For the Nine-Month Periods Ended	
	September 30,	
	2012	2011
Net cash flows provided by operations	\$ 22,156	\$ 22,156
Net cash flows used in investing activities	(8,669)	(8,669)
Net cash flows used in financing activities	(17,350)	(17,350)

use our cost of developing new networks and services, funding other strategic initiatives, and operating our business depend on a variety of factors.





d 140,000, respectively, of common stock purchase warrants for the lessor in return for a credit of \$17,960 and \$3,940, respectively, on

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ls and procedures and internal control over financial reporting occurred during the period covered by this Report that would have mater

**PART II OTHER INFORMATION**

ulatory proceedings in the ordinary course of our business at the state and federal levels. These include proceedings before both the Fed

amended (filed as Exhibit 2.1 to Registrant's Registration number 000-27031 and incorporated herein by reference).	#
Registrant's Registration Statement on Form 10-SB, file dated herein by reference)	#
nt's Common Stock (filed as Exhibit 4.1 to the Company's ended December 31, 1999, and incorporated herein by	#

Amended Certificate of Incorporation and the Ninth Section #  
on (filed as Exhibit 2.1 to Registrant's Registration Statement  
-27031 and incorporated by reference).

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II and V of Registrant's Bylaws (filed as Exhibit 2.1 to  
 t on Form 10-SB, file number 000-27031 and incorporated

#

Interim Financing in the amount of \$505,000 (filed as  
 ly Report on Form 10-QSB for the Quarter ended  
 herein by reference).

#

Florida Investors for Interim Financing in the amount of  
 gistrant's Quarterly Report on Form 10-QSB for the  
 incorporated herein by reference).

#

Florida Investors for Interim Financing in the amount of  
 gistrant's Quarterly Report on Form 10-QSB for the  
 incorporated herein by reference).

#

Georgia Investors for Interim Financing in the amount of  
 gistrant's Quarterly Report on Form 10-QSB for the  
 incorporated herein by reference).

#

Georgia Investors for Interim Financing in the amount of  
 gistrant's Quarterly Report on Form 10-QSB for the  
 incorporated herein by reference).

#

Illinois Investors for Interim Financing in the amount of  
 gistrant's Quarterly Report on Form 10-QSB for the  
 incorporated herein by reference).

#

Mississippi Investors for Interim Financing in the amount of  
 gistrant's Quarterly Report on Form 10-QSB for the  
 incorporated herein by reference).

#

Interim Financing in the amount of \$500,000 (filed as  
 ly Report on Form 10-QSB for the Quarter ended  
 herein by reference).

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Interim Financing in the amount of \$500,000 (filed as  
 ly Report on Form 10-QSB for the Quarter ended  
 herein by reference).

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...m Financing in the amount of \$500,000 (filed as ...rly Report on Form 10-QSB for the Quarter ended ...erein by reference).	
...ote for September 29, 2000, private placement (filed as ...10-KSB for the fiscal year ended December 31, 2000 and	#
...ptember 29, 2000, private placement (filed as ...10-KSB for the fiscal year ended December 31, 2000 and	#
...greement (filed as Exhibit 4.16 to Registrant's ...1 June 30, 2001 and incorporated herein by reference)	#
...ertificate (filed as Exhibit 4.17 to Registrant's ...1 June 30, 2001 and incorporated herein by reference)	#
...ment between the Company and National Securities ...1999 (filed as Exhibit 10.1 to Registrant's Form 10-KSB ...31, 1999, and incorporated herein by reference).	#

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November 9, 2000, issued to Roger P. Baresel (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
December 29, 2000, issued to Roger P. Baresel (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
dated February 29, 2000, issued to Wallace L Walcher (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
dated February 17, 1999, issued to Timothy J. Kilkenny (filed as Registration Statement on Form 10-SB, file number 000-27031 reference).	#
dated October 19, 1999, issued to Wesdon C. Peacock (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
dated April 14, 2000, issued to Jason C. Ayers (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
dated May 1, 2000, issued to B. Don Turner (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
ement dated December 8, 2000, issued to Jason C. Ayers, n Turner and Wallace L. Walcher (filed as Exhibit 10.24 to for the fiscal year ended December 31, 2000).	#
November 9, 2000, issued to Roger P. Baresel (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
November 9, 2000, issued to Roger P. Baresel (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
December 29, 2000, issued to Roger P. Baresel (filed as Exhibit 10-KSB for the fiscal year ended December 31, 2000).	#
dated October 13, 2000, issued to Roger P. Baresel (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
dated October 12, 1999, issued to Travis Lane (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#

January 5, 2001, issued to Generation Capital Associates (filed as s Form 10-KSB for the fiscal year ended December 31, 2000).	#
ent dated November 8, 2000 between FullNet Communications, Corporation (filed as Exhibit 10.31 to Registrant s year ended December 31, 2000).	#
January 25, 2000, issued to Fullnet of Tahlequah, Inc.	#
February 7, 2000, issued to David Looper	#
February 29, 2000, issued to Wallace L. Walcher	#
March 2, 2000, issued to Lary Smith	#
March 15, 2001, issued to higganbotham.com L.L.C.	#
September 19, 2001, issued to Northeast Rural Services	#
September 19, 2001, issued to Northeast Rural Services	#

<i>Exhibit Number</i>	<i>Exhibit</i>	
10.39	Form of Convertible Promissory Note dated September 6, 2002	#
10.40	Employment Agreement with Timothy J. Kilkenny dated July 31, 2002	#
10.41	Employment Agreement with Roger P. Baresel dated July 31, 2002	#
10.42	Letter from Grant Thornton LLP to the Securities and Exchange Commission dated January 30, 2003	#
10.43	Form 8-K dated January 30, 2003 reporting the change in certifying accountant	#
10.44	Form 8-K dated September 20, 2005 reporting the change in certifying accountant	#
10.45	Secured Promissory Note and Security Agreement dated December 30, 2009, issued to High Capital Funding, LLC	#
10.46	Employment Agreement with Jason Ayers dated January 1, 2011	#
22.1	Subsidiaries of the Registrant	#
31.1	Certification pursuant to Rules 13a-14(a) and 15d-14(a) of Timothy J. Kilkenny	*
31.2	Certification pursuant to Rules 13a-14(a) and 15d-14(a) of Roger P. Baresel	*
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 by Timothy J. Kilkenny	*
32.2	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 by Roger P. Baresel	*
101.INS	XBRL Instance Document	**
101.SCH	XBRL Taxonomy Extension Schema Document	**
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	**
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	**
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	**
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	**



**SIGNATURES**

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CERTIFICATIONS

/s/ Timothy J. Kilkenny

Chief Executive Officer

CERTIFICATIONS

/s/ Roger P. Baresel,

President and Chief Financial Officer

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**