CytoDyn Inc.
Form 10-Q
April 13, 2017
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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 February 28, 2017

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	**75-3056237**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer or Identification No.)**
1111 Main Street, Suite 660	
Vancouver, Washington	**98660**
(Address of principal executive offices)	**(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

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 March 31, 2017 there were 149,468,244 shares outstanding of the registrant s $0.001 par value common stock.

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PART I

Item 1. Financial Statements.

CytoDyn Inc.

Consolidated Balance Sheets

	February 28, 2017 (unaudited)	May 31, 2016
Assets		
Current assets:		
Cash	$ 7,795,806	$ 9,641,776
Prepaid expenses	221,830	141,714
Prepaid service fees	4,716,418	1,710,852
Total current assets	12,734,054	11,494,342
Furniture and equipment, net	18,783	24,550
Intangibles, net	2,004,739	2,267,239
Total assets	$ 14,757,576	$ 13,786,131
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 5,233,522	$ 2,467,973
Accrued liabilities and salaries	57,896	242,708
Accrued license fee	66,800	870,000
Total current liabilities	5,358,218	3,580,681
Long-term liabilities:		
Derivative liability	3,982,400	
Total long-term liabilities	3,982,400	
Total liabilities	9,340,618	3,580,681
Commitments and Contingencies		
Stockholders equity		
Series B convertible preferred stock, $0.001 par value; 400,000 shares authorized, 92,100 and 95,100 shares issued and outstanding at February 28, 2017 and May 31, 2016, respectively.	92	95
Common stock, $0.001 par value; 350,000,000 and 250,000,000 shares authorized, 149,468,244 and 123,335,634 issued and outstanding at February	149,468	123,336

28, 2017 and May 31, 2016, respectively		
Additional paid-in capital	121,427,465	107,307,933
Accumulated (deficit)	(116,160,067)	(97,225,914)
Total stockholders equity	5,416,958	10,205,450
Total liabilities and stockholders equity	$ 14,757,576	$ 13,786,131

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Operations

(Unaudited)

	Three Months Ended		Nine Months Ended	
	February 28, 2017	February 29, 2016	February 28, 2017	February 29, 2016
Operating expenses:				
General and administrative	$ 1,391,463	$ 2,217,795	$ 4,651,451	$ 4,618,363
Research and development	6,534,423	2,741,051	14,603,532	9,711,360
Amortization and depreciation	91,031	90,191	276,171	270,573
Total operating expenses	8,016,917	5,049,037	19,531,154	14,600,296
Operating loss	(8,016,917)	(5,049,037)	(19,531,154)	(14,600,296)
Interest income	3,588	2,202	12,971	2,771
Loss on extinguishment of convertible notes				(584,177)
Change in fair value of derivative liability	(26,666)		1,196,800	646,505
Interest expense:				
Amortization of discount on convertible notes				(1,791,967)
Amortization of debt issuance costs				(604,625)
Amortization of discount on related party convertible notes				(94,344)
Interest related to derivative liability			(540,333)	
Interest related to warrant extensions	(72,437)		(72,437)	
Inducement interest				(2,061,600)
Interest on notes payable				(118,709)
Total interest expense	(72,437)		(612,770)	(4,671,245)
Loss before income taxes	(8,112,432)	(5,046,835)	(18,934,153)	(19,206,442)
Provision for taxes on income				
Net loss	$ (8,112,432)	$ (5,046,835)	$ (18,934,153)	$ (19,206,442)
Basic and diluted loss per share	$ (0.06)	$ (0.05)	$ (0.14)	$ (0.22)
Basic and diluted weighted average common shares outstanding	142,175,678	104,844,162	134,138,391	86,916,655

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Cash Flows

(Unaudited)

	Nine Months Ended	
	February 28, 2017	February 29, 2016
Cash flows from operating activities:		
Net loss	$ (18,934,153)	$ (19,206,442)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	276,171	270,573
Amortization of debt issuance costs		604,625
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	(1,196,800)	(646,505)
Loss on extinguishment of convertible notes		584,177
Interest expense associated with debt conversion and exercise inducement		757,611
Interest expense associated with extension of warrant expirations	72,437	866,713
Stock-based compensation	984,772	1,546,383
Changes in current assets and liabilities:		
(Increase)decrease in prepaid expenses	(3,085,682)	(1,024,967)
(Decrease)increase in accounts payable and accrued expenses	1,777,535	(5,540,840)
Net cash used in operating activities	(19,565,387)	(19,572,837)
Cash flows from investing activities:		
Furniture and equipment purchases	(7,904)	
Net cash used in investing activities	(7,904)	
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants	19,133,755	33,268,466
Proceeds from warrant exercises	397,880	94,283
Payment of principal and interest on convertible notes payable		(789,140)
Payment of offering costs	(1,804,314)	(3,848,664)
Net cash provided by financing activities	17,727,321	28,724,945
Net change in cash	(1,845,970)	9,152,108
Cash, beginning of period	9,641,776	1,050,060
Cash, end of period	$ 7,795,806	$ 10,202,168

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.

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CYTODYN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF FEBRUARY 28, 2017

(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 has developed 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 nine months ended February 28, 2017 are not necessarily indicative of the results that may be expected for the entire fiscal 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 nine-month periods ended February 28, 2017 and February 29, 2016, (b) the financial position at February 28, 2017 and (c) cash flows for the nine-month periods ended February 28, 2017 and February 29, 2016.

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, if any, 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 $18,934,153 for the nine months ended February 28, 2017 and had an accumulated deficit of $116,160,067 as of February 28, 2017. 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 lead product candidate, obtain U.S. Food & Drug Administration (FDA) approval, outsource manufacturing of the lead product candidates, and ultimately achieve initial revenues and attain profitability. The Company is currently engaging in significant research and development activities related to the lead product candidate, 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.

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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 February 28, 2017 and May 31, 2016 approximated $7.5 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 nine months ended February 28, 2017 and February 29, 2016. 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 commercial use 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 (BLA), 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 February 28, 2017 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 February 28, 2017 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.

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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 February 28, 2017 and May 31, 2016 is as follows:

	Fair Value Measurement at February 28, 2017 (1) Using Level 3	Total	Fair Value Measurement at May 31, 2016 Using Level 3	Total
Liability:				
Derivative liability	$ 3,982,400	$ 3,982,400	$	$
Total liability	$ 3,982,400	$ 3,982,400	$	$