CytoDyn Inc.
Form 10-Q
October 09, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended August 31, 2018

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1933
For the transition period from _____ to _____

Commission File Number: 000-49908

CYTODYN INC.

(Exact name of registrant as specified in its charter)

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

(Registrant s telephone number, including area code) (360) 980-8524

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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 September 28, 2018, there were 255,762,949 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

	August 31, 2018 (unaudited)	May 31, 2018
Assets		
Current assets:		
Cash	$ 4,749,413	$ 1,231,445
Prepaid expenses	338,384	227,173
Prepaid service fees	2,451,983	1,862,009
Total current assets	7,539,780	3,320,627
Furniture and equipment, net	12,038	11,228
Intangibles, net	1,479,624	1,567,143
Total assets	$ 9,031,442	$ 4,898,998
Liabilities and Stockholders (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 20,711,613	$ 15,841,859
Accrued liabilities and compensation	633,746	757,778
Accrued license fees	233,800	133,600
Accrued interest payable	104,630	
Convertible note payable, net	2,455,386	
Total current liabilities	24,139,175	16,733,237
Long-term liabilities:		
Convertible note payable, net	2,618,372	
Derivative liability	2,071,199	1,323,732
Total long-term liabilities	4,689,571	1,323,732
Total liabilities	28,828,746	18,056,969
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 August 31, 2018 and May 31, 2018, respectively	92	92
Common stock, $0.001 par value; 450,000,000 and 375,000,000 shares authorized, 233,880,390 and 216,881,790 issued and 233,721,379 and	233,880	216,881

216,722,779 outstanding at August 31, 2018 and May 31, 2018, respectively		
Additional paid-in capital	167,521,847	159,764,611
Accumulated (deficit)	(187,552,964)	(173,139,396)
Less: treasury stock, at par (159,011 shares at $0.001)	(159)	(159)
Total stockholders (deficit)	(19,797,304)	(13,157,971)
Total liabilities and stockholders (deficit) equity	$ 9,031,442	$ 4,898,998

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Operations

(Unaudited)

	Three Months Ended August 31,	
	2018	2017
Operating expenses:		
General and administrative	$ 1,996,428	$ 1,569,680
Research and development	11,403,294	8,148,175
Amortization and depreciation	88,971	89,146
Total operating expenses	13,488,693	9,807,001
Operating loss	(13,488,693)	(9,807,001)
Interest income	979	787
Change in fair value of derivative liability	(747,467)	(362,666)
Interest expense:		
Amortization of discount on convertible notes	(64,580)	(444,152)
Amortization of debt issuance costs	(9,178)	(113,700)
Inducement interest related to warrant exercise		(826,252)
Interest on convertible notes payable	(104,630)	(75,289)
Total interest expense	(178,388)	(1,459,393)
Loss before income taxes	(14,413,569)	(11,628,273)
Provision for taxes on income		
Net loss	$ (14,413,569)	$ (11,628,273)
Basic and diluted loss per share	$ (0.07)	$ (0.08)
Basic and diluted weighted average common shares outstanding	218,594,628	151,738,244

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Cash Flows

(Unaudited)

	Three Months Ended August 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (14,413,569)	$ (11,628,273)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	88,971	89,146
Amortization of debt issuance costs	9,178	113,700
Amortization of discount on convertible notes	64,580	444,152
Inducement interest related to warrant exercise		826,252
Change in fair value of derivative liability	747,467	362,666
Stock-based compensation	283,346	254,953
Changes in current assets and liabilities:		
(Increase) decrease in prepaid expenses	(701,185)	1,009,448
Increase in accounts payable and accrued expenses	4,950,552	1,527,847
Net cash used in operating activities	(8,970,660)	(7,000,109)
Cash flows from investing activities:		
Furniture and equipment purchases	(2,262)	
Net cash used in investing activities	(2,262)	
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants	8,499,300	
Proceeds from warrant exercises		1,647,500
Proceeds from convertible notes payable	5,000,000	4,888,500
Payment of offering costs	(1,008,410)	(365,227)
Net cash provided by financing activities	12,490,890	6,170,773
Net change in cash	3,517,968	(829,336)
Cash, beginning of period	1,231,445	1,775,583
Cash, end of period	$ 4,749,413	$ 946,247
Non-cash investing and financing transactions:		
Financing costs associated with placement agent warrants	$	$ 70,383
Debt discount and issuance costs associated with convertible notes payable	$ 700,000	$ 1,574,628

See accompanying notes to consolidated financial statements.

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CYTODYN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF AUGUST 31, 2018

(UNAUDITED)

Note 1 Organization

CytoDyn Inc. (the Company , we or us) 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 (GvHD). In addition, we are expanding the clinical focus of PRO 140 to include the evaluation in certain cancer and immunological indications where CCR antagonism has shown initial promise.

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, 2018 and 2017 and notes thereto in the Company s Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended May 31, 2018, filed with the Securities and Exchange Commission on July 27, 2018 and September 28, 2018, respectively. Operating results for the three months ended August 31, 2018 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 months ended August 31, 2018 and August 31, 2017, (b) the financial position at August 31, 2018 and (c) cash flows for the three months ended August 31, 2018 and August 31, 2017.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Advanced Genetic Technologies, Inc. (AGTI) and CytoDyn Veterinary Medicine LLC (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 2018 presentation. These reclassifications did not have any effect on total current assets, total assets, total current liabilities, total liabilities, total stockholders (deficit) 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 $14,413,569 for the three months ended August 31, 2018 and has an accumulated deficit of $187,552,964 as of August 31, 2018. 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 August 31, 2018 and May 31, 2018 approximated $4.7 million and $1.1 million, respectively.

Identified Intangible Assets

The Company follows the provisions of Financial Accounting Standards Board (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 months ended August 31, 2018 and 2017. 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 (BLA) that has been acknowledged by the FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely manner and management is reasonably certain that all regulatory and legal 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 August 31, 2018 and May 31, 2018, 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 August 31, 2018 and May 31, 2018, 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 August 31, 2018 and May 31, 2018 is as follows:

	Fair Value Measurement at August 31, 2018 (1)		Fair Value Measurement at May 31, 2018 (1)	
	Using Level 3	Total	Using Level 3	Total
Liability:				
Derivative liability	$ 2,071,199	$ 2,071,199	$ 1,323,732	$ 1,323,732
Total liability	$ 2,071,199	$ 2,071,199	$ 1,323,732	$ 1,323,732

(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 August 31, 2018 and May 31, 2018.

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 three months ended August 31, 2018 and the year ended May 31, 2018:

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

Placement agent warrants issued with registered direct equity offering	819,200
Fair value adjustments	(3,855,468)
Balance at May 31, 2018	1,323,732
Fair value adjustments	747,467
Balance at August 31, 2018	$ 2,071,199

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

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requisite service period or when designated milestones have been achieved. The Company estimates forfeitures at the time of grant and revised, if necessary, in subsequent periods, if actual forfeitures differ from those estimates. Based on limited historical experience of forfeitures, the Company estimated future unvested forfeitures at 0% for all periods presented.

Common Stock

On 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. On June 7, 2018, 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 375,000,000 to 450,000,000. 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.

On November 1, 2017, the Company held a special meeting of stockholders, at which the stockholders approved a proposal to effect a reverse stock split at a ratio of any whole number between one-for-two and one-for-fifteen, as determined by the board of directors, and a simultaneous reduction in the total number of authorized shares of common stock to 200,000,000 at any time before August 24, 2018, if and as determined by the board of directors. The Company did not effect a reverse stock split prior to the August 24, 2018 expiration date, therefore the board of directors no longer has the authorization or ability to effect a reverse stock split.

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 August 31, 2018, 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.

Treasury Stock

Treasury stock purchases are accounted for under the par value method, whereby the cost of the acquired stock is recorded at par value. During the year ended May 31, 2018, the Company purchased 159,011 shares of $0.001 par value treasury stock for shares tendered in satisfaction of income tax withholding, in connection with incentive compensation paid to certain officers in the form of common stock.

Debt Discount

During the three months ended August 31, 2018 and the year ended May 31, 2018, the Company incurred approximately $0.6 million and $1.5 million of debt discount related to the issuance of convertible notes, as described in Note 4. The discount is amortized over the life of the convertible promissory notes. During the three months ended August 31, 2018, and August 31, 2017 the Company recorded approximately $65,000 and $444,000, respectively, of related amortization.

Debt Issuance Cost

During the three months ended August 31, 2018 and the year ended May 31, 2018, the Company incurred direct costs associated with the issuance of a convertible notes, as described in Note 4, and recorded approximately $0.1 million and $0.4 million, respectively of debt issuance costs. In connection with the debt issuance costs, the Company

recognized approximately $9,000 and $114,000 of related amortization for the three months ended August 31, 2018 and August 31, 2017, respectively.

Offering Costs

The Company incurred direct incremental costs associated with the sale of equity securities, as described in Notes 10 and 11. The costs were approximately $3.5 million for the year ended May 31, 2018, and approximately $1.0 million and $-0- for the three months ended August 31, 2018 and August 31, 2017, respectively. The offering costs were recorded as a component of equity upon receipt of proceeds.

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 145,856,851 and 80,582,715 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 three months ended August 31, 2018 and August 31, 2017, respectively. Additionally, as of August 31, 2018, shares of Series B convertible preferred stock in the aggregate of 92,100 shares can potentially convert into 921,000 shares of common stock.

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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.

The Tax Cuts and Jobs Act (the Act) was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21% effective as of January 1, 2018. In accordance with Section 15 of the Internal Revenue Code, we utilized a blended rate of 28.62% for our fiscal 2018 tax year, by applying a prorated percentage of the number of days prior to and subsequent to the January 1, 2018 effective date. For the fiscal year ended May 31, 2018, we recorded provisional charges for the re-measurement of the deferred tax assets and reduced our deferred taxes before the valuation allowance by $17,497,051 to our income tax expense. The net tax expense for the year ended May 31, 2018, is zero, due to the reduction in the deferred tax valuation allowance. The Company has a full valuation allowance as of August 31, 2018 and May 31, 2018, as management does not consider it more than likely than not that the benefits from the deferred taxes will be realized.

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 March 2018, FASB issued Accounting Standards Update (ASU) No. 2018-05, *Income Taxes (Topic 740), Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*. The amendments in this Update add various Securities and Exchange Commission (SEC) paragraphs pursuant to the issuance of SEC Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* (Act) (SAB 118). The SEC issued SAB 118 to address concerns about reporting entities ability to timely comply with the accounting requirements to recognize all of the effects of the Act in the period of enactment. SAB 118 allows disclosure that timely determination of some or all of the income tax effects from the Act are incomplete by the due date of the financial statements and if possible to provide a reasonable estimate. The Company has provided a reasonable estimate in the notes to the consolidated financial statements.

In July 2017, 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.

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Note 4 Convertible Instruments

Series B Convertible Preferred Stock

During fiscal 2010, the Company issued 400,000 shares of Series B, $0.001 par value Convertible Preferred Stock (Series B) at $5.00 per share for cash proceeds totaling $2,009,000, of which 92,100 shares remain outstanding at August 31, 2018. Each share of the Series B is convertible into ten shares of the Company s $0.001 par value common stock, including any accrued dividends, with an effective fixed conversion price of $0.50 per share. The holders of the Series B can only convert their shares to common shares provided the Company has sufficient authorized common shares at the time of conversion. Accordingly, the conversion option was contingent upon the Company increasing its authorized common shares, which occurred in April 2010, when the Company s stockholders approved an increase in the authorized shares of common stock to 100,000,000. At the commitment date, which occurred upon such stockholder approval, the conversion option related to the Series B was beneficial. The intrinsic value of the conversion option at the commitment date resulted in a constructive dividend to the Series B holders of approximately $6,000,000. The constructive dividend increased and decreased additional paid-in capital by identical amounts. The Series B has liquidation preferences over the common shares at $5.00 per share plus any accrued dividends. Dividends are payable to the Series B holders when declared by the board of directors at the rate of $0.25 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. As of August 31, 2018 and May 31, 2018, the undeclared, accrued dividends were approximately $199,200 and $199,000, respectively, or 398,400 and 387,000 shares of common stock, respectively.

Short-term Convertible Notes

During the year ended May 31, 2018, the Company issued approximately $4.89 million in aggregate principal of short-term Convertible Notes, with a maturity date of January 31, 2018, and related warrants to investors for cash. The principal amount of the short-term Convertible Notes, including any accrued but unpaid interest thereon, was 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 short-term Convertible Notes bore 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 Company determined that the conversion feature related to these short-term Convertible 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 short-term Convertible Notes for the fair value of the related warrants.

In connection with the sale of the short-term Convertible Notes, 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 investors. The Company determined the fair value of the warrants at issuance using the Black-Scholes option pricing model utilizing certain weighted average assumptions, such as expected stock price volatility, expected term of the warrants, risk-free interest rates and expected dividend yield at the grant date.

	2018
Expected dividend yield	0%
Stock price volatility	69.80%
Expected term	5 year
Risk-free interest rate	1.77 - 1.93%

Grant-date fair value	$0.30 - $0.39

The fair value of the warrants, coupled with the beneficial conversion features, were recorded as a debt discount to the short-term Convertible Notes and a corresponding increase to additional paid-in capital was amortized over the term of the short-term Convertible Notes. The Company incurred debt discount of approximately $1.5 million related to the beneficial conversion feature and detachable warrants issued with the short-term Convertible Notes during the year ended May 31, 2018. Accordingly, the Company recognized approximately $-0- and $0.4 million of non-cash debt discount during the three months ended August 31, 2018 and August 31, 2017. In connection with the short-term Convertible Notes, the Company incurred direct issuance costs of approximately $0.4 million during the year ended May 31, 2018. The issuance costs were amortized over the term of the short-term Convertible Notes and accordingly, the Company recognized approximately $-0- and $114,000 of debt issuance costs during the three months ended August 31, 2018 and August 31, 2017, respectively.

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On January 31, 2018, in connection with a registered direct equity offering, as fully described in Note 11, the short-term Convertible Notes in an aggregate principal amount of $5,788,500, plus accrued unpaid interest of approximately $243,000 were sold for 12,062,728 shares of common stock. The short-term Convertible Note investors also received warrants to purchase 7,718,010 shares of common stock. The securities were sold at a combined purchase price of $0.50 per share of common stock and related warrants, for aggregate gross proceeds to the Company of approximately $6.0 million. The Company repaid one short-term Convertible Note, including accrued interest in the aggregate of approximately $259,000. During the three months ended August 31, 2018 and August 31, 2017, the Company recognized approximately $-0- and $75,000, of interest expense related to the short-term Convertible Notes.

Activity related to the short-term Convertible Notes was as follows:

	August 31, 2018	May 31, 2018
Face amount of short-term Convertible Notes	$	$ 6,038,500
Unamortized discount		
Registered direct equity offering		(5,788,500)
Note repayment		(250,000)
Carrying value of short-term Convertible Notes	$	$

Long-term Convertible Note

On June 26, 2018, the Company entered into a securities purchase agreement, pursuant to which the Company issued a convertible promissory note (the Note) with a two-year term to an institutional accredited investor in the initial principal amount of $5.7 million. The investor gave consideration of $5.0 million to the Company. The Note bears interest of 10% and is convertible into common stock, at $0.55 per share. The Note is convertible in total, or in part, of the outstanding balance, at any time after six months from the issue date upon five trading days notice, subject to certain adjustments and ownership limitations specified in the Note. The Investor may redeem any portion of the Note, at any time after six months from the issue date upon five trading days notice, subject to a maximum monthly redemption amount of $350,000. The securities purchase agreement requires the Company to reserve shares for future conversions or redemptions by dividing the outstanding principal balance plus accrued interest by the conversion price of $0.55 per share times 1.5.

In connection with the Note, the Company recorded debt discount of $0.6 million and debt issuance costs of $0.1 million. The discount and issuance costs will be amortized over the life of the Note, and accordingly, the Company recognized approximately $10,000 and $-0- amortization of debt issuance costs for the three months ended August 31, 2018 and August 31, 2017, respectively and approximately $65,000 and $-0- of amortization of debt discount for the three months ended August 31, 2018 and August 31, 2017, respectively. During the three months ended August 31, 2018 and August 31, 2017, the Company recognized approximately $104,000 and $-0-, of interest expense related to the Note.

Activity related to the Note was as follows:

	August 31, 2018			
	Short term	Long term	Total	May 31, 2018
Face amount of Note	$ 2,100,000	$ 3,600,000	$ 5,700,000	$
Monthly redemption	700,000	(700,000)		
Unamortized discount	(344,614)	(281,628)	(626,242)	
Carrying value of Note	$ 2,455,386	$ 2,618,372	$ 5,073,758	$

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.

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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, 2018 and August 31, 2018:

	Shares Indexed	Derivative Liability
Inception date September 15, 2016	7,733,334	$ 5,179,200
Balance May 31, 2018	7,733,334	1,323,732
Balance August 31, 2018	7,733,334	$ 2,071,199

The Company recognized approximately $747,000 and $363,000 of non-cash loss, due to the changes in the fair value of the liability associated with such classified warrants during the three months ended August 31, 2018 and August 31, 2017, 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, 2018 and August 31, 2018, using the following assumptions:

	September 15, 2016	May 31, 2018	August 31, 2018
Fair value of underlying stock	$ 0.78	$ 0.49	$ 0.69
Risk free rate	1.20%	2.63%	2.72%
Expected term (in years)	5	3.3	3.04
Stock price volatility	106%	64%	64%
Expected dividend yield			
Probability of Fundamental Transaction	50%	50%	50%
Probability of holder requesting cash payment	50%	50%	50%

Due to the fundamental transaction provision contained in the warrants, 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 provisions.

Note 6 Stock Options and Warrants

The Company has one active stock-based equity plan at August 31, 2018, the CytoDyn Inc. 2012 Equity Incentive Plan, as amended (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 August 31, 2018, the Company had 2,403,048 shares available for future stock-based grants under the 2012 Plan.

Stock Options

During the three months ended August 31, 2018, the Company granted annual stock option awards to directors to purchase a total of 680,822 shares of common stock. The exercise price of the stock option awards is $0.49 per share, except for one stock option award covering 80,822 shares of common stock, which has an exercise price of $0.47 per share. These stock option awards vest quarterly over one year and have a ten-year term. The grant date fair value related to these stock options was $0.31 per share, except the stock option award covering 80,822 shares of common stock, which was $0.30 per share. These awards reflect an increase in the annual non-employee director stock option award from 75,000 to 100,000 shares per year, effective for fiscal year 2019.

During the three months ended August 31, 2018, the Company granted a stock option award covering 950,000 shares of common stock with an exercise price of $0.49 per share, to its Executive Chairman. This stock option award vests ratably over 24 months, has a ten-year term and a grant date fair value of $0.41 per share.

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During the three months ended August 31, 2018, the Company granted stock options, covering an aggregate of 875,000 shares of common stock, to executive management and employees with exercise prices of $0.49 per share. The stock option awards vest annually over three years, with a ten-year term and grant date fair values of $0.31 per share.

Warrants

On June 15, 2018, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued warrants covering 1,970,000 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 the registered direct offering, the Company also issued warrants covering 133,600 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.

During the three months ended August 31, 2018, in connection with a private equity offering, as fully described in Note 10, the Company issued common stock warrants covering a total of 7,514,300 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 1,422,860 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of $0.50 per share.

During the year ended May 31, 2018, the Company determined to extend the expiration dates of certain warrants from May 31, 2017 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 amended 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.

Compensation expense related to stock options and compensatory warrants for the three months ended August 31, 2018 and August 31, 2017 was approximately $283,000 and $255,000, respectively. The grant date fair value of options and compensatory warrants vested during the three month periods ended August 31, 2018 and August 31, 2017 was approximately $692,000 and $447,000, respectively. As of August 31, 2018, there was approximately $1.1million of unrecognized compensation expense related to share-based payments for unvested options, which is expected to be recognized over a weighted average period of 1.6 years.

The following table represents stock option and warrant activity as of and for the three months ended August 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options and warrants outstanding May 31, 2018	132,385,269	$ 0.80	3.78	$ 3,673
Granted	13,546,582	0.67		

Exercised					
Forfeited/expired/cancelled	(75,000)		0.65		
Options and warrants outstanding August 31, 2018	145,856,851		0.79	3.74	1,710,190
Outstanding exercisable August 31, 2018	141,382,362	$	0.79	3.58	$ 1,200,567

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 August 31, 2018, the Company has recorded and is amortizing $3,500,000 of intangible assets in the form of patents. The Company estimates the acquired patents have an estimated life of ten years. Subsequent to the acquisition date, the Company has continued to expand, amend and file new patents central to its current clinical trial strategies, which, in turn, have extended the protection period for certain methods of using PRO 140 and formulations comprising PRO 140 out through at least 2031 and 2038, respectively, in various countries.

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The following presents intangible assets activity:

	August 31, 2018	May 31, 2018
Gross carrying amounts	$ 3,500,000	$ 3,500,000
Accumulated amortization	(2,056,365)	(1,968,846)
Total amortizable intangible assets, net	1,443,635	1,531,154
Patents currently not amortized	35,989	35,989
Carrying value of intangibles, net	$ 1,479,624	$ 1,567,143

Amortization expense related to acquired patents was approximately $87,500 for the three months ended August 31, 2018 and 2017, respectively. 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 approximately the next four 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. The Company accrues an 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 was 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 when it serves as the manufacturer. In addition, the Company will incur royalties of up to 0.75% to 2% of net sales, depending upon who serves as the manufacturer, when the Company commences their first commercial sale, which will continue as long as the license agreement is maintained.

Note 9 Commitments and Contingencies

Under the Progenics Purchase Agreement, the Company acquired rights to the HIV viral-entry inhibitor drug candidate 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 FDA regulatory filings. In connection with purchase, the Company has two remaining milestone payments, (i) $0.5 million upon filing a BLA with the FDA or non-U.S. equivalent regulatory body and (ii) $5.0 million, which will become due 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. In addition, the Company will incur 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 a milestone obligation of $1.5 million owed to Progenics as a result of the first dosing in a U.S. Phase 3 trial. To the extent that the remaining milestone payment and royalties are not timely made, under the terms of the Progenics 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 milestone 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 Progenics 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 the Company has paid various milestone obligations, with one remaining milestone payment of $0.5 million, which will become due upon FDA approval or approval by another non-U.S. equivalent regulatory body. In addition, the Company will incur royalties of up to 3.5% 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 or until annual royalties paid exceed that amount. To the extent the remaining milestone payment 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. 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. The Company has entered into project work orders, as amended, for each of 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 $1.4 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 $2.3 million. During the year ended May 31, 2017, the Company entered into agreements with contract

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manufacturing companies. Under the terms of the agreements, the Company incurred approximately $2.1 million of execution fees for process validation and manufacturing activities, of which the remaining $0.7 million is reflected as a current asset, as of August 31, 2018. 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 $1.7 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 three months ended August 31, 2018, the Company conducted a private equity offering, in which accredited investors purchased unregistered common stock at $0.50 per share with warrant coverage rate of 50%. Pursuant to the offering, the Company sold a total of 15,028,600 shares of common stock, $0.001 par value, for aggregate gross proceeds of approximately $7.5 million and issued to the investors five-year warrants covering 7,514,300 shares of common stock with an exercise price of $0.75 per share. The Company received net proceeds from the offering of approximately $6.6 million. In addition, the placement agent received warrants covering 1,422,860 shares of common stock (or 10% of total shares sold to investors) with a per share exercise price of $0.50, a five-year term. The placement agent warrants include a cashless exercise provision.

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 Registered 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.

A summary of the cash proceeds of the Registered 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 Registered 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 January 31, 2018, the Company entered into subscription agreements with certain investors who owned convertible promissory notes of the Company (the Notes) for the sale by the Company of 12,062,728 shares of common stock in a registered direct offering (the January 31 Offering). The investors in the January 31 Offering also received warrants to purchase 7,718,010 shares of common stock. The securities were sold at a combined purchase price of $0.50 per share of common stock and related warrants, for aggregate gross proceeds to the Company of approximately $6.0 million. The Notes matured on January 31, 2018, upon which date the Company became obligated to pay the principal amount of approximately $6.0 million on the Notes, plus accrued but unpaid interest of approximately $0.3 million, for aggregate payment obligations at maturity of approximately $6.3 million. The common stock and warrants were issued in full satisfaction of approximately $6.0 million of such payment obligations, with one holder of an aggregate principal amount and accrued unpaid interest of approximately $0.3 million electing to be repaid in cash instead of participating in the January 31, 2018 Offering. As a result, all of the proceeds from the January 31 Offering were used to satisfy the Company s payment obligations pursuant to the Notes. The warrants will be exercisable for a period of five years commencing on their issuance date, at an exercise price of $0.75 per share of common stock, subject to certain ownership limitations and adjustments as provided under the terms of the warrants. The number of shares of common stock underlying the warrant issued to each investor was calculated as the difference between (x) the number of shares of common stock issued to each investor in the January 31, 2018 Offering in respect of the payment obligations relating solely to principal amounts on the Notes and (y) the number of shares of common stock underlying certain

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warrants originally issued to such investor in the original Notes offering. The effect was to bring each investor from 50% warrant coverage in the original offering of Notes, assuming conversion of the principal amount thereof at an original conversion price of $0.75 per share, to 100% warrant coverage after the January 31 Offering, assuming reinvestment of the principal amount on the Notes at $0.50 per share. The warrants in the January 31 Offering, had an original exercise price of $1.00 per share, therefore, due to the reduction of exercise price to $0.75 per share, the Company recognized a non-cash inducement interest expense of approximately $2.4 million due to the modification. In connection with this January 31 Offering, the Company paid a commission of $164,425 to the placement agent.

On June 15, 2018, the Company entered into subscription agreements with certain investors for the sale of 1,970,000 shares of common stock at a purchase price of $0.50 per shares in a registered direct offering, pursuant to a registration statement on Form S-3. The investors in the offering also received warrants to purchase 1,970,000 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 offering of approximately $0.9 million. In addition, the placement agent received warrants covering 133,600 shares of common stock (or 8% of total shares sold to investors) with a per share exercise price of $0.55, a five-year term and include a cashless exercise provision.

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 months ended August 31, 2018 and 2017, the Company incurred an expense of approximately $15,800 and $10,800, respectively, for qualified non-elective contributions.

Note 13 Related Party Transactions

On July 26, 2017, Jordan G. Naydenov, a director with the Company, participated in the private placement of convertible promissory notes, as fully described in Note 4. Mr. Naydenov purchased a convertible 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. Carl C. Dockery, the principal of AVCP, is a director of the Company. AVCP purchased a convertible 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.

On January 31, 2018 each of Mr. Caracciolo, Mr. Naydenov and AVCP participated with other investors in the offering of common stock and warrants in satisfaction of the payment obligations relating to the convertible promissory notes, as fully described in Note 11 above.

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.

On July 12, 2018, the Company announced certain leadership changes in connection with the strategic expansion and entry into certain cancer and immunologic indications. In connection with such leadership changes and effective July 11, 2018 Denis R. Burger, Ph.D. and A. Bruce Montgomery, M.D. resigned as members of the Company s board of directors and Dr. Burger has also resigned as Chief Science Officer of the Company, which is not an executive officer position. In connection with the resignations of Dr. Burger and Dr. Montgomery, on July 10, 2018, the Company s board of directors determined to accelerate all outstanding unvested stock options held by Dr. Burger and Dr. Montgomery, to vest immediately upon the effectiveness of their resignations and to retain the stock options exercise period through their respective expiration date. Stock options covering 500,000 shares held by Dr. Burger and stock options covering 100,000 shares held by Dr. Montgomery were subject to acceleration. The terms of the stock options remained otherwise unchanged.

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Note 14 Subsequent Events

Between September 4, 2018 and October 4, 2018, the Company conducted a private equity offering, in which accredited investors purchased common stock at $0.50 per share with warrant coverage ratio of 50%. Pursuant to the offering, the Company sold a total of 22,661,570 shares of common stock, $0.001 par value, for aggregate gross proceeds of approximately $11.3 million and issued to the investors five-year warrants covering 11,330,785 shares of common stock with an exercise price of $0.75 per share. In connection with the equity offering, the Company paid an aggregate cash fee of approximately $1.3 million to the placement agent and issued warrants covering an aggregate of 2,174,157 shares of common stock to the placement agent as additional compensation. The placement agent warrants have a five-year term and an exercise price of $0.50 per share. The Company also paid a one-time non-accountable expense fee of $25,000 to the placement agent for its services in connection with the offering.

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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, intend, predict, plan, estimate, project, continue, could, may, and similar terms and expressions are intended to identify forward-looki 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

Phase 2b Extension Study for HIV, as Monotherapy

Currently, there are a total of six patients in this ongoing extension study and each has surpassed almost four years of suppressed viral load with PRO 140 as a single agent therapy. These patients are continuing in extension studies of this monotherapy trial by self-administering, subcutaneous weekly injection of PRO 140.

Phase 2b/3 Pivotal Trial for HIV, as Combination Therapy

This is a pivotal 25-week trial for PRO 140 as a combination therapy to a highly active antiretroviral therapy (HAART) drug regimens. This trial was a double blind, placebo controlled trial. In late February 2018, the Company reported that it had enrolled 52 patients and the trial s primary endpoint was achieved with a p-value of 0.0032. The primary endpoint for efficacy was defined as 0.5log reduction in viral load after one week of therapy with PRO 140 in combination with the patient s failing HAART regimen. Following the achievement of primary endpoint, the trial is continuing to enroll under an open label for safety analysis. Nearly all patients have successfully completed this trial and most of the patients have transitioned into a FDA-cleared rollover study, in order to provide continued access to PRO 140 therapy, at the request of their treating physician. Management projects that the total costs of this trial, including the open label portion, may range from $12 million to $13 million. The successful results of this trial serves as the basis for our BLA filing, which is expected to be completed in the first half of 2019.

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 in order to maintain suppressed viral load. If this study enrolls 50 patients from the Phase 2b/3 trial and all patients remain in the rollover study for one year, management estimates the cost of this study to be approximately $4 million to $5 million.

Phase 2b/3 Investigative Trial for HIV, as Long-term Monotherapy

This is a trial of over 300 patients that assesses using PRO 140 subcutaneously as a long-acting single-agent maintenance therapy for 48 weeks in patients with suppressed viral load with CCR5-tropic HIV-1 infection. The primary endpoint is the proportion of participants with a suppressed viral load to those who experienced virologic failure. The secondary endpoint is length of time to virologic failure. Enrollment of the first several patients was announced in December 2016. We are currently evaluating two higher-dose arms, one with 525 mg dose (a 50% increase from the original dosage of 350 mg), as well as a 700 mg dose. We believe that a higher dose will result in a higher response rate, which is supported by preliminary data. We expect to increase the number of sites in order to accelerate enrollment upon the availability of additional capital. The estimates for the total cost of this trial currently range

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from $22 million to $25 million, but such estimates will be updated upon the determination of the increased 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. We expect enrollment to be completed in 2018, subject to the foregoing variables. Patients who are completing this trial are transitioning to a FDA-cleared rollover study, 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 multi-center100-day study with 60 patients is designed to evaluate the feasibility of the use of PRO 140 as an add-on therapy to standard GvHD prophylaxis treatment for prevention of acute GvHD in adult patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) undergoing allogeneic hematopoietic stem cell transplantation (HST). Enrollment of the first patient was announced in May of 2017. On October 5, 2017, the Company announced that the FDA had granted orphan drug designation to PRO 140 for the prevention of GvHD. In March 2018, we announced that the Independent Data Monitoring Committee (IDMC) for PRO 140 Phase 2 trial in GvHD had completed a planned interim analysis of trial data on the first 10 patients enrolled. Following this review of data from the first 10 patients in the Phase 2 trial, the Company filed amendments to the protocol with the FDA. The amendments included switching the pre-treatment conditioning regimen from aggressive myeloablative (MA) conditioning to a reduced intensity conditioning (RIC), and switching from a blinded one-for-one randomized placebo-controlled design to an open-label design under which all enrollees receive PRO 140. The amendments also provide for a 100% increase in the dose of PRO 140 (to 700 mg) to more closely mimic preclinical dosing. The next review of data by the IDMC will occur following enrollment of 10 patients under the amended protocol after each patient has been dosed for 30 days. Management estimates the cost of this trial to be approximately $3.5 to $4 million.

Cancer and Immunological Applications for PRO 140

We are continuing to explore opportunities for clinical applications for PRO 140 involving the CCR5 receptor, other than HIV-related treatments, such as inflammatory conditions, autoimmune diseases and cancer.

The target of PRO 140 is the important immunologic receptor CCR5. The CCR5 receptor is more than the pathway to HIV replication; it is also a crucial component in inflammatory responses. This opens the potential for multiple pipeline opportunities for PRO 140.

The CCR5 receptor is a protein located on the surface of white blood cells that serves as a receptor for chemical attractants called chemokines. Chemokines are the key orchestrators of leukocyte trafficking by attracting immune cells to the sites of inflammation.

At the site of an inflammatory reaction, chemokines are released. These chemokines are specific for CCR5 and cause the migration of T-cells to these sites promoting further inflammation. The mechanism of action of PRO 140 has the potential to block the movement of T-cells to inflammatory sites, which could be instrumental in diminishing or eliminating inflammatory responses. CCR5 is also expressed on certain cancers. Some disease processes that could benefit from CCR5 blockade include many types of common cancers, graft-vs-host disease (a reaction occurring in some patients after bone marrow transplantation), autoimmunity and chronic inflammation, such as rheumatoid arthritis and psoriasis. Also recent published data by Dr. Richard Pestell, the Company s Interim Chief Medical Officer, has shown that the cancer cells within the tumor consist of two types of cells one, with CCR5 and others without them. The data published clearly indicated that the only cancer cells that can metastasize[(1)] are the cells with CCR5. Metastasis is the cause of death in the vast majority of cancer patients. Moreover, Dr. Pestell s prior publication indicates that CCR5 antagonists can turn off the calcium signal, which in turn stops the migration of CCR5 positive cancer cells[(2)]. Turning off this calcium signal appears to block the guided migration a stop the metastasis[(2)]. PRO 140

has demonstrated (in an in-vitro study) that it also turns off this calcium signal, thereby stopping metastasis of these cells. Furthermore, these published studies showed current chemotherapies induced CCR5, and CCR5 antagonists enhance the effectiveness of current chemotherapies, potentially allowing a reduction in chemotherapy, which may provide an improved quality of life for patients[(1)].

Due to its mechanism of action, we believe PRO 140 has significant advantages in terms of safety and reduced side effects over other CCR5 antagonists. Prior studies have demonstrated that PRO 140 does not cause direct activation of T-cells. We have already reported encouraging human safety data for our clinical trials with PRO 140 in HIV-infected patients.

We have initiated our first clinical trial with PRO 140 in an immunological indication a Phase 2 clinical trial with PRO 140 for GvHD in patients with AML or MDS who are undergoing bone marrow stem cell transplantation. GvHD represents an unmet medical need, with patients who contract GvHD during stem cell transplant having a significantly decreased 1-year survival rate with relapsed GvHD as the leading cause of death. Our pre-clinical study in GvHD has been published in the peer-reviewed journal *Biology of Blood and Marrow Transplantation.*

We are also expanding the clinical focus with PRO 140 to include the evaluation in certain cancer and immunological indications where CCR5 antagonism has shown initial promise. We expect to file an investigational new drug application (IND) with the FDA to begin a clinical trial with PRO 140 for metastatic triple-negative breast cancer before the end of 2018.

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.

ProstaGene Transaction

On August 27, 2018, the Company entered into a Transaction Agreement (the Acquisition Agreement) with ProstaGene, LLC, a Delaware limited liability company (ProstaGene), and Dr. Richard G. Pestell, M.D., Ph.D (Dr. Pestell), pursuant to which the Company

(1) Jiao X, Velasco-Velázquez MA, Wang M, Li Z, Rui H, Peck AR, Korkola JE, Chen X, Xu S, DuHadaway JB, Guerrero-Rodriguez S, Addya S, Sicoli D, Mu Z, Zhang G, Stucky A, Zhang X, Cristofanilli M, Fatatis A, Gray JW, Zhong JF, Prendergast GC, Pestell RG, CCR5 Governs DNA Damage Repair and Breast Cancer Stem Cell Expansion. Cancer Res. 2018 Apr 1;78(7):1657-1671. doi: 10.1158/0008-5472.CAN-17-0915. Epub 2018 Jan 22.PMID: 29358169

(2) Velasco-Velázquez M[1], Jiao X, De La Fuente M, Pestell TG, Ertel A, Lisanti MP, Pestell RG. CCR5 antagonist blocks metastasis of basal breast cancer cells. Cancer Res. 2012 Aug 1;72(15):3839-50. doi: 10.1158/0008-5472.CAN-11-3917. Epub 2012 May 25.

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agreed, on the terms and subject to the conditions stated therein, to purchase from ProstaGene substantially all of the assets and rights, and to assume certain obligations and liabilities, associated with ProstaGene s business (the ProstaGene Assets, and such transaction, the ProstaGene Transaction).

The Company, Point NewCo, Inc., a wholly owned subsidiary of the Company (NewCo), Point Merger Sub, Inc., a wholly owned subsidiary of NewCo (MergerCo), ProstaGene, and Dr. Pestell are parties to the Acquisition Agreement. Pursuant to the Acquisition Agreement, in order to achieve certain tax efficiencies relating to the ProstaGene Transaction, the Company will reorganize into a holding company by merging MergerCo into the Company (the Merger), with the Company surviving as a wholly owned subsidiary of NewCo (the Surviving Corporation). In the Merger, pursuant to Section 251(g) of the Delaware General Corporation Law, all of the outstanding capital stock of the Company (including any convertible debt, warrants, options, or other rights to acquire the same) will be converted automatically, on a share-for-share basis, into equivalent capital stock of NewCo (and rights to acquire the same). NewCo will become the successor to the Company for all purposes, including under applicable securities laws. Stockholder approval of the Merger is not required.

As consideration for the ProstaGene Assets, NewCo will issue to Sellers either (collectively, the Stock Payment Shares) (i) an aggregate of 27,000,000 shares of NewCo common stock, par value $0.001 per share (the NewCo Common Stock) or (ii) an aggregate of 270,000 shares of NewCo Series C preferred stock, par value $0.001 per share (NewCo Series C Preferred Stock), which will automatically convert into an aggregate of 27,000,000 shares of NewCo Common Stock (the Conversion Shares) upon the stockholder approval described below. Whether NewCo Common Stock or NewCo Series C Preferred Stock is issued upon closing depends on whether the stockholders of the Company have previously approved an amendment to the Company s Certificate of Incorporation to increase sufficiently the number of authorized shares of common stock, as specified in the Acquisition Agreement. If no such increase is obtained, the Company will issue to Sellers shares of NewCo Series C Preferred Stock, which will be redeemable after June 30, 2019 for cash, at a price per share equal to the closing price of the Company s common stock one trading day before the closing date of the ProstaGene Transaction.

In connection with the ProstaGene Transaction, Dr. Pestell has agreed to enter into an employment agreement upon the closing date of the ProstaGene Transaction (the Employment Agreement) appointing Dr. Pestell as Chief Medical Officer. The Employment Agreement provides for a three year term of employment, unless terminated by either party pursuant to the terms of the Employment Agreement. The Employment Agreement also provides for, among other things, (i) an annual base salary of $400,000, (ii) a target annual bonus equal to 50% of Dr. Pestell s base salary, (iii) an annual supplemental bonus in an amount to be determined at the sole discretion of the board of directors of the Company, and (iv) other customary benefits described in the form of employment agreement. The Company will also issue Dr. Pestell a stock option award under its equity incentive plan, covering 350,000 shares of Company Common Stock or NewCo Common Stock, as the case may be, vesting in three equal annual installments over a three-year period from the grant date.

The Sellers have agreed to a noncompetition covenant commencing on the closing date of the ProstaGene Transaction and ending on the later of (i) five (5) years from the closing date, and (ii) one (1) year following the termination of Dr. Pestell s employment for any reason. Further, Dr. Pestell has agreed to certain procedures providing the Company a right of first look to license or acquire any intellectual property created by Dr. Pestell as a principal investigator for certain outside academic institutions, as well as certain procedures for managing potential conflicts of interest in respect of any such outside research activities.

The Acquisition Agreement includes certain indemnification rights for NewCo and the Surviving Corporation (and certain of their related parties and affiliates) by the Sellers and for ProstaGene (and certain of its related parties and affiliates) by NewCo and the Surviving Corporation. Upon the closing date of the ProstaGene Transaction, Stock

Payment Shares equivalent to an aggregate of 5,400,000 shares of NewCo Common Stock (the Indemnification Shares) will be withheld from the Sellers and will serve as the source of recovery for the Company against any indemnification claims against the Sellers. To the extent not necessary to satisfy any indemnification claims, Indemnification Shares will be released to the Sellers in three equal six-month installments over an eighteen-month period commencing on the closing date of the ProstaGene Transaction.

Pursuant to the Acquisition Agreement, Stock Payment Shares equivalent to 8,342,000 shares of NewCo Common Stock being paid to Dr. Pestell (the Restricted Shares), will be subject to a Stock Restriction Agreement (the Stock Restriction Agreement) restricting transfer of such Restricted Shares for a three-year period from the closing date of the ProstaGene Transaction. In the event Dr. Pestell s employment with the Company is terminated other than by the Company without Cause (as defined in the Employment Agreement) or by Dr. Pestell for Good Reason (as defined in the Employment Agreement), the Company will have an option, to repurchase such Restricted Shares from Dr. Pestell at a purchase price of $0.001 per share. The Restricted Shares will vest and be released from the Stock Restriction Agreement in three equal annual installments commencing one year after the closing date of the ProstaGene Transaction.

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The Acquisition Agreement may be terminated (i) by mutual written consent of the Company and the Sellers, (ii) by either the Company or the Sellers if the other party is in breach of the Acquisition Agreement, or (iii) in any event, on December 31, 2018 if the Acquisition Agreement has not been consummated, unless such date is extended by mutual written consent of the Company and the Sellers. Pursuant to the Acquisition Agreement, Sellers are not obligated to close the ProstaGene Transaction if a material adverse change (as defined in the Acquisition Agreement) in the business of the Company has occurred prior to the closing date of the ProstaGene Transaction.

Upon the signing of the Acquisition Agreement, the board of directors of the Company appointed Dr. Pestell as Interim Chief Medical Officer, pursuant to a consulting arrangement under which Dr. Pestell will receive a prorated salary of $400,000 through his appointment as Chief Medical Officer upon the closing of the ProstaGene Transaction.

Results of Operations for the three months ended August 31, 2018 and 2017 are as follows:

For the three months ended August 31, 2018 and August 31, 2017, the Company had no activities that produced revenues from operations.

For the three months ended August 31, 2018, the Company incurred a net loss of approximately $14.4 million, as compared to a net loss of approximately $11.6 million for the similar period in 2017. The increase in net loss of approximately $2.8 million related primarily to increases in research and development expenses of approximately $3.3 million, increases in general and administrative expenses of approximately $0.4 million, and non-cash expense from change in derivative liability of approximately $0.4 million, offset by a reduction in interest expenses of approximately $1.3 million. The loss per share for the quarter ended August 31, 2018 was $(0.07) compared to $(0.08) in the same period a year ago.

For the three months ended August 31, 2018 and August 31, 2017, operating expenses totaled approximately $13.5 million and $9.8 million, respectively, consisting of research and development, general and administrative expenses, and amortization and depreciation. The increase in operating expenses of approximately $3.7 million, or 38%, was attributable to increases in research and development expenses of approximately $3.3 million and an increase in general and administrative expenses of approximately $0.4 million.

General and administrative expenses, which totaled approximately $2.0 million for the three months ended August 31, 2018, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The increase in general and administrative expenses of approximately $0.4 million, or 27%, for the three months ended August 31, 2018 over the comparable period a year ago was due to increased consulting and professional services and insurance.

Research and development (R&D) expenses, which totaled approximately $11.4 million for the three months ended August 31, 2018, increased approximately $3.3 million, or 40%, over the comparable 2017 quarter principally due to higher clinical trial and manufacturing-related expenses. For the quarter ended August 31, 2018, R&D expenditures continue to be primarily devoted to: (1) one pivotal Phase 2b/3 combination therapy trial and its roll-over trial, one investigative Phase 2b/3 monotherapy trial and its roll-over 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 expense 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 the first quarter of 2019.

For the three months ended August 31, 2018, the Company recognized a non-cash charge associated with the increase in fair value of a derivative liability of approximately $0.7 million, as compared to a non-cash charge of approximately $0.4 in the similar 2017 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 non-cash charge, as a consequence of a decrease or increase, respectively, in the calculated derivative liability.

For the three months ended August 31, 2018, the Company incurred approximately $0.2 million in interest expense, as compared to the approximate $1.5 million for the same quarter in 2017. The components of interest expense included amortization of discount on convertible notes, amortization of debt issuance costs and interest related to convertible promissory notes.

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 manufacturing of new commercial PRO 140, along with the necessary regulatory processes to confirm its qualification for future sale, if approved. The

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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, 2018.

Liquidity and Capital Resources

The Company s cash position at August 31, 2018 increased approximately $3.5 million to approximately $4.7 million, as compared to a balance of approximately $1.2 million as of May 31, 2018. The net increase in cash for the three months ended August 31, 2018 was attributable to net cash provided by financing activities of approximately $12.5 million, offset in part by cash used in operating activities of approximately $9.0 million.

As of August 31, 2018, the Company had negative working capital of approximately $16.6 million compared to negative working capital of approximately $13.4 million at May 31, 2018, an increase in negative working capital of approximately $3.2 million attributable primarily to cash used in operations.

Cash Flows

Net cash used in operating activities totaled approximately $9.0 million during the three months ended August 31, 2018, which reflects an increase of approximately $2.0 million of net cash used in operating activities over the three months ended August 31, 2017. The increase in net cash used in operating activities was due to an increase in net loss of approximately $2.8 million, which was mitigated in part by the effect of a comparative net change in working capital components totaling approximately $1.7 million, offset by a decrease in non-cash expense items of approximately $0.9 million for the three months ended August 31, 2018 as compared to the similar period in 2017.

Net cash used in investing activities was immaterial during the three months ended August 31, 2018, and there was no activity during the three months ended August 31, 2017.

Net cash provided by financing activities of approximately $12.5 million during the three months ended August 31, 2018, increased approximately $6.3 million over the $6.2 million of net cash provided by financing activities during the three months ended August 31, 2017. The increase in net cash provided from financing activities was attributable to net proceeds from the sale of common stock and warrants of approximately $7.5 million, an increase of approximately $0.5 million in net proceeds from the sale of convertible notes, offset by a reduction of approximately $1.7 million in proceeds from the exercise of warrants during the three months ended August 31, 2018.

Capital Requirements

We have not generated revenue to date, and will not generate product revenue in the foreseeable future. We expect that we will continue to incur significant operating losses as expenses continue to increase as we proceed with clinical trials with respect to PRO 140 and continues to advance PRO 140 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 PRO 140, along with the increasing activities to prepare and file a BLA for PRO 140 as a combination therapy. We will require a significant amount of additional capital in the future for our clinical trials and to advance our manufacturing activities of PRO 140 necessary for completion of our BLA filing.

In connection with this undertaking, we have 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 our 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 we terminate the agreement with our CMO, we 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 $1.7 million. These CMO undertakings are anticipated to require approximately $12 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.

We have entered into project work orders for each of our clinical trials with our CRO and related laboratory vendors. Under the terms of these agreements, we have prepaid certain execution fees for direct services costs. In connection with our clinical trials, we have entered into separate project work orders for each trial with our CRO. In the event that we terminate any trial, we 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 $1.4 million. In the remote circumstance that we terminate all clinical trials, the collective financial penalties may range from an approximate low of $0.5 million to an approximate high of $2.3 million.

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Under the Progenics Purchase Agreement, we are required to pay Progenics the following ongoing milestone payments and royalties: (i) $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 (ii) 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. In addition, under a Development and License Agreement, dated April 30, 1999 (the PDL License), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was previously assigned to us, we are required to pay AbbVie Inc. additional milestone payments and royalties as follows: (i) $0.5 million upon filing a BLA with the FDA or non-U.S. equivalent regulatory body; (ii) $0.5 million upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iii) royalties of up to 3.5% 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.

Going Concern

As reported in the accompanying financial statements, for the three months ended August 31, 2018 and August 31, 2017, we incurred net losses of approximately $14.4 million and $11.6 million, respectively. We have no activities that produced revenue in the periods presented and has sustained operating losses since inception.

We currently require and will continue to require a significant amount of additional capital to fund operations, pay our accounts payables, and our ability to continue as a going concern is dependent upon our ability to raise such additional capital, commercialize our product and achieve profitability. If we are not able to raise such additional capital on a timely basis or on favorable terms, we may need to scale back our operations or slow down or cease certain clinical trials or CMO activities, which could materially delay the timeframe to BLA submission. In extreme cases, we could be forced to file for bankruptcy protection, discontinue our operations or liquidate our assets.

Since inception, we have financed our activities principally from the sale of public and private equity securities and proceeds from convertible notes payable and related party notes payable. We intend to finance our future operating activities and our 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, we have approximately 19 million shares of common stock authorized and available for issuance under our certificate of incorporation, as amended, and approximately $166 million available for future registered offerings of securities under our universal shelf registration statement on Form S-3, which was declared effective on March 9, 2018 (assuming the full exercise of outstanding warrants, at the currently applicable exercise prices, that were previously issued in registered transactions thereunder).

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 we raise 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 our operations. Any other third-party funding arrangements could require us to relinquish valuable rights. We may require additional capital beyond currently anticipated needs. Additional capital, if available, may not be available on reasonable or non-dilutive terms. Please refer to the matters discussed under the heading Risk Factors above.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred losses for all periods presented and have a substantial accumulated deficit. As of August 31, 2018, these factors, among several others, raise substantial doubt about our ability to continue as a going concern.

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

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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

We do 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, we are 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 our 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 gain (for a decrease) of the same amount. Similarly, a 10% increase or decrease in stock price volatility would increase or decrease the value of the warrant derivative liability by approximately $0.2 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 not have a material effect on the value of the warrant derivative liability. 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 three months ended August 31, 2018, we recorded a non-cash charge, or unrealized non-cash loss, from an increase in the fair value of the derivative liability associated with certain warrants of approximately $0.7 million, due primarily to an increase in our common stock price and a decrease in the calculated stock price volatility.

Foreign Currency Exchange Risk

We may face certain exposure to fluctuation in foreign currency exchange rates, due primarily to a license agreement with a third-party licensor under which we are 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.

Interest Rate Risk

As of August 31, 2018, we have only one promissory note, which has a fixed interest rate, thus we have no exposure to interest rate risk in the event of a fluctuation in interest rates.

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 August 31, 2018. 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 August 31, 2018.

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Internal Control Over Financial Reporting

Changes in Control Over Financial Reporting

No changes occurred during the quarter ended August 31, 2018, 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.

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

Risks Related to Our Business

If the Company is unable to complete the ProstaGene Transaction and retain Dr. Pestell as Chief Medical Officer, the Company s ability to explore certain cancer indications for PRO 140 could be impaired, and the Company could find it more difficult to continue raising the capital necessary to fund its ongoing business operations.

In the event the ProstaGene Transaction is not consummated, Dr. Pestell may not be retained as the Company s Chief Medical Officer. The failure to retain Dr. Pestell could impair the Company s ability to explore certain cancer indications for PRO 140. Moreover, Dr. Pestell has been an important figure in certain recent capital raising activities. The failure to retain Dr. Pestell could make it more difficult to continue raising the capital necessary to fund the Company s ongoing business operations, including the preparation and filing of a BLA for the use of PRO 140 as a combination therapy to treat HIV. As a result of the foregoing, the failure to complete the ProstaGene Transaction could materially and adversely impact the Company and cause the market price of its common stock to decline.

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:

2.1	Acquisition Agreement by and among CytoDyn Inc., Point NewCo, Inc., Point Merger Sub, Inc., ProstaGene, LLC, and Dr. Richard Pestell, dated August 27, 2018 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K, as amended, filed August 28, 2018).
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 2018 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed September 4, 2018).
10.1	Form of Subscription Agreement (September 2018 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed September 4, 2018).
10.2	Form of Indemnification Agreement.
10.3	Consulting Agreement between CytoDyn Inc. and Richard G. Pestell, M.D., Ph.D. dated as of August 27, 2018.
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: October 9, 2018

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

Dated: October 9, 2018

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