

CytoDyn Inc.
Form 10-Q
January 13, 2017
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended November 30, 2016

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1933

For the transition period from _____ to _____

Commission File Number: 000-49908

CYTODYN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

75-3056237
(I.R.S. Employer or
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

(Former name, former address and former fiscal year, if changed since last report)

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 check mark 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 (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Edgar Filing: CytoDyn Inc. - Form 10-Q

Indicate by check mark 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 Exchange Act): Yes No

On December 31, 2016 there were 142,221,981 shares outstanding of the registrant's \$0.001 par value common stock.

Table of Contents

TABLE OF CONTENTS

	PAGE
<u>PART I</u>	3
<u>ITEM 1. FINANCIAL STATEMENTS</u>	3
<u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	21
<u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	24
<u>ITEM 4. CONTROLS AND PROCEDURES</u>	24
<u>PART II</u>	26
<u>ITEM 1. LEGAL PROCEEDINGS</u>	26
<u>ITEM 1A. RISK FACTORS</u>	26
<u>ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	26
<u>ITEM 3. DEFAULTS UPON SENIOR SECURITIES</u>	26
<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	26
<u>ITEM 5. OTHER INFORMATION</u>	26
<u>ITEM 6. EXHIBITS</u>	26

Table of Contents**PART I****Item 1. Financial Statements.**

CytoDyn Inc.

Consolidated Balance Sheets

	November 30, 2016 (unaudited)	May 31, 2016
Assets		
Current assets:		
Cash	\$ 8,811,237	\$ 9,641,776
Prepaid expenses	338,912	141,714
Prepaid service fees	4,413,312	1,710,852
Total current assets	13,563,461	11,494,342
Furniture and equipment, net	17,892	24,550
Intangibles, net	2,092,239	2,267,239
Total assets	\$ 15,673,592	\$ 13,786,131
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 5,902,621	\$ 2,467,973
Accrued liabilities and salaries	58,125	242,708
Accrued license fee	380,500	870,000
Total current liabilities	6,341,246	3,580,681
Long-term liabilities:		
Derivative liability	3,955,734	
Total long-term liabilities	3,955,734	
Total liabilities	10,296,980	3,580,681
Commitments and Contingencies		
Stockholders equity		
Series B convertible preferred stock, \$0.001 par value; 400,000 shares authorized, 95,100 shares issued and outstanding at November 30, 2016 and May 31, 2016, respectively	95	95
Common stock, \$0.001 par value; 350,000,000 and 250,000,000 shares authorized, 138,221,982 and 123,335,634 issued and outstanding at	138,222	123,336

Edgar Filing: CytoDyn Inc. - Form 10-Q

November 30, 2016 and May 31, 2016, respectively		
Additional paid-in capital	113,285,930	107,307,933
Accumulated (deficit)	(108,047,635)	(97,225,914)
Total stockholders' equity	5,376,612	10,205,450
Total liabilities and stockholders' equity	\$ 15,673,592	\$ 13,786,131

See accompanying notes to consolidated financial statements.

Table of Contents

CytoDyn Inc.

Consolidated Statements of Operations

(Unaudited)

	Three Months Ended November 30,		Six Months Ended November 30,	
	2016	2015	2016	2015
Operating expenses:				
General and administrative	\$ 1,679,925	\$ 1,142,519	\$ 3,259,988	\$ 2,400,568
Research and development	4,383,636	1,661,069	8,069,109	6,970,309
Amortization and depreciation	92,556	90,191	185,140	180,382
Total operating expenses	6,156,117	2,893,779	11,514,237	9,551,259
Operating loss	(6,156,117)	(2,893,779)	(11,514,237)	(9,551,259)
Interest income	5,648	211	9,383	569
Loss on extinguishment of convertible notes				(584,177)
Change in fair value of derivative liability	1,223,466		1,223,466	646,505
Interest expense:				
Amortization of discount on convertible notes		(1,114,901)		(2,121,491)
Amortization of debt issuance costs		(362,038)		(712,377)
Amortization of discount on related party convertible notes				(94,344)
Interest related to derivative liability	(540,333)		(540,333)	
Inducement interest		(866,713)		(1,624,324)
Interest on notes payable		(27,373)		(118,709)
Total interest expense	(540,333)	(2,371,025)	(540,333)	(4,671,245)
Loss before income taxes	(5,467,336)	(5,264,593)	(10,821,721)	(14,159,607)
Provision for taxes on income				
Net loss	\$ (5,467,336)	\$ (5,264,593)	\$ (10,821,721)	\$ (14,159,607)
Basic and diluted loss per share	\$ (0.04)	\$ (0.06)	\$ (0.08)	\$ (0.18)
Basic and diluted weighted average common shares outstanding	136,023,544	84,089,964	130,185,627	78,003,528

See accompanying notes to consolidated financial statements.

Table of Contents

CytoDyn Inc.

Consolidated Statements of Cash Flows

(Unaudited)

	Six Months Ended November 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (10,821,721)	\$ (14,159,607)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	185,140	180,382
Amortization of debt issuance costs		604,628
Amortization of discount on convertible notes		2,121,491
Amortization of discount on related party notes		94,344
Interest expense associated with derivative liability	540,333	
Change in fair value of derivative liability	(1,223,466)	(646,505)
Loss on extinguishment of convertible notes		584,177
Interest expense associated with conversion and exercise inducement		757,611
Interest expense associated with extension of warrant expiration		866,713
Stock-based compensation	687,634	590,661
Changes in current assets and liabilities:		
(Increase) decrease in prepaid expenses	(2,899,658)	139,857
(Decrease) increase in accounts payable and accrued expenses	2,760,563	350,119
Net cash used in operating activities	(10,771,175)	(8,516,129)
Cash flows from investing activities:		
Furniture and equipment purchases	(3,480)	
Net cash used in investing activities	(3,480)	
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants	10,729,500	12,941,248
Proceeds from warrant exercises	397,880	
Payment of principal and interest on convertible notes payable		(789,140)
Payment of offering costs	(1,183,264)	(1,433,569)
Net cash provided by financing activities	9,944,116	10,718,539
Net change in cash	(830,539)	2,202,410
Cash, beginning of period	9,641,776	1,050,060
Cash, end of period	\$ 8,811,237	\$ 3,252,470

Supplemental disclosure of cash flow information:

Cash paid during the period for:			
Interest		\$	\$ 26,890
Non-cash investing and financing transactions:			
Common stock issued upon conversion of convertible debt		\$	\$ 7,947,342
Common stock issued or to be issued for accrued interest payable		\$	\$ 143,479
Derivative liability associated with warrants		\$ 5,179,200	\$

See accompanying notes to consolidated financial statements.

Table of Contents

CYTODYN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2016

(UNAUDITED)

Note 1 Organization

CytoDyn Inc. (the Company) was originally incorporated under the laws of Colorado on May 2, 2002 under the name RexRay Corporation (its previous name) and, effective August 27, 2015, reincorporated under the laws of Delaware. We are a clinical-stage 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.

The Company is developing a class of therapeutic monoclonal antibodies to address unmet medical needs in the areas of HIV and graft versus host disease.

Note 2 Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and reflect all adjustments, which consist solely of normal recurring adjustments, needed to fairly present the financial results for these periods. The consolidated financial statements and notes thereto are presented as prescribed by Form 10-Q. Accordingly, certain information and note disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been omitted. The accompanying consolidated financial statements should be read in conjunction with the financial statements for the fiscal years ended May 31, 2016 and 2015 and notes thereto in the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2016, filed with the Securities and Exchange Commission on July 19, 2016. Operating results for the three and six-months ended November 30, 2016 are not necessarily indicative of the results that may be expected for the entire year. In the opinion of management, all adjustments have been made, which consist only of normal recurring adjustments necessary for a fair statement of (a) the results of operations for the three and six-month periods ended November 30, 2016 and November 30, 2015, (b) the financial position at November 30, 2016 and (c) cash flows for the six-month periods ended November 30, 2016 and November 30, 2015.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, AGTI and CVM, both of which are dormant entities. All intercompany transactions and balances are eliminated in consolidation.

Reclassifications

Certain prior year amounts shown in the accompanying consolidated financial statements have been reclassified to conform to the 2016 presentation. These reclassifications did not have any effect on total current assets, total assets, total current liabilities, total liabilities, total stockholders' equity, net loss or loss per share.

Going Concern

The consolidated accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company had losses for all periods presented. The Company incurred a net loss of \$10,821,721 for the six-months ended November 30, 2016 and has an accumulated deficit of \$108,047,635 as of November 30, 2016. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent upon its ability to obtain additional operating capital, complete development of its product candidates, obtain U.S. Food & Drug Administration (FDA) approval, outsource manufacturing of the product candidates, and ultimately achieve initial revenues and attain profitability. The Company is currently engaging in significant research and development activities related to these product candidates, and expects to incur significant research and development expenses in the future primarily related to its clinical trials. These research and development activities are subject to significant risks and uncertainties. The Company intends to finance its future development activities and its working capital needs largely from the sale of equity and debt securities, combined with additional funding from other traditional sources. There can be no assurance, however, that the Company will be successful in these endeavors.

Table of Contents

Use of Estimates

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

Cash

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. Balances in excess of federally insured limits at November 30, 2016 and May 31, 2016 approximated \$8.7 million and \$9.4 million, respectively.

Identified Intangible Assets

The Company follows the provisions of FASB ASC Topic 350 Intangibles-Goodwill and Other, which establishes accounting standards for the impairment of long-lived assets such as intangible assets subject to amortization. The Company reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. If the sum of the undiscounted expected future cash flows over the remaining useful life of a long-lived asset group is less than its carrying value, the asset is considered impaired. Impairment losses are measured as the amount by which the carrying amount of the asset group exceeds the fair value of the asset. There were no impairment charges for the three and six-months ended November 30, 2016 and 2015. The value of the Company's patents would be significantly impaired by any adverse developments as they relate to the clinical trials pursuant to the patents acquired as discussed in Notes 7 and 9.

Research and Development

Research and development costs are expensed as incurred. Clinical trial costs incurred through third parties are expensed as the contracted work is performed. Where contingent milestone payments are due to third parties under research and development collaboration arrangements or other contractual agreements, the milestone payment obligations are expensed when the milestone conditions are probable and the amount of payment is reasonably estimable.

Pre-launch Inventory

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 Biologics License Application that has been acknowledged by the FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely 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 November 30, 2016 and May 31, 2016, the Company did not have pre-launch inventory that qualified for capitalization pursuant to U.S. GAAP ASC 330 Inventory.

Fair Value of Financial Instruments

At November 30, 2016 and May 31, 2016, the carrying value of the Company's cash, accounts payable and accrued liabilities approximate their fair value due to the short-term maturity of the instruments. The Company carries derivative financial instruments at fair value as required by U.S. GAAP.

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. The Company follows the provisions of FASB ASC 815 Derivatives and Hedging (ASC 815), as their instruments are recorded as a derivative liability, at fair value, and FASB ASC 480 Distinguishing Liabilities from Equity (ASC 480), as it relates to warrant liability, with changes in fair value reflected in income.

Table of Contents*Fair Value Hierarchy*

The three levels of inputs that may be used to measure fair value are as follows:

Level 1. Quoted prices in active markets for identical assets or liabilities.

Level 2. Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets with insufficient volume or infrequent transactions (less active markets), or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated with observable market data for substantially the full term of the assets or liabilities. Level 2 inputs also include non-binding market consensus prices that can be corroborated with observable market data, as well as quoted prices that were adjusted for security-specific restrictions.

Level 3. Unobservable inputs to the valuation methodology are significant to the measurement of the fair value of assets or liabilities. These Level 3 inputs also include non-binding market consensus prices or non-binding broker quotes that the Company was unable to corroborate with observable market data.

Liability measured at fair value on a recurring basis by level within the fair value hierarchy as of November 30, 2016 and May 31, 2016 is as follows:

	Fair Value Measurement at November 30, 2016 (1)		Fair Value Measurement at May 31, 2016	
	Using Level 3	Total	Using Level 3	Total
Liability:				
Derivative liability	\$ 3,955,734	\$ 3,955,734	\$	\$
Total liability	\$ 3,955,734	\$ 3,955,734	\$	\$

(1) The Company did not have any assets or liabilities measured at fair value using Level 1 or 2 of the fair value hierarchy as of November 30, 2016 and May 31, 2016.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurements. These instruments are not quoted on an active market, so the Company uses a Binomial Lattice Model to estimate the value of the derivative liability. A Binomial Lattice Model was used because management believes it reflects all the assumptions that market participants would likely consider in negotiating the transfer of the warrant. The Company's derivative liability is classified within Level 3 of the fair value hierarchy because certain unobservable inputs were used in the valuation model.

The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the six months ended November 30, 2016 and the year ended May 31, 2016:

Edgar Filing: CytoDyn Inc. - Form 10-Q

Balance at May 31, 2015	\$ 2,008,907
Note conversion June 24, 2015	(521,133)
Note conversion June 24, 2015	(841,269)
Fair value adjustments	(646,505)
Balance at May 31, 2016	\$
Investor warrants issued with registered direct equity offering	4,360,000
Agent warrants issued with registered direct equity offering	819,200
Fair value adjustments	(1,223,466)
Balance at November 30, 2016	\$ 3,955,734

Stock-Based Compensation

U.S. GAAP requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award (requisite service period) or when designated milestones have been achieved.

Table of Contents

The Company accounts for stock-based awards established by the fair market value of the instrument using the Black-Scholes option pricing model utilizing certain weighted average assumptions including stock price volatility, expected term and risk-free interest rates, as of the grant date. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the stock-based award. The expected volatility is based on the historical volatility of the Company's common stock on monthly intervals. The computation of the expected option term is based on the simplified method, as the Company issuances are considered plain vanilla options. For stock-based awards with defined vesting, the Company recognizes compensation expense over the requisite service period or when designated milestones have been achieved. The Company estimates forfeitures at the time of grant and revised, if necessary, in subsequent periods, if actual forfeitures differ from those estimates. Based on limited historical experience of forfeitures, the Company estimated future unvested forfeitures at 0% for all periods presented.

Common Stock

On March 18, 2016, at a special meeting of stockholders, a proposal was approved to increase the total number of authorized shares of common stock of the Company from 200,000,000 to 250,000,000. Subsequently, on August 24, 2016, at the Annual Meeting of Stockholders, a proposal was approved to increase the total number of authorized shares of common stock from 250,000,000 to 350,000,000.

Preferred Stock

The Company's Board of Directors is authorized to issue up to 5,000,000 shares of preferred stock without stockholder approval. As of November 30, 2016, the Company has authorized the issuance of 400,000 shares of Series B convertible preferred stock, of which 95,100 shares are outstanding. The remaining preferred shares authorized have no specified rights.

Debt Issuance Costs

During the year ended May 31, 2015, the Company incurred direct costs associated with the issuance of short-term convertible notes, as described in Note 4, and recorded approximately \$708,000 of debt issuance costs and approximately \$350,000 and \$708,000 of related amortization for the three and six months ended November 30, 2015. There were no debt issuance costs during 2016.

Offering Costs

During the six-months ended November 30, 2016 and the year ended May 31, 2016, the Company incurred approximately \$1.2 and \$3.9 million in direct incremental costs associated with the sale of the equity securities, as described in Note 10. The offering costs were recorded as a component of equity when the proceeds were received.

Stock for Services

The Company periodically issues warrants to consultants for various services. The Black-Scholes option pricing model, as described more fully above, is utilized to measure the fair value of the equity instruments on the date of issuance. The Company recognizes the compensation expense associated with the equity instruments over the requisite service or vesting period.

Loss per Common Share

Basic loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share would include the weighted average number of shares of common stock outstanding and potentially dilutive common stock equivalents. Because of the net losses for all periods presented, the basic and diluted weighted average shares outstanding are the same since including the additional shares would have an anti-dilutive effect on the loss per share. For this reason, common stock options and warrants to purchase 64,415,987 and 44,618,007 shares of common stock were not included in the computation of basic and diluted weighted average number of shares of common stock outstanding for the six-months ended November 30, 2016 and November 30, 2015, respectively. Additionally, as of November 30, 2016, shares of Series B convertible preferred stock in the aggregate of 95,100 shares can potentially convert into 951,000 shares of common stock.

Income Taxes

Deferred taxes are provided on the asset and liability method, whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Future tax benefits for net operating loss carry forwards are recognized to the extent that realization of these benefits is considered more likely than not. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Table of Contents

The Company follows the provisions of FASB ASC 740-10 Uncertainty in Income Taxes (ASC 740-10). A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there are no unrecognized benefits for all periods presented. The Company has not recognized interest expense or penalties as a result of the implementation of ASC 740-10. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefit in interest expense and penalties in operating expenses and penalties in operating expenses.

Note 3 Recent Accounting Pronouncements

Recent accounting pronouncements, other than below, issued by the FASB (including its EITF), the AICPA and the SEC did not or are not believed by management to have a material effect on the Company's present or future financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), *Leases (Topic 842)* effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods. The ASU is to be applied using a modified retrospective approach with optional practical expedients and other special transition provisions. Early adoption is permitted. The ASU supersedes FASB ASC 840, *Leases*, and adds FASB ASC 842. It also amends and supersedes a number of other paragraphs throughout the FASB ASC. Management is currently assessing the impact the adoption of ASU 2016-02 will have on the Company's Consolidated Financial Statements.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09 (ASU 2016-09), *Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early application is permitted for reporting periods where financial statements have not yet been made available for issuance. The ASU requires different transition methods and disclosures based on the type of amendment included in the ASU. Management is currently assessing the impact the adoption of ASU 2016-09 will have on the Company's Consolidated Financial Statements.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. The amendments in ASU 2014-15 are effective for reporting periods beginning after December 15, 2016, with early adoption permitted. Management is currently assessing the impact the adoption of ASU 2014-15 will have on our Consolidated Financial Statements.

Note 4 Convertible Instruments*Series B Convertible Preferred Stock*

During fiscal 2010, the Company issued 400,000 shares of Series B, \$0.001 par value Convertible Preferred Stock (Series B) at \$5.00 per share for cash proceeds totaling \$2,009,000, of which 95,100 shares remain outstanding at November 30, 2016. Each share of the Series B is convertible into ten shares of the Company's \$0.001 par common stock including any accrued dividends, with an effective fixed conversion price of \$.50 per share. The holders of the Series B can only convert their shares to common shares provided the Company has sufficient authorized common shares at the time of conversion. Accordingly, the conversion option was contingent upon the Company increasing its authorized common shares, which occurred in April 2010, when the Company's stockholders approved an increase in

the authorized shares of common stock to 100,000,000. At the commitment date, which occurred upon such stockholder approval, the conversion option related to the Series B was beneficial. The intrinsic value of the conversion option at the commitment date resulted in a constructive dividend to the Series B holders of approximately \$6,000,000. The constructive dividend increased and decreased additional paid-in capital by identical amounts. The Series B has liquidation preferences over the common shares at \$5.00 per share plus any accrued dividends. Dividends are payable to the Series B holders when declared by the board of directors at the rate of \$.25 per share per annum. Such dividends are cumulative and accrue whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available and are payable only upon conversion of the Series B in cash or shares of common stock at the Company's option. The Series B holders have no voting rights.

2013 Convertible Notes

During the year ended May 31, 2013, the Company issued \$6,588,250 in aggregate original principal amount of unsecured convertible notes (the 2013 Convertible Notes) to investors for cash. Each outstanding 2013 Convertible Note was convertible at the election of the holder at any time into common shares at a fixed conversion price. At issuance, total principal of \$6,208,250 was convertible at \$0.75 per share, and \$380,000 was convertible at \$0.65 per share. The 2013 Convertible Notes were payable in full between November 30, 2013 and March 6, 2016, and bore interest at rates ranging from 5% to 10% per year, payable in cash semi-annually in arrears beginning on April 1, 2013. At November 30, 2016 and May 31, 2016, there were no convertible notes outstanding.

Table of Contents

In connection with the initial sale of the 2013 Convertible Notes, detachable common stock warrants to purchase a total of 8,527,984 common shares with a two-year term at exercise prices ranging from \$0.75 to \$2.00 per share were issued to the investors. The Company determined the fair value of the warrants at issuance using the Black-Scholes option pricing model utilizing certain weighted average assumptions, such as expected stock price volatility, term of the warrants, risk-free interest rates and expected dividend yield at the grant date.

Additionally, at the commitment date, the Company determined that the conversion feature related to the 2013 Convertible Notes was beneficial to the investors. As a result, the Company determined the intrinsic value of the conversion feature utilizing the fair value of the underlying common stock at the commitment date and the effective conversion price after discounting the 2013 Convertible Notes for the fair value of the warrants. The fair value of the warrants and the intrinsic value of the beneficial conversion feature were recorded as a debt discount to the 2013 Convertible Notes, with a corresponding increase to additional paid-in capital. The debt discount was amortized over the life of the 2013 Convertible Notes. During the six-months ended November 30, 2016 and 2015, the Company recognized approximately \$ -0- and \$6,800, respectively, as interest expense related to amortization of the debt discount. The unamortized discount was fully amortized upon any conversion of the 2013 Convertible Notes before maturity. Activity related to the 2013 Convertible Notes for the six-months ended November 30, 2016 and fiscal year ended May 31, 2016 was as follows:

	November 30, 2016	May 31, 2016
Face amount of Notes	\$	\$ 50,000
Unamortized discount		
Conversions		(50,000)
Total carrying value of Notes	\$	\$

During the fiscal year ended May 31, 2016 the board approved a one-year extension of expiration dates on the aforementioned detachable common stock warrants with an original term of two years, covering approximately 6.3 million shares of common stock, with an exercise price of \$1.00 per share. Current expiration dates ranging from October 2015 through January 2016 were extended to October 2016 through January 2017. The extensions were effective October 1, 2015 upon the receipt of certain executed documentation from the warrant holders. Pursuant to U.S. GAAP, the Company recognized non-cash interest expense of approximately \$866,700 in connection with this extension, which represented the incremental increase in the fair value of the modified warrants.

The Company determined the fair value of the new warrants using the Black-Scholes option pricing model utilizing certain weighted-average assumptions, such as expected stock price volatility, term of the warrants, risk-free rate and expected dividend yield at the commitment date.

	2016	
Expected dividend yield	0%	
Stock price volatility	64.56%	69.30%
Expected term	1 year	
Risk-free interest rate	0.33%	
Grant-date fair value	\$0.15	\$0.18

AVCP Convertible Notes

During the year ended May 31, 2015, the Company issued a three-month unsecured convertible promissory note (the AVCP Bridge Note) and together with the AVCP Two-Year Note, the AVCP Convertible Notes) in the aggregate principal amount of \$1,500,000 to Alpha Venture Capital Partners, L.P. (AVCP), an affiliate of one of the Company's directors. As described in greater detail below, the AVCP Bridge Note, along with the AVCP Two-Year Note, were subsequently converted in a transaction occurring during the year ended May 31, 2016. The principal amount of the AVCP Bridge Note plus unpaid accrued interest was convertible at the election of the holder into shares of the Company's common stock at any time prior to maturity at an initial conversion price of \$1.00 per share. The AVCP Bridge Note bore simple interest of 1.2% per month, payable at maturity on May 5, 2015, and monthly

Table of Contents

thereafter, upon the Company's election to exercise a one-time option to extend the maturity by an additional three months, which the Company exercised on April 1, 2015 (extending the maturity date to August 5, 2015). Prepayment was permitted without penalty subject to the Company's obligation to pay at least three months' interest on the principal amount. The conversion price was subject to (i) adjustment for stock splits and similar corporate events and (ii) reduction to a price per share that is 10% below the lowest sale price that is below \$.9444 per share, for shares of common stock sold or deemed sold in future securities offerings, including sales to AVCP and its designees subject to certain exempt transactions. Without AVCP's prior written consent, the Company was not permitted to incur additional indebtedness for borrowed money, other than up to an additional \$6.0 million in convertible promissory notes that may be issued to AVCP or related parties, unless such indebtedness was subordinated in right of payment to the Company's obligations under the AVCP Bridge Note and any additional notes issued to AVCP or related parties.

During the year ended May 31, 2015, the Company issued an additional two-year term unsecured convertible promissory note (the "AVCP Two-Year Note") in the aggregate principal amount of \$2,000,000 to AVCP, an affiliate of one of the Company's directors, as described under Note 9 below. As described in greater detail below, along with the AVCP Bridge Note, the AVCP Two-Year Note was subsequently converted in a transaction occurring during the year ended May 31, 2016. The AVCP Two-Year Note bore simple interest at the annual rate of 5%, payable quarterly. The principal balance of the AVCP Two-Year Note was due and payable in full on September 26, 2016, subject to acceleration of payment in the event of default. Prepayment was permitted without penalty. The AVCP Two-Year Note included events of default for nonpayment of principal or interest when due or other breaches of the AVCP Two-Year Note, as well as for breach of any term of the AVCP Two-Year Note and related warrant agreement. The principal amount of the AVCP Two-Year Note plus unpaid accrued interest was convertible at the election of the holder into shares of the Company's common stock at any time prior to maturity at an initial conversion price of \$1.00 per share. The conversion price was subject to adjustment on the same terms, and contained similar consent rights to the issuance of additional indebtedness, as the AVCP Bridge Note above.

As a result of the private placement of approximately \$4 million in convertible notes during the fourth quarter of fiscal year ended May 31, 2015, as described below, the conversion price of the AVCP Convertible Notes was reduced to \$0.675 per share of common stock, which was 90% of the weighted-average price of the deemed issued shares of \$0.75 related to the approximately \$4 million offering of 2015 Convertible Notes described below. The decrease in the conversion price caused the number of shares of common stock issuable upon conversion of the AVCP Convertible Notes to increase from 3,500,000 to 5,185,185 shares of common stock.

The Company accounted for the AVCP Convertible Notes and related warrants, fully described below, as a financing transaction, wherein proceeds were allocated to the financial instruments issued. Prior to making the accounting allocation, the AVCP Convertible Notes and warrants were evaluated for proper classification under FASB ASC 480 Distinguishing Liabilities from Equity and ASC 815. The debt discounts associated with the notes were amortized over the term of the notes and the Company recognized approximately \$ -0- and \$94,000 in non-cash amortization expense for the six-months ended November 30, 2016 and November 30, 2015, respectively.

In connection with the original issuance of the two AVCP Convertible Notes, the Company issued warrants to AVCP covering 250,000 and 75,000 shares of the Company's common stock exercisable at a price of \$0.50 per share on September 26, 2014 and February 6, 2015, respectively. The warrants are currently exercisable in full, include a cashless exercise feature, and will expire on December 31, 2019 and February 29, 2020, respectively. The aforementioned warrants have a term of five years from inception and an exercise price of \$0.50 per share and meet the conditions for equity classification per ASC 815. The fair value of the warrants was determined using a Black-Scholes option model using the following assumptions:

	Warrants issued on September 26, 2014	Warrants issued on February 6, 2015
Risk free interest rate	1.82%	1.48%
Expected life	5 years	5 years
Expected volatility	136%	119%
Dividend yield	0.00%	0.00%

Based on the previous conclusions, the Company allocated the cash proceeds first to the derivative liability at its fair value and then to the warrants at their relative fair value, with the residual allocated to the host AVCP Convertible Notes as presented below.

On June 23, 2015, the Company, Alpha Venture Capital Management, LLC and AVCP entered into a Debt Conversion and Termination Agreement pursuant to which (i) AVCP agreed to convert the \$3,535,627 in aggregate indebtedness as of June 23, 2015 under the AVCP Convertible Notes in exchange for 5,237,966 shares of the Company's common stock; (ii) subject to the conversion of the two AVCP Convertible Notes, the Company agreed to issue AVCP an additional five-year warrant covering 1,000,000 shares of common stock at an exercise price of \$0.675 per share and (iii) subject to the AVCP's receipt of the common shares and warrant, the parties agreed to (a) terminate the subscription agreements; and (b) release and discharge each other party from all claims and

Table of Contents

obligations arising under the two AVCP Convertible Notes and subscription agreements. As a result of the debt conversion, during the six-months ended November 30, 2015, the Company recognized a loss on extinguishment of the AVCP Convertible Notes of approximately \$584,000, a non-cash gain on the change in the fair value of the derivative liability of approximately \$647,000 and non-cash inducement interest expense of approximately \$758,000 arising from the aforementioned warrant.

	Year Ended May 31, 2016				May 31, 2016
	May 31, 2015	Debt Discount	Fair Value	Conversion	
AVCP Convertible notes payable	\$ 2,637,618	\$ 94,344	\$	\$(2,731,962)	\$
Compound embedded derivative	2,008,907		(646,505)	(1,362,402)	
Warrants (equity allocation)	215,732				
Accrued interest on notes payable				(35,627)	
Fair Value of Common Stock Issued				4,714,168	
Loss on conversion				(584,177)	
	\$ 4,862,257	\$ 94,344	\$ (646,505)	\$	\$

Short-Term Convertible Notes

During the year ended May 31, 2015, the Company issued approximately \$4.0 million of six-month unsecured convertible promissory notes (the Short-Term Convertible Notes) and related warrants to investors for cash, of which approximately \$1.3 million in aggregate original principal amount remained outstanding, following the consummation of the tender offer transaction on September 21, 2015, as described below. Each Short-Term Convertible Note was originally convertible, at the election of the holder, at any time into common shares at a \$0.75 per share. The Short-Term Convertible Notes bore interest of 7% per annum, payable in cash upon maturity. In connection with the issuance of the Short-Term Convertible Notes, the Company also issued warrants with a five-year term to purchase a total of 1,061,586 shares of common stock at an exercise price of \$0.75. The Company determined the fair value of the warrants using the Black-Scholes option pricing model utilizing certain weighted-average assumptions, such as expected stock price volatility, term of the warrants, risk-free interest rate and expected dividend yield at the commitment date.

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

	2015	
Expected dividend yield	0%	
Stock price volatility	88.79%	
Expected term	5 years	
Risk-free interest rate	1.46%	1.58%
Grant-date fair value	\$0.52	\$0.76

Additionally, at the commitment date, the Company determined that the conversion feature related to the Short-Term Convertible Notes was beneficial to the investors. As a result, the Company determined the intrinsic value of the beneficial conversion feature utilizing the fair value of the underlying common stock at the commitment date and the effective conversion price after discounting the Short-Term Convertible Notes for the fair value of the warrants. The fair value of the warrants and the intrinsic value of the conversion feature were recorded as a debt discounts to the

Short-Term Convertible Notes, and a corresponding increase to additional paid-in capital. The debt discounts were amortized over the life of the Short-Term Convertible Notes. The Company recognized approximately \$ -0- and \$1,784,000 as interest expense related to the amortization of the debt during the six-months ended November 30, 2016 and 2015, respectively. There were no Short-Term Convertible Notes outstanding at May 31, 2016. The unamortized discounts were fully amortized upon any conversion of the Short-Term Convertible Notes before maturity.

During the year ended May 31, 2016, the Company tendered an offer to settle the balances of the Short-Term Convertible Notes. The Company offered to exchange the Short-Term Convertible Notes for (i) the issuance of restricted shares of common stock, for the settlement of the balance of the Short-Term Convertible Notes, principal and accrued but unpaid interest as of September 21, 2015, which was the commitment date, at a conversion price of \$0.675 per share, and (ii) the amendment of the related warrants to reduce the exercise price to \$0.675 per share. The offer represented a 10.0% discount to \$0.75, which was the conversion price of the Short-Term Convertible Notes and exercise price of the related warrants. On September 21, 2015, the offering period and withdrawal rights for the exchange offer expired, and the Company completed the exchange offer for approximately \$2.7 million in aggregate original principal amount of Short-Term Convertible Notes.

Following the consummation of the exchange offer described above, an aggregate principal amount of \$525,000 and accrued but unpaid interest of \$17,830 converted into 723,773 shares of common stock. The principal and interest for Short-Term Convertible Notes that were not exchanged in the exchange offer, or that are not otherwise converted pursuant to their terms, became due and

Table of Contents

payable between October 30, 2015 and November 15, 2015, six months from their issuance. The Company repaid the remaining aggregate principal and interest on such Short-Term Convertible Notes of approximately \$789,000 on their respective maturity dates. Related to the tender offer conversions, the Company recognized approximately \$330,000 in non-cash interest expense and approximately \$108,000 commission expense to assist the Company in conversion of the debt at the commitment date.

Activity related to the Short-Term Convertible Notes for the six-months ended November 30, 2016, and fiscal year ended May 31, 2016 was as follows:

	November 30, 2016	May 31, 2016
Face amount of Notes	\$	\$ 3,981,050
Unamortized discounts		
Tender offer conversions		(2,693,800)
Conversions		(525,000)
Payments upon maturity		(762,250)
Total carrying value of Notes	\$	\$

Note 5 Derivative Liability:*Investor warrants*

The investor warrants issued with the September 2016 registered direct equity offering, and the placement agent warrants issued in conjunction with the offering, as fully described in Note 11, contain a provision for net cash settlement in the event that there is a fundamental transaction (contractually defined as a merger, sale of substantially all assets, tender offer or share exchange). If a fundamental transaction occurs in which the consideration issued consists principally of cash or stock in a non-public company, then the warrant holder has the option to receive cash, equal to the fair value of the remaining unexercised portion of the warrant. Due to this contingent cash settlement provision, the investor and placement agent warrants require liability classification as derivatives in accordance with ASC 480 and ASC 815 and are recorded at fair value.

The following tables summarize the fair value of the derivative liability and linked common shares as of May 30, 2016, the warrant derivative liability inception date (September 15, 2016) and November 30, 2016:

	May 30, 2016	September 15, 2016	November 30, 2016
Total warrant derivative liability	\$	\$ 5,179,200	\$ 3,955,734
Shares indexed to derivative liability		7,733,334	7,733,334

Changes in the fair value of the derivative liability, carried at fair value, are reported as Change in fair value of derivative liability in the Consolidated Statements of Operations. During the six-months ended November 30, 2016, the Company recognized a non-cash gain of approximately \$1,223,500, due to changes in the fair value of the liability associated with such classified warrants.

Edgar Filing: CytoDyn Inc. - Form 10-Q

ASC 820 provides requirements for disclosure of liabilities that are measured at fair value on a recurring basis in periods subsequent to the initial recognition. Fair values for the warrants were determined using a Binomial Lattice (Lattice) valuation model.

The Company estimated the fair value of their warrant derivative liability as of inception and November 30, 2016, using the following assumptions:

	September 15, 2016	November 30, 2016
Fair value of underlying stock	\$ 0.78	\$ 0.67
Risk free rate	1.20%	1.81%
Expected term (in years)	5.00	4.79
Stock price volatility	106%	103%
Expected dividend yield		
Probability of Fundamental Transaction	50%	50%
Probability of holder requesting cash payment	50%	50%

Table of Contents

Due to the fundamental transaction provision, which could provide for early redemption of the warrants, the model also considered subjective assumptions related to the fundamental transaction provision. The fair value of the warrants will be significantly influenced by the fair value of the Company's stock price, stock price volatility, changes in interest and management's assumptions related to the fundamental transaction provision.

AVCP Notes

The following tables summarize the fair value of the derivative liability and linked common shares of the AVCP Notes, as of the derivative liability inception dates (September 26, 2014 and February 6, 2015) and fiscal year end May 31, 2016:

	September 26, 2014	February 6, 2015	May 31, 2015	May 31, 2016
Total AVCP Notes derivative liability	\$ 767,038	\$ 403,266	\$ 2,008,907	\$
Shares indexed to derivative liability	2,000,000	1,500,000	5,185,185	

Changes in the fair value of the derivative liability, carried at fair value, are reported as "Change in fair value of derivative liability" in the Consolidated Statements of Operations. During the six-months ended November 30, 2016 and November 30, 2015 the Company recognized a non-cash gain of approximately \$ -0- and \$647,000 respectively, due to the change in derivative liability related to the embedded derivative in the AVCP Notes.

ASC 815 does not permit an issuer to account separately for individual derivative terms and features embedded in hybrid financial instruments that require bifurcation and liability classification as derivative financial instruments. Rather, such terms and features must be combined together and fair valued as a single, compound embedded derivative. The Company selected a Binomial Lattice Model to value the compound embedded derivative because it believes this technique is reflective of all significant assumptions that market participants would likely consider in negotiating the transfer of this convertible note. Such assumptions include, among other inputs, stock price volatility, risk-free rates, credit risk assumptions, early redemption and conversion assumptions, and the potential for future adjustment of the conversion price due to a future dilutive financing.

Significant inputs and assumptions used in the Binomial Lattice Model for the derivative liability were as follows:

	September 26, 2014	February 6, 2015	May 31, 2015	June 23, 2015
Quoted market price on valuation date	\$ 0.79	\$ 0.96	\$0.99	\$ 0.90
Contractual conversion rate	\$ 1.00	\$ 1.00	\$1.00	\$ 1.00
Adjusted conversion price (a)	\$ 0.9759	\$ 1.00	\$0.675	\$ 0.675
Contractual term to maturity (years)	2.00	0.49	0.18 1.33	0.12
Expected volatility	123%	124%	90% 114%	48%
Contractual interest rate	5%	2%	1.5% 5.0%	1.2%
Risk-free rate	0.59%	0.045%	0.041% 0.48%	0.001%
Risk adjusted rate	2.69%	2.78%	2.80%	2.80%
Probability of event of default	5.00%	5.00%	5.00%	5.00%

- (a) The adjusted conversion price input used in the Binomial Lattice Model considers both (i) the reduction of the conversion price to \$0.675 on April 30, 2015, as result of a private placement offering in which Common Stock was sold for a weighted average price of \$0.75 and (ii) potential adjustment to the stated conversion price due to a future dilutive issuance. This input was calculated using a probability-weighted approach which considered the likelihood of various scenarios occurring including (i) potential success or failure of various phases for PRO 140, (ii) the probability the Company will enter into a future financing and (iii) and the potential price of a future financing.

The fair value of the derivative liability is significantly influenced by the Company's trading market price of its stock, stock price volatility, changes in interest, assumptions regarding the adjusted conversion price and early redemption or conversion of the AVCP Notes.

Table of Contents**Note 6 Stock Options and Warrants**

The Company has one active stock-based equity plan at November 30, 2016, the CytoDyn Inc. 2012 Equity Incentive Plan (the 2012 Plan) and one stock-based equity plan that is no longer active, but under which certain prior awards remain outstanding, the CytoDyn Inc. 2004 Stock Incentive Plan (the 2004 Plan and, together with the 2012 Plan, the Incentive Plans). The 2012 Plan was approved by stockholders at the Company s 2012 annual meeting to replace the 2004 Plan. The 2012 Plan was amended by stockholder approval in February 2015 to increase the number of shares available for issuance from 3,000,000 to 5,000,000 shares of common stock and in March 2016 to increase the number of shares available for issuance from 5,000,000 to 7,000,000 shares of common stock. As of November 30, 2016, the Company had 550,930 shares available for future stock-based grants under the 2012 Plan.

Stock Options

During the six-months ended November 30, 2016, the Company granted annual stock option awards to directors to purchase a total of 300,000 shares of common stock with an exercise price of \$1.09 per share. These option awards vest quarterly over one year and have a ten-year term. The grant date fair value related to these options was \$0.78 per share. An additional stock option covering 100,000 shares of common stock was granted to a director. The option has an exercise price of \$0.68 and vests 25% immediately with the remainder ratably over one year. The grant date fair value related to the option award was \$0.53 per share.

During the six-months ended November 30, 2016, the Company granted options covering an aggregate of 1,050,000 shares of common stock to executive management and certain employees with exercise prices of \$1.09 and \$1.10 per share. The options vest annually over three years, have a ten-year term and grant date fair values of \$0.75 and \$0.76 per share, respectively.

Warrants

During the six-months ended November 30, 2016, in connection with private equity offerings, as fully described in Note 10, the Company issued common stock warrants covering 182,375 shares of common stock to investors. The warrants have a five-year term and an exercise price of \$1.35 per share. During the six months ended November 30, 2016, holders of warrants covering 774,097 shares of common stock exercised the right to purchase such shares at either \$0.50 or \$0.75 per share and the Company received proceeds of approximately \$398,000. Additionally, warrants covering 138,864 shares with an exercise price of \$0.75 per share were exercised pursuant to a cashless exercise provision.

During the six-months ended November 30, 2016, in connection with a registered direct equity offering completed in September 2016, as fully described in Note 11, the Company issued common stock warrants covering 6,666,667 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of \$1.00 per share. In connection with this offering, the Company also issued common stock warrants covering 1,066,667 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of \$0.825 per share.

Compensation expense related to stock options and warrants for the three and six-months ended November 30, 2016 and November 30, 2015 was approximately \$335,000 and \$688,000 and \$239,000 and \$591,000, respectively. The grant date fair value of options and warrants vested during the three and six-month periods ended November 30, 2016 and November 30, 2015 was approximately \$279,000 and \$530,000 and \$123,000 and \$324,000, respectively. As of November 30, 2016, there was approximately \$1,124,000 of unrecognized compensation expense related to share-based payments for unvested options, which is expected to be recognized over a weighted average period of

1.83 years.

Table of Contents

The following table represents stock option and warrant activity as of and for the six-months ended November 30, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options and warrants outstanding May 31, 2016	63,307,150	\$ 0.83	3.20	\$ 9,863,492
Granted	9,365,709	1.00		
Exercised	(912,961)	0.55		
Forfeited/expired/cancelled	(7,343,911)	1.12		
Options and warrants outstanding November 30, 2016	64,415,987	0.83	3.98	83,000
Outstanding exercisable November 30, 2016	61,352,320	\$ 0.82	3.77	\$ 79,000

Note 7 Acquisition of Patents

As discussed in Note 8 below, the Company consummated an asset purchase on October 16, 2012, and paid \$3,500,000 for certain assets, including intellectual property, certain related licenses and sublicenses, FDA filings and various forms of the PRO 140 drug substance. The Company followed the guidance in Financial Accounting Standards Topic 805 to determine if the Company acquired a business. Based on the prescribed accounting, the Company acquired assets and not a business. As of November 30, 2016, the Company has recorded and is amortizing \$3,500,000 of intangible assets in the form of patents. The Company estimates the acquired patents have an estimated life of ten years. Subsequent to the acquisition date, the Company has continued to expand, amend and file new patents central to its current clinical trial strategies, which, in turn, have extended the protection period for certain methods of using PRO 140 and formulations comprising PRO 140 out through at least 2026 and 2031, respectively, in various countries.

The following presents intangible assets activity:

	November 30, 2016	May 31, 2016
Gross carrying amounts	\$ 3,500,000	\$ 3,500,000
Accumulated amortization	(1,443,750)	(1,268,750)
Total amortizable intangible assets, net	2,056,250	2,231,250
Patents currently not amortized	35,989	35,989
Carrying value of intangibles, net	\$ 2,092,239	\$ 2,267,239

Table of Contents

Amortization expense related to patents was approximately \$87,500 and \$175,000 for the three and six-months ended November 30, 2016 and 2015. The estimated aggregate future amortization expense related to the Company's intangible assets with finite lives is estimated at approximately \$350,000 per year for the next five years.

Note 8 License Agreements

During the year ended May 31, 2016, the Company executed a license agreement with a third-party licensor 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. In connection with this license agreement, the Company became the primary obligor of an additional £600,000 (approximately US\$807,000 utilizing then-current exchange rates), which was timely paid by June 30, 2016. During the year ended May 31, 2016, the Company accrued an additional expense of £600,000 (approximately US\$870,000 utilizing then-current exchange rates) in connection with the June 30, 2016 obligation. Future annual license fees and royalty rate will vary depending on whether the Company manufactures PRO 140, 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 (approximately US\$380,000) when it serves as the manufacturer. The Company has accrued the annual license fee of approximately \$380,000, as of November 30, 2016.

Note 9 Commitments and Contingencies

Under the Asset Purchase Agreement, dated July 25, 2012, between the Company and Progenics Pharmaceuticals, Inc. (Progenics) (the Asset Purchase Agreement), the Company acquired from Progenics its rights to the 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 to Progenics \$3,500,000 in cash to close the transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) \$1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-US equivalent, which was paid during the year ended May 31, 2016; (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 up to 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. During the year ended May 31, 2016, the Company paid \$1.5 million of such milestones owed to Progenics as a result of the first dosing in a U.S. Phase 3 trial. To the extent that such milestone payments and royalties are not timely made, under the terms of the Asset Purchase Agreement, Progenics has certain repurchase rights relating to the assets sold to the Company thereunder.

Payments to the third-party licensor for system know-how technology (see Note 8) and 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.) (PDL) and Progenics, which was assigned to the Company in the Asset Purchase Agreement, pursuant to which the Company has an exclusive worldwide license to develop, make, have made, import, use, sell, offer to sell or have sold products that incorporate the humanized form of the PRO 140 antibody developed by PDL under the agreement and must pay additional milestone payments and royalties as follows: (i) \$1,000,000 upon initiation of a Phase 3 clinical trial, which was paid during the year ended May 31, 2016; (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. During the year ended May 31, 2016, the Company paid \$1 million of such milestones. To the extent that such milestone payments and royalties are not timely made, under the terms of the PDL License, AbbVie Inc. has certain termination rights relating

to the Company's license of PRO 140 thereunder. Pursuant to the foregoing Asset Purchase Agreement and PDL License, the Company accrued an expense of \$2,500,000 as of May 31, 2015 in connection with the anticipated milestone payments related to the first patient dosing in a Phase 3 clinical trial, all of which was paid during the year ended May 31, 2016, as described above.

The Company has entered into project work orders, as amended, for each of its clinical trials with its clinical research organization (CRO) and related laboratory vendors. Under the terms of these agreements, the Company incurs execution fees for direct services costs, which are recorded as a current asset. In the event the Company were to terminate any trial, it may incur certain financial penalties which would become payable to the CRO. Conditioned upon the form of termination of any one trial, the financial penalties may range from an approximate low of \$0.1 million to an approximate high of \$0.6 million. In the remote circumstance that the Company would terminate all clinical trials, the collective financial penalties may range from an approximate low of \$0.4 million to an approximate high of \$1.4 million.

During the six-months ended November 30, 2016, the Company entered into agreements with commercial manufacturing companies. Under the terms of the agreements, the Company accrued approximately \$2.1 million of execution fees for process validation and

Table of Contents

manufacturing activities, which is reflected as a current asset, as of November 30, 2016. In the event the Company were to terminate any of the agreements, it may incur certain financial penalties which would become payable to the manufacturers. Conditioned on the timing of termination, the financial penalties may range from an approximate low of \$1.0 million to an approximate high of \$3.0 million.

Note 10 Private Securities Offerings

During the year ended May 31, 2016, the Company conducted a series of private equity offerings (the Equity Offerings), in which accredited investors purchased unregistered common stock at either \$0.75 or \$1.00 per share with warrant coverage of 50% or 25%, respectively, based on the number of shares of common stock purchased. Pursuant to the Equity Offerings, the Company sold a total of 48,659,338 shares of common stock, for aggregate gross proceeds of approximately \$37.6 million and issued warrants with a five-year term covering 23,254,230 shares of common stock. In conjunction with the Equity Offerings, the Company paid an aggregate cash fee of approximately \$3.9 million to the placement agent and issued warrants covering an aggregate of 4,960,314 shares of common stock to the placement agent as additional compensation. The placement agent warrants had aggregate Black-Scholes valuations of approximately \$2.7 million at issuance.

In June 2016, the Company conducted a private equity offering, in which accredited investors purchased unregistered common stock at \$1.00 per share with warrant coverage of 25%, based on the number of shares of common stock purchased. Pursuant to the offering, the Company sold a total of 729,500 shares of common stock for aggregate gross proceeds of \$729,500 and issued to the investors warrants with a five-year term covering 182,375 shares of common stock with an exercise price of \$1.35 per share.

Note 11 Registered Direct Equity Offering

In September 2016, the Company entered into Securities Purchase Agreements with certain institutional investors for the sale of 13,333,334 shares of common stock at a purchase price of \$0.75 per share in a registered direct equity offering (the Registered Offering), pursuant to a registration statement on Form S-3. The investors in this Registered Offering also received warrants to purchase 6,666,667 shares of common stock with an exercise price of \$1.00 per share and a five-year term. The Company received net proceeds from the offering of approximately \$9 million after placement fees of 8% of the gross proceeds and various expenses. In addition, the placement agent received warrants covering 1,066,667 shares (or 8% of total shares sold to investors) with a per share exercise price of \$0.825 and a five-year term.

A summary of the cash proceeds of the offering is shown below:

Gross proceeds from sale of common stock	\$ 10,000,000
Placement agent fees and expenses	1,010,000
Total net proceeds	\$ 8,990,000

As fully described in Note 5 above, the investor warrants and the placement agent warrants issued in conjunction with the Registered Offering are required to be accounted for in accordance with ASC 480 and ASC 815.

A summary of the ASC 480 allocation of the proceeds of the offering is as follows:

Allocated to common stock and additional paid in capital	\$ 6,334,417
Allocated to warrant liabilities	2,655,583
Total net proceeds	\$ 8,990,000

Closing costs included 1,066,667 warrants valued at \$819,200 for placement agent fees. Based upon the estimated fair value of the stock and warrants in the units, the Company allocated \$241,986 to financing expense and \$577,214 as stock issuance costs.

Note 12 Employee Benefit Plan

The Company has an employee savings plan (the Plan) pursuant to Section 401(k) of the Internal Revenue Code (the Code), covering all of its employees. The Company makes a qualified non-elective contribution of 3%, which consequently vests immediately. In addition, participants in the Plan may contribute a percentage of their compensation, but not in excess of the maximum allowed under the Code. During the three and six-months ended November 30, 2016 and 2015, the Company incurred an expense of approximately \$9,800 and \$18,600 and \$5,700 and \$5,700, respectively, for qualified non-elective contributions.

Table of Contents

Note 13 Related Party Transactions

On January 19, 2016, the Company entered into an amendment to its existing Consulting Agreement with Denis R. Burger, Ph.D., dated February 21, 2014, as previously amended November 3, 2014 (the Consulting Agreement). The Amendment names Dr. Burger, who is currently a member of the Board of Directors, to the non-executive position of Chief Science Officer and increases Dr. Burger's advisory responsibilities in that capacity. The Amendment also increases the compensation payable to Dr. Burger under the Consulting Agreement to \$20,000 per month, which is in addition to any fees that Dr. Burger currently earns as a director. The Amendment was approved by the Audit Committee of the Board of Directors.

On May 10, 2016, Jordan G. Naydenov, a director with the Company, participated in the private equity offerings, as fully described in Note 9 above. Mr. Naydenov invested \$1 million and received 1 million shares of common stock and a warrant covering 250,000 shares of common stock at an exercise price of \$1.35. The terms and conditions of Mr. Naydenov's investment were identical to those offered to all other investors in the offering.

The Audit Committee of the Board of Directors, comprised of independent directors, reviews and approves all related party transactions. The above terms and amounts are not necessarily indicative of the terms and amounts that would have been incurred had comparable transactions been entered into with independent parties.

Note 14 Subsequent Events

On December 12, 2016, the Company entered into Securities Purchase Agreements with certain investors for the sale by the Company of up to 4,000,000 shares of common stock, at a purchase price of \$0.75 per share in a registered direct equity offering. The investors in this offering also received common stock warrants covering 2,000,000 shares of common stock. The aggregate gross and net proceeds for the sale of the common stock and warrants in the offering was \$3.0 million. Subject to certain ownership limitations, the warrants are exercisable commencing on the issuance date at an exercise price of \$1.00 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the date of issuance.

The Company determined to extend the expiration dates of certain warrants to May 31, 2017, covering an aggregate of 6,310,667 shares of common stock. The warrants were originally issued in connection with the sale of the 2013 Convertible Notes, as identified in Note 4. The warrants currently have an exercise price of \$1.00 per share, and all but two warrants were exercisable through October 2016. One warrant, for the purchase of 186,667 shares of common stock, was exercisable through December 2016 and one warrant, for the purchase of 160,000 shares of common stock, is exercisable until January 15, 2017. The extended expiration date on all of these warrants is May 30, 2017. The Company's offer to extend the expiration dates of such warrants to May 31, 2017 expired on January 11, 2017 and was subject to the execution of a release of claims by each of the warrant holders.

Table of Contents**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

This filing, contains forward-looking statements. The words anticipate, believe, expect, intend, predict, plan, estimate, project, continue, could, may, and similar terms and expressions are intended to identify forward-looking statements. These statements include, among others, information regarding future operations, future capital expenditures and future net cash flows. Such statements reflect current views with respect to future events and financial performance and involve risks and uncertainties, including, without limitation, regulatory initiatives and compliance with governmental regulations, the ability to raise additional capital, the results of clinical trials for the Company's drug candidates, and various other matters, many of which are beyond the Company's control. Should one or more of these risks or uncertainties occur, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated. Consequently, all of the forward-looking statements made in this filing are qualified by these cautionary statements and there can be no assurance of the actual results or developments.

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the other sections of this Quarterly Report, including the Company's financial statements and related notes appearing elsewhere herein. To the extent not otherwise defined herein, capitalized terms shall have the same meanings as in such financial statements and related notes. This discussion and analysis contains forward-looking statements including information about possible or assumed results of the Company's financial condition, operations, plans, objectives and performance that involve risk, uncertainties and assumptions. The actual results may differ materially from those anticipated and set forth in such forward-looking statements.

Results of Operations***Clinical Trials Update***

Phase 2b Extension Study for HIV, as Monotherapy. As previously disclosed, there are 11 trial participants in the extension study who successfully passed 37 weeks of therapy and were not discontinued. Currently, 10 out of those 11 trial participants have now surpassed two years of suppressed viral load with PRO 140 as a single agent therapy. This extension study remains ongoing.

Phase 3 Trial for HIV, as Combination Therapy. A pivotal 25-week trial for PRO 140 as a combination therapy to existing HAART drug regimens originally designed for 300 patients. Several patients have completed this trial and have transitioned to a roll-over protocol, as requested by the treating physicians to enable the patients to continue with a suppressed viral load. Previously, the FDA agreed to reduce the number of patients in this study from 300 to 150 patients. In October 2016, the FDA agreed to additional protocol modifications, including a further reduction in patients for this trial from 150 down to 30 patients and lowered the primary endpoint for viral load reduction from a viral load of 0.7log to viral load of 0.5log. Based upon these new protocol modifications, management projects that the total estimated costs for this trial will range from \$8 million to \$9 million.

Phase 3 Investigative Trial for HIV, as Long-term Monotherapy. A strategic trial including 300 patients to assess the treatment strategy of using PRO 140 subcutaneously as a long-acting single-agent maintenance therapy for 48 weeks in patients with suppressed viral load with CCR5-tropic HIV-1 infection. The primary endpoint is the number of patients who can maintain suppressed viral load under a PRO 140 monotherapy replacing their HAART regimen for 48 weeks. The secondary endpoint is the number of weeks a patient is off of their ART regimen. Enrollment of the first several patients was announced in December 2016 and is expected to accelerate, as experienced in the previous Phase 2b monotherapy trial. Management estimates the total cost of this trial to range from \$15 million to \$17 million.

Phase 2 Trial for Graft versus Host Disease. This Phase 2, randomized, double-blind, placebo-controlled, multi-center 100-day study with 60 patients is designed to evaluate the feasibility of the use of PRO 140 as an add-on therapy to standard GvHD prophylaxis treatment for prevention of acute GvHD in adult patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) undergoing allogeneic hematopoietic stem cell transplantation (HST). Enrollment of the first patient is expected in the first half of calendar 2017. Management estimates the cost of this trial to be approximately \$3.5 million to \$4 million.

Rollover Study. This study is designed for patients who successfully complete the Phase 3 Combination Therapy trial and the treating physicians request a continuation of PRO 140 therapy for their patients. If this study enrolls 30 patients from the Phase 3 trial and all patients remain in the Rollover study for one year, management estimates the cost of this study to be approximately \$3.5 million to \$4 million.

Results of Operations for the three months ended November 30, 2016 and 2015 are as follows:

For the three months ended November 30, 2016 and November 30, 2015, the Company had no activities that produced revenues from operations.

Table of Contents

For the three months ended November 30, 2016, the Company incurred a net loss of approximately \$5.5 million, as compared to a net loss of approximately \$5.3 million for the corresponding period in 2015. The moderately higher net loss of approximately \$0.2 million was attributable to increases in research and development expenses of approximately \$2.7 million and general and administrative expenses of approximately \$0.5 million, which were offset in part by a reduction in non-cash interest expense of approximately \$1.8 million and a non-cash unrealized gain of approximately \$1.2 million arising from a reduction in derivative liability associated with certain warrants.

For the three months ended November 30, 2016 and November 30, 2015, operating expenses totaled approximately \$6.2 million and \$2.9 million, respectively, consisting of research and development, general and administrative expenses and amortization and depreciation. The increase in operating expenses of approximately \$3.3 million reflected increased research and development of approximately \$2.7 million, coupled with increased general and administrative expenses of approximately \$0.5 million.

General and administrative expenses, which totaled approximately \$1.7 million for the three months ended November 30, 2016, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The increase in general and administrative expenses of approximately \$0.5 million for the three months ended November 30, 2016 over the comparable period a year ago was due to higher salaries owing, in part, to increased number of employees and increases for certain professional fees and corporate insurance coverages.

Research and development expenses, which totaled approximately \$4.4 million for the three months ended November 30, 2016, increased approximately \$2.7 million over the same 2015 period. This increase was attributable to higher clinical trial expenses, combined with an expansion of the Company's chemistry, manufacturing and controls (or CMC) activities in connection with the preparation of a biologics license application (BLA) for submission to the FDA. The Company expects research and development expenses to trend higher, as the two ongoing Phase 3 trials with PRO 140 continue, and the Company expects to incur certain additional expenses as the Company continues to expand activities related to manufacturing PRO 140 material for future use that conforms with current good manufacturing practices (or cGMP) established by the FDA.

For the three months ended November 30, 2016, the Company recognized a reduction in derivative liability of approximately \$1.2 million, which is associated with certain warrants. This non-cash unrealized gain, or benefit, was offset by non-cash interest expense of approximately \$0.5 million, as compared to \$2.4 million of non-cash interest expense incurred in the comparable quarter of 2015, as all outstanding debt was converted or repaid during the year ended May 31, 2016. The Company continues to evaluate the need for additional financing as described under the heading "Liquidity and Capital Resources" below.

The future trends of all expenses are expected to be primarily driven by the future outcomes of clinical trials and the correlative effect on research and development expenses, especially FDA regulatory requirements. Additional expenses are anticipated to be incurred in connection with the manufacturing of new commercial grade PRO 140, along with the necessary regulatory processes to confirm its qualification for future sale, if approved. The Company's ability to continue to fund operating expenses will depend on its ability to raise additional capital. See in particular, Item 1A Risk Factors in the Annual Report on Form 10-K for the year ended May 31, 2016.

Results of Operations for the six months ended November 30, 2016 and 2015 are as follows:

For the six-months ended November 30, 2016, the Company had a net loss of \$10.8 million, as compared to a net loss of approximately \$14.2 million for the similar 2015 period. The approximate decrease of \$3.4 million in net loss for 2016 from 2015 was primarily attributable to a decline in interest expense of approximately \$4.1 million, coupled with

an increase in the benefit of a reduction in derivative liability of approximately \$0.6 million, offset in part by increases in general and administrative expenses of approximately \$0.9 million and research and development expenses of approximately \$1.1 million.

For the six months ended November 30, 2016 and November 30, 2015, operating expenses totaled approximately \$11.5 million and \$9.6 million, respectively, consisting primarily of research and development, general and administrative expenses and amortization and depreciation. The increase in operating expenses of approximately \$1.9 million over the comparable 2015 period reflected higher general and administrative expenses of approximately \$0.9 million together with increased research and development of approximately \$1.1 million.

General and administrative expenses, which totaled approximately \$3.3 million for the six months ended November 30, 2016, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The increase in general and administrative expenses of approximately \$0.9 million for the six months ended November 30, 2016 over the comparable 2015 period was due to higher total compensation expenses combined with increases for professional fees and corporate insurance coverages.

Table of Contents

Research and development expenses, which totaled approximately \$8.1 million for the six months ended November 30, 2016, increased approximately \$1.1 million over the same 2015 period. This increase was attributable to higher clinical trial expenses, combined with an expansion of the Company's CMC activities in connection with the preparation of a BLA. The Company expects research and development expenses to trend higher, as the two ongoing Phase 3 trials with PRO 140 continue, and the Company expects to incur certain additional expenses as the Company continues to expand activities related to manufacturing cGMP PRO 140 material for future use.

For the six months ended November 30, 2016 the Company recognized an unrealized gain, or a non-cash benefit from a decline in derivative liability of approximately \$1.2 million, as compared to an approximate benefit of \$0.6 million in the comparable 2015 period. Interest expense for the six months ended November 30, 2016 of approximately \$0.5 million dropped approximately \$4.1 million compared to the same six-month period a year ago, as all outstanding debt was converted or repaid during the year ended May 31, 2016 and no inducement interest expense was incurred during the current six-month period. The Company continues to evaluate the need for additional financing as described under the heading "Liquidity and Capital Resources" below.

The future trends of all expenses will be primarily driven by the future outcomes of clinical trials and the correlative effect on research and development expenses, especially FDA regulatory requirements, in addition to the manufacturing of new commercial grade PRO 140, along with the necessary regulatory processes to confirm its qualification for future sale, if approved. The Company's ability to continue to fund operating expenses will depend on its ability to raise additional capital. See in particular, Item 1A Risk Factors in the Annual Report on Form 10-K for the year ended May 31, 2016.

Liquidity and Capital Resources

The Company's cash position at November 30, 2016 decreased approximately \$0.8 million to approximately \$8.8 million, as compared to a balance of approximately \$9.6 million as of May 31, 2016. The net decrease in cash for the six-months ended November 30, 2016 was attributable to net cash provided by financing activities of approximately \$9.9 million, offset by net cash used in operating activities of approximately \$10.8 million used in operating activities.

As of November 30, 2016, the Company had positive working capital of approximately \$7.2 million compared to positive working capital of approximately \$7.9 million at May 31, 2016, a decrease of approximately \$0.7 million attributable primarily to growth in accounts payable.

Net cash used in operating activities totaled approximately \$10.8 million during the six-months ended November 30, 2016, which reflects an increase of approximately \$2.3 million of net cash used in operating activities over the six-months ended November 30, 2015. The increase in net cash used in operating activities was due to the effect on working capital owing to a comparable increase in current assets and current liabilities totaling approximately \$5.7 million, offset in part by a decline in the net loss of approximately \$3.3 million and a substantial reduction in interest expense for the six months ended November 30, 2016.

Net cash used in investing activities was immaterial for both six month periods.

Net cash provided by financing activities of approximately \$9.9 million during the six months ended November 30, 2016 declined approximately \$0.8 million compared to \$10.7 million during the six months ended November 30, 2015. The decline in net cash provided from financing activities was attributable to an approximate reduction in net proceeds from the sale of common stock and warrants of approximately \$2.0 million, offset by approximate proceeds from the exercise of warrants of \$0.4 million in the current six month period and payments to retire debt of approximately \$0.8 million during the six months ended November 30, 2015.

As reported in the accompanying financial statements, for the six-months ended November 30, 2016 and November 30, 2015, the Company incurred net losses of approximately \$10.8 million and \$14.1 million, respectively. The Company has no activities that produced revenue in the periods presented and has sustained operating losses since inception. The Company's ability to continue as a going concern is dependent upon its ability to raise additional capital, commence operations and achieve a level of profitability. Since inception, the Company has financed its activities principally from the sale of public and private equity securities and proceeds from convertible notes payable and related party notes payable. The Company intends to finance its future operating activities and its working capital needs largely from the sale of equity securities and perhaps debt securities, combined with additional funding from other traditional financing sources. The sale of equity and convertible debt securities may result in dilution to stockholders and those securities may have rights senior to those of common shares. If the Company raises additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these activities or other debt could contain covenants that would restrict the Company's operations. Any other third-party funding arrangements could require the Company to relinquish valuable rights. The Company will require additional capital beyond its currently anticipated needs. On August 26, 2016, the Company filed a registration statement on Form S-3 universal shelf registration statement covering \$100 million of securities. On September 9, 2016, the registration statement was declared effective. The Company intends to utilize this shelf registration statement to raise additional capital through the sale of its securities. Additional capital, if available, may not be available on reasonable terms. Please refer to the risk factors under Item 1.A. to the Company's Annual Report on Form 10-K.

Table of Contents

The Company has not generated revenue to date, and will not generate product revenue in the foreseeable future. The Company expects to continue to incur operating losses as it proceeds with clinical trials with respect to PRO 140 and continue to advance it through the product development and regulatory process. The future trends of all expenses will be driven by the future outcomes of the clinical trials and their correlative effect on research and development expenses, especially FDA regulatory requirements, in addition to the manufacturing of new commercial grade PRO 140, along with the necessary regulatory processes to confirm its qualification for future sale, if approved. The Company will require a significant amount of additional capital in the future to fulfill BLA requirements related to manufacturing PRO 140 for commercial use. In connection with this undertaking, the Company recently entered into an arrangement with a new third party contract manufacturing organization (CMO) to provide process transfer, validation and manufacturing services for PRO 140. Management believes its new CMO will best serve the Company's strategic objectives for the anticipated BLA filing and, if approved, the long-term commercial manufacturing capabilities for PRO 140. This new CMO undertaking is anticipated to require approximately \$25 million of additional capital over the next two calendar years.

Under the Asset Purchase Agreement (the Asset Purchase Agreement), dated July 25, 2012, between the Company and Progenics Pharmaceuticals, Inc. (Progenics), the Company acquired from Progenics its proprietary HIV viral-entry inhibitor drug candidate PRO 140 (PRO 140), a humanized anti-CCR5 monoclonal antibody, as well as certain other related assets, including the existing inventory of bulk PRO 140 drug product, intellectual property, certain related licenses and sublicenses, and U.S. Food and Drug Administration (FDA) regulatory filings. On October 16, 2012, the Company paid \$3,500,000 in cash to Progenics to close the acquisition transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) \$1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-US equivalent, which was paid during the three months ended February 29, 2016; (ii) \$5,000,000 at the time of the first US new drug application approval by the FDA or other non-U.S. approval for the sale of PRO 140; and (iii) royalty payments of up to five percent (5%) on net sales during the period beginning on the date of the first commercial sale of PRO 140 until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years, in each case determined on a country-by-country basis. Payments to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the PDL License), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the PRO 140 transaction, pursuant to which the Company must pay additional milestone payments and royalties as follows: (i) \$1,000,000 upon initiation of a Phase 3 clinical trial, which was paid during the three months ended February 29, 2016; (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, it is management's conclusion that the probability of achieving the subsequent future scientific research milestones is not reasonably determinable, thus the future milestone payments payable to Progenics and its sub-licensors are deemed contingent consideration and, therefore are not currently accruable.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not Applicable.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

As of November 30, 2016, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, management has evaluated the effectiveness of the design and operations of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective as of November 30, 2016, as a result of material weaknesses in internal control over financial reporting because of inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions. Management continues to implement controls and procedures, and continues to remediate the material weaknesses noted above. With the assistance of a third party consultant, management has completed a detailed best-practices risk assessment of all

Table of Contents

general ledger accounts in its financial accounting system and is in the process of completing its documentation of all internal controls. The Company's third party consultant has also commenced testing of the effectiveness of the internal control framework for the second fiscal quarter ending November 30, 2016. Despite the existence of a limited number of material weaknesses, management believes the financial information presented herein is materially correct and fairly presents the financial position and operating results of the quarter ended November 30, 2016 in accordance with U.S. GAAP.

Internal Control Over Financial Reporting

Changes in Control Over Financial Reporting

Although changes in the Company's internal control over financial reporting occurred during the quarter ended November 30, 2016, management believes that such changes did not materially affect, or are not reasonably likely to materially affect, the Company's internal control over financial reporting. Notwithstanding the foregoing, the Company continued to document its framework of internal controls and its third party consultant initiated a review of the sufficiency of the control environment and has commenced testing the effectiveness of such controls as of November 30, 2016, with the objective to provide management and the audit committee of the board of directors with an interim report regarding the Company's progress to remediate material weaknesses previously identified and reported. It is management's goal to fully remediate all material weaknesses by the end of the May 31, 2017 fiscal year.

Table of Contents

PART II

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

There have been no material changes in the risk factors applicable to us from those identified in the Annual Report on Form 10-K filed with the SEC on July 19, 2016.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits:

- | | |
|-----------|---|
| 4.1 | Form of Warrant Agreement (September 2016 Offering) (incorporated by reference to Exhibit 4.1 to the Registrants Current Report on Form 8-K filed September 12, 2016). |
| 10.1 | Form of Securities Purchase Agreement (September 2016 Offering) (incorporated by reference to Exhibit 10.1 to the Registrants Current Report on Form 8-K filed September 12, 2016). |
| 31.1* | Rule 13a-14(a) Certification by CEO of Registrant. |
| 31.2 * | Rule 13a-14(a) Certification by CFO of the Registrant. |
| 32.1 * | Certification of CEO of the Registrant pursuant to 18 U.S.C. Section 1350. |
| 32.2 * | Certification of CFO of the Registrant pursuant to 18 U.S.C. Section 1350. |
| 101.INS * | XBRL Instance Document. |
| 101.SCH * | XBRL Taxonomy Extension Schema Document. |

Edgar Filing: CytoDyn Inc. - Form 10-Q

- 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.

* Filed herewith.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CYTODYN INC.

(Registrant)

Dated: January 13, 2017

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

Dated: January 13, 2017

/s/ Michael D. Mulholland
Michael D. Mulholland
Chief Financial Officer, Treasurer and Corporate
Secretary

Table of Contents

EXHIBIT INDEX

4.1	Form of Warrant Agreement (September 2016 Offering) (incorporated by reference to Exhibit 4.1 to the Registrants Current Report on Form 8-K filed September 12, 2016).
10.1	Form of Securities Purchase Agreement (September 2016 Offering) (incorporated by reference to Exhibit 10.1 to the Registrants Current Report on Form 8-K filed September 12, 2016).
31.1 *	Rule 13a-14(a) Certification by CEO of the Registrant.
31.2 *	Rule 13a-14(a) Certification by CFO of the Registrant.
32.1 *	Certification of CEO of the Registrant pursuant to 18 U.S.C. Section 1350.
32.2 *	Certification of CFO of the Registrant pursuant to 18 U.S.C. Section 1350.
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.

* Filed herewith.