CytoDyn Inc. Form 10-Q January 08, 2018 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, 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 (State or other jurisdiction of

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

incorporation or organization)

**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

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

Large Accelerated Filer

Accelerated Filer

Non-accelerated Filer

**Smaller Reporting Company** 

**Emerging Growth Company** 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2017, there were 169,861,458 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

	ember 30, 2017 unaudited)	M	ay 31, 2017
Assets			
Current assets:			
Cash	\$ 1,296,839	\$	1,775,583
Prepaid expenses	294,364		207,314
Prepaid service fees	3,143,385		4,138,041
Total current assets	4,734,588		6,120,938
Furniture and equipment, net	14,036		17,281
Intangibles, net	1,742,181		1,917,219
Total assets	\$ 6,490,805	\$	8,055,438
Liabilities and Stockholders (Deficit) Equity			
Current liabilities:			
Accounts payable	\$ 9,716,970	\$	4,281,204
Accrued compensation	926,542		637,190
Accrued license fees	517,400		167,000
Accrued interest on convertible notes	180,673		
Convertible notes payable, net	5,391,998		1,058,611
Total current liabilities	16,733,583		6,144,005
Long-term liabilities:			
Derivative liability	2,547,733		3,014,667
Total long-term liabilities	2,547,733		3,014,667
Total liabilities	19,281,316		9,158,672
Commitments and Contingencies			
Stockholders (Deficit) Equity			
Series B convertible preferred stock, \$0.001 par value; 400,000 shares			
authorized, 92,100 shares issued and outstanding at November 30, 2017			
and May 31, 2017, respectively	92		92
Common stock, \$0.001 par value; 375,000,000 and 350,000,000 shares			
authorized, 165,135,154 and 149,468,244 issued and outstanding at			
November 30, 2017 and May 31, 2017, respectively	165,135		149,468

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Additional paid-in capital	132,609,936	1	121,736,921
Accumulated (deficit)	(145,565,674)	(1	122,989,715)
Total stockholders (deficit)	(12,790,511)		(1,103,234)
Total liabilities and stockholders (deficit) equity	\$ 6,490,805	\$	8,055,438

See accompanying notes to consolidated financial statements.

# CytoDyn Inc.

# **Consolidated Statements of Operations**

(Unaudited)

	Th	ree Months End	led	November 30, 2016		nths Ended mber 30, 2016	
Operating expenses:							
General and administrative	\$	1,608,743	\$	1,679,925	\$ 3,178,420	\$	3,259,988
Research and development		9,077,172		4,383,636	17,225,348		8,069,109
Amortization and depreciation		89,136		92,556	178,282		185,140
Total operating expenses		10,775,051		6,156,117	20,582,050		11,514,237
Operating loss		(10,775,051)		(6,156,117)	(20,582,050)	(	(11,514,237)
Interest income		422		5,648	1,206		9,383
Change in fair value of derivative liability		829,600		1,223,466	466,934		1,223,466
Interest expense:							
Amortization of discount on convertible							
notes		(728,843)			(1,172,995)		
Amortization of debt issuance costs		(168,429)			(282,129)		
Interest related to derivative liability				(540,333)			(540,333)
Inducement interest related to warrant					(006.050)		
exercise		(107.004)			(826,252)		
Interest on convertible notes payable		(105,384)			(180,673)		
Total interest expense		(1,002,656)		(540,333)	(2,462,049)		(540,333)
Loss before income taxes		(10,947,685)		(5,467,336)	(22,575,959)	(	(10,821,721)
Provision for taxes on income							
Net loss	\$	(10,947,685)	\$	(5,467,336)	\$ (22,575,959)	\$ (	(10,821,721)
Basic and diluted loss per share	\$	(0.07)	\$	(0.04)	\$ (0.15)	\$	(0.08)
Basic and diluted weighted average common shares outstanding		157,843,773		136,023,544	154,774,327	1	30,185,627

See accompanying notes to consolidated financial statements.

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# CytoDyn Inc.

# Consolidated Statements of Cash Flows

# (Unaudited)

		Six Mont Novem		
		2017		2016
Cash flows from operating activities:				
Net loss	\$	(22,575,959)	\$ (	(10,821,721)
Adjustments to reconcile net loss to net cash used by operating activities:				
Amortization and depreciation		178,282		185,140
Amortization of debt issuance costs		282,129		
Amortization of discount on convertible notes		1,172,995		
Inducement interest related to warrant exercise		826,252		
Interest expense associated with derivative liability				540,333
Change in fair value of derivative liability		(466,934)		(1,223,466)
Stock-based compensation		529,617		687,634
Changes in current assets and liabilities:				
(Increase) decrease in prepaid expenses		907,606		(2,899,658)
(Decrease) increase in accounts payable and accrued expenses		6,256,192		2,760,563
Net cash used in operating activities	(	(12,889,820)	(	(10,771,175)
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		7,050,651		10,729,500
Proceeds from warrant exercises		1,647,500		397,880
Proceeds from convertible notes payable		4,888,500		
Payment of offering costs		(1,175,575)		(1,183,264)
				,
Net cash provided by financing activities		12,411,076		9,944,116
				, ,
Net change in cash		(478,744)		(830,539)
Cash, beginning of period		1,775,583		9,641,776
- 18-19, 1-19-11-11-11-11-11-11-11-11-11-11-11-11		-,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		2,012,110
Cash, end of period	\$	1,296,839	\$	8,811,237
	Ψ	-,, 0,007	Ψ	-, <b>,</b> ,
Non-cash investing and financing transactions:				
Financing costs associated with placement agent warrants	\$	70,383	\$	
2 manually 2000 appointed with precedent agent waitants	Ψ	, 0,505	Ψ	

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Debt discount associated with convertible notes payable	\$	1,574,628	\$	
	Φ		Φ	5 170 200
Derivative liability associated with warrants	\$		\$	5,179,200

See accompanying notes to consolidated financial statements.

#### CYTODYN INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### AS OF NOVEMBER 30, 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 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, 2017 and 2016 and notes thereto in the Company s Annual Report on Form 10-K for the fiscal year ended May 31, 2017, filed with the Securities and Exchange Commission on July 20, 2017. Operating results for the three and six months ended November 30, 2017 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, 2017 and November 30, 2016, (b) the financial position at November 30, 2017 and (c) cash flows for the six month periods ended November 30, 2017 and November 30, 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 are eliminated in consolidation.

# Reclassifications

Certain prior year amounts shown in the accompanying consolidated financial statements have been reclassified to conform to the 2017 presentation. These reclassifications did not have any effect on total current assets, 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 \$22,575,959 for the six months ended November 30, 2017 and has an accumulated deficit of \$145,565,674 as of November 30, 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 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.

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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 November 30, 2017 and May 31, 2017 approximated \$1.2 million and \$1.5 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, 2017 and 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 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 requirements will be satisfied. 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, 2017 and May 31, 2017, 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, 2017 and May 31, 2017, 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 November 30, 2017 and May 31, 2017 is as follows:

		easurement at 30, 2017 (1)		easurement at 2017 (1)
	Using		Using	. ,
	Level 3	Total	Level 3	Total
Liability:				
Derivative liability	\$ 2,547,733	\$ 2,547,733	\$ 3,014,667	\$3,014,667
Total liability	\$ 2,547,733	\$ 2,547,733	\$3,014,667	\$3,014,667

(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, 2017 and May 31, 2017.

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, 2017 and the year ended May 31, 2017:

Investor warrants issued with registered direct equity offering \$4,360,000 819,200

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Placement agent warrants issued with registered direct equity offering

oneing	
Fair value adjustments	(2,164,533)
Balance at May 31, 2017	3,014,667
Fair value adjustments	(466,934)
Balance at November 30, 2017	\$ 2,547,733

### **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.

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.

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#### **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. On August 24, 2016, at the 2016 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. On August 24, 2017, at the 2017 Annual Meeting of Stockholders, a proposal was approved to increase the total number of authorized shares of common stock from 350,000,000 to 375,000,000. Subsequent to each stockholders meeting, an amendment to the Company s Certificate of Incorporation was filed with the Secretary of State of the State of Delaware to give effect to each authorized share increase.

## **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, 2017, the Company has authorized the issuance of 400,000 shares of Series B convertible preferred stock, of which 92,100 shares were outstanding. The remaining preferred shares authorized have no specified rights.

#### **Debt Discount**

During the six months ended November 30, 2017 and the year ended May 31, 2017, the Company incurred approximately \$1.6 million and \$92,000 of debt discount related to the issuance of short-term convertible notes issued with detachable warrants, as described in Note 4. The discount is amortized over the life of the convertible promissory notes. During the six months ended November 30, 2017, the Company recorded approximately \$1.2 million of related amortization.

#### **Debt Issuance Cost**

During the six months ended November 30, 2017, the Company incurred direct costs associated with the issuance of short-term convertible notes, as described in Note 4, and recorded approximately \$0.4 million of debt issuance costs and recognized approximately \$0.3 million of related amortization.

#### **Registered Direct Offering Costs**

During the six months ended November 30, 2017 and the year ended May 31, 2017, the Company incurred approximately \$0.4 million and \$1.8 million in direct incremental costs associated with the sale of equity securities, as described in Note 11. 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 87,551,801 and 64,415,987 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, 2017 and November 30, 2016, respectively. Additionally, as of November 30, 2017, shares of Series B convertible preferred stock in the aggregate of 92,100 shares can potentially convert into 921,000 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.

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.

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## **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 July 2017, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity s own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. Management is currently assessing the impact the adoption of ASU 2017-11 will have on the Company s Consolidated Financial Statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718)*, *Scope of Modification Accounting*. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for public business entities for reporting periods for which financial statements have not yet been issued. Management is currently assessing the impact the adoption of ASU 2017-09 will have on the Company s Consolidated Financial Statements.

# **Note 4** Convertible Instruments

Series B Convertible Preferred Stock

During fiscal 2010, the Company issued 400,000 shares of Series B Convertible Preferred Stock, par value \$0.001 (Series B) at \$5.00 per share for cash proceeds totaling \$2,009,000, of which 92,100 shares remain outstanding at November 30, 2017. Each share of the Series B is convertible into ten shares of the Company s 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 million. 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. The Series B holders have no voting rights.

Short-Term Convertible Notes

During the year ended May 31, 2017, the Company issued \$1.15 million of unsecured convertible promissory notes (the Notes), with a maturity date of January 31, 2018, and related warrants to investors for cash. The principal amount of the Notes, including any accrued but unpaid interest thereon, is convertible at the election of the holder at any time into shares of common shares at any time prior to maturity at a conversion price of \$0.75 per share. The Notes bear simple interest at the annual rate of 7%. Principal and accrued interest, to the extent not previously paid or converted, is due and payable on the maturity date. At the commitment date, the conversion price was greater than the fair value of the common stock. Accordingly, no beneficial conversion feature was recorded. The Company incurred approximately \$92,000 of debt discount related to the detachable warrants issued with the 2017 Notes, which is being amortized over the term of the notes.

On June 14, 2017, the Company s Board of Directors approved a modification in the warrant terms issued in connection with the Notes. The warrant coverage was increased from 25% to 50% and the exercise price of the warrant was reduced from \$1.35 to \$1.00 per share. On June 19, 2017, in connection with the new terms, the Company issued an incremental 383,333 warrant shares to these previous Note holders.

During the six months ended November 30, 2017, the Company issued approximately \$4.89 million in aggregate principal of additional Notes and related warrants, as described above. At the commitment dates, the Company determined that the conversion feature related to these Notes to be 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 on the commitment dates and the effective conversion price after discounting the Notes for the fair value of the related warrants.

In connection with the sale of the Notes during the six months ended November 30, 2017, and year ended May 31, 2017, detachable common stock warrants to purchase a total of 4,025,656 common shares, with an exercise price of \$1.00 per share and a five-year term were issued to the Note holders. 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, expected term of the warrants, risk-free interest rates and expected dividend yield at the grant date.

	2017
Expected dividend yield	0%
Stock price volatility	69.5 - 69.80%
Expected term	5 year
Risk-free interest rate	1.75 - 1.83%
Grant-date fair value	\$ 0.28 - \$0.39

The fair value of the warrants, coupled with the beneficial conversion features, were recorded as a debt discount to the Notes and a corresponding increase to additional paid-in capital and will be amortized over the life of the Notes. The Company incurred debt discount of approximately \$1.6 million during the six months ended November 30, 2017, related to the beneficial conversion feature and detachable warrants issued with the Notes. During the year ended May 31, 2017 the Company incurred debt discount of approximately \$92,000 related to the detachable warrants issued with the Notes. Accordingly, the Company recognized approximately \$1.2 million and \$-0-, of non-cash debt discount during the six months ended November 30, 2017 and year ended May 31, 2017, respectively. In connection with the Notes, the Company incurred direct issuance costs of approximately \$0.4 million during the six months ended November 30, 2017. The issuance costs are amortized over the term of the Notes and accordingly, the Company

recognized approximately \$0.3 million of debt issuance costs during the six months ended November 30, 2017.

Activity related to the Notes was as follows:

	Nove	mber 30, 2017	M	ay 31, 2017
Face amount of Notes	\$	6,038,500	\$	1,150,000
Unamortized discount		(493,000)		(92,000)
Unamortized issuance costs		(153,500)		
Total carrying value of Notes	\$	5,392,000	\$	1,058,000

## **Note 5** Derivative Liability

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 successor entity, then the warrantholder 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 warrant derivative liability and related common shares as of inception date September 15, 2016, May 31, 2017 and November 30, 2017:

	Shares Indexed	Deriv	ative Liability
Balance May 31, 2016		\$	
Inception date September 15, 2016	7,733,334		5,179,200
Balance May 31, 2017	7,733,334		3,014,667
Balance November 30, 2017	7,733,334	\$	2,547,733

The Company recognized approximately \$0.5 and \$1.2 million of net non-cash gain, due to the changes in the fair value of the liability associated with such classified warrants during the six months ended November 30, 2017 and November 30, 2016, respectively.

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 the warrant derivative liability as of inception date September 15, 2016, May 31, 2017 and November 30, 2017, using the following assumptions:

	-	mber 15, 2016	May 31, 2017	mber 30, 2017
Fair value of underlying stock	\$	0.78	\$ 0.60	\$ 0.59
Risk free rate		1.20%	1.71%	2.08%
Expected term (in years)		5	4.29	3.79
Stock price volatility		106%	94%	80%
Expected dividend yield				
Probability of Fundamental Transaction		50%	50%	50%
Probability of holder requesting cash				
payment		50%	50%	50%

Due to the fundamental transaction provisions, 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.

#### **Note 6** Stock Options and Warrants

The Company has one active stock-based equity plan at November 30, 2017, 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. At the annual meeting of stockholders held on August 24, 2017, the stockholders approved an amendment to the 2012 Plan to increase the

number of shares available for issuance from 7,000,000 to 15,000,000 shares of common stock. As of November 30, 2017, the Company had 5,693,807 shares available for future stock-based grants under the 2012 Plan, as amended.

Stock Options

During the six months ended November 30, 2017, the Company granted annual stock option awards to directors to purchase a total of 450,000 shares of common stock with an exercise price of \$0.57 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 \$0.36 per share.

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During the six months ended November 30, 2017, the Company granted an option award covering 600,000 shares of common stock with an exercise price of \$0.57 per share, to its Chief Science Officer. This option vests annually over three years, has a ten-year term and a grant date fair value of \$0.35 per share.

During the six months ended November 30, 2017, the Company granted options, covering an aggregate of 800,000 shares of common stock, to executive management and employees with exercise prices of \$0.57 per share. The options vest annually over three years, have a ten-year term and grant date fair values of \$0.35 per share.

#### Warrants

During the six months ended November 30, 2017, the Company granted a warrant covering an aggregate of 200,000 shares of common stock, with an exercise price of \$0.64 per share, to a consultant. The warrant vests 25% upon grant date, 25% on December 31, 2017 and 50% upon achieving certain future milestones. The warrant has a five-year term and a grant date fair value of \$0.26 per share.

During the six months ended November 30, 2017, the Company granted a warrant covering an aggregate of 100,000 shares of common stock, with an exercise price of \$0.75 per shares, to a consultant. The warrant vests immediately, has a five year term and a grant date fair value of \$0.29 per share.

During the six months ended November 30, 2017, in connection with unsecured convertible promissory Notes, as fully described in Note 4, the Company issued common stock warrants, covering 3,258,990 shares of common stock to Note holders. The warrants have a five-year term and an exercise price of \$1.00 per share. In connection with the promissory Notes, the Company issued warrants covering 350,766 to the placement agent. The warrants have a five year term and an exercise price of \$0.825.

On June 14, 2017, the Company s Board of Directors approved a modification in the warrant terms issued in connection with the promissory Notes, as fully described in Note 4. The warrant coverage was increased from 25% to 50% and the exercise price of the warrant was reduced to \$1.00 per share from \$1.35 per share. On June 19, 2017, in connection with new terms, the Company issued an incremental 383,333 warrant shares to the Note holders during the year ended May 31, 2017.

During the six months ended November 30, 2017, in connection with a private equity offering, as fully described in Note 10, the Company issued common stock warrants covering 6,651,800 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of \$0.75 per share. In connection with this offering, the Company also issued common stock warrants covering 452,180 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of \$0.55 per share.

On September 8, 2017, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued common stock warrants covering 1,668,163 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 213,573 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.

On October 11, 2017, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued common stock warrants covering 940,380 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of \$0.75 per share. In connection with this offering, the Company also issued common stock warrants covering 150,461 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of \$0.715 per share.

On November 24, 2017, the Company filed an Offer to Amend and Exercise (the Offer) certain warrants covering an aggregate of 51,090,113 shares of common stock, at a potentially reduced exercise price of \$0.50 per share. The original exercise price on these certain warrants ranged from \$0.50 to \$1.35 per share and have expiration dates beginning October 2018 continuing through October 2022. The Offer was scheduled to expire December 22, 2017, but was extended on December 21, 2017 to expire on January 26, 2018. The Offer is subject to the completion of an election to participate and exercise by the holder, certain representations and warranties by the holder and remittance of exercise proceeds to the Company.

On November 30, 2017, in connection with a registered direct equity offering dated September 8, 2017, as fully described in Note 11, the Company issued incremental common stock warrants covering 251,504 shares of common stock to investors. The investor warrants have a five-year term from initial investment date, September 8, 2017, and an exercise price of \$0.75 per share. In connection with this offering, the Company also issued common stock warrants covering 26,702 shares of common stock to the placement agent. The placement agent warrants have a five-year term from September 8, 2017, and an exercise price of \$0.715 per share.

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During the six months ended November 30, 2017, the Company determined to extend the expiration dates of certain warrants to June 30, 2017 covering 3,295,000 shares of common stock. The warrants were originally issued in connection with 2012 convertible promissory notes and had an exercise price of \$1.00 per share. The extension to June 30, 2017 was contingent upon immediate exercise of the warrants at a reduced exercise price of \$0.50 per share. The Company received proceeds of approximately \$1.6 million and pursuant to U.S. GAAP, the Company recognized non-cash inducement interest expense of approximately \$0.8 million, which represented the incremental increase in the fair value of the extended warrants.

The Company determined the fair value of the warrant extension 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 date of exercise.

	2017
Expected dividend yield	0%
Stock price volatility	61.48%
Expected term	1 month
Risk-free interest rate	0.84%
Grant-date fair value	\$ 0.25

Compensation expense related to stock options and warrants for the three and six months ended November 30, 2017 and November 30, 2016 was approximately \$275,000 and \$530,000 and \$335,000 and \$688,000, respectively. The grant date fair value of options and warrants vested during the three and six month periods ended November 30, 2017 and November 30, 2016 was approximately \$127,000 and \$574,000 and \$279,000 and \$530,000, respectively. As of November 30, 2017, there was approximately \$1.0 million of unrecognized compensation expense related to share-based payments for unvested options, which is expected to be recognized over a weighted average period of 1.43 years.

The following table represents stock option and warrant activity as of and for the six months ended November 30, 2017:

				Weighted	
				Average	
		W	eighted	Remaining	Aggregate
	Number of	A	verage Co	ontractual Li	feIntrinsic
	Shares	Exer	cise Price	e in Years	Value
Options and warrants outstanding - May 31, 2017	77,859,626	\$	0.86	3.40	\$ 40,250
Granted	16,497,852		0.78		
Exercised	(3,295,000)	)	0.50		
Forfeited/expired/cancelled	(3,510,677)	)	0.98		
•					
Options and warrants outstanding - November 30, 2017	87,551,801		0.83	3.51	70,500
Outstanding exercisable - November 30, 2017	83,426,884	\$	0.83	3.25	\$ 37,750

## **Note 7** Acquisition of Patents

As discussed in Note 9 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, 2017, the Company has recorded and is amortizing \$3,500,000 of intangible assets in the form of patents. The Company estimates the acquired and enforceable patents have an estimated life of 10 years. Subsequent to the acquisition date, the Company has continued to expand, amend and file patent applications 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 2038, respectively, in various countries.

The following presents intangible assets activity:

Gross carrying amounts Accumulated amortization	Nove \$	mber 30, 2017 3,500,000 (1,793,808)	May 31, 2017 \$ 3,500,000 (1,618,770)
Total amortizable intangible assets, net		1,706,192	1,881,230
Patents currently not amortized		35,989	35,989
Carrying value of intangibles, net	\$	1,742,181	\$ 1,917,219

Amortization expense related to patents was approximately \$87,500 and \$175,000 for the three and six months ended November 30, 2017 and 2016. 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

The Company has 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 £600,000 (approximately US\$807,000 utilizing current exchange rates), which was timely paid by June 30, 2016. The Company continues to accrue for a current annual license fee of £300,000 (approximately US\$400,000 utilizing current exchange rates), which is payable annually in December, except for the December 2017 payment, which has been extended to March 15, 2018. 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\$400,000) when it serves as the manufacturer.

#### **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 \$3.5 million in cash to close the transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) \$1.5 million 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) \$5.0 million 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. 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.

Payments to the third-party licensor 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) \$1.0 million upon initiation of a Phase 3 clinical trial, which was paid during the year ended May 31, 2016; (ii) \$0.5 million upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) \$0.5 million 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 \$2.5 million 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. 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 PDL, Progenics and its sub-licensors are deemed contingent consideration and, therefore are not currently accruable.

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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 \$0.3 million. In the remote circumstance that the Company would terminate all clinical trials, the collective financial penalties may range from an approximate low of \$0.5 million to an approximate high of \$1.6 million.

During the year ended May 31, 2017, the Company entered into agreements with contract manufacturing companies. Under the terms of the agreements, the Company incurred approximately \$3.2 million of execution fees for process validation and manufacturing activities, of which the remaining \$2.1 million is reflected as a current asset, as of November 30, 2017. 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 up to an approximate high of \$4.0 million.

From time to time, the Company is involved in routine litigation that arises in the ordinary course of business. There are no pending significant legal proceedings to which the Company is a party for which management believes the ultimate outcome would have a material adverse effect on the Company s financial position.

## **Note 10 Private Securities Offerings**

During the year ended May 31, 2017, 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, \$0.001 par value, for aggregate gross proceeds of \$729,500 and issued to the investors five-year warrants covering 182,375 shares of common stock with an exercise price of \$1.35 per share.

During the six months ended November 30, 2017, the Company conducted a private equity offering, in which accredited investors purchased unregistered common stock at \$0.50 per share with warrant coverage of 100%, based on the number of shares of common stock purchased. Pursuant to the offering, the Company sold a total of 6,651,800 shares of common stock for aggregate gross proceeds of \$3,325,900 and issued warrants covering an aggregate of 6,651,800 shares of common stock with a five-year term and an exercise price of \$0.75 per share. In connection with the offering the placement agent received a warrant covering 452,180 shares of common stock, with an exercise price of \$0.55 per share and a five-year term.

In connection with the September 2017 Offering, as fully described below in Note 11, on November 30, 2017, the Company completed an offer and sale (the Make-Whole Offering ) of an aggregate of 503,015 shares of Common Stock (the Make-Whole Shares ) and warrants to purchase up to 251,504 shares of common stock (the Make-Whole Warrants and, collectively with the Make-Whole Shares, the Make-Whole Securities ). The Make-Whole Securities issued were unregistered.

The Make-Whole Securities were offered pursuant to a form of Waiver and Subscription Agreement (the Waiver and Subscription Agreement). The Make-Whole Securities represent the difference in the numbers of shares of Common Stock and warrants that would have been sold to investors in the September 2017 Offering had the reduced purchase price of \$0.65 per share of Common Stock and related Warrants in the October 2017 Offering, registered direct offering (as compared to \$0.75 in the September 2017 Offering) and the reduced warrant exercise price of \$0.75 in the October 2017 Offering (as compared to \$1.00 in the September 2017 Offering) applied to the September 2017

Offering as well. The Make-Whole Securities were offered as consideration for the release of potential claims by participating investors. In connection with these arrangements, the exercise prices of any warrants previously sold in the September 2017 Offering to participating investors has also been reduced to \$0.75 from \$1.00. In addition, warrants previously issued to the placement agent (or its designees) in respect of participating investors have also been proportionately adjusted to reflect a reduced exercise price of \$0.715 (as compared to \$0.825 in the September 2017 Offering) and 26,702 additional shares.

## **Note 11 Registered Direct Equity Offerings**

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 \$9.0 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.

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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.

On December 12, 2016, the Company entered into securities purchase agreements with certain investors for the sale of 4,000,000 shares of common stock at a purchase price of \$0.75 per share in a registered direct offering (the December Offering ), pursuant to a registration statement on Form S-3. The investors in this December Offering also received warrants to purchase 2,000,000 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 December Offering of \$3.0 million.

On January 31, 2017, the Company entered into subscription agreements with certain investors for the sale of 1,534,999 shares of common stock at a purchase price of \$0.75 per share in a registered direct offering (the January Offering ), pursuant to a registration statement on Form S-3. The investors in the January Offering also received warrants to purchase 767,498 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 January Offering of approximately \$1.0 million after placement fees of 9% of the gross proceeds and various expenses. In addition, the placement agent received warrants covering 122,799 shares (or 8% of total shares sold to investors) with a per share exercise price of \$0.825 and a five-year term.

On February 28, 2017, the Company entered into subscription agreements with certain investors for the sale of 5,670,661 shares of common stock at a purchase price of \$0.75 per share in a registered direct offering (the February Offering ), pursuant to a registration statement on Form S-3. The investors in the February Offering also received warrants to purchase 2,835,323 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 February Offering of approximately \$3.8 million after placement fees of 9% of the gross proceeds and various expenses. In addition, the placement agent received warrants covering 453,652 shares (or 8% of total shares sold to investors) with a per share exercise price of \$0.825 and a five-year term.

On September 8, 2017, the Company entered into subscription agreements with certain investors for the sale of 3,336,331 shares of common stock at a purchase price of \$0.75 per shares in a registered direct offering (the September 2017 Offering), pursuant to a registration statement on Form S-3. The investors in this September 2017 Offering also received warrants to purchase 1,668,163 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 September 2017 Offering of approximately \$2.3 million after placement fees of 9% of the gross proceeds and various expenses. In addition, the placement agent received warrants covering 213,573 shares (or 8% of total shares sold to investors) with a per share exercise price of \$0.825 and a five-year term.

On October 11, 2017, the Company entered into subscription agreements with certain investors for the sale of 1,880,765 shares of common stock at a purchase price of \$0.65 per shares in a registered direct offering (the October 2017 Offering), pursuant to a registration statement on Form S-3. The investors in this October 2017 Offering also received warrants to purchase 940,380 shares of common stock with an exercise price of \$0.75 per share and a five-year term. The Company received net proceeds from the October 2017 Offering of approximately \$1.1 million. In addition, the placement agent received warrants covering 150,461 shares (or 8% of total shares sold to investors) with a per share exercise price of \$0.715 and a five-year term.

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# 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, 2017 and 2016, the Company incurred an expense of approximately \$10,800 and \$21,500 and \$9,800 and \$18,600, respectively, for qualified non-elective contributions.

### **Note 13 Related Party Transactions**

On May 31, 2017, Anthony D. Caracciolo, Executive Chairman of the Company, participated in the private placement of Notes, as fully described in Note 4. Mr. Caracciolo purchased a promissory note, bearing interest of 7%, for \$1,000,000 in aggregate principal and received a warrant covering 333,333 shares of common stock at an exercise price of \$1.00. The terms and conditions of Mr. Caracciolo s investment were identical to those offered to all other investors in the offering and his investment was approved by the Audit Committee of the Board of Directors.

On July 26, 2017, Jordan G. Naydenov, a director with the Company, participated in the private placement of Notes, as fully described in Note 4. Mr. Naydenov purchased a promissory note, bearing interest of 7%, for \$100,000 in aggregate principal and received a warrant covering 66,666 shares of common stock at an exercise price of \$1.00. The terms and conditions of Mr. Naydenov s investment were identical to those offered to all other investors in the offering and his investment was approved by the Audit Committee of the Board of Directors.

On July 28, 2017, Alpha Venture Capital Partners, LP ( AVCP ), participated in the private placement of Convertible Promissory Notes, as fully described in Note 4 above. Mr. Carl Dockery, the principal of AVCP, is a director of the Company. AVCP purchased a promissory note, bearing interest of 7%, for \$50,000 in aggregate principal and received a warrant covering 33,333 shares of common stock at an exercise price of \$1.00. The terms and conditions of the AVCP investment were identical to those offered to all other investors in the offering and his investment was approved by the Audit Committee of the Board of Directors.

On November 8, 2017, in connection with a private equity offering, a limited liability company in which Anthony D. Caracciolo, Executive Chairman of the Company, holds a partial ownership interest purchased \$100,000 of common stock and warrants on terms identical to those applicable to the other investors in the private equity 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**

From December 5 through December 20, 2017, the Company conducted private equity offerings, in which accredited investors purchased unregistered common stock at \$0.50 per share with warrant coverage of 100%, based on the number of shares of common stock purchased. Pursuant to the offerings, the Company sold a total of 2,948,666 shares of common stock for aggregate gross proceeds of approximately \$1.5 million and issued warrants covering an aggregate of 2,948,666 shares of common stock with a five-year term and an exercise price of \$0.75 per share. In connection with the offerings, the placement agent received warrants covering 243,667 shares (or 10% of total shares sold to investors) with an exercise price of \$0.55 per share.

On December 21, 2017, the Company extended the expiration date for the warrant tender Offer, as fully described in Note 6 above, to January 26, 2018.

The Tax Cuts and Jobs Act ( TCJA ) was enacted into law on December 22, 2017 (the enactment date). The corporate tax rate will be reduced to 21% from 35% for tax years beginning after December 31, 2017. This will affect the value of the Company s deferred tax asset and related valuation allowance. However, the Company s deferred tax asset has a full valuation allowance. The TCJA also limits net operating loss carryforwards ( NOLs ) arising in tax years beginning after December 31, 2017, however, existing NOLs that arose in years prior to December 31, 2017 are not affected by the TCJA. The Company is currently evaluating the TCJA and its potential effects on its financial statements.

On December 29, 2017, the Company conducted a private equity offering, in which accredited investors purchased unregistered common stock at \$0.50 per share with warrant coverage of 100%, based on the number of shares of common stock purchased. Pursuant to the offering, the Company sold a total of 1,777,638 shares of common stock for aggregate gross proceeds of approximately \$0.9 million and issued warrants covering an aggregate of 1,777,638 shares of common stock with a five-year term and an exercise price of \$0.75 per share. In connection with the offerings, the placement agent received warrants covering 177,764 shares (or 10% of total shares sold to investors) with an exercise price of \$0.55 per share.

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## 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, predict, intend, plan, could, may, and similar terms and expressions are intended to identify forward-look estimate, continue, 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 sufficiency of the Company s cash position and 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

<u>Phase 2b Extension Study for HIV, as Monotherapy</u>. There were 11 trial participants in the extension study who successfully completed 37 weeks of therapy and were not discontinued. There were eight trial participants who surpassed three years of suppressed viral load with PRO 140 as a single-agent therapy. Certain patients have dropped out of the study for various undisclosed reasons. This extension study remains ongoing with six patients.

Phase 2b/3 Pivotal Trial for HIV, as Combination Therapy. A pivotal 25-week trial for PRO 140 as a combination therapy to existing HAART drug regimens. Several patients have completed this trial and have transitioned to a rollover protocol, as requested by the treating physicians to enable the patients to have continued access to PRO 140. At an October 2017 meeting, the FDA accepted the 40 patients enrolled at that time in the Company s Phase 2b/3 pivotal combination trial as evaluable and further agreed that the trial s independent data monitoring committee can conduct an interim efficacy analysis of primary endpoint. The FDA also confirmed that at least 50 patients will be required for the completion of this trial. As previously reported, the FDA also confirmed that 300 patients will be required for the safety analysis in a BLA, which can be provided by all of the Company s HIV trials, providing that those patients have been on a PRO 140 therapy for 24 weeks, with the same or higher dose as the combination therapy trial.

On December 7, 2017, the Company reported that the Independent Data Monitoring Committee (IDMC) for the PRO 140 pivotal combination therapy trial had completed a planned interim analysis of efficacy data of the first 40 patients and had recommended that the trial be continued as planned, with the protocol defined sample size and power to achieve primary endpoint. The Company expects to complete enrollment in January 2018. Management projects that the total estimated costs for this trial may range from \$10 million to \$11 million.

Rollover Study for HIV, as Combination Therapy. This study is designed for patients who successfully complete the Phase 2b/3 combination therapy trial and for whom the treating physicians request a continuation of PRO 140 therapy. If this study enrolls 50 patients from the Phase 3 combination therapy trial and all patients remain in the rollover study for one year, management estimates the cost of this study to be approximately \$6 million to \$7 million.

Phase 2b/3 Investigative Trial for HIV, as Long-term Monotherapy. An investigative 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 to assess the clinical safety of PRO 140 monotherapy regimen and to evaluate the proportion of participants experiencing virologic failure. The secondary endpoint is length of time to virologic failure. Enrollment of the first several patients was announced in December 2016. The Company is currently exploring a high-dose arm, with a 50% increase in dosage, within the trial s protocol in order to evaluate an increased response rate among certain patients. The Company expects to increase the number of sites in order to accelerate enrollment following the completion of enrollment of the pivotal combination therapy trial. The estimates for the total cost of this trial currently range from \$22 million to \$25 million, but such estimates will be updated upon the determination of the requisite number of sites, the rate of patient enrollment and the overall duration of the trial, all of which could cause the total trial costs to vary from the foregoing range. The Company expects enrollment to be completed in 2018, subject to the foregoing variables. Patients who are completing this trial are transitioning to a rollover protocol, as requested by the treating physicians to enable the patients to have continued access to PRO 140 as a single-agent maintenance therapy.

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 prophylaxis as an add-on therapy to standard GvHD 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 was announced in May of 2017. Management estimates the cost of this trial to be approximately \$3.5 million to \$4 million. On October 5, 2017, the Company announced that the FDA had granted orphan drug designation to PRO 140 for the prevention of graft versus host disease.

The Company will require a significant amount of additional capital to complete the foregoing clinical trials for HIV and make its BLA submission. See Liquidity and Capital Resources below.

## Results of Operations for the three months ended November 30, 2017 and 2016 are as follows:

For the three months ended November 30, 2017 and November 30, 2016, the Company had no activities that produced revenues from operations.

For the three months ended November 30, 2017, the Company incurred a net loss of approximately \$10.9 million, as compared to a net loss of approximately \$5.5 million for the corresponding period in 2016. The increase in net loss of approximately \$5.4 million related primarily to an increase in operating expenses of approximately \$4.6 million, as described below, higher comparative interest expense of approximately \$0.5 million, offset in part by a reduction in the non-cash benefit of a change in derivative liability of approximately \$0.4 million. The loss per share for the quarter ended November 30, 2017 was \$(0.07) compared to \$(0.04) in the comparable 2016 period.

For the three months ended November 30, 2017 and November 30, 2016, operating expenses totaled approximately \$10.8 million and \$6.2 million, respectively, consisting of research and development, general and administrative expenses and amortization and depreciation. The increase in operating expenses of approximately \$4.6 million reflected increased research and development expenses of approximately \$4.7 million, offset in part by a slight decrease in general and administrative expenses of approximately \$0.1 million.

General and administrative expenses, which totaled approximately \$1.6 million for the three months ended November 30, 2017, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The slight reduction in general and administrative expenses of approximately \$0.1 million for the three months ended November 30, 2017 over the comparable period a year ago was due to reduced stock-based compensation and certain professional fees, offset in part by increased corporate insurance coverages.

Research and development ( R&D ) expenses of approximately \$9.1 million for the three months ended November 30, 2017 increased approximately \$4.7 million over the comparable 2016 quarter principally due to higher clinical trial and manufacturing-related expenses. For the quarter ended November 30, 2017, R&D expenditures continue to be primarily devoted to: (1) one pivotal Phase 2b/3 combination therapy trial, one investigative Phase 2b/3 monotherapy trial, one Phase 2 GvHD trial, (2) increased CMC (chemistry, manufacturing and controls) activities to address regulatory compliance requirements of a future BLA filing and to advance the preparations for manufacturing new PRO 140 and (3) preparation of the non-clinical section necessary to complete the BLA filing with the FDA.

We expect R&D expenses to continue to increase in future periods, as the activity within the Company s clinical trials expands and the biologics manufacturing processes and related regulatory compliance activities increase, all of which support the Company s objectives to advance the preparation for an anticipated BLA filing in late 2018, if a breakthrough therapy designation is granted by the FDA.

For the quarter ended November 30, 2017, the Company recognized a non-cash benefit associated with the reduction in fair value of a derivative liability of approximately \$0.8 million, as compared to a non-cash benefit of approximately \$1.2 million in the similar 2016 quarter. The warrants that contain a provision which gives rise to a derivative liability originated in September 2016. For each reporting period, we determine the fair value of the derivative liability and record a corresponding non-cash benefit or a non-cash charge, as a consequence of a decrease or increase, respectively, in the calculated derivative liability.

For the three months ended November 30, 2017, the Company incurred approximately \$1.0 million in interest expense, of which is primarily non-cash. The components of interest expense included amortization of discount on convertible notes, amortization of debt issuance costs and interest on convertible notes. The comparable quarter a year ago included only originating interest expense associated with the derivative liability, as there was no outstanding debt during the comparable period last year.

The future trends in all expenses will be driven, in large part, by the future outcomes of clinical trials and the correlative effect on research and development expenses, as well as general and administrative expenses, 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 requires a significant amount of additional capital and its ability to continue to fund operations will continue to depend on its ability to raise such capital. See, in particular, Liquidity and Capital Resources below and Item 1A Risk Factors in the Annual Report on Form 10-K for the year ended May 31, 2017.

### Results of Operations for the six months ended November 30, 2017 and 2016 are as follows:

For the six months ended November 30, 2017 and November 30, 2016, the Company had no activities that produced revenues from operations.

For the six months ended November 30, 2017, the Company had a net loss of approximately \$22.6 million, as compared to a net loss of approximately \$10.8 million for the similar 2016 period. The approximate increase of \$11.8 million in net loss for 2017 over 2016 was primarily attributable to an increase in research and development expenses of approximately \$9.2 million, an increase in interest expense of approximately \$1.9 million, coupled with a decrease in the benefit of a reduction in the fair value of a derivative liability of approximately \$0.8 million. The loss per share for the six months ended November 30, 2017 was \$(0.15) compared to a loss per share of \$(0.08) in the comparable 2016 period.

For the six months ended November 30, 2017 and November 30, 2016, operating expenses totaled approximately \$20.6 million and \$11.5 million, respectively, consisting primarily of research and development, general and administrative expenses and amortization and depreciation. The increase in operating expenses over the comparable 2016 period were attributable to increased research and development expenses of approximately \$9.2 million, offset in part by a slight decrease in general and administrative expenses of approximately \$0.1 million.

General and administrative expenses, which totaled approximately \$3.2 million for the six months ended November 30, 2017, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The decrease in general and administrative expenses of approximately \$0.1 million for the six months ended November 30, 2017 over the comparable 2016 period was due to lower stock-based compensation and professional fees, offset slightly by higher other operating expenses.

Research and development expenses, which totaled approximately \$17.2 million for the six months ended November 30, 2017, increased approximately \$9.2 million over the same 2016 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 2b/3 trials with PRO 140 for HIV therapy continue, along with the related rollover studies, combined with the Phase 2 GvHD trial, and the increasing expenses to expand activities related to manufacturing cGMP PRO 140 material for the BLA and for future use.

For the six months ended November 30, 2017 the Company recognized an unrealized gain, or a non-cash benefit from a decline in derivative liability of approximately \$0.4 million, as compared to an approximate non-cash benefit of \$1.2 million in the comparable 2016 period. The warrants that contain a provision which gives rise to a derivative liability originated in September 2016. For each reporting period, we determine the fair value of the derivative liability and record a corresponding non-cash benefit or a non-cash charge, as a consequence of a decrease or increase, respectively, in the calculated derivative liability.

Interest expense for the six months ended November 30, 2017 of approximately \$2.5 million increased approximately \$2.0 million over the same six-month period a year ago, due primarily to the issuance of approximately \$4.8 million in aggregate principal of short-term convertible promissory notes due on January 31, 2018. Accordingly, interest expense was comprised of amortization of debt discount, debt issuance costs and accrued interest payable, as well as non-cash inducement interest of approximately \$0.8 million related to the extension of the expiration date of certain warrants. In the comparable six-month period in 2016, there was no outstanding debt or the incurrence of inducement interest expense.

The future trends in all expenses will be driven, in large part, by the future outcomes of clinical trials and the correlative effect on research and development expenses, as well as general and administrative expenses, 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 requires a significant amount of additional capital, and its ability to continue to fund operations will continue to depend on its ability to raise such capital. See, in particular, Liquidity and Capital Resources below and Item 1A Risk Factors in the Annual Report on Form 10-K for the year ended May 31, 2017.

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## Liquidity and Capital Resources

The Company s cash position at November 30, 2017 decreased approximately \$0.5 million to approximately \$1.3 million, as compared to a balance of approximately \$1.8 million as of May 31, 2017. The net decrease in cash for the six months ended November 30, 2017 was attributable to net cash used in operating activities of approximately \$12.9 million, offset in part by cash provided by financing activities of approximately \$12.4 million.

As of November 30, 2017, the Company had negative working capital of approximately \$12.0 million compared to negative working capital of approximately \$0.02 million at May 31, 2017, a decrease of approximately \$11.98 million attributable primarily to cash used in operations.

#### Cash Flows

Net cash used in operating activities totaled approximately \$12.9 million during the six months ended November 30, 2017, which reflects an increase of approximately \$2.1 million of net cash used in operating activities over the six months ended November 30, 2016. The increase in net cash used in operating activities was due to an increase in net loss of approximately \$11.8 million, which was mitigated in part by the effect of a comparative net change in working capital components totaling approximately \$7.3 million, coupled with an increase in non-cash interest expense of approximately \$1.7 million and offset by an approximate \$0.8 million reduction in the non-cash benefit of the change in fair value of the derivative liability for six months ended November 30, 2017.

There were no investing activities during the six months ended November 30, 2017, compared to the approximately \$3,500 in the comparable period a year ago.

Net cash provided by financing activities of approximately \$12.4 million during the six months ended November 30, 2017, increased approximately \$2.5 million over the \$9.9 million of net cash provided by financing activities during the six months ended November 30, 2016. The increase in net cash provided from financing activities during the six months ended November 30, 2017 was attributable to proceeds of approximately \$4.9 million from the sale of convertible notes, an increase of approximately \$1.2 million in warrant exercise proceeds over the prior comparable period, offset by lower net proceeds from the sale of common stock and warrants of approximately \$3.7 million.

# Capital Requirements

The Company has not generated revenue to date, and will not generate product revenue in the foreseeable future. We expect that the Company will continue to incur operating losses as expenses continue to increase as it proceeds with clinical trials with respect to PRO 140 and continues to advance it through the product development and regulatory process. The future trends of all expenses will be driven, in large part, by the future outcomes of the clinical trials and their correlative effect on general and administrative expenses, 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 for its clinical trials to fulfill BLA requirements related to manufacturing PRO 140 for commercial use.

In connection with this undertaking, the Company has entered into an arrangement with a third party contract manufacturing organization (the CMO) to provide process transfer, validation and manufacturing services for PRO 140. Management believes the 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. Management will continue to assess manufacturing capacity requirements as new market information becomes available. In the event that the Company terminates the agreement with its CMO, the Company may incur certain financial penalties which would

become payable to the CMO. Conditioned on the timing of termination, the financial penalties may range up to an approximate high of \$4.0 million. These CMO undertakings are anticipated to require approximately \$17 million of additional capital over the next several fiscal quarters, including the estimated costs to fill, label, and package product into the final commercial package for commercial sale.

The Company has entered into project work orders for each of its clinical trials with its clinical research organization (the CRO) and related laboratory vendors. Under the terms of these agreements, the Company has prepaid certain execution fees for direct services costs. In connection with its clinical trials, the Company has entered into separate project work orders for each trial with its CRO. In the event that the Company terminates any trial, the Company 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 \$0.3 million. In the remote circumstance that the Company terminates all clinical trials, the collective financial penalties may range from an approximate low of \$0.5 million to an approximate high of \$1.6 million.

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 \$3.5 million in cash to Progenics to close the acquisition transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) \$1.5 million 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) \$5.0 million 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 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) \$1.0 million upon initiation of a Phase 3 clinical trial, which was paid during the three months ended February 29, 2016; (ii) \$0.5 million upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) \$0.5 million 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 clinical development and regulatory 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.

On January 31, 2018, approximately \$6.0 million in aggregate principal of convertible notes issued between May 31, 2017 and July 28, 2017 will become due and payable. Unless the holders elect to convert the principal amount of such notes plus accrued interest at an annual rate of 7.0%, or an aggregate of approximately \$6.3 million, into common stock at a conversion price of \$0.75 per share, or agree to amend or extend such notes, the Company will be required to repay such amount to its investors in cash, which will require not less than an equal amount of new capital. Moreover, such required capital, if available, may not be on terms and conditions consistent with the Company s recent financing activities, or on favorable terms to the Company. See Going Concern.

### Going Concern

As reported in the accompanying financial statements, for the six months ended November 30, 2017 and November 30, 2016, the Company incurred net losses of approximately \$22.6 million and \$10.8 million, respectively. The Company has no activities that produced revenue in the periods presented and has sustained operating losses since inception.

The Company currently requires and will continue to require a significant amount of additional capital to fund operations, repay its outstanding convertible notes due January 31, 2018, pay its accounts payables, and its ability to continue as a going concern is dependent upon its ability to raise such additional capital, commercialize its product and achieve profitability. If the Company is not able to raise such additional capital on a timely basis or on favorable terms, the Company may need to scale back its operations or slow down or cease certain clinical trials or CMO activities, which could materially delay the timeframe to BLA submission. In extreme cases, the Company could be

forced to file for bankruptcy protection, discontinue its operations or liquidate its assets.

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 operating activities and its working capital needs largely from the sale of equity and debt securities, combined with additional funding from other traditional financing sources. As of the date of this filing, the Company had approximately \$77.8 million of securities available for issuance or approximately \$62.9 million, assuming the full exercise of previously issued warrants in future financing rounds registered under its universal shelf registration statement on Form S-3, which was declared effective on September 9, 2016.

The sale of equity and convertible debt securities to raise additional capital 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 may require additional capital beyond currently anticipated needs. 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.

## 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.

The Company s exposure to market risk is limited to changes in the market price of its common stock and to a lesser extent foreign currency exchange risk.

## Common Stock Price Risk

The Company does not use derivative instruments to hedge risks relating to its ongoing business operations or for speculative purposes. However, as described in greater detail in Note 5 (Derivative Liability) to the accompanying financial statements, the Company is required to account for certain outstanding series of warrants as derivative instruments.

All derivative instruments are required to be recorded on the balance sheet at their fair values. Each quarter, management determines the fair value of the warrants accounted for as derivative instruments using a binomial lattice valuation mode. The key inputs in determining fair value of such derivative liabilities include the Company's stock price and stock price volatility, and the then applicable risk free interest rate. Changes in these inputs affect the valuation of such derivatives and result in non-cash gain or loss each quarterly period. For example, a 10% increase or decrease in stock price would increase or decrease the value of the warrant derivative liability by approximately \$0.4 million, resulting in a non-cash loss (for an increase or decrease the value of the warrant derivative liability by approximately \$0.4 million, resulting in a non-cash loss (for an increase) or gain (for a decrease) of the same amount. Finally, a 10% increase or decrease in the risk free interest rate would increase or decrease the value of the warrant derivative liability by approximately \$0.4 million, resulting in a non-cash loss (for an increase) or gain (for a decrease) of the same amount. Management s discretion is required to estimate certain other factors described in Note 5 to the accompanying financial statements, which also contribute to the fair value estimates of such derivative liability.

During the six months ended November 30, 2017, the Company recorded a non-cash benefit, or unrealized non-cash gain, from a reduction in the fair value of the derivative liability associated with certain warrants of approximately \$0.8 million, due primarily to a decrease in the Company s common stock price and increases in stock price volatility and risk free interest rate.

### Foreign Currency Exchange Risk

The Company may face certain exposure to fluctuation in foreign currency exchange rates, due primarily to a license agreement with a third-party licensor under which the Company is required to pay annual license fees and/or royalties denominated in British pounds sterling. For more information about this license agreement, see Note 8 (License Agreements) to the accompanying financial statements. Nevertheless, fluctuations in foreign exchange rates have not previously had, nor does management believe that they will have, any material impact on earnings, cash flows or other financial results of the Company.

### Item 4. Controls and Procedures.

## **Disclosure Controls and Procedures**

Under the supervision and with the participation of management, including the Chief Executive Officer and the Chief Financial Officer of the Company, the Company has evaluated the effectiveness of its disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of November 30, 2017. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective as of November 30, 2017.

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# Internal Control Over Financial Reporting

Changes in Control Over Financial Reporting

No changes occurred during the quarter ended November 30, 2017, that materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

## **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 20, 2017.

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.

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# Item 6. Exhibits.

(a) Exhibits:

3.1	Certificate of Amendment to the Certificate of Incorporation of CytoDyn Inc. (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed September 8, 2017)
4.1	Form of Warrant Agreement (September 2017 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed September 8, 2017)
4.2	Form of Warrant Agreement (October 2017 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed October 11, 2017)
4.3	Form of Warrant Agreement (November 2017 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed November 8, 2017)
4.4	Form of Consultant Warrant (November 2017 Offering) (incorporated by reference to Exhibit 4.4 to the Registrant s Current Report on Form 8-K filed June 22, 2017)
4.5	Form of Placement Agent Warrant (September/October 2017 Offering)
10.1	Form of Subscription Agreement (September 2017 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed September 8, 2017).
10.2	Form of Securities Purchase Agreement (September 2017 Offering) (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed September 8, 2017).
10.3	Form of Placement Agent Agreement (September 2017 Offering) (incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K filed September 8, 2017).
10.4	Form of Subscription Agreement (October 2017 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed October 11, 2017).
10.5	Form of Subscription Agreement (November 2017 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed November 8, 2017)
10.6	Form of Waiver and Subscription Agreement (Make-Whole Offering) (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed December 6, 2017)
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.
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.

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## **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 8, 2018 /s/ Nader Z. Pourhassan

Nader Z. Pourhassan

President and Chief Executive Officer

Dated: January 8, 2018 /s/ Michael D. Mulholland

Michael D. Mulholland

Chief Financial Officer, Treasurer and Corporate Secretary