UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended February 28, 2017

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

For the transition period from ______ to _____

Commission File Number: 000-49908

CYTODYN INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

1111 Main Street, Suite 660 Vancouver, Washington (Address of principal executive offices) 75-3056237 (I.R.S. Employer or Identification No.)

> 98660 (Zip Code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes \boxtimes No \square

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

Non-accelerated Filer \Box

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes 🗆 No 🗵

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

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PART I

Item 1. Financial Statements.

CytoDyn Inc. Consolidated Balance Sheets

Assets Current assets: 21,830 \$ 7,795,806 \$ 9,641,776 Prepaid expenses 221,830 141,714 Prepaid service fees 4,716,418 1,710,852 Total current assets 12,734,054 11,494,342 Fumiture and equipment, net 18,783 24,550 Intangibles, net 2,004,739 2,267,239 Total assets \$ 14,757,576 \$ 13,786,131 Liabilities and Stockholders' Equity Current liabilities: \$ 5,233,552 \$ 2,467,973 Accrued liabilities and staires 57,886 242,708 \$ 24,2708 Accrued liabilities and staires 57,886 242,708 \$ 2,000,739 Accrued liabilities 5,358,218 3,580,681 \$ 2,000 \$ 2,000 Total current liabilities: $3,982,400$ - - - Derivative liabilities $3,982,400$ - - - Total long-term liabilities $3,982,400$ - - - - Series B convertible preferred stock, \$0.001 par value; 400,000 shares authorized, 92,100 and 95		February 28, 2017 (unaudited)	May 31, 2016
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Accumulated (deficit) (116,160,067) (97,225,914) Total stockholders' equity 5,416,958 10,205,450	Additional paid-in capital	,	,
Total stockholders' equity 5,416,958 10,205,450			

See accompanying notes to consolidated financial statements.

CytoDyn Inc. Consolidated Statements of Operations (Unaudited)

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

See accompanying notes to consolidated financial statements.

CytoDyn Inc. Consolidated Statements of Cash Flows (Unaudited)

	Nine Months Ended		
	February 28, 2017	February 29, 2016	
Cash flows from operating activities:			
Net loss	\$ (18,934,153)	\$ (19,206,442)	
Adjustments to reconcile net loss to net cash used by operating activities:			
Amortization and depreciation	276,171	270,573	
Amortization of debt issuance costs	—	604,625	
Amortization of discount on convertible notes	_	2,121,491	
Amortization of discount on related party notes	—	94,344	
Interest expense associated with derivative liability	540,333		
Change in fair value of derivative liability	(1,196,800)	(646,505)	
Loss on extinguishment of convertible notes	—	584,177	
Interest expense associated with debt conversion and exercise inducement		757,611	
Interest expense associated with extension of warrant expirations	72,437	866,713	
Stock-based compensation	984,772	1,546,383	
Changes in current assets and liabilities:	(2.005.(02)	(1.004.0(7))	
(Increase)decrease in prepaid expenses	(3,085,682)	(1,024,967)	
(Decrease) increase in accounts payable and accrued expenses	1,777,535	(5,540,840)	
Net cash used in operating activities	(19,565,387)	(19,572,837)	
Cash flows from investing activities:			
Furniture and equipment purchases	(7,904)	<u> </u>	
Net cash used in investing activities	(7,904)		
Cash flows from financing activities:			
Proceeds from sale of common stock and warrants	19,133,755	33,268,466	
Proceeds from warrant exercises	397,880	94,283	
Payment of principal and interest on convertible notes payable	—	(789,140)	
Payment of offering costs	(1,804,314)	(3,848,664)	
Net cash provided by financing activities	17,727,321	28,724,945	
Net change in cash	(1,845,970)	9,152,108	
Cash, beginning of period	9,641,776	1,050,060	
Cash, end of period	\$ 7,795,806	\$ 10,202,168	
Supplemental disclosure of cash flow information:			
Cash paid during the period for:			
Interest	\$ —	\$ 26,890	
	φ	φ 20,070	
Non-cash investing and financing transactions:	¢	¢ 7047242	
Common stock issued upon conversion of convertible debt	\$	\$ 7,947,342	
Common stock issued or to be issued for accrued interest payable	\$	\$ 143,479	
Derivative liability associated with warrants	\$ 5,179,200	\$	

See accompanying notes to consolidated financial statements.

CYTODYN INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF FEBRUARY 28, 2017 (UNAUDITED)

Note 1 - Organization

CytoDyn Inc. (the "Company") was originally incorporated under the laws of Colorado on May 2, 2002 under the name RexRay Corporation (its previous name) and, effective August 27, 2015, reincorporated under the laws of Delaware. We are a clinical-stage biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies to treat Human Immunodeficiency Virus ("HIV") infection. Our lead product candidate, PRO 140, belongs to a class of HIV therapies known as entry inhibitors. These therapies block HIV from entering into and infecting certain cells.

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

Note 2 - Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect all adjustments, which consist solely of normal recurring adjustments, needed to fairly present the financial results for these periods. The consolidated financial statements and notes thereto are presented as prescribed by Form 10-Q. Accordingly, certain information and note disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been omitted. The accompanying consolidated financial statements should be read in conjunction with the financial statements for the fiscal years ended May 31, 2016 and 2015 and notes thereto in the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2016, filed with the Securities and Exchange Commission on July 19, 2016. Operating results for the three and nine months ended February 28, 2017 are not necessarily indicative of the results that may be expected for the entire fiscal year. In the opinion of management, all adjustments have been made, which consist only of normal recurring adjustments necessary for a fair statement of (a) the results of operations for the three and nine-month periods ended February 28, 2017 and February 29, 2016, (b) the financial position at February 28, 2017 and (c) cash flows for the nine-month periods ended February 28, 2017 and February 29, 2016.

Principles of Consolidation

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

Reclassifications

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

Going Concern

The consolidated accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company had losses for all periods presented. The Company incurred a net loss of \$18,934,153 for the nine months ended February 28, 2017 and had an accumulated deficit of \$116,160,067 as of February 28, 2017. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

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

Use of Estimates

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

Cash

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. Balances in excess of federally insured limits at February 28, 2017 and May 31, 2016 approximated \$7.5 million and \$9.4 million, respectively.

Identified Intangible Assets

The Company follows the provisions of FASB ASC Topic 350 Intangibles-Goodwill and Other, which establishes accounting standards for the impairment of long-lived assets such as intangible assets subject to amortization. The Company reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. If the sum of the undiscounted expected future cash flows over the remaining useful life of a long-lived asset group is less than its carrying value, the asset is considered impaired. Impairment losses are measured as the amount by which the carrying amount of the asset group exceeds the fair value of the asset. There were no impairment charges for the three and nine months ended February 28, 2017 and February 29, 2016. The value of the Company's patents would be significantly impaired by any adverse developments as they relate to the clinical trials pursuant to the patents acquired as discussed in Notes 7 and 9.

Research and Development

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

Pre-launch Inventory

The Company may scale-up and make commercial quantities of its product candidate prior to the date it anticipates that such product will receive final FDA approval. The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for commercial use by the FDA on a timely basis, or ever. This risk notwithstanding, the Company may scale-up and build pre-launch inventories of product that have not yet received final governmental approval when the Company believes that such action is appropriate in relation to the commercial value of the product launch opportunity. The determination to capitalize is made once the Company (or its third party development partners) has filed a Biologies License Application ("BLA"), that has been acknowledged by the FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely manner and management is reasonably certain that all regulatory and legal hurdles will be cleared. This determination is based on the particular facts and circumstances relating to the expected FDA approval of the drug product being considered. As of February 28, 2017 and May 31, 2016, the Company did not have pre-launch inventory that qualified for capitalization pursuant to U.S. GAAP ASC 330 "Inventory."

Fair Value of Financial Instruments

At February 28, 2017 and May 31, 2016, the carrying value of the Company's cash, accounts payable and accrued liabilities approximate their fair value due to the short-term maturity of the instruments. The Company carries derivative financial instruments at fair value as required by U.S. GAAP.

Derivative financial instruments consist of financial instruments that contain a notional amount and one or more underlying variables (e.g., interest rate, security price, variable conversion rate or other variables), require no initial net investment and permit net settlement. Derivative financial instruments may be free-standing or embedded in other financial instruments. The Company follows the provisions of FASB ASC 815 "Derivatives and Hedging" ("ASC 815"), as their instruments are recorded as a derivative liability, at fair value, and FASB ASC 480 "Distinguishing Liabilities from Equity" (ASC 480), as it relates to warrant liability, with changes in fair value reflected in income.

Fair Value Hierarchy

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

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

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

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

Liability measured at fair value on a recurring basis by level within the fair value hierarchy as of February 28, 2017 and May 31, 2016 is as follows:

	Fair Value M February 2	easurement at 8, 2017 (1)	Fair Value Measurement a May 31, 2016		
	Using	Using			
	Level 3	Level 3 Total		Total	
Liability:					
Derivative liability	\$3,982,400	\$3,982,400	<u>\$ </u>	<u> </u>	
Total liability	\$3,982,400	\$3,982,400	\$	\$	

(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 February 28, 2017, and May 31, 2016.

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

The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the nine months ended February 28, 2017 and the year ended May 31, 2016:

Balance at May 31, 2015	\$ 2,008,907
Note conversion June 24, 2015	(521,133)
Note conversion June 24, 2015	(841,269)
Fair value adjustments	(646,505)
Balance at May 31, 2016	<u>\$ </u>
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	(1,196,800)
Balance at February 28, 2017	\$ 3,982,400

Stock-Based Compensation

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



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

Common Stock

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

Preferred Stock

The Company's Board of Directors is authorized to issue up to 5,000,000 shares of preferred stock without stockholder approval. As of February 28, 2017, the Company has authorized the issuance of 400,000 shares of Series B convertible preferred stock, of which 92,100 shares were outstanding. The remaining preferred shares authorized have no specified rights.

Debt Issuance Costs

During the year ended May 31, 2015, the Company incurred direct costs associated with the issuance of short-term convertible notes, as described in Note 4, and recorded approximately \$708,000 of debt issuance costs and approximately \$-0- and \$605,000 of related amortization for the three and nine months ended February 29, 2016. There were no debt issuance costs during 2017.

Offering Costs

During the nine months ended February 28, 2017 and the year ended May 31, 2016, the Company incurred approximately \$1.8 and \$3.9 million in direct incremental costs associated with the sale of the equity securities, as described in Note 10 and 11. The offering costs were recorded as a component of equity when the proceeds were received.

Stock for Services

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

Loss per Common Share

Basic loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share would include the weighted average number of shares of common stock outstanding and potentially dilutive common stock equivalents. Because of the net losses for all periods presented, the basic and diluted weighted average shares outstanding are the same since including the additional shares would have an anti-dilutive effect on the loss per share. For this reason, common stock options and warrants to purchase 77,509,269 and 62,736,584 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 nine months ended February 28, 2017 and February 29, 2016, respectively. Additionally, as of February 28, 2017, shares of Series B convertible preferred stock in the aggregate of 92,100 shares can potentially convert into 921,000 shares of common stock.

Income Taxes

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

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

Note 3 – Recent Accounting Pronouncements

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

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

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

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

Note 4 – Convertible Instruments

Series B Convertible Preferred Stock

During fiscal 2010, the Company issued 400,000 shares of Series B, \$0.001 par value Convertible Preferred Stock ("Series B") at \$5.00 per share for cash proceeds totaling \$2,009,000, of which 92,100 shares remain outstanding at February 28, 2017. Each share of the Series B is convertible into ten shares of the Company's \$0.001 par common stock including any accrued dividends, with an effective fixed conversion price of \$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 per annum. Such 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 and are payable only upon conversion of the Series B in cash or shares of common stock at the Company's option. The Series B holders have no voting rights.

During the three months ended February 28, 2017, a holder of Series B elected to convert 3,000 shares into common stock. The Company issued 40,602 shares of \$0.001 par value common stock, which included accrued and unpaid dividends of approximately \$5,300.

2013 Convertible Notes

During the year ended May 31, 2013, the Company issued \$6,588,250 in aggregate original principal amount of unsecured convertible notes (the "2013 Convertible Notes") to investors for cash. Each outstanding 2013 Convertible Note was convertible at the election of the holder at any time into common shares at a fixed conversion price. At issuance, total principal of \$6,208,250 was convertible at

\$0.75 per share, and \$380,000 was convertible at \$0.65 per share. The 2013 Convertible Notes were payable in full between November 30, 2013 and March 6, 2016, and bore interest at rates ranging from 5% to 10% per year, payable in cash semi-annually in arrears beginning on April 1, 2013. At February 28, 2017 and May 31, 2016, there were no convertible notes outstanding.

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

Additionally, at the commitment date, the Company determined that the conversion feature related to the 2013 Convertible Notes was beneficial to the investors. As a result, the Company determined the intrinsic value of the conversion feature utilizing the fair value of the underlying common stock at the commitment date and the effective conversion price after discounting the 2013 Convertible Notes for the fair value of the warrants. The fair value of the warrants and the intrinsic value of the beneficial conversion feature were recorded as a debt discount to the 2013 Convertible Notes, with a corresponding increase to additional paid-in capital. The debt discount was amortized over the life of the 2013 Convertible Notes. During the nine months ended February 28, 2017 and February 29, 2016, the Company recognized approximately \$-0- and \$7,000, respectively, as interest expense related to amortization of the debt discount. The unamortized discount was fully amortized upon any conversion of the 2013 Convertible Notes for the nine months ended May 31, 2016 was as follows:

	February 28, 2017	May 31, 2016
Face amount of Notes	\$	\$ 50,000
Unamortized discount		
Conversions		(50,000)
Total carrying value of Notes	\$	\$

During the fiscal year ended May 31, 2016, the board approved a one-year extension of expiration dates on the aforementioned detachable common stock warrants which had an original term of two years, covering approximately 6.3 million shares of common stock, with an exercise price of \$1.00 per share. The then-current expiration dates ranged from October 2015 through January 2016 and were extended to October 2016 through January 2017. The extensions were effective beginning October 1, 2016 upon the receipt of certain executed documentation from the warrantholders. Pursuant to U.S. GAAP, the Company recognized non-cash interest expense of approximately \$866,700 in connection with this extension, which represented the incremental increase in the fair value of the modified warrants. As fully disclosed in Note 6 below, these warrants were granted an additional and final extension with all extended expirations dates being May 31, 2017.

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

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

AVCP Convertible Notes

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

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

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

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

The Company accounted for the AVCP Convertible Notes and related warrants, fully described below, as a financing transaction, wherein proceeds were allocated to the financial instruments issued. Prior to making the accounting allocation, the AVCP Convertible Notes and warrants were evaluated for proper classification under FASB ASC 480 "Distinguishing Liabilities from Equity" and ASC 815. The debt discounts associated with the notes were amortized over the term of the notes and the Company recognized approximately \$-0- and \$94,000 in non-cash amortization expense for the nine months ended February 28, 2017 and February 29, 2016, respectively.

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

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

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

On June 23, 2015, the Company, Alpha Venture Capital Management, LLC and AVCP entered into a Debt Conversion and Termination Agreement pursuant to which (i) AVCP agreed to convert the \$3,535,627 in aggregate indebtedness as of June 23, 2015 under the AVCP Convertible Notes in exchange for 5,237,966 shares of the Company's common stock; (ii) subject to the conversion of the two AVCP Convertible Notes, the Company agreed to issue AVCP an additional five-year warrant covering 1,000,000 shares of common stock at an exercise price of \$0.675 per share and (iii) subject to the AVCP's receipt of the common shares and warrant, the parties agreed to (a) terminate the subscription agreements; and (b) release and discharge each other party from all claims and obligations arising under the two AVCP Convertible Notes and subscription agreements. As a result of the debt conversion, during the nine months ended February 29, 2016, the Company recognized a loss on extinguishment of the AVCP Convertible Notes of

approximately \$584,000, a non-cash gain on the change in the fair value of the derivative liability of approximately \$647,000 and non-cash inducement interest expense of approximately \$758,000 arising from the aforementioned warrant.

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

Short-Term Convertible Notes

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

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

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

Additionally, at the commitment date, the Company determined that the conversion feature related to the Short-Term Convertible Notes was beneficial to the investors. As a result, the Company determined the intrinsic value of the beneficial conversion feature utilizing the fair value of the underlying common stock at the commitment date and the effective conversion price after discounting the Short-Term Convertible Notes for the fair value of the warrants. The fair value of the warrants and the intrinsic value of the conversion feature were recorded as a debt discounts to the Short-Term Convertible Notes, and a corresponding increase to additional paid-in capital. The debt discounts were amortized over the life of the Short-Term Convertible Notes. The Company recognized approximately \$-0- and \$1,784,000 as interest expense related to the amortization of the debt during the nine months ended February 28, 2017 and February 29, 2016, respectively. There were no Short-Term Convertible Notes outstanding at May 31, 2016. The unamortized discounts were fully amortized upon any conversion of the Short-Term Convertible Notes before maturity.

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

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

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

Activity related to the Short-Term Convertible Notes for the nine months ended February 28, 2017, and fiscal year ended May 31, 2016 was as follows:

	February 28, 2017		May 31, 2016
Face amount of Notes	\$		\$ 3,981,050
Unamortized discount			
Tender offer conversions		—	(2,693,800)
Conversions		—	(525,000)
Payments upon maturity			(762,250)
Total carrying value of Notes	\$		\$

Note 5 – Derivative Liability:

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

The following tables summarize the fair value of the warrant derivative liability and related common shares as of inception date (September 15, 2016), November 30, 2016 and February 28, 2017:

	September 15, 2016	November 30, 2016	February 28, 2017	
Total warrant derivative liability	\$ 5,179,200	\$ 3,955,734	\$ 3,982,400	
Shares indexed to derivative liability	7,733,334	7,733,334	7,733,334	

Changes in the fair value of the derivative liability, carried at fair value, are reported as "Change in fair value of derivative liability" in the Consolidated Statements of Operations. During the nine months ended February 28, 2017, the Company recognized a net, non-cash gain of \$1,196,800, due to changes in the fair value of the liability associated with such classified warrants and non-cash interest expense of approximately \$540,000.

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, November 30, 2016 and February 28, 2017, using the following assumptions:

	*	mber 15, 2016	ember 30, 2016	uary 28, 2017
Fair value of underlying stock	\$	0.78	\$ 0.67	\$ 0.71
Risk free rate		1.20%	1.81%	1.85%
Expected term (in years)		5	4.79	4.54
Stock price volatility		106%	103%	101%
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, which could provide for early redemption of the warrants, the model also considered subjective assumptions related to the fundamental transaction provision. The fair value of the warrants will be significantly influenced by the fair value of the Company's stock price, stock price volatility, changes in interest and management's assumptions related to the fundamental transaction provision.

AVCP Notes

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

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

Changes in the fair value of the derivative liability, carried at fair value, are reported as "Change in fair value of derivative liability" in the Consolidated Statements of Operations. During the three and nine months ended February 28, 2017 and February 29, 2016 the Company recognized a non-cash gain of approximately \$-0- and \$647,000 respectively, due to the change in derivative liability related to the embedded derivative in the AVCP Notes.

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

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

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

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

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

Note 6 - Stock Options and Warrants

The Company has one active stock-based equity plan at February 28, 2017, the CytoDyn Inc. 2012 Equity Incentive Plan (the "2012 Plan") and one stock-based equity plan that is no longer active, but under which certain prior awards remain outstanding, the CytoDyn Inc. 2004 Stock Incentive Plan (the "2004 Plan" and, together with the 2012 Plan, the "Incentive Plans"). The 2012 Plan was approved by stockholders at the Company's 2012 annual meeting to replace the 2004 Plan. The 2012 Plan was amended by stockholder approval in February 2016 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. On February 12, 2017, the board of directors approved an amendment to the 2012 Plan to increase the number of shares from 7,000,000 to 15,000,000 shares of common stock and modify certain other provisions in the 2012 Plan. The amendment is conditioned upon stockholder approval at the 2017 annual meeting of shareholders. As of February 28, 2017, the Company had 7,550,930 shares available for future stock-based grants under the 2012 Plan, subject to stockholder approval of the increase in the number of shares available for issuance under the 2012 Plan.

Stock Options

During the three months ended February 28, 2017, the Company's Compensation Committee granted a Time-Based Option covering 550,000 shares of common stock to the Executive Chairman and a Milestone-Based Option covering 450,000 shares of common stock. The Time-Based Option has an exercise price of \$0.76 and a ten-year term. The option vests in equal monthly installments over the next two years and has a grant date fair value of \$0.64 per share. The grant of the Milestone-Based Option is conditioned on stockholder approval of the increase in the number of shares authorized for issuance under the 2012 Plan, as discussed above. The Milestone-Based Option will not be exercisable unless and until approval of the share increase, for the 2012 Plan, as discussed above, is obtained from the stockholders. At that time the vesting will be contingent upon the achievement of certain strategic milestones specified by the Compensation Committee.

During the nine months ended February 28, 2017, the Company granted annual stock option awards to directors to purchase a total of 300,000 shares of common stock with an exercise price of \$1.09 per share. These option awards vest quarterly over one year and have a tenyear term. The grant date fair value related to these options was \$0.78 per share. An additional stock option covering 100,000 shares of common stock was granted to a director. The option has an exercise price of \$0.68 and vests 25% immediately with the remainder ratably over one year, has a ten-year term and grant date fair value of \$0.53 per share.

During the nine months ended February 28, 2017, the Company granted options covering an aggregate of 1,050,000 shares of common stock to executive management and certain employees with exercise prices of \$1.09 and \$1.10 per share. The options vest annually over three years, have a ten-year term and grant date fair values of \$0.75 and \$0.76 per share, respectively.

Warrants

In connection with a private equity offering completed in June 2016, as fully described in Note 10, the Company issued common stock warrants covering 182,375 shares of common stock to investors. The warrants have a five-year term and an exercise price of \$1.35 per share. During the nine months ended February 28, 2017, holders of warrants covering 774,097 shares of common stock exercised the right to purchase such shares at either \$0.50 or \$0.75 per share and the Company received proceeds of approximately \$398,000. Additionally, warrants covering 138,864 shares with an exercise price of \$0.75 per share were exercised pursuant to a cashless exercise provision.

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

On December 12, 2016, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued common stock warrants covering 2,000,000 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of \$1.00 per share.

On January 31, 2017, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued common stock warrants covering 767,498 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of \$1.00 per share. In connection with this offering, the Company also issued common stock warrants covering 122,799 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of \$0.825 per share.

On February 28, 2017, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued common stock warrants covering 2,835,323 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of \$1.00 per share. In connection with this offering, the Company also issued common stock warrants covering 453,652 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of \$0.825 per share.

In January 2017, the Company determined to extend the expiration dates of certain warrants to May 31, 2017, covering an aggregate of 6,310,667 shares of common stock. The warrants were originally issued in connection with the sale of the 2013 Convertible Notes, as identified in Note 4. The warrants currently have an exercise price of \$1.00 per share, and all but two warrants were exercisable through October 2016. One warrant, for the purchase of 186,667 shares of common stock, was exercisable through December 2016 and one warrant, for the purchase of 160,000 shares of common stock, was exercisable until January 15, 2017. The extended expiration date on all of these warrants is May 30, 2017. The extension was subject to the execution of a release of claims by each of the warrantholders. Pursuant to U.S. GAAP, the Company recognized non-cash interest expense of approximately \$72,000 in connection with this extension, which represented the incremental increase in the fair value of the modified warrants.

Compensation expense related to stock options and warrants for the three and nine months ended February 28, 2017 and February 29, 2016 was approximately \$297,000 and \$985,000 and \$955,000 and \$1,546,000, respectively. The grant date fair value of options and warrants vested during the three and nine-month periods ended February 28, 2017 and February 29, 2016 was approximately \$231,000 and \$762,000 and \$362,000 and 686,000, respectively. As of February 28, 2017, there was approximately \$1,156,000 of unrecognized compensation expense related to share-based payments for unvested options, which is expected to be recognized over a weighted average period of 1.90 years.

The following table represents stock option and warrant activity, as of and for the nine-months ended February 28, 2017:

	Number of Shares	Av	ighted erage ise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value	e
Options and warrants outstanding—May 31, 2016	63,307,150	\$	0.83	3.20	\$ 9,863,492	2
Granted	16,544,981		0.98		—	
Exercised	(912,862)		0.55		—	
Forfeited/expired/cancelled	(1,430,000)		1.57		—	
Options and warrants outstanding—February 28,						
2017	77,509,269		0.86	3.65	167,000)
Outstanding exercisable—February 28, 2017	73,831,019	\$	0.85	3.40	\$ 157,146	5

Note 7 – Acquisition of Patents

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 February 28, 2017, the Company has recorded and is amortizing \$3,500,000 of intangible assets in the form of patents. The Company estimates the acquired patents have an estimated life of ten years. Subsequent to the acquisition date, the Company has continued to expand, amend and file new patents central to its current clinical trial strategies, which, in turn, have extended the protection period for certain methods of using PRO 140 and formulations comprising PRO 140 out through at least 2026 and 2031, respectively, in various countries.

The following presents intangible assets activity:

	February 28, 2017	May 31, 2016
Gross carrying amounts	\$ 3,500,000	\$ 3,500,000
Accumulated amortization	(1,531,250)	(1,268,750)
Total amortizable intangible assets, net	1,968,750	2,231,250
Patents currently not amortized	35,989	35,989
Carrying value of intangibles, net	\$ 2,004,739	\$ 2,267,239

Amortization expense related to patents was approximately \$87,500 and \$262,500 for the three and nine months ended February 28, 2017 and February 29, 2016. The estimated aggregate future amortization expense related to the Company's intangible assets with finite lives is estimated at approximately \$350,000 per year for the next five years.

Note 8 – License Agreements

During the year ended May 31, 2016, the Company executed a license agreement with a third-party licensor covering the licensor's "system know-how" technology with respect to the Company's use of proprietary cell lines to manufacture new PRO 140 material. In connection with this license agreement, the Company became the primary obligor of an additional £600,000 (approximately US\$807,000 utilizing then-current exchange rates), which was timely paid by June 30, 2016. During the year ended May 31, 2016, the Company accrued an additional expense of £600,000 (approximately US\$870,000 utilizing then-current exchange rates) in connection with the June 30, 2016 obligation. Future annual license fees and royalty rate will vary depending on whether the Company manufactures PRO 140, utilizes the third-party licensor as a contract manufacturer, or utilizes an independent party as a contract manufacturer. The licensor does not charge an annual license fee of £300,000 (approximately US\$380,000) when it serves as the manufacturer. As of February 28, 2017 the Company has accrued approximately \$67,000 of the \$380,000 annual calendar-year license fee, which is payable December 2017.

Note 9 - Commitments and Contingencies

Under the Asset Purchase Agreement, dated July 25, 2012, between the Company and Progenics Pharmaceuticals, Inc. ("Progenics") (the "Asset Purchase Agreement"), the Company acquired from Progenics its rights to the HIV viral-entry inhibitor drug candidate PRO 140 ("PRO 140"), a humanized anti-CCR5 monoclonal antibody, as well as certain other related assets, including the existing inventory of bulk PRO 140 drug product, intellectual property, certain related licenses and sublicenses, and U.S. Food and Drug administration ("FDA") regulatory filings. On October 16, 2012, the Company paid to Progenics \$3,500,000 in cash to close the transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) \$1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-US equivalent, which was paid during the year ended May 31, 2016; (ii) \$5,000,000 at the time of the first U.S. new drug application approval by the FDA or other non-U.S. approval for the sale of PRO 140; and (iii) royalty payments of up to 5% on net sales during the period beginning on the date of the first commercial sale of PRO 140 until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years, in each case determined on a country-by country basis. During the year ended May 31, 2016, the Company paid \$1.5 million of such milestones owed to Progenics as a result of the first dosing in a U.S. Phase 3 trial. To the extent that such milestone payments and royalties are not timely made, under the terms of the Asset Purchase Agreement, Progenics has certain repurchase rights relating to the assets sold to the Company thereunder.

Payments to the third-party licenser for "system know-how" technology (see Note 8) and to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the "PDL License"), between Protein Design Labs (now AbbVie Inc.) ("PDL") and Progenics, which was assigned to the Company in the Asset Purchase Agreement, pursuant to which the Company has an exclusive worldwide license to develop, make, have made, import, use, sell, offer to sell or have sold products that incorporate the humanized form of the PRO 140 antibody developed by PDL under the agreement and must pay additional milestone payments and royalties as follows: (i) \$1,000,000 upon initiation of a Phase 3 clinical trial, which was paid during the year ended May 31, 2016; (ii) \$500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) \$500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iv) royalties of up to 7.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of \$150,000 until royalties paid exceed that amount. During the year ended May 31, 2016, the Company paid \$1 million of such milestones. To the extent that such milestone payments and royalties are not timely made, under the terms of the PDL License, AbbVie Inc. has certain termination rights relating to the Company's license of PRO 140 thereunder. Pursuant to the foregoing Asset Purchase Agreement and PDL License, the Company accrued an expense of \$2,500,000 as of May 31, 2015 in connection with the anticipated milestone payments related to the first patient dosing in a Phase 3 clinical trial, all of which was paid during the year ended May 31, 2016, as described above.

The Company has entered into project work orders, as amended, for each of its clinical trials with its clinical research organization ("CRO") and related laboratory vendors. Under the terms of these agreements, the Company incurs execution fees for direct services costs, which are recorded as a current asset. In the event the Company were to terminate any trial, it may incur certain financial penalties which would become payable to the CRO. Conditioned upon the form of termination of any one trial, the financial penalties may range from an approximate low of \$0.1 million to an approximate high of \$0.5 million. In the remote circumstance that the Company would terminate all clinical trials, the collective financial penalties may range from an approximate low of \$0.4 million to an approximate high of \$1.4 million.

During the nine months ended February 28, 2017, the Company entered into agreements with commercial manufacturing companies. Under the terms of the agreements, the Company accrued approximately \$2.1 million of execution fees for process validation and manufacturing activities, which is reflected as a current asset, as of February 28, 2017. In the event the Company were to terminate any of the agreements, it may incur certain financial penalties which would become payable to the manufacturers. Conditioned on the timing of termination, the financial penalties may range from an approximate low of \$1.0 million to an approximate high of \$3.0 million.

Note 10 - Private Securities Offerings

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

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

Note 11 - Registered Direct Equity Offerings

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

A summary of the cash proceeds of the offering is as follows:

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 connection with the Registered Offering are required to be accounted for in accordance with ASC 480 and ASC 815.

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

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

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

On December 12, 2016, the Company entered into purchase agreements with certain investors for the sale of 4,000,000 shares of common stock at a purchase price of \$0.75 per share in a registered direct offering (the "December Offering"), pursuant to a registration statement on Form S-3. The investors in this December Offering also received warrants to purchase 2,000,000 shares of common stock with an exercise price of \$1.00 per share and a five-year term. The Company received net proceeds from the December Offering of \$3.0 million.

On January 31, 2017, the Company entered into purchase agreements with certain investors for the sale of 1,534,999 shares of common stock at a purchase price of \$0.75 per share in a registered direct offering (the "January Offering"), pursuant to a registration statement on Form S-3. The investors in the January Offering also received warrants to purchase 767,498 shares of common stock with an exercise price of \$1.00 per share and a five-year term. The Company received net proceeds from the January Offering of approximately \$1.0 million after placement fees of 9% of the gross proceeds and various expenses. In addition, the placement agent received warrants covering 122,799 shares (or 8% of total shares sold to investors) with a per share exercise price of \$0.825 and a five-year term.

On February 28, 2017, the Company entered into purchase agreements with certain investors for the sale of 5,670,661 shares of common stock at a purchase price of \$0.75 per share in a registered direct offering (the "February Offering"), pursuant to a registration statement on Form S-3. The investors in the February Offering also received warrants to purchase 2,835,323 shares of common stock with an exercise price of \$1.00 per share and a five-year term. The Company received net proceeds from the February Offering of approximately \$3.8 million after placement fees of 9% of the gross proceeds and various expenses. In addition, the placement agent received warrants covering 453,652 shares (or 8% of total shares sold to investors) with a per share exercise price of \$0.825 and a five-year term.

Note 12 - Employee Benefit Plan

The Company has an employee savings plan (the "Plan") pursuant to Section 401(k) of the Internal Revenue Code (the "Code"), covering all of its employees. The Company makes a qualified non-elective contribution of 3%, which consequently vests immediately. In addition, participants in the Plan may contribute a percentage of their compensation, but not in excess of the maximum allowed under the Code. During the three and nine months ended February 28, 2017 and February 29, 2016, the Company incurred an expense of approximately \$10,800 and \$29,500 and \$6,000 and \$9,500, respectively, for qualified non-elective contributions.

Note 13 - Related Party Transactions

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

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

Effective January 26, 2017, the Company appointed Anthony D. Caracciolo, Chairman of the Board of Directors, to Executive Chairman. In connection with this appointment, the Company entered into an employee agreement with Mr. Caracciolo for an annual base salary of \$200,000 and Time-Based and Milestone-Based Stock Options, as described in Note 6 above. The terms of the employment agreement were approved in advance by the Compensation Committee.

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

Note 14 - Subsequent Event

On April 10, 2017, the Company's Board of Directors adopted a resolution to increase the number of directors by one and appointed Scott A. Kelly, M.D., to fill the resulting vacancy.

On April 10, 2017, in connection with Dr. Kelly's appointment as director, the Company granted to Dr. Kelly a non-qualified stock option to purchase up to 7,123 shares of the Company's common stock, representing a pro rata portion of the annual option grant received by each director for the fiscal year ending May 31, 2017.

The option grant was made pursuant to the 2012 Plan and is conditioned on stockholder approval of the increase in the number of shares authorized for issuance under the 2012 Plan (the "Plan Approval") at the 2017 annual meeting of stockholders. The option has a per share exercise price of \$0.61 (which was the closing sale price of the Company's common stock on the grant date) and a ten-year term and will vest on May 31, 2017, provided that the option will not be exercisable unless and until the Plan Approval is obtained.

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

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

Results of Operations

Clinical Trials Update

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

<u>Phase 2b/3 Trial for HIV, as Combination Therapy</u>. A pivotal 25-week trial for PRO 140 as a combination therapy to existing HAART drug regimens originally designed for 300 patients. Several patients have completed this trial and have transitioned to a roll-over protocol, as requested by the treating physicians to enable the patients to have continued access to PRO 140. Previously, the FDA agreed to reduce the number of patients in this study from 300 to 150 patients. In October 2016, the FDA agreed to additional protocol modifications, including a further reduction in patients for this trial from 150 down to 30 patients and lowered the primary endpoint for viral load reduction from a viral load of 0.7log to viral load of 0.5log. Based upon these new protocol modifications, management projects that the total estimated costs for this trial will range from \$8 million to \$9 million. Enrollment is expected to be completed in the second calendar quarter of 2017.

<u>Phase 2b/3 Investigative Trial for HIV, as Long-term Monotherapy</u>. A strategic trial including 300 patients to assess the treatment strategy of using PRO 140 subcutaneously as a long-acting single-agent maintenance therapy for 48 weeks in patients with suppressed viral load with CCR5-tropic HIV-1 infection. The primary endpoint is the number of patients who can maintain suppressed viral load under a PRO 140 monotherapy replacing their HAART regimen for 48 weeks. The secondary endpoint is the number of weeks a patient is off of their ART regimen. Enrollment of the first several patients was announced in December 2016 and is expected to accelerate, as experienced in the previous Phase 2b monotherapy trial. Management estimates the total cost of this trial to range from \$15 million to \$17 million. Enrollment is expected to be completed by the end of calendar 2017.

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

<u>Rollover Study</u>. This study is designed for patients who successfully complete the Phase 2b/3 Combination Therapy trial and the treating physicians request a continuation of PRO 140 therapy for their patients. If this study enrolls 30 patients from the Phase 2b/3 trial for combination therapy and all patients remain in the Rollover study for one year, management estimates the cost of this study to be approximately \$3.5 million to \$4 million.



Results of Operations for the three months ended February 28, 2017 and February 29, 2016 are as follows:

For the three months ended February 28, 2017 and February 29, 2016, the Company had no activities that produced revenues from operations.

For the three months ended February 28, 2017, the Company incurred a net loss of approximately \$8.1 million, as compared to a net loss of approximately \$5 million for the similar period in 2016. The higher net loss of approximately \$3.1 million was attributable to increases in research and development expenses of approximately \$3.8 million, non-cash expenses of approximately \$0.1 million, offset in part by a reduction in general and administrative expenses of approximately \$0.8 million.

For the three months ended February 28, 2017 and February 29, 2016, operating expenses totaled approximately \$8 million and \$5 million, respectively, consisting of research and development, general and administrative expenses, and amortization and depreciation. The increase in operating expenses of approximately \$3 million was attributable to increases in research and development expenses of approximately \$3.8 million, offset in part by a reduction in general and administrative expenses of approximately \$0.8 million.

General and administrative expenses, which totaled approximately \$1.4 million for the three months ended February 28, 2017, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The reduction in general and administrative expenses of approximately \$0.8 million for the three months ended February 28, 2017 from the comparable period a year ago was due to lower annual incentive compensation and stock-based compensation.

Research and development expenses, which totaled approximately \$6.5 million for the three months ended February 28, 2017, increased approximately \$3.8 million over the same 2016 period. This increase was attributable to higher clinical trial expenses, combined with an expansion of the Company's chemistry, manufacturing and controls (or "CMC") activities in connection with the preparation of a biologics license application ("BLA") for submission to the FDA. The Company expects research and development expenses to trend higher, as the two ongoing Phase 2b/3 trials with PRO 140 continue, along with the incurrence of increased expenses as the Company continues to expand activities related to manufacturing PRO 140 material in connection with the preparation of a BLA and for future use that conforms with current good manufacturing practices (or "cGMP") established by the FDA.

For the three months ended February 28, 2017, the Company recognized a small increase in derivative liability, thereby recognizing a non-cash expense of approximately \$27,000, which is associated with certain warrants issued in September 2016, along with non-cash interest expense of approximately \$72,000, derived from the modest extension of certain warrants.

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

Results of Operations for the nine months ended February 28, 2017 and February 29, 2016 are as follows:

For the nine months ended February 28, 2017, the Company had a net loss of approximately \$18.9 million, as compared to a net loss of approximately \$19.2 million for the similar 2016 period. The approximate reduction of \$0.3 million in net loss for 2017 from 2016 was primarily attributable to a decrease in interest expense of approximately \$4 million, an increase in the non-cash benefit of a change in derivative liability of approximately \$0.6 million, coupled with the absence of a non-cash loss on the extinguishment of convertible notes, offset in part by an increase in research and development of approximately \$4.9 million.

For the nine months ended February 28, 2017 and February 29, 2016, operating expenses totaled approximately \$19.5 million and \$14.6 million, respectively, consisting primarily of research and development, general and administrative expenses and amortization and depreciation. The increase in operating expenses of approximately \$4.9 million over the comparable 2016 period reflected higher research and development of approximately \$4.9 million, owing to increased clinical trial costs and CMC (chemistry, manufacturing and controls) activities related to BLA preparation activities.

General and administrative expenses, which totaled approximately \$4.7 million for the nine months ended February 28, 2017, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. These expenses were relatively comparable to the approximate \$4.6 million for the nine months ended February 29, 2016.

Research and development expenses, which totaled approximately \$14.6 million for the nine months ended February 28, 2017, increased approximately \$4.9 million over the same 2016 period. This increase was attributable to higher clinical trial expenses, combined with an expansion of the Company's CMC activities in connection with the preparation of a BLA. The Company expects research and development expenses to trend higher, as the two ongoing Phase 2b/3 trials with PRO 140 continue, along with the incurrence of increased expenses as the Company continues to expand activities related to manufacturing cGMP PRO 140 material in connection with the preparation of a BLA and for future commercial use, if approved.

For the nine months ended February 28, 2017, the Company did not incur a loss on extinguishment of convertible notes, as all previously outstanding debt was converted into common stock or repaid during the prior fiscal year ended May 31, 2016.

For the nine months ended February 28, 2017, the Company recognized an unrealized gain, or non-cash benefit, of approximately \$1.2 million arising from a change in derivative liability associated with the issuance of certain warrants in September 2016. As such, the gain was not comparable to the year-ago period.

For the nine months ended February 28, 2017, the Company incurred non-cash interest expense of approximately \$0.6 million in connection with certain warrants issued in September 2016 and the modest extension of the expiration dates of certain warrants. Interest expense for the current nine-month period declined approximately \$4 million from the same period a year ago owing to the non-comparable inducement interest expense incurred last year and the conversion or repayment of all previously outstanding debt, offset by interest expense in current year derived from the extension of certain warrant exercise dates.

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

Liquidity and Capital Resources

The Company's cash position at February 28, 2017 decreased approximately \$1.8 million to approximately \$7.8 million, as compared to a balance of approximately \$9.6 million, as of May 31, 2016. The net decrease in cash for the nine months ended February 28, 2017 was attributable to net cash used in operating activities of approximately \$19.6 million, offset in part by net cash provided by financing activities of approximately \$17.7 million.

As of February 28, 2017, the Company had positive working capital of approximately \$7.4 million compared to positive working capital of approximately \$7.9 million, at May 31, 2016, a decrease of approximately \$0.5 million attributable primarily to growth in accounts payable.

Net cash used in operating activities of approximately \$19.6 million during the nine months ended February 28, 2017, was comparable to the similar 2016 period. For the current nine-month period, the effect of the net loss of approximately \$18.9 million on cash used in operating activities was further increased by the net change in working capital items of approximately \$1.3 million, offset in part by a net adjustment of non-cash items of approximately \$0.7 million. As compared to the same nine-month period ended a year ago, the net change in working capital items used approximately \$6.6 million of cash, which was offset in part by a net adjustment of non-cash items of totaling approximately \$6.2 million.

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

Net cash provided by financing activities of approximately \$17.7 million during the nine months ended February 28, 2017 declined approximately \$11 million compared to \$28.7 million during the nine months ended February 29, 2016. The decline in net cash provided from financing activities was attributable to a reduction in net proceeds from the sale of common stock and warrants of approximately \$12.2 million, coupled with an increase of approximately \$0.3 million in proceeds from the exercise of warrants in the current nine-month period, offset by payments to retire debt of approximately \$0.8 million during the nine months ended February 29, 2016.

As reported in the accompanying financial statements, for the nine months ended February 28, 2017, and February 29, 2016, the Company incurred net losses of approximately \$18.9 million and \$19.2 million, respectively. The Company had no activities that produced revenue in the periods presented and has sustained operating losses since inception. The Company's ability to continue as a going concern is dependent upon its ability to raise additional capital, commence operations and achieve a level of profitability. Since inception, the Company has financed its activities principally from the public and private sale of equity securities and proceeds from convertible notes payable and related party notes payable. The Company intends to finance its future operating activities and its working capital needs largely from the sale of equity securities and perhaps debt securities, combined with additional funding from

other traditional financing sources. The sale of equity and convertible debt securities may result in dilution to stockholders and those securities may have rights senior to those of common shares. If the Company raises additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these activities or other debt could contain covenants that would restrict the Company's operations. Any other third-party funding arrangements could require the Company to relinquish valuable rights. The Company will require additional capital beyond its currently anticipated needs. On August 26, 2016, the Company filed a registration statement on Form S-3 universal shelf registration statement covering \$100 million of securities. On September 9, 2016, the registration statement was declared effective. The Company intends to utilize this shelf registration statement to raise additional capital through the sale of its securities. As of February 28, 2017, the Company had approximately \$81.6 million remaining available to be issued under this shelf registration statement. Additional capital, if available, may not be available on reasonable terms or at all. Please refer to the risk factors under Item 1A. to the Company's Annual Report on Form 10-K.

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

Under the Asset Purchase Agreement (the "Asset Purchase Agreement"), dated July 25, 2012, between the Company and Progenics Pharmaceuticals, Inc. ("Progenics"), the Company acquired from Progenics its proprietary HIV viral-entry inhibitor drug candidate PRO 140 ("PRO 140"), a humanized anti-CCR5 monoclonal antibody, as well as certain other related assets, including the existing inventory of bulk PRO 140 drug product, intellectual property, certain related licenses and sublicenses, and U.S. Food and Drug administration ("FDA") regulatory filings. On October 16, 2012, the Company paid \$3,500,000 in cash to Progenics to close the acquisition transaction. The Company is also required to pay Progenics the following milestone payments and royalties: (i) \$1,500,000 at the time of the first dosing in a U.S. Phase 3 trial or non-US equivalent, which was paid during the three months ended February 29, 2016; (ii) \$5,000,000 at the time of the first US new drug application approval by the FDA or other non-U.S. approval for the sale of PRO 140; and (iii) royalty payments of up to five percent (5%) on net sales during the period beginning on the date of the first commercial sale of PRO 140 until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years, in each case determined on a country-by country basis. Payments to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the "PDL License"), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the PRO 140 transaction, pursuant to which the Company must pay additional milestone payments and royalties as follows: (i) \$1.000,000 upon initiation of a Phase 3 clinical trial, which was paid during the three months ended February 29, 2016; (ii) \$500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (iii) \$500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iv) royalties of up to 7.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of \$150,000 until royalties paid exceed that amount.

As of the date of this filing, it is management's conclusion that the probability of achieving the subsequent future scientific research milestones is not reasonably determinable, thus the future milestone payments payable to Progenics and its sub-licensors are deemed contingent consideration and, therefore are not currently accruable.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not Applicable.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

As of February 28, 2017, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, management has evaluated the effectiveness of the design and operations of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective as of February 28, 2017, as a result of material weaknesses in internal control over financial reporting because of inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions. Management continues to implement controls and procedures, and continues to remediate the material weaknesses noted above. With the assistance of a third party consultant, management has completed a detailed best-practices risk assessment of all general ledger accounts in its financial accounting system and is concluding its documentation of all internal controls and continues to test the effectiveness of the internal control framework during the third fiscal quarter ending February 28, 2017. Despite the existence of a limited number of material weaknesses, management believes the financial information presented herein is materially correct and fairly presents the financial position and operating results of the quarter ended February 28, 2017, in accordance with U.S. GAAP.

Internal Control Over Financial Reporting

Changes in Control Over Financial Reporting

Although changes in the Company's internal control over financial reporting continued during the quarter ended February 28, 2017, management believes that such changes did not materially affect, or are not reasonably likely to materially affect, the Company's internal control over financial reporting as of February 28, 2017. Notwithstanding the foregoing, the Company continued to document its framework of internal controls and management continues to progress with an assessment of the sufficiency of the control environment and is testing the effectiveness of such controls as of February 28, 2017, with the objective to provide the audit committee of the board of directors with an interim report regarding the Company's progress to remediate material weaknesses previously identified and reported. Management believes it will meet its objective to fully remediate all material weaknesses by the end of the May 31, 2017 fiscal year.

PART II

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

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

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits:

4.1	Form of Warrant Agreement (December 2016 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed December 12, 2016).
4.2	Form of Warrant Agreement (January 2017 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 31, 2017).
4.3	Form of Warrant Agreement (February 2017 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed February 28, 2017).
10.1	Form of Securities Purchase Agreement (December 2016 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 12, 2016).
10.2	Form of Subscription Agreement (January 2017 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 31, 2017).
10.3	Form of Subscription Agreement (February 2017 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed February 28, 2017).
10.4#	Development and Manufacturing Services Agreement, dated as of November 9, 2016, by and between CytoDyn Inc. and CMC ICOS Biologics, Inc.
10.5#	Work Statement No. 01, dated as of November 9, 2016, by and between CytoDyn Inc. and CMC ICOS Biologics, Inc.
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.
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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.

Confidential treatment will be requested with respect to certain portions of this exhibit. Omitted portions will be submitted separately to the U.S. Securities and Exchange Commission.



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: April 13, 2017

/s/ Nader Z. Pourhassan

Nader Z. Pourhassan President and Chief Executive Officer

Dated: April 13, 2017

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

EXHIBIT INDEX

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- * Filed herewith.
- # Confidential treatment will be requested with respect to certain portions of this exhibit. Omitted portions will be submitted separately to the U.S. Securities and Exchange Commission.



EXECUTION COPY

DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT

This agreement is made as of November 9, 2016 ("Effective Date") between CMC ICOS BIOLOGICS, INC., a Washington corporation ("CMC"), and CYTODYN INC., a Delaware corporation ("Customer").

- · CMC provides bioprocessing services to pharmaceutical and biotechnology companies;
- Customer wishes to contract with CMC for the provision of the Services pursuant to one or more Work Statements that may be entered into from time to time during the Term; and
- CMC is willing to perform the Services on the terms in this agreement and the Quality Agreement.

Therefore, the parties agree as follows:

1. **DEFINITIONS.** Capitalized terms used in the main body of this agreement but not otherwise defined in the main body are defined in Appendix I.

2. PERFORMANCE OF THE SERVICES

- 2.1 <u>Work Statements</u>. The Services will be described in one or more Work Statements. As of the Effective Date, the parties are entering into Work Statement No. 1 attached as Appendix III. From time to time during the Term, the parties may enter into additional Work Statements for the performance of Services. Each Work Statement will be signed by each party and will be governed by this agreement.
- 2.2 <u>Standards</u>. CMC will use Commercially Reasonable Efforts to perform the Services and meet the Timeline and, where required by the Work Statement, comply with applicable cGMP standards and the Specification. The parties will evaluate CMC's efforts taking into account the experimental nature of the Services, and the Services being dependent on living systems.
- 2.3 <u>Totality of Services</u>. CMC will not perform any Services other than those described in the Work Statement. Due to the nature of the Services, however, changes to the Services may be necessary to achieve the Objective. If changes to the Services are necessary, the parties will promptly meet to negotiate and agree on those changes in writing. Changes to the Services may affect the Price and Timeline.
- 2.4 Project Team
 - 2.4.1 Each party will name and notify the other party of its representatives who will form the project team and who will be responsible for planning, executing and discussing issues regarding the Services and communicating with the other party ("**Project Team**").



- 2.4.2 The Project Team will schedule meetings at least once every two weeks or as otherwise agreed by the Project Team for the purpose of communicating updates on the performance of the Services and providing an initial forum for discussing and resolving any issues encountered with the Services. These meetings will be conducted by telephone or, if necessary, by face-to-face meetings. Each party is responsible for its own costs in attending these meetings.
- 2.4.3 Any decision by the Project Team that amends the Services will not be binding unless it is recorded in writing and agreed to and signed by authorized representatives of both parties per Section 15.4.

3. CUSTOMER MATERIALS

- 3.1 <u>Transfer</u>. Customer must deliver and transfer to the CMC Facility and CMC's personnel the Customer Materials and other information described in the Work Statement by the deadline in the Work Statement. If relevant, that information must include a full description of the Process and all Customer Know-How relevant to the Cell Line, Customer Materials, Drug Substance and Process. All information must be provided in written form and in English.
- 3.2 <u>Customer Assistance</u>. Customer must promptly and, in any event, within five Business Days after the request, make available to CMC suitably qualified and skilled employees to assist in the transfer of the Customer Know-How, Customer Materials and Process to CMC.
- 3.3 <u>MSDS</u>. At least 30 Business Days before the delivery of the Customer Materials (including, where applicable, the Cell Line) Customer must provide to CMC an accurate and complete written risk assessment (in English) for genetically modified organisms that details the hazards, storage and handling recommendations for the Customer Materials ("Materials and Safety Data Sheet").
- 3.4 <u>Return of Customer Materials</u>. Within 30 days after completion of the Services, Customer must notify CMC whether it wants CMC to return the Customer Materials to Customer or a third party storage facility or if it wants CMC to dispose of the Customer Materials, in each case, at Customer's expense. If Customer fails to give the notice required by this Section 3.4 within 30 days after the completion of the relevant Services, CMC will either dispose of Customer Materials at Customer's expense, in its sole discretion and without liability to Customer.

4. TIMELINE CHANGES, SPECIFICATION AND CGMP CHANGES

4.1 <u>Timeline Changes</u>

4.1.1. The parties may revise the Timeline by mutual agreement; provided, that the revised Timeline is in writing and agreed by the Project Team.

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4.1.2 In addition, CMC may revise the Timeline if a Non-Fault Delay occurs, keeping the revised Timeline as close as possible to the Timeline in effect immediately before the Non-Fault Delay. CMC is not liable for failure to meet the Timeline to the extent that any Non-Fault Delay contributes to the failure.

4.2 Specification and Quantities

- 4.2.1 CMC must use Commercially Reasonable Efforts to manufacture Product to meet the Specification where required by the Work Statement. However, CMC is not obligated to manufacture Product to meet the Specification if:
 - (a) the Product has not been previously manufactured to that Specification by CMC at the same scale and using the same Process and Cell Line; or
 - (b) the Batch is the first Batch at GMP scale to be manufactured to Specification or it has never been manufactured to Specification by CMC under this agreement.
- 4.2.2 The Specification may be revised by the parties if agreed by the Project Team in writing and signed by both parties. If the parties cannot agree to a revised Specification, the previous agreed on Specification applies. The parties shall engage in good faith discussions regarding any revisions to the Specification requested by a regulatory authority within the US or Europe.
- 4.2.3 All quantities of Product are estimates only. CMC is not liable for any low or unexpected yield, except to the extent caused by its gross negligence, willful misconduct or breach of this Agreement.
- 4.3 <u>Changes in cGMP</u>. If there are any material and unforeseen changes in cGMP or manufacturing regulations issued under law that impact the Services and
 - 4.3.1 are specific to the Product and not of general requirement for biologics contract manufacturing services; and
 - 4.3.2 require capital or other investment by CMC for the performance of the Services in excess of the total Price of the Services resulting in the financial returns under this agreement being substantially affected to CMC's detriment;

then CMC must notify Customer and the parties must in good faith discuss ways to continue the Services while overcoming the financial detriment by, for example, increasing the Price in an equitable and reasonable manner. If the parties do not reach agreement within 30 Business Days after CMC's notice and CMC has substantiated the financial detriment, then either party may terminate this agreement on notice.

5. MANUFACTURING CAPACITY AND CANCELLATION FEES

5.1 Reservations and Scheduling

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- 5.1.1 As of the Effective Date, and at the execution of each Work Statement, CMC will reserve Slots in its cGMP manufacturing suite sufficient for those cGMP Batches to be manufactured under the Services according to the then-current Timeline.
- 5.1.2 If the Timeline is amended and that amendment affects the scheduled Slot for any Batch, CMC will update its manufacturing schedule and reserve a new Slot for each affected Batch. CMC will reserve those Slots as near in time to the existing vacated Slots as CMC's then-current schedule will permit, taking into account reserved slots under CMC's existing manufacturing schedule for its whole facility.

5.2 <u>Cancellation of cGMP Batches</u>

- 5.2.1 Customer must pay CMC the cancellation fees stated below if any cGMP Batch or other Batch scheduled for manufacture in CMC's cGMP facility (e.g., an engineering batch) is delayed, vacated or cancelled as a result of
 - (a) Customer terminating the Batch, Slot or this agreement except for termination of this agreement under Section 12.2 ("Termination for Default") where CMC is the "Defaulting Party;"
 - (b) CMC terminating the Batch, Slot or this agreement pursuant to Section 4.3 ("Changes in cGMP"), 12.2 ("Termination for Default") where Customer is the "Defaulting Party" or 12.5 ("Termination for Certain Unresolved Indemnity Claims");
 - (c) CMC terminating the Batch, Slot or this agreement pursuant to Section 12.4 ("Termination for Scientific or Technical Delays").
 - (d) a Non-Fault Delay (each, "Cancelled Batch").
- 5.2.2 Customer must pay the following amounts to CMC for each Cancelled Batch ("Cancellation Fees"); [*]:

Timing of Notice of Cancellation	Cancellation Fees*
Notice [*] prior to the scheduled Commencement Date and notice of cancellation served on the Commencement Date or during a Batch.	[*] Price of the Cancelled Batch
Notice served [*] before the scheduled Commencement Date.	[*] Price of the Cancelled Batch
Notice served [*] before the scheduled Commencement Date.	[*] Price of the Cancelled Batch
Notice served [*] before the scheduled Commencement Date.	[*] Price of the Cancelled Batch

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For Section 5.2.2, the date of service of notice of a Cancelled Batch is the earlier of (a) the date notice to terminate a Batch, Slot or this agreement is given by the terminating party to the other party; (b) the date that the new Timeline has been agreed by the parties; or (c) CMC has given notice that the Timeline has been updated.

If CMC sells to a new third party customer ("Other Customer") capacity not previously reserved or contemplated by that Other Customer at the time of the cancellation, filling the Slot that would have been used for Customer had the Cancelled Batch not occurred, then CMC shall reduce the payment due under Section 5.2.2 by a sum equal to the fee paid by the Other Customer (after accounting for out-of-pocket costs incurred by CMC to accomplish such mitigation).

6. PACKAGING, DELIVERY, STORAGE, EXAMINATION, DEFECTS AND SAMPLES

6.1 <u>Packaging</u>. CMC will package all Cell Lines, Product and perishable Deliverables to be Delivered in accordance with the Specification, the applicable Work Statement, CMC's applicable packaging SOPs, Regulatory Obligations and industry standards applicable to the handling and packaging of biologic material.

6.2 <u>Delivery</u>

- 6.2.1 CMC will provide Customer with advance notice of the anticipated date of Delivery of Product. Notice will be provided at least five Business Days before CMC is to Deliver that Product.
- 6.2.2 Except as stated in Section 6.2.4 or in the Specifications, all Product that CMC manufactures under this agreement will be released to Customer Ex Works (Incoterms 2012) at CMC's Facilities at 9:00 am local time on the date specified in CMC's notice to Customer. Product will be considered "delivered" on the date Product is so released ("Delivery" or "Delivered"). Customer may arrange collection at any time during normal business hours on Business Days or other times as may be agreed by the parties.
- 6.2.3 CMC has no obligation to clear for export or import any Deliverables but will reasonably assist Customer, at Customer's expense, in obtaining, export or import licenses, consents or permissions.
- 6.2.4 Data, results, Batch records and Drug History Records will be delivered by mail, electronic mail or posted to a shared data room or sharepoint site.
- 6.3 <u>Release For Further Processing</u>. Subject to, and if permitted by, Regulatory Obligations, Customer may request that CMC Deliver Product to Customer before CMC issues a Certificate of Analysis ("**Release For Further Processing**"). Any Product that is the subject of Release For Further Processing must until the applicable Certificate of Analysis is issued by CMC

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- 6.3.1 not be administered to any living organism;
- 6.3.2 be handled by Customer with the utmost care as if it were an unknown substance; and
- 6.3.3 be accepted at Customer's sole risk and liability.

Unless caused by CMC's gross negligence or willful misconduct, CMC is not liable for any loss or damage caused by Product that is the subject of Release For Further Processing.

- 6.4 <u>Title and Risk</u>. Title and risk of loss in the Deliverables transfers to Customer on Delivery.
- 6.5 <u>Storage and Transport</u>. If Customer elects to have a shipping company or other agent ("Shipping Company") collect and transport the Product on Delivery, Customer must
 - 6.5.1 inform CMC of Customer's designated Shipping Company before the collection of the Product;
 - 6.5.2 coordinate with the Shipping Company for the shipment of the Product; and
 - 6.5.3 ensure that the Product is stored and transported in accordance with the Shipping Guidelines.

CMC is not responsible for any shipping costs of the Shipping Company.

- 6.6 <u>Storage</u>. If Customer or Customer's Shipping Company is unable to collect the Product at the time of Delivery, CMC will store the Product for a period of 20 Business Days after Delivery, at Customer's request. Storage of the Product at CMC's premises after Delivery is at Customer's sole risk and expense, except that CMC will be responsible for damage to the Product to the extent that damage is caused during storage by CMC solely by an act of CMC's gross negligence or misconduct. If the Product has not been collected by Customer or Customer's Shipping Company within 20 Business Days after Delivery, CMC will notify Customer. If Customer or Customer's Shipping Company fails to collect the Product within five (5) Business Days after the date of that notice, CMC may, without notifying Customer and without any liability to Customer, either, in its sole discretion, dispose of the Product or continue to store the Product at a cost to Customer in the amount stated in Appendix II. If CMC elects to continue to store the Product, then CMC may subsequently dispose of the Product if Customer or Customer's Shipping Company states of the Product if Customer or Customer's Shipping Company states of the Product if Customer or Customer's Shipping Company states are cost to Customer in the amount stated in Appendix II. If CMC elects to continue to store the Product, then CMC may subsequently dispose of the Product if Customer or Customer's Shipping Company fails to collect the Product if Customer or Customer's Shipping Company fails to collect the Product if Customer or Customer's Shipping Company states of the Product if Customer or Customer's Shipping Company fails to collect the Product within five Business Days after notice given in accordance with Section 15.9.
- 6.7 <u>Samples</u>. CMC must store regulatory reserve samples (e.g., GMP retention samples) of all cGMP Product released by CMC's quality department with a Certificate of Analysis for the period required by applicable Regulatory Obligations and industry standards applicable to the storage of reserve samples, which in the absence of a definitive time period is 15 years from the date of release or Delivery of the applicable Product. CMC is solely responsible for the maintenance and disposal of these regulatory reserve samples. After the expiration of the relevant time period, CMC may, without notifying Customer,

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destroy the samples or otherwise dispose of them in its sole discretion unless Customer contacts CMC in writing pursuant to Section 15.9 before the expiration date, and CMC and Customer then agree to an alternate plan in a written agreement signed by both parties before the expiration of that period.

- 6.8 <u>Shipping Guidelines</u>. If Customer intends to test the Product and wants to reserve its right to make a claim against CMC under this Section 6 for defective Product, Customer must ensure that the Product since collection from CMC's Facility is always stored and transported in accordance with the Shipping Guidelines. Failure to comply with the Shipping Guidelines before or after serving a Defect Notice (as defined below) will invalidate Customer's right to make any claim under this agreement for defects in those Products.
- 6.9 Examination of Products for Defects
 - 6.9.1 Customer must promptly examine and test the Products for (a) defect and non-conformity with any applicable cGMP standards that the Products are required to meet under this agreement, and (b) in the case of Product manufactured to Specification and released with a Certificate of Analysis, the failure of the Product to meet Specification (a "Defect"). Product that is not specified in the Work Statement to meet cGMP cannot be considered Defective Product.
 - 6.9.2 Where any alleged Defect is identified, Customer must notify CMC in writing (**"Defect Notice"**) within [*] after receipt of the Product. To be effective, a Defect Notice must identify
 - (a) the Product;
 - (b) the date of Delivery and collection;
 - (c) reasonable detail of the Defect, including test results;
 - (d) where applicable full disclosure of the methodology of all analytical tests performed on the Product and the results of those tests;
 - (e) confirmation that the Products have been stored and transported in accordance with the applicable Shipping Guidelines; and
 - (f) where the Customer asserts that the Defect is due to CMC, the reasons for that assertion.
 - 6.9.3 In consultation with CMC, Customer must return samples of the Products that are subject to the Defect Notice in accordance with the Shipping Guidelines to CMC within 15 Business Days after the date of the Defect Notice.
 - 6.9.4 Following receipt of the Defect Notice, CMC must promptly investigate whether the Defect is due to CMC's negligence or failure to comply with its obligations under this agreement and must report to Customer within 20 Business Days after receipt of the samples whether CMC accepts responsibility for the Defect.

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6.9.5 If a Defect in any Product is not notified to CMC in accordance with the provisions and time limits stipulated in this Section 6.9, the Product will be considered accepted and free of Defects, and Customer will have no further remedy against CMC for that Batch of Product.

6.10 Consequences of Defective Product

- 6.10.1 If Customer demonstrates that the Defect is due to CMC's fault and not as a result of any third party or Customer action or inaction and CMC accepts that finding, then CMC will use Commercially Reasonable Efforts to either replace or rework the Defective Product at CMC's election and at no additional cost to Customer. CMC will undertake those efforts as soon as reasonably practicable taking into account CMC's other obligations and commercial commitments to third parties.
- 6.10.2 If there is a dispute regarding a Defect ("**Disputed Product**"), then (a) analysts from both parties must directly communicate to determine that the parties' respective methods of analysis are the same and are being executed in the same manner and to attempt to determine whether any non-compliance may have been caused during the shipment of the sample from CMC's Facility, and (b) carefully controlled and split samples as agreed must be sent from one site to the other for testing. This process may involve Customer sending a representative and a sample of the Disputed Product to CMC, and the parties conducting jointly agreed on tests on the samples. The parties must use good faith efforts for a period of 30 days after completing those tests to resolve whether the Disputed Product is Defective due to CMC's failure to manufacture in accordance with this agreement.
- 6.10.3 If the parties cannot resolve their dispute in the manner described above as to whether a Disputed Product meets the Specification, the parties must require an independent agreed-on laboratory to test the Disputed Product. The costs of the independent laboratory will be shared by the parties equally; provided, however, that the party that is determined to be incorrect as to whether the Disputed Product meets the Specification will be responsible for those reasonable costs and must reimburse the correct party for its share of the reasonable costs incurred. The decision of the independent laboratory must be in writing. The decision will be binding on the parties as to whether the Disputed Product meets thes been a manifest error, in which case, the parties will revert to the dispute resolution procedure in Section 15.
- 6.11 <u>Rejected Product</u>. Customer must segregate and must not use any Product for any human clinical testing or trials or any other purpose (other than compliance testing pursuant to this Section 6) after it becomes aware of a basis for rejection or a Defect Notice. On a final determination that any Product is Defective, Customer must either (a) return all remaining Product to CMC, or (b) destroy all remaining Product, in either case, at CMC's election and as soon as possible after request by CMC.
- 6.12 <u>Examination and Correction of Non-Manufacturing Deliverables</u>. Customer must promptly examine and test the Deliverables (other than Products) for any non-conformity with any applicable standards that those Deliverables are required to meet under this

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agreement. Where any alleged non-conformity is identified, Customer must notify CMC in writing within 45 Business Days after delivery of the Deliverable. To be effective, that notice must identify the Deliverable and provide reasonable detail of the non-conformity. From receipt of the notice, CMC must promptly investigate whether the non-conformity is due to CMC's negligence or failure to comply with its obligations under this agreement and must report to Customer within 20 Business Days after receipt of the notice whether it accepts responsibility for the non-conformity. If Customer demonstrates that the non-conformity is due to CMC's fault and not as a result of any third party or Customer action or inaction and CMC accepts that finding, then CMC will use Commercially Reasonable Efforts to either promptly replace or correct the Deliverable at no additional cost to Customer; provided, that Customer has timely and properly notified CMC of the non-conformity per this Section 6.12.

6.13 <u>Exclusive Remedies</u>. The remedies and obligations under Sections 6.9 and 6.10 are Customer's sole remedy for Defective Products. The remedies and obligations under Sections 6.12 are Customer's sole remedy for defective or non-conforming Deliverables that are not Products.

7. PRICE AND PAYMENT TERMS

- 7.1 <u>Amounts</u>. All amounts stated in this agreement are denominated, and must be paid, in U.S. Dollars. The Price stated in the Work Statement is exclusive of (a) taxes, duties and other fees imposed by any government authority (other than taxes on CMC's income); (b) external analysis costs; (c) raw materials and (d) shipping and handling. Customer must pay these amounts in addition to the Price. Customer must also reimburse CMC for all travel costs requested by or required by Customer.
- 7.2 <u>Payment Schedule</u>. Unless a different payment schedule is provided in the Work Statement, CMC will issue invoices for the Price of Stages as follows:
 - 7.2.1 For all Stages other than those described in Section 7.2.2:
 - (a) 50% of the Price of each Stage on commencement of the Stage; and
 - (b) 50% of the Price of the Stage on completion by CMC.
 - 7.2.2 For all Stages where the Stage relates to the manufacture of cGMP Product or where the performance of the Stage takes place in CMC's GMP facility:
 - (a) 25% of the Price of the Stage as a non-refundable fee on the date of this agreement;
 - (b) 25% of the Price of the Stage 30 days before the Commencement Date of that Stage;
 - (c) 40% of the Price of the Stage once the Drug Substance has been purified and put into containers; and
 - (d) 10% of the Price of the Stage on Delivery.

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For clarity, external analysis costs, raw materials and shipping and handling for Stages will be invoiced separately.

- 7.3 Incidental Costs
 - 7.3.1 <u>Raw Materials</u>. The costs for raw materials and handling are described in the Work Statement.
 - 7.3.2 External Analysis. The costs and handling for external analysis are described in the Work Statement.
 - 7.3.3 <u>Handling Fees</u>. Customer must pay CMC a handling and processing fee for shipments as described in Appendix II, which covers packaging and other costs for preparing Deliverables for shipment.
 - 7.3.4 <u>Other Fees</u>. Customer must pay CMC the other fees as described in Appendix II if relevant.
- 7.4 <u>Payments</u>. Unless otherwise directed by CMC, all invoices must be paid by wire transfer of immediately available funds to the following account:

Unless otherwise stated on an invoice, Customer must pay all invoices in full without any deductions within 30 days after issue by CMC.

- 7.5 Late Payments. If any undisputed amount is not paid in full when due under this agreement, CMC may
 - 7.5.1 charge Customer interest at a rate of [*] on the overdue amount on a compounded basis until payment is received, and
 - 7.5.2 suspend the performance of the Services. Where performance is suspended, CMC will have no liability to Customer for the suspension or delay in the Timeline.
- 7.6 <u>Acceptance of Invoices</u>. All invoices will be considered accepted by Customer unless Customer notifies CMC to the contrary within five Business Days after delivery of the applicable invoice.

8. INTELLECTUAL PROPERTY

8.1 <u>Pre-Existing Intellectual Property</u>. Each party retains sole ownership of any Intellectual Property owned or controlled by that party as of the Effective Date or before the commencement of the Services ("**Pre-Existing IPR**"). The parties agree and acknowledge that Customer sublicenses the Lonza Technology, and that Lonza Technology shall be treated as Customer Pre-Existing IPR for purposes of this Agreement. Nothing in this agreement assigns or transfers ownership of Pre-Existing IPR.

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- 8.2 <u>CHEF1 Technology</u>. Notwithstanding anything to the contrary in this agreement, CMC retains sole ownership of all right, title and interest in (a) the CHEF1 Technology; (b) any polynucleotides or vectors comprising any CHEF1 Technology and any host cells transfected with those polynucleotides or vectors; (c) all Intellectual Property rights in any of (a) or (b); and (d) all improvements or modifications to any of (a), (b) or (c) (collectively, "**CHEF1 Property**"). Nothing in this agreement grants or obligates CMC to grant any rights in the CHEF1 Property to Customer or any third party, except to the extent that the CHEF1 Property results in an improvement to, invention relating to, or is otherwise incorporated into the Product, Drug Substance, Cell Line or Process pursuant to the Services or any Work Order, in which case all right, title and interest in such improvement, invention or Process shall be Customer IPR
- 8.3 <u>Customer's Grant of License for the Services</u>. Customer hereby grants to CMC and its Affiliates for the Term a non-exclusive, royalty-free, sublicensable, license, or sublicense, as the case may be, under the Customer Intellectual Property Rights and Customer IPR solely to the extent required for the proper performance of the Services. This license terminates automatically on the termination of this agreement.
- 8.4 <u>Intellectual Property Created in the Course of the Services</u>. Without affecting Section 8.2, all data, information and Intellectual Property first generated by or on behalf of Customer in the performance of the Services and that is solely and specifically related to the Cell Line, Drug Substance or Product and not useful for general biologics manufacturing activities unrelated to the Cell Line, Drug Substance or Product will be owned by Customer (**"Customer IPR"**). CMC hereby assigns (and shall cause all of its contractors and its and their respective personnel to assign) to Customer all right, title and interest of CMC in any Customer IPR.
- 8.5 <u>CMC IPR</u>. All Pre-Existing IPR of CMC and all Intellectual Property developed by or on behalf of CMC or any of its contractors in the performance of the Services other than Customer IPR (collectively, **"CMC IPR"**) will be owned by CMC. Customer hereby assigns to CMC all right, title and interest of Customer in any CMC IPR.
- 8.6 License to CMC IPR. Provided that Customer has satisfied its payment obligations under this agreement, CMC hereby grants to Customer a perpetual, irrevocable, non-exclusive, royalty free, sublicensable, worldwide, transferable license to use CMC Intellectual Property Rights and CMC IPR (excluding any CHEF1 Property) owned or controlled by CMC (or any of its successors or assigns to the extent necessary or desirable to make, have made, use, sell, offer to sell and import the Product and use the Cell Line or Process to manufacture Product. However, this license does not include the right to disclose any Confidential Information of CMC or CMC's Know-How to a third party, unless such third party agrees to maintain the confidential Information and CMC's Know-How and use such Confidential Information and CMC's Know-How solely in connection with the manufacture of Customer's Product. This license automatically terminates if CMC terminates the Term pursuant to Section 12.2.1 or 12.4.

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- 8.7 <u>Right to File for Protection</u>. Each party may file patent protection on any Intellectual Property it owns in accordance with Section 8.1, 8.2, 8.4 or 8.5, and the other party will promptly on request cooperate at the requesting party's reasonable expense, with any requests to assist or enable the party's protection including signing and delivering documents and other information necessary for the valid application and prosecution of any patent.
- 8.8 <u>Party's Name</u>. Except as otherwise provided in this agreement or required by any applicable law, regulation or order of an administrative agency or court of competent jurisdiction, neither party shall use the name of the other party or of the other party's Affiliates, directors, officers or employees in any advertising, news release or other publication except that CMC may identify Customer by name as a customer of CMC.
- 8.9 <u>No Implied Licenses</u>. Except for the licenses expressly granted in this agreement, no rights or licenses are granted by implication, estoppel or otherwise.
- 8.10 <u>Third Party Intellectual Property</u>. Unless specifically approved by Customer in writing, CMC will not use any Intellectual Property of any third party in connection with the Services or develop any Process, Cell Line, Drug Substance or Product in a manner such that use of any Intellectual Property of any third party would be necessary or desireable for the practice of such Process or for the production or use of such Cell Line, Drug Substance or Product.

9. CONFIDENTIAL INFORMATION

- 9.1 The Recipient Party must
 - 9.1.1 use the Confidential Information of the Disclosing Party as reasonably necessary to carry out this agreement;
 - 9.1.2 protect the Confidential Information of the Disclosing Party against unauthorized use or disclosure applying standards of care reasonably expected and no less stringent than the standards applied to protection of Recipient Party's own confidential information of a similar nature; and
 - 9.1.3 not disclose any Confidential Information of the Disclosing Party to any person or entity except to its Permitted Recipients but then only on a need-to-know basis to those Permitted Recipients who are bound by confidentiality restrictions as restrictive as this Section 9.
- 9.2 The obligations in Section 9.1 do not apply to information that:
 - 9.2.1. at the time of its disclosure by the Disclosing Party, was available to the public and could be obtained without reference to the Confidential Information by any person with no more than reasonable diligence;
 - 9.2.2 becomes generally available to the public other than by reason of a breach of this agreement or any breaches of confidence by the Recipient Party or its Permitted Recipients;

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- 9.2.3 at the time of disclosure and as evidenced by the Recipient Party's written records, was lawfully already within its possession; or
- 9.2.4 is independently developed by the Recipient Party without reference to the Confidential Information of the Disclosing Party.
- 9.3 The Recipient Party may disclose certain Confidential Information of the Disclosing Party, without violating the obligations of this agreement, to the extent that disclosure is required by and in compliance with a valid order of a court or other governmental body having jurisdiction, provided that the Recipient Party provides the Disclosing Party with reasonable prior written notice of the disclosure and makes a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order preventing or limiting the disclosure.
- 9.4 If the Recipient Party or any of its Permitted Recipients becomes aware of any actual or potential unauthorized use or disclosure of the Confidential Information of the Disclosing Party, the Recipient Party must inform the Disclosing Party as soon as reasonably possible after it becomes aware of that actual or potential unauthorized use or disclosure. The Recipient Party must cooperate in any action that the Disclosing Party may decide to take.
- 9.5 Except as otherwise provided in this agreement or otherwise required by law, neither Customer nor CMC will disclose any terms of this agreement to any third party without the prior written consent of the other party except to its Permitted Recipients but then only on a need-to-know basis to those Permitted Recipients who are bound by confidentiality restrictions as restrictive as this Section 9.
- 9.6 Except as provided in Section 9.7, on the termination of this agreement or at the request of the Disclosing Party, the Recipient Party must promptly return to the Disclosing Party any Confidential Information of the Disclosing Party then in its possession or control except where that Confidential Information is covered under surviving license rights between the parties. However, each party may retain in its legal files a single copy of any document that contains the Disclosing Party's Confidential Information solely for the purpose of determining the scope of the obligations under this agreement. Neither party is obligated to destroy electronic files securely archived in accordance with its customary data retention policies.
- 9.7 Notwithstanding anything to the contrary, both during and at all times after the Term, Customer and its successors, assigns and licensees may use and disclose any Confidential Information of CMC that is included in the CMC Intellectual Property Rights or CMC IPR (excluding any CHEF1 Property) in accordance with the license granted to Customer in Section 8.6.
- 9.8 Notwithstanding anything to the contrary, all information included in the Customer IPR that solely and specifically relates to the Process, the Cell Line, the Drug Substance or the Product and not useful for general biologics manufacturing activity unrelated to the Cell Line, Drug Substance or Product shall be deemed to be Customer's Confidential Information and not CMC's Confidential Information, and the exceptions in Section 9.2 shall not apply to such Confidential Information.

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10. LIMITED WARRANTIES

- 10.1 Customer Warranties. Customer warrants and represents to CMC that:
 - 10.1.1 Customer has all necessary rights to supply to CMC the Customer Materials (including the Cell Line if provided by Customer) and the Customer Intellectual Property Rights, and CMC has and will have the right to use those items for the performance of the Services and manufacture of the Product;
 - 10.1.2 the Materials and Safety Data Sheet is accurate and complete in all material respects and the Customer Materials (including the Cell Line if provided by Customer) are free from all contaminants, including virus, bacteria (other than the Cell Line itself) and other vectors, and if handled and used in accordance with the Materials and Safety Data Sheet supplied by Customer will not, to Customer's knowledge, cause a health hazard or biohazard;
 - 10.1.3 to its knowledge, the use of the Cell Line and Process, the Customer Materials, the Customer Intellectual Property Rights and the manufacture of the Product does not and will not infringe any Intellectual Property rights of any third parties; and
 - 10.1.4 (a) to its knowledge, the Cell Line and Process if provided by Customer and Customer Materials are viable, adequate and suitable for the effective performance of the Services and manufacture of the Product according to the Specification, (b) it knows of no reason (suspected or otherwise) why the Objective cannot be achieved or the Services successfully performed and (c) the information supplied to CMC regarding the Cell Line provided by Customer and Process is accurate and complete in all material respects.
- 10.2. CMC Warranties. CMC warrants and represents to Customer that:
 - 10.2.1 it has the necessary permits, facilities, third party contractors and skilled personnel that may be reasonably anticipated to be necessary of a biologics contract manufacturer for the regular provision of manufacturing and development services of biologic material;
 - 10.2.2 all Deliverables will be Delivered free of financial encumbrances or liens created by CMC but no warranty is given in this Section 10.2.2 as to (a) noninfringement of third party Intellectual Property rights, or (b) freedom to use;
 - 10.2.3. to its knowledge, the CMC Intellectual Property Rights used in the Services do not infringe third party Intellectual Property rights except that no warranty is given to the extent that infringement arises from the combination of CMC Intellectual Property Rights with the Cell Line, Process, Customer Materials or Customer Intellectual Property Rights;
 - 10.2.4 where Stages are to be performed according to cGMP, CMC will apply the appropriate cGMP standards to the performance of those Stages;

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- 10.2.5 the Services will performed in accordance with the Regulatory Obligations and all applicable industry standards;
- 10.2.6 where Product is released with a Certificate of Analysis by CMC, the Product at the time of release will comply with the criteria specified in that Certificate of Analysis;
- 10.2.7 neither it nor any of its officers, employees or other persons associated with it has been or is listed by any government agency as being debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for participation in government procurement programs or other government contracts.
- 10.3 <u>Disclaimer of All Other Warranties</u>. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT FOR THOSE EXPRESS WARRANTIES IN THIS SECTION 10, NEITHER PARTY MAKES OR GIVES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED (WHETHER BY STATUTE, CUSTOM, COURSE OF DEALING OR OTHERWISE) AND EACH PARTY HEREBY DISCLAIMS ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT AND TITLE.

11. INDEMNIFICATION

- 11.1 <u>CMC's Indemnity</u>. Customer must indemnify and defend CMC and its Affiliates and each of their respective directors and officers and Testing Laboratories (**"CMC Parties"**) against any and all losses, demands, claims, liabilities, damages, costs and expenses (including court costs and reasonable attorneys' fees and expenses) (**"Claims"**) that the CMC Parties incur as a result of any of the following, except to the extent caused by a CMC Party's negligence or misconduct:
 - 11.1.1 alleged or actual infringement or misappropriation of any Intellectual Property rights of any third party arising from CMC's use of the Cell Line, Process, Customer Intellectual Property Rights or Customer Materials (in each case, except to the extent covered by CMC's obligations under Section 11.2);
 - 11.1.2 Claims resulting from the administration, use, handling, storage or other disposition of the Product or Drug Substance in any form;
 - 11.1.3 contamination or damage to CMC's operations or any facility caused by the Cell Line or Customer Materials except to the extent the Cell Line and Customer Materials were not handled in accordance with the Materials and Safety Data Sheet or the Specification;
 - 11.1.4 use of any Product that was the subject of a Release for Further Processing in accordance with Section 6.3; and
 - 11.1.5 any acts or omissions of any third party auditor of Customer.
- 11.2 <u>Customer's Indemnity</u>. CMC must indemnify and defend Customer and its Affiliates and each of their respective directors and officers (**"Customer Parties"**) against any and all Claims that the Customer Parties incur as a result of any of the following, except to the extent caused by a Customer Party's negligence or misconduct:

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- 11.2.1 inaccuracy in a Certificate of Analysis such that the certified Product at the time of Delivery does not meet the Specification when certified to meet it;
- 11.2.2 failure of CMC to manufacture the Product according to cGMP when the Product is released by CMC at the time of Delivery as a cGMP Product;
- 11.2.3 actual or alleged infringement or misappropriation of any Intellectual Property rights of any third party to the extent that infringement or misappropriation is due to CMC's use of the CMC Intellectual Property Rights in the performance of the Services or any Process, Cell Line or other item developed by CMC (but excluding claims where the use is in combination with the Cell Line, Customer Materials, Process or Customer Intellectual Property Rights and there would not be any infringement absent such combined use); and
- 11.2.4 CMC's breach of any of its warranties or obligations under Sections 2.2, 4.2, 4.3, 5.1, 6.1, 6.2, 6.6, 6.7, 9, 10.2 of this Agreement.
- 11.3 Indemnification Procedure. The party ("Indemnitee") that claims indemnification under this Section 11 must:
 - 11.3.1 promptly, and in any event within 15 Business Days of it receiving notice of the Claim, notify the other party (**"Indemnitor"**) in writing of the Claim; provided, that failure to give that notice will not relieve the Indemnitor of its indemnification and defense obligations except to the extent the failure materially prejudices the ability of the Indemnitor to defend against the Claim;
 - 11.3.2 permit the Indemnitor to control the defense of the Claim; and
 - 11.3.3 have the right (at the Indemnitee's expense) to participate in the defense of the Claim.
- 11.4 <u>Settlement</u>. The Indemnitor must not settle or consent to an adverse judgment in any Claim indemnified by the Indemnitor that adversely affects the interests of the Indemnitee or imposes additional obligations on the Indemnitee, without the prior written consent of the Indemnitee.
- 11.5 <u>IP Claims</u>. Each party must promptly (and within five Business Days if permissible under applicable law or stock exchange rules) notify the other party of any third party allegation of infringement or misappropriation of any third party Intellectual Property rights due to the handling, storage or use of the Cell Line, Customer Materials, Customer Intellectual Property Rights or CMC Intellectual Property Rights or the manufacture of the Product.

12. TERM AND TERMINATION

12.1 <u>Term</u>. The term of this agreement commences on the Effective Date and terminates on the later of (a) the date that all Stages under all Work Statements have been completed and (b) ten years from the Effective Date, unless sooner terminated in accordance with Section 4.3, 12.2, 12.3, 12.4, 12.5 or 15.1 or extended by mutual written agreement of the parties (**"Term"**).

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- 12.2 <u>Termination for Default.</u> Either party (**"Non-Defaulting Party"**) may terminate this agreement on notice to the other party (**"Defaulting Party"**) if
 - 12.2.1 the Defaulting Party fails to pay any amount payable under this agreement within 20 Business Days after the due date;
 - 12.2.2 the Defaulting Party commits a material breach of its obligations under this agreement and fails to remedy it during a period of 20 Business Days starting on the date of receipt of notice from the Non-Defaulting Party identifying the breach and requiring it to be remedied;
 - 12.2.3 a petition is filed against the Defaulting Party for an involuntary proceeding under any applicable bankruptcy or other similar law and that petition has not been dismissed within 60 days after filing or a court having jurisdiction has appointed a receiver, liquidator, trustee or similar official of the Defaulting Party for any substantial portion of its property, or ordered the winding up or liquidation of its affairs; or
 - 12.2.4 the Defaulting Party commences a voluntary proceeding under applicable bankruptcy or other similar law, has made any general assignment for the benefit of creditors, or has failed generally to pay its debts as they become due.
- 12.3 <u>Termination for Convenience</u>
 - 12.3.1 Customer may terminate this agreement or any Stage of the Services at any time before completion of the Services or Stage by giving no less than 60 Business Days' notice in writing to CMC detailing the Stages of the Services that are to be terminated.
 - 12.3.2 CMC may terminate this agreement at any time after the completion of all Stages under all Work Statements and there are no Services contemplated under this agreement by giving 30 days' written notice to Customer; provided that the parties shall negotiate in good faith for additional Services or a commercial supply agreement prior to any such termination by CMC.
- 12.4 <u>Termination for Scientific or Technical Difficulties</u>. CMC may terminate this agreement or any Stage on 60 Business Days' notice if CMC reasonably concludes that it cannot technically or scientifically deliver the Services contemplated by this agreement or any Stage despite applying its Commercially Reasonable Efforts. During the 60-Business Days' notice period or when CMC notifies Customer that it has become aware that a technical or scientific problem has or may arise, the parties must in good faith discuss the difficulties and scientific and technical hurdles in an attempt to resolve those problems. If the parties agree during those discussions that the Services can be delivered then the notice to terminate will expire and this agreement (or the Stage as the case may be) will continue in effect. If agreement cannot be reached this agreement or Stage, at CMC's election, will terminate on expiration of the 60-Business Days' notice period.

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12.5 <u>Termination for Certain Unresolved Indemnity Claims</u>. If a Claim for indemnification is made under Section 11.1.1 or 11.2.3 and the parties do not reach an agreement to settle or overcome the Claim within 90 Business Days after notification under Section 11.3.1, the party to whom the indemnity Claim has been made, may, on 20 Business Days' notice in writing terminate this agreement.

12.6 Effect of Termination

- 12.6.1 Upon termination of this agreement for any reason, Customer shall pay to CMC:
 - (a) undisputed payments due by Customer to CMC for Services performed up to and including the day of termination for all completed Stages and for partially completed Stages an amount calculated on a pro-rata basis taking into account the Price for the cancelled Stages (fairly determined by the Project Team taking into account FTE hours, materials, profit element and irreversible commitments incurred by CMC);
 - (b) undisputed payments due pursuant to Section 5.2; and
 - (c) undisputed payments due at the time of termination pursuant to Section 7 and also in accordance with the payment terms in the Work Statement.
- 12.6.2 Upon termination of this agreement for any reason, provided that Customer has paid all undisputed amounts outstanding, CMC will, within 30 days of (a) those payments having been made or (b) the date of termination of this agreement, (whichever is the later) provide the Customer with all Deliverables then manufactured or generated and all transferable work in progress and all Product then manufactured and released, subject to Regulatory Obligations at Customer's sole risk.
- 12.7 <u>Survival</u>. Termination will not affect the accrued rights of CMC or Customer arising under this agreement before the effective date of termination. The provisions of this agreement which by their terms would continue beyond any termination or expiration of this agreement, including Sections 1, 3.4, 6.7, 7, 8, 9, 11, 12.6, 13, 14 and 15 will survive termination or expiration of this agreement to the degree necessary to permit their complete fulfillment or discharge.

13. TECHNOLOGY TRANSFER

13.1 <u>Scope</u>. Upon termination or during the notice period for termination of this agreement, other than where Customer is the "Defaulting Party," Customer may seek assistance from CMC for the transfer to a single skilled and qualified manufacturer of the then-current Process solely for the purpose of manufacturing Product for Customer ("Technology Transfer"); provided, that CMC is not obligated to transfer any CHEF1 Property. Following CMC's receipt of that request, the parties will establish a schedule and plan for effecting the transfer and CMC will cooperate with Customer in implementing that plan. As part of the Technology Transfer CMC will make available for collection, subject to any Regulatory Obligations and rights of third parties and Section 12.6.2, all Customer Materials, Cell Line and one copy of all documentation (to the extent not previously delivered to Customer) generated pursuant to the Services (exclusive of CMC's SOPs) up to the date of termination.

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13.2 Limits. The obligations of CMC under Section 13.1 will only be exercisable by Customer within a period of 180 days after the date of termination and CMC is not obliged to commit any human resources greater than 60 FTE days. Customer must pay CMC's costs of cooperating with and providing the Technology Transfer at a daily FTE rate of \$2,000 or as agreed upon in a Work Statement and all other costs will be charged at cost plus 10%. Customer will not, and CMC will not be obliged to, transfer any CMC Intellectual Property Rights or CMC IPR pursuant to this Technology Transfer until the contract manufacturer to whom the Process is transferred enters into a confidentiality agreement and limited royalty free license to use CMC's Confidential Information, CMC Intellectual Property Rights and CMC IPR solely in connection with the manufacture of Customer's Product with Customer in order to protect CMC's Confidential Information, CMC Intellectual Property Rights and CMC IPR.

14. LIMITATIONS OF LIABILITY

- 14.1 <u>Limitation of Liability</u>. CMC's aggregate liability to Customer for any loss or damage suffered by Customer as a result of breach of this agreement or any other liability (except for gross negligence, willful misconduct or misrepresentation or claims under the indemnities) under this agreement or in connection with the Services is limited, in the aggregate, to [*].
- 14.2 <u>Disclaimer of Certain Damages</u>. EXCEPT AS PROVIDED IN SECTION 14.3, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL (INCLUDING LOST PROFITS) OR SPECIAL DAMAGES ARISING OUT OF ITS BREACH OF THIS AGREEMENT OR ANY OTHER LIABILITY (INCLUDING NEGLIGENCE, MISREPRESENTATION OR CLAIMS UNDER THE INDEMNITIES) ARISING IN CONNECTION WITH THIS AGREEMENT, EVEN IF THOSE DAMAGES WERE FORESEEABLE AND WHETHER THOSE DAMAGES ARISE IN TORT, IN CONTRACT OR OTHERWISE.
- 14.3 <u>Exclusions</u>. The limitations in Sections 14.1 and 14.2 do not apply to (a) claims arising from either party's gross negligence or willfull misconduct; (b) liability for any fraud or fraudulent misrepresentation; (c) amounts owing by a party under Section 7; or (d) claims indemnified by Customer under Section 11.1.

15. MISCELLANEOUS

15.1 Excused Performance. CMC will not be liable to Customer nor be considered to have breached this agreement for failure or delay in performing to the extent, and for so long as, the failure or delay is caused by or results from causes beyond the reasonable control of CMC including but not limited to: acts of state or governmental action, orders, legislation, regulations, restrictions, priorities or rationing, riots, disturbance, war (declared or undeclared), strikes, lockouts, slowdowns, prolonged shortage of energy supplies, interruption of transportation, embargo (inability to procure or shortage of supply materials, equipment or production facilities), fire, earthquake, flood, hurricane, typhoon, explosion and accident. CMC must notify Customer of any force majeure event that prevents CMC from performing the Services. If a force majeure event continues for more

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than 180 days after CMC's notice, and is adversely affecting the performance of this agreement, each party will have the right terminate this agreement on 30 days' notice. In that event, Customer will pay for all Services performed prior to the date of termination. In addition, Customer will not have any claim for damages as a result of such termination or non-performance of the Services.

- 15.2 <u>Insurance</u>. During the Term, the parties must maintain a comprehensive general liability, product liability and umbrella liability insurance with insurance companies and in amounts as is customary for companies in their respective industry and conducting activities of comparable size and scope for (a) [*] after the termination of this agreement, or (b) the last use of the Product.
- 15.3 <u>Amendment</u>. Other than as provided for elsewhere in this agreement, any amendment of this agreement (or any document entered into pursuant to this agreement) will be valid only if it is in writing and signed by each party.
- 15.4 <u>Assignment</u>. This Agreement is not assignable by either party except with the written consent of the other party; provided, however that either party may assign this Agreement to any of its Affiliates and in the event of a sale of all or substantially all of the assets or stock of such party without the consent of the other party.
- 15.5 <u>Subcontracting</u>. CMC may subcontract to (a) its Affiliates, any of the Services provided that the Affiliate may not further subcontract those Services; (b) Testing Laboratories, only those parts of the Services identified in the Work Statement; and (c) any other third party, any of the Services, with the prior written consent of Customer (that consent not to be unreasonably withheld, delayed or conditioned). CMC will remain responsible for the activities of its subcontractors except to the extent that Customer requires CMC to use a subcontractor that Customer selects over CMC's objection.
- 15.6 <u>Waiver</u>. In no event will any delay, failure or omission (in whole or in part) in enforcing, exercising or pursuing any right, power, privilege, claim or remedy conferred by or arising under this agreement or by law, be deemed to be or construed as a waiver of that or any other right, power, privilege, claim or remedy in respect of the circumstances in question, or operate so as to bar the enforcement of that, or any other right, power, privilege, claim or remedy, in any other instance at any time or times subsequently.
- 15.7 <u>Severability</u>. If any provision of this agreement is found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, that invalidity or unenforceability will not affect the other provisions of this agreement which shall remain in full force and effect. The parties must, in the circumstances referred to in this Section 15.7, attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision that achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision.
- 15.8 <u>Notices</u>. Any notice or other communication given under this agreement (including under Section 3.4 or 6.6) must be in writing and in English and signed by or on behalf of the party giving it and must be given by hand or by delivering it or sending it by prepaid post or overnight delivery service, to the address and for the attention of the relevant party set out in this Section 15.8 (or as otherwise notified by that party under this Section 15.8). Any notice will be deemed to have been received:

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15.8.1 if hand delivered or sent by prepaid overnight delivery service, at the time of delivery; or

15.8.2 if sent by post, five Business Days from the date of posting.

The addresses of the parties for the purposes of this Section 15.8 are:

CMC ICOS Biologics, Inc.

22021 20th Ave. S.E. Bothell, Washington U.S.A. 98021

For the attention of: Legal Department

Customer CytoDyn Inc. 1111 Main Street, Suite 660 Vancouver, Washington 98660

For the attention of: Michael D. Mulholland Chief Financial Officer

CMC has no obligation to notify any person or entity other than as provided in Section 15.8.

- 15.9 <u>Applicable Law</u>. This agreement will be interpreted and governed, and all rights and obligations of the parties determined, in accordance with the laws of the state of New York (regardless of choice of law provisions to the contrary). The parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.
- 15.10 <u>Dispute Resolution</u>. Before resorting to litigation, unless emergency relief is required by either party when either party will be free to resort to litigation, the parties must use their reasonable efforts to negotiate in good faith and settle amicably any dispute that may arise out of or relate to this agreement (or its construction, validity or termination) (a "**Dispute**"). If a Dispute cannot be settled through negotiations by appropriate representatives of each of the parties, either party may give to the other a notice in writing (a "**Dispute Notice**"). Within seven days of the Dispute Notice being given the parties must each refer the Dispute to their respective Chief Executive Officers, who shall meet in order to attempt to resolve the dispute. If within 30 days of the Dispute Notice (a) the Dispute is not settled by agreement in writing between the parties or (b) the parties have failed to discuss the Dispute or use good faith negotiations, the Dispute may be submitted to and finally be settled by the state or federal courts located in the state of New York.
- 15.11 <u>Relationship of the Parties</u>. Nothing in this agreement operates to create a partnership or joint venture between the parties or authorizes either party to act as agent for the other. Neither party has authority to act in the name of or otherwise to bind the other in any way.
- 15.12 Entire Agreement. This agreement, and the documents referred to in it, constitutes the entire agreement and understanding of the parties and supersedes any previous agreement between the parties relating to the subject matter of this agreement. If any

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term of this agreement conflicts with any term of the Quality Agreement, the conflicting term of this agreement will prevail except for issues related to quality or quality-related activities. This Agreement is written in English, and the English version of this Agreement will control.

15.13 Counterparts. This agreement may be executed in any number of counterparts.

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THIS DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT has been executed by the parties on the date first written above.

CMC ICOS Biologics, Inc.))
Signature: /s/ Gustavo Mahler)
Print Name: Gustavo Mahler)
Position: CEO & President)
)
CUSTOMER))
Signature: <u>/s/ Nader Pourhassan</u>)
Name: Nader Pourhassan)
Position: President and CEO)
)

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APPENDIX I

Definitions

"Affiliate" means, with respect to any entity, any other entity that directly or indirectly controls, is controlled by or is under common control with that entity. For this definition, "control" means that more than 50% of the controlled entity's shares or ownership interests representing the right to make decisions for that entity are owned or controlled, directly or indirectly, by the controlling entity.

"**Batch**" means one fermentation run using the Cell Line at a specified fermenter scale and those harvesting, purification, analytical and further processing steps applicable to the manufacture of Drug Substance from that run as described in the Work Statement.

"Business Day" means any day that is not a Saturday, Sunday or U.S. public holiday.

"Cell Line" means the cell line described in the Work Statement provided by Customer or to be developed by CMC using Customer Materials as part of the Services, and any modified strains of that cell line constructed in accordance with the Services and any progeny clone of those cell lines.

"Certificate of Analysis" means CMC's standard form certificate of analysis confirming that Product to which the certificate relates meets the Specification and any other criteria identified on the certificate.

"**cGMP**" means Current Good Manufacturing Practices as promulgated under each of the following as in effect on the Effective Date and as amended or revised after the Effective Date: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 *et seq.*) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210 and 211) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; and (b) the ICH guide Q7a "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" as applied to investigational drugs (Section 19).

"cGMP Batch" means a Batch that is stipulated in the Work Statement to be manufactured according to cGMP.

"cGMP Product" means Product manufactured under a cGMP Batch.

"CHEF1® Technology" means the Chinese Hamster EF-1 regulatory DNA ("CHEF1") as further described in US Patent Number 5,888,809 and the technology described in US Patent Number 5,888,809.

"**CMC Facility**" means CMC's then current facility at Bothell, Washington or any of CMC's or its Affiliates' facilities in Berkeley, California, Copenhagen, Denmark or as specified in writing in a Work Statement.

"CMC Intellectual Property Rights" means Intellectual Property rights and CMC Know-How (excluding CHEF1 Technology) owned or controlled by CMC and used in the Services.

"CMC Know-How" means all information, techniques and technical information known to CMC or developed during the Services (excluding the CHEF1 Technology or improvements thereto) that are not of general public knowledge.

"Commencement Date" means, with respect to a cGMP Batch, the date on which an ampoule of cells is thawed for the fermentation or cell culture for manufacture of Drug Substance.

"**Commercially Reasonable Efforts**" means the degree of skill, care, diligence, prudence, knowledge and effort which would be reasonably and ordinarily expected of a skilled and experienced company engaged in the development of manufacturing processes for, and the cGMP manufacture of, biological products that are similar to the Product and/or the intermediate Products in compliance with good industry standards.

"**Confidential Information**" means information of a confidential nature and in any form (oral, written or otherwise) the use of which is governed according to the provisions of Section 9.

"**Customer Intellectual Property Rights**" means Intellectual Property rights and Customer Know-How owned by Customer or licensed to Customer by a third party covering any aspect of the Services or materials, techniques or processes used in the Services. Customer Intellectual Property rights shall include Lonza Technology.

"**Customer Know-How**" means ideas, concepts, discoveries, inventions, developments and non-public, confidential or proprietary trade secrets, techniques, methodologies, modifications, innovations, improvements, designs and design concepts, and any other information that is necessary or useful for the research, development, manufacture, use, import, export, sale, offer for sale, transfer, or regulatory approval of products or processes, including but not limited to all information, techniques and technical information known to Customer in connection with the Cell Line, Customer Materials or Process which is not of general public knowledge.

"Customer Materials" means the Cell Line, vectors, plasmids and all other materials supplied by Customer, its Affiliate or agent to CMC or made available to CMC by Customer including, without limitation, those described in the Work Statement.

"Deliverables" means the data, results and materials generated from the performance of the Services including Drug History Record and Product.

"**Drug History Record**" means all lot disposition documentation relevant to a cGMP Batch to be provided to Customer with the Product from that cGMP Batch as described in the Work Statement, including a Certificate of Analysis.

"Drug Substance" means the biological or chemical entities described or classified in the Work Statement expressed by the Cell Line in fermenter and harvested, purified, processed and filtered in bulk into containers pursuant to the applicable Process.

"Intellectual Property" means all intellectual property rights, including patents and patent applications, and any and all continuations, continuations-in-part, divisionals, utility models, extensions (including extensions under the U.S Patent Term Restoration Act), renewals, substitutions and additions thereof and all reissues, revalidations and re-examinations thereof, including any and all patents issuing there from and any and all foreign counter-parts thereof, supplementary protection certificates, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know-how, techniques and confidential information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term and together with any renewals or extensions.

"Lonza Technology" means the glutamine synthetase gene expression system consisting of myeloma cell line NS0, Chinese hamster ovary cell line CHO-K1sv, vector pEE12.4, vector pEE6.4 and related know-how owned by Lonza Sales AG.

"**Non-Fault Delay**" means a delay in the Services caused by or contributed to by (a) the acts or omissions of Customer or its representatives, including errors or defects in the Customer Materials; (b) the experimental nature of the Services or the Services being dependent on living systems; (c) additions or changes to the Services made at Customer's request; or (d) circumstances beyond CMC's reasonable control.

"Objective" means the desired outcome of the Services as described in the Work Statement.

"**Permitted Recipients**" means the directors, officers, employees, Testing Laboratories or professional advisers who are required, on a need-to-know basis, in the course of their duties to receive and consider the Confidential Information for the purpose of enabling the relevant party to perform its obligations under this agreement; provided, that those persons are under obligations of confidence no less onerous than those set out in Section 9 imposed on the Recipient Party.

"**Price**" means the price for the Services (or any part or Stage of the Services as context requires) as defined in the Work Statement and itemized on a Stage by Stage basis.

"Process" means the method for manufacture, harvesting and purification of the Product.

"Product" means the Drug Substance derived from a Batch.

"Quality Agreement" means the agreement between the parties defining the quality responsibilities, including cGMP standards, regarding the performance of the Services.

"**Regulatory Obligations**" means those mandatory regulatory requirements applicable in Europe and the U.S. to the manufacture of cGMP Product for human use.

"Services" means any or all parts of the development and manufacturing services to be conducted by CMC as fully described in the relevant Work Statement.

"Shipping Guidelines" means the storage and transport guidelines for the Product that are determined by mutual written agreement of the parties.

"Slot" means, with respect to CMC's cGMP manufacturing suite, the period of time the suite is reserved in preparation for and the performance of a Batch.

"**Specification**" means the specification of the Product either as defined in the Work Statement or as otherwise agreed between the parties or modified in accordance with Section 4.2.2.

"**Stage**" means a particular activity or series of conjoined activities that constitute a main step in the Services and that is more specifically identified in the Work Statement by the breakdown of the Services into numbered stages.

"Standard Operating Procedures" or "SOPs" means the standard operating procedures of CMC in place from time to time that define CMC's methods of performing activities applicable to the Services.

"Testing Laboratories" means any third party instructed by CMC to carry out tests on the Cell Line, Customer Materials, Drug Substance or Product pursuant to the performance of the Services.

"Timeline" means the non-binding estimated timeline for the performance of the Services as set out in the Work Statement.

"Work Statement" means the work statement attached as Appendix II and any other work statements that may be agreed on by the parties during the Term, as may be revised by the written agreement of the parties from time to time. To be valid, a Work Statement must be signed by both parties.

APPENDIX II

Incidental Fees

Raw Materials*

External Testing and Other External Costs

Packing, Shipping and Handling

Storage Fees

Out of Scope Work Agreed by the Parties

*Invoiced 60 days in advance of the Commencement Date of the applicable Stage. Raw materials that must be ordered with longer lead times will be invoiced upon placement of the order by CMC and Customer agrees to pay such invoices in accordance with the terms of the Agreement.

APPENDIX III

Work Statement



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WORK STATEMENT NO. 01

THIS WORK STATEMENT NO. 01 ("96901 DMSA WS01") is dated as of November 9, 2016 ("Effective Date") by and between CMC ICOS BIOLOGICS, INC. ("CMC") and CYTODYN INC., a Delaware corporation ("Customer"), and upon execution will be incorporated into and governed by the terms and conditions of the Development and Manufacturing Services Agreement between Customer and CMC dated November 9, 2016 (the "Agreement"). Capitalized terms used in this Work Statement but not otherwise defined will have the same meanings as set forth in the Agreement.

Customer engages CMC to provide the Services, as follows.

1. <u>API/Drug Substance and Product</u>.

CytoDyn's PRO 140 is a fully humanized IgG4 monoclonal antibody directed against CCR5, a molecular portal that HIV uses to enter T-cells. PRO 140 is being developed by CytoDyn as an HIV therapeutic. PRO 140 was designated a fast track product candidate by the FDA in 2006. CytoDyn has filed a request for Breakthrough Therapy Designation with the FDA and in July 2016 initiated its first Ph3 clinical trial with PRO 140. For additional information on PRO 140, see http://www.cytodyn.com/drug-pipeline/pro-140

2. <u>Services</u>. CMC will provide the following Services to Customer:

The specific Services to be conducted by CMC, estimated timelines, and stage duration are described in the attached Proposal 96901v08: *Process Transfer, Validation and Manufacturing for CytoDyn's PRO140*, dated October 20, 2016

3. Facility. The Services described above will be rendered at the following facility of CMC:

CMC Biologics 22021 20th Ave SE Bothell, WA 98021 USA.

- 4. <u>Customer Materials</u>. Customer will provide to CMC the following materials to be used by CMC to perform the Services within 7 days after signature of this Work Statement:
 - Materials requirements are detailed in the attached Proposal, Stage 2 Project Information Transfer, pgs 15-16.

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5. Product Specific Equipment.

Customer shall pay CMC an estimated [*] to procure the following product specific equipment:

- GE AKTA Process, max flow 2,000 L / hour
- GE AxiCHrom, set of 1x 80cm and 2x 60cm columns

The equipment described above shall be owned by CMC and shall be retained by CMC at the end of the Term.

6. <u>CMC Representatives</u>.

- Tony F. Weighous Director, Business Development Phone: 858-344-6998 Email: <u>tweighous@cmcbio.com</u>
- Tracy Kinjerski Senior Director, Business Development Phone: 717-642-5291 Email: <u>tkinjerski@cmcbio.com</u>

7. <u>Customer Representative</u>.

- Nitya Ray PhD
 Senior Vice President, Manufacturing
 Phone: 360-980-8524
 Email: <u>nray@cytodyn.com</u>
- 8. <u>Compensation</u>. The total compensation due CMC for Services under this Work Statement is [*] *provided however*, that the parties may agree to an adjustment to the total compensation if CMC is able to use process validation data that has already been generated by Customer or another third party and the scope of Services of Part C is reduced. CMC will invoice Customer for all amounts due under this Work Statement. Such amounts will be invoiced in United States Dollars to the attention of Tracie L. Melchoir, CPA, Director of Accounting. The Invoice Schedule will be maintained and issued periodically by the Project Manager. All undisputed payments will be made by Customer within *thirty (30) days* after issue of an invoice by CMC. Payments will be made in United States Dollars.

9. Payments Due on Signature of Work Statement.

• Upon signature of this Work Statement, CMC will invoice Customer in the amount of [*]. The amount that make up this invoice are detailed on pg 13 of the attached Proposal and are comprised of:

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- 50% of the Price of each Stage commencing in the first three months of the project;
- 25% GMP facility reservation fee for each manufacturing batch performed in the first 12 months after signature of this Work Statement; and
- 10% of the total price of Development Stages commencing in the first three months of the project as the Development General Materials flat fee.

10. Incidental Fees.

(a) Storage Fees for Deliverables

• Product storage fee will be [*] plus insurance or as otherwise agreed by the parties through an amendment of this Work Statement.

(b) Storage Fee for Documents

- The offsite long term document storage fee will be a minimum of [*], depending on the volume of documents stored, plus insurance or as otherwise agreed by the parties through an amendment of this Work Statement.
 - Storage of GMP records is provided for under the Quality Agreement ([*]). For reference: CMC's records retention policy calls for storage as related to production (executed batch records, QC testing data, and ancillary documentation) to be kept onsite in CMC's archives for two years plus the current year and then be transferred to offsite long term storage for the duration of the retention period.
 - For documents not covered under the Quality Agreement, storage beyond two years plus the current year will be at the Customer's discretion. If the client choses to send them to the off-site long-term storage used by CMC, the storage fee will be as above. Otherwise, the documents will be shipped to the Customer at the Customer's expense.

(c) Handling Fee for Shipments

• As provided under "Explanation of Additional Costs" on pg 12 of the attached Proposal, CMC Biologics will invoice CytoDyn on a monthly basis for any packing, shipping and handling charges (handling charges are \$500 inside USA and \$1,000/outside USA).

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• As agreed by the parties, simple shipments of a few samples, for example to an outside test facility, will be charged a reduced rate.

(d) External Analysis Costs

• As provided under "Explanation of Additional Costs" on pg 12 of the attached Proposal, external testing and other external costs will be invoiced as specified in the Agreement, i.e. at vendor's list price plus a handling charge of [*].

(e) Raw Materials

As provided under "Explanation of Additional Costs" on pgs 11 - 12 of the attached Proposal:

- Development General Materials' costs shall be covered by a flat [*] fee applied to the price of the applicable stage. For clarity, Development General Materials include all the elementary chemicals and laboratory raw materials that are typically required in the process of biological development and used outside of the GMP area (including, but not limited to, kits, reagents, tubing, single-use bags, pipettes, salts etc.). Development General Material' costs may be invoiced to CytoDyn up to sixty (60) days in advance of the commencement of the applicable Stage.
- Development Specific Materials include specific raw materials that are unique to CytoDyn's project and will be necessary for work performed outside of CMC Biologics' GMP areas. Development Specific Materials shall be invoiced at the purchase price plus a handling charge of [*]. An initial estimated invoice may be sent to CytoDyn sixty (60) calendar days prior to start of the relevant Stage. A complete detailed invoice setting out any additional payment required by CytoDyn or that a credit is due CytoDyn shall be sent on completion of the Stage.
- A General Manufacturing Consumables Fee of [*] will be invoiced in advance of all Manufacturing Stages.
- Manufacturing Materials listed on the Bill of Materials shall be invoiced at the purchase price plus a handling charge of [*]. An initial estimated invoice will be sent to CytoDyn sixty (60) calendar days prior to start of the relevant Stage. A complete detailed invoice setting out any additional payment required by CytoDyn or that a credit is due to CytoDyn shall be sent on completion of the Stage.

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- Estimated bill of materials may be invoiced 60 days in advance of the Commencement Date. Raw materials that must be ordered with longer lead times may be invoiced upon placement of the order by CMC and CytoDyn agrees to pay such invoices in accordance with the terms of the Agreement.
- Resin estimates are based on the following assumptions: 5.0 g/L titer, 50 g/L resin capacity and a cost of [*]. The number of cycles may be increased based on development and characterization data.
 - The assumption that columns can be loaded to 50 g/L capacity will be tested and verified at CMC. Resin costs will increase if 50 g/L capacity is not feasible.

(f) Travel Expenses

• As provided under "Explanation of Additional Costs" on pg 12 of the attached Proposal, necessary travel and related costs will be passed through to CytoDyn and will be consistent with CMC Biologics' internal travel policy.

(g) Other Fees

• As provided under "Explanation of Additional Costs" on pg 12 of the attached Proposal, out of scope work, if requested by CytoDyn and agreed with CMC Biologics, will be invoiced at [*] per FTE hour.

11. Assumptions.

The activities outlined in this Work Statement are based on the following assumptions:

- The scope of the studies, estimated timelines and prices quoted are provided based on the information provided by Customer. More detailed discussions may be required to determine the scope of such program, which may subsequently have an impact on the timelines and prices quoted.
- · Hazardous or raw materials of animal origin are not used in the process.
- The estimated timelines and cost will be re-negotiated in good faith between CMC and Customer if Process changes or investments in equipment are realized during the project.

All terms and conditions of the Agreement will apply to this Work Statement. In the event of any conflict between this Work Statement and the terms of the Agreement, the terms of the Agreement will control.

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[Signatures on next page]

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IN WITNESS WHEREOF the parties have caused this Work Statement No. 01 to be executed by their respective representatives duly authorized as of the day and year first above written.

WORK STATEMENT AGREED TO AND ACCEPTED BY:

CYTODYN INC.

By /s/ Nader Pourhassan

Nader Pourhassan

Title: President & CEO

Date <u>11-10-2016 | 21:04 EST</u>

CMC ICOS BIOLOGICS, INC.

By /s/ Gustavo Mahler

Dr. Gustavo Mahler, PhD Title President & CEO Date 11-10-2016 | 23:54 PST

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APPENDIX 1

(Proposal stages to be included)

All terms and conditions of the Agreement will apply to this Work Statement. In the event of any conflict between this Work Statement and the terms of the Agreement, the terms of the Agreement will control.

[Remainder of page left blank intentionally]

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I, Nader Z. Pourhassan, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of CytoDyn Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
- 4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
 - d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the registrant's most-recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
- 5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: April 13, 2017

/s/ Nader Z. Pourhassan

Nader Z. Pourhassan President and Chief Executive Officer I, Michael D. Mulholland, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of CytoDyn Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
- 4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
 - d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the registrant's most-recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
- 5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: April 13, 2017

/s/ Michael D. Mulholland Michael D. Mulholland Chief Financial Officer

Certification of Chief Executive Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the Quarterly Report of CytoDyn Inc. (the "Company") on Form 10-Q for the fiscal quarter ended February 28, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Form 10-Q"), I, Nader Z. Pourhassan, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 13, 2017

/s/ Nader Z. Pourhassan

Nader Z. Pourhassan President and Chief Executive Officer

Certification of Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the Quarterly Report of CytoDyn Inc. (the "Company") on Form 10-Q for the fiscal quarter ended February 28, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Form 10-Q"), I, Michael D. Mulholland, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 13, 2017

/s/ Michael D. Mulholland

Michael D. Mulholland Chief Financial Officer