CytoDyn Inc.
Form 10-Q
January 09, 2019
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended November 30, 2018

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

For the transition period from _____ to _____

Commission File Number: 000-49908

CYTODYN INC.

(Exact name of registrant as specified in its charter)

Delaware	**83-1887078**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer or Identification No.)**
1111 Main Street, Suite 660	
Vancouver, Washington	**98660**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large Accelerated Filer	Accelerated Filer
Non-accelerated Filer	Smaller Reporting Company
	Emerging Growth Company

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

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

On December 31, 2018, there were 292,923,481 shares outstanding of the registrant s $0.001 par value common stock.

Table of Contents

TABLE OF CONTENTS

	PAGE
PART I	3
ITEM 1. FINANCIAL STATEMENTS	3
ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	28
ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	34
ITEM 4. CONTROLS AND PROCEDURES	34
PART II	35
ITEM 1. LEGAL PROCEEDINGS	35
ITEM 1A. RISK FACTORS	35
ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	35
ITEM 3. DEFAULTS UPON SENIOR SECURITIES	35
ITEM 4. MINE SAFETY DISCLOSURES	35
ITEM 5. OTHER INFORMATION	36
ITEM 6. EXHIBITS	36

Table of Contents

PART I

Item 1. Financial Statements.

CytoDyn Inc.

Consolidated Balance Sheets

	November 30, 2018 (unaudited)	May 31, 2018
Assets		
Current assets:		
Cash	$ 772,361	$ 1,231,445
Prepaid expenses	200,890	227,173
Prepaid service fees	2,954,624	1,862,009
Total current assets	3,927,875	3,320,627
Furniture and equipment, net	10,127	11,228
Intangibles, net	16,452,951	1,567,143
Total assets	$ 20,390,953	$ 4,898,998
Liabilities and Stockholders (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 18,852,414	$ 15,841,859
Accrued liabilities and compensation	560,013	757,778
Accrued license fees	347,333	133,600
Accrued interest on convertible notes	23,001	
Convertible note payable, net	4,200,000	
Total current liabilities	23,982,761	16,733,237
Long-term liabilities:		
Convertible note payable, net	1,396,974	
Derivative liabilities	3,075,142	1,323,732
Total long-term liabilities	4,472,116	1,323,732
Total liabilities	28,454,877	18,056,969
Commitments and Contingencies		
Stockholders (Deficit) equity		
Series B convertible preferred stock, $0.001 par value; 400,000 shares authorized, 92,100 shares issued and outstanding at November 30, 2018 and May 31, 2018, respectively	92	92
Common stock, $0.001 par value; 600,000,000 and 375,000,000 shares authorized, 290,808,960 and 216,881,790 issued and 290,649,949 and	290,810	216,881

216,722,779 outstanding at November 30, 2018 and May 31, 2018, respectively		
Additional paid-in capital	193,503,678	159,764,611
Accumulated (deficit)	(201,858,345)	(173,139,396)
Less: treasury stock, at par (159,011 shares at $0.001)	(159)	(159)
Total stockholders (deficit)	(8,063,924)	(13,157,971)
Total liabilities and stockholders (deficit) equity	$ 20,390,953	$ 4,898,998

See accompanying notes to consolidated financial statements.

Table of Contents

CytoDyn Inc.

Consolidated Statements of Operations

(Unaudited)

	Three Months Ended November 30,		Six Months Ended November 30,	
	2018	2017	2018	2017
Operating expenses:				
General and administrative	$ 2,663,745	$ 1,608,743	$ 4,594,804	$ 3,178,420
Research and development	12,869,244	9,077,172	24,337,910	17,225,348
Amortization and depreciation	154,801	89,136	243,772	178,282
Total operating expenses	15,687,790	10,775,051	29,176,486	20,582,050
Operating loss	(15,687,790)	(10,775,051)	(29,176,486)	(20,582,050)
Interest income	1,021	422	2,002	1,206
Change in fair value of derivative liabilities	281,055	829,600	(466,412)	466,934
Interest expense:				
Amortization of discount on convertible notes	(52,954)	(728,843)	(117,534)	(1,172,995)
Amortization of debt issuance costs	(10,411)	(168,429)	(19,589)	(282,129)
Loss on extinguishment of convertible note	(1,519,603)		(1,519,603)	
Inducement interest related to warrant exercise				(826,252)
Interest on convertible note payable	(143,617)	(105,384)	(248,247)	(180,673)
Total interest expense	(1,726,585)	(1,002,656)	(1,904,973)	(2,462,049)
Loss before income taxes	(17,132,299)	(10,947,685)	(31,545,869)	(22,575,959)
Income tax benefit	2,826,919		2,826,919	
Net loss	$ (14,305,380)	$ (10,947,685)	$ (28,718,950)	$ (22,575,959)
Basic and diluted loss per share	$ (0.06)	$ (0.07)	$ (0.12)	$ (0.15)
Basic and diluted weighted average common shares outstanding	259,088,835	157,843,773	238,731,091	154,774,327

See accompanying notes to consolidated financial statements.

Table of Contents

CytoDyn Inc.

Consolidated Statements of Cash Flows

(Unaudited)

	Six Months Ended November 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (28,718,950)	$ (22,575,959)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	243,772	178,282
Amortization of debt issuance costs	19,589	282,129
Amortization of discount on convertible notes	117,534	1,172,995
Inducement interest related to warrant exercise		826,252
Interest expense associated with derivative liabilities		
Change in fair value of derivative liabilities	466,412	(466,934)
Stock-based compensation	1,510,486	529,617
Loss on extinguishment of convertible note	1,519,603	
Deferred income tax benefit	(2,826,919)	
Changes in current assets and liabilities:		
(Increase) decrease in prepaid expenses	(1,807,629)	907,606
Increase in accounts payable and accrued expenses	3,283,113	6,256,192
Net cash used in operating activities	(26,192,989)	(12,889,820)
Cash flows from investing activities:		
Furniture and equipment purchases	(2,262)	
Net cash used in investing activities	(2,262)	
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants	23,463,585	7,050,651
Proceeds from warrant exercises		1,647,500
Proceeds from convertible note payable	5,000,000	4,888,500
Payment of offering costs	(2,727,418)	(1,175,575)
Net cash provided by financing activities	25,736,167	12,411,076
Net change in cash	(459,084)	(478,744)
Cash, beginning of period	1,231,445	1,775,583
Cash, end of period	$ 772,361	$ 1,296,839
Non-cash investing and financing transactions:		

Financing costs associated with placement agent warrants	$	$ 70,383
Accrued interest converted into note payable	$ 225,245	$
Debt discount associated with convertible notes payable	$ 700,000	$ 1,574,628
Common stock issued for acquisition of ProstaGene, LLC	$ 11,558,000	
Derivative liability associated a convertible note payable	$ 1,284,998	$

See accompanying notes to consolidated financial statements.

Table of Contents

CytoDyn Inc.

Consolidated Statement of Changes in Stockholders (Deficit)/ Equity

(Unaudited)

	Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance May 31, 2017	92,100	$ 92	149,468,244	$ 149,468		$
First Quarter Fiscal Year Ended May 31, 2018						
Proceeds from warrant exercise ($0.50/share)			3,295,000	3,295		
Offering costs related to warrant tender offer						
Proceeds from private equity offering ($0.50/share)						
Offering costs related to private equity offering						
Proceeds from registered direct offering ($0.50/share)						
Offering costs related to registered direct offering						
Legal fees in connection with equity offerings						
Interest expense related to warrant tender offer						
Interest expense related to conversion of notes payable						
Stock issued for bonuses and tendered for income tax						
Stock issued for board compensation						
Stock-based compensation						
Interest expense related to warrant extension						
Debt discount related to convertible notes payable						
Net loss August 31, 2017						
Balance August 31, 2017	92,100	$ 92	152,763,244	$ 152,763		$
Second Quarter Fiscal Year Ended May 31, 2018						
Proceeds from warrant exercise ($0.50/share)						
Offering costs related to warrant tender offer						
Proceeds from private equity offering ($0.50/share)			6,651,800	6,652		
Offering costs related to private equity offering						
Proceeds from registered direct offering ($0.50/share)			5,720,111	5,720		
Offering costs related to registered direct offering						
Legal fees in connection with equity offerings						
Interest expense related to conversion of notes payable						
Interest expense related to warrant tender offer						
Stock issued for bonuses and tendered for income tax						
Stock issued for board compensation						
Stock-based compensation						
Interest expense related to warrant extension						

Debt discount related to convertible notes payable						
Net loss November 30, 2017						
Balance November 30, 2017	92,100	$	92	165,135,155	$ 165,135	$

See accompanying notes to consolidated financial statements

Table of Contents

CytoDyn Inc.

Consolidated Statement of Changes in Stockholders (Deficit)/ Equity

(Unaudited)

	Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Third Quarter Fiscal Year Ended May 31, 2018						
Proceeds from warrant exercise ($0.50/share)						
Offering costs related to warrant tender offer						
Proceeds from private equity offering ($0.50/share)			28,635,104	28,635		
Offering costs related to private equity offering						
Proceeds from registered direct offering ($0.50/share)			15,133,742	15,134		
Offering costs related to registered direct offering						
Legal fees in connection with equity offerings						
Interest expense related to conversion of notes payable						
Interest expense related to warrant tender offer						
Stock issued for bonuses and tendered for income tax						
Stock issued for board compensation						
Stock-based compensation						
Interest expense related to warrant extension						
Debt discount related to convertible notes payable						
Net loss February 28, 2018						
Balance February 28, 2018	92,100	$ 92	208,904,001	$ 208,904		$
Fourth Quarter Fiscal Year Ended May 31, 2018						
Proceeds from warrant exercise ($0.50/share)			3,027,263	3,027		
Offering costs related to warrant tender offer						
Proceeds from private equity offering ($0.50/share)						
Offering costs related to private equity offering						
Proceeds from registered direct offering ($0.50/share)			4,640,000	4,640		

Offering costs related to registered direct offering						
Legal fees in connection with equity offerings						
Interest expense related to conversion of notes payable						
Interest expense related to warrant tender offer						
Stock issued for bonuses and tendered for income tax			310,526	310	159,011	(159)
Stock issued for board compensation						
Stock-based compensation						
Interest expense related to warrant extension						
Debt discount related to convertible notes payable						
Net Loss May 31, 2018						
Balance May 31, 2018	92,100	$ 92	216,881,790	$ 216,881	159,011	$ (159)

See accompanying notes to consolidated financial statements

Table of Contents

CytoDyn Inc.

Consolidated Statement of Changes in Stockholders (Deficit)/ Equity

(Unaudited)

	Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance May 31, 2018	92,100	$ 92	216,881,790	$ 216,881	159,011	$ (159)
First Quarter Fiscal Year Ended May 31, 2019						
Acquisition of ProstaGene LLC						
Issuance of stock payment shares						
Proceeds from registered direct offering ($0.50/share)			1,970,000	1,970		
Offering costs related to registered direct offering						
Proceeds from private equity offering ($0.50/share)			15,028,600	15,029		
Offering costs related to private equity offering						
Legal fees in connection with equity offerings						
Stock-based compensation						
Net Loss August 31, 2018						
Balance August 31, 2018	92,100	$ 92	233,880,390	$ 233,880	159,011	$ (159)
Second Quarter Fiscal Year Ended May 31, 2019						
Acquisition of ProstaGene LLC			18,658,000	18,658		
Issuance of stock payment shares			8,342,000	8,342		
Proceeds from registered direct offering ($0.50/share)						
Offering costs related to registered direct offering						
Proceeds from private equity offering ($0.50/share)			29,928,570	29,930		
Offering costs related to private equity offering						
Legal fees in connection with equity offerings						
Stock-based compensation						
Net Loss November 30, 2018						
Balance November 30, 2018	92,100	$ 92	290,808,960	$ 290,810	159,011	$ (159)

See accompanying notes to consolidated financial statements

Table of Contents

CytoDyn Inc.

Consolidated Statement of Changes in Stockholders (Deficit)/ Equity

(Unaudited)

	Additional Paid-In Capital	Accumulated Deficit	Total	Fiscal Year To Date
Balance May 31, 2017	$ 121,736,921	$ (122,989,715)	$ (1,103,234)	$ (1,103,234)
First Quarter Fiscal Year Ended May 31, 2018				
Proceeds from warrant exercise ($0.50/share)	1,644,205		1,647,500	1,647,500
Offering costs related to warrant tender offer				
Proceeds from private equity offering ($0.50/share)				
Offering costs related to private equity offering				
Proceeds from registered direct offering ($0.50/share)				
Offering costs related to registered direct offering				
Legal fees in connection with equity offerings				
Interest expense related to warrant tender offer				
Interest expense related to conversion of notes payable				
Stock issued for bonuses and tendered for income tax				
Stock issued for board compensation				
Stock-based compensation	254,952		254,952	254,952
Interest expense related to warrant extension	826,252		826,252	826,252
Debt discount related to convertible notes payable	1,645,010		1,645,010	1,645,010
Net loss August 31, 2017		(11,628,273)	(11,628,273)	(11,628,273)
Balance August 31, 2017	$ 126,107,340	$ (134,617,988)	$ (8,357,793)	$ (8,357,793)
Second Quarter Fiscal Year Ended May 31, 2018				
Proceeds from warrant exercise ($0.50/share)				1,647,500
Offering costs related to warrant tender offer				
Proceeds from private equity offering ($0.50/share)	3,318,745		3,325,397	3,325,397
Offering costs related to private equity offering	(312,456)		(312,456)	(312,456)
	3,719,534		3,725,254	3,725,254

Proceeds from registered direct offering ($0.50/share)				
Offering costs related to registered direct offering	(319,228)		(319,228)	(319,228)
Legal fees in connection with equity offerings	(178,664)		(178,664)	(178,664)
Interest expense related to conversion of notes payable				
Interest expense related to warrant tender offer				
Stock issued for bonuses and tendered for income tax				
Stock issued for board compensation				
Stock-based compensation	274,665		274,665	529,617
Interest expense related to warrant extension				826,252
Debt discount related to convertible notes payable				1,645,010
Net loss November 30, 2017		(10,947,685)	(10,947,685)	(22,575,958)
Balance November 30, 2017	$ 132,609,936	$ (145,565,673)	$ (12,790,510)	$ (12,790,510)

See accompanying notes to consolidated financial statements

Table of Contents

CytoDyn Inc.

Consolidated Statement of Changes in Stockholders (Deficit)/ Equity

(Unaudited)

	Additional Paid-In Capital	Accumulated Deficit	Total	Fiscal Year To Date
Balance November 30, 2017	$ 132,609,936	$ (145,565,673)	$ (12,790,510)	$ (12,790,510)
Third Quarter Fiscal Year Ended May 31, 2018				
Proceeds from warrant exercise ($0.50/share)				1,647,500
Offering costs related to warrant tender offer				
Proceeds from private equity offering ($0.50/share)	14,288,916		14,317,551	17,642,948
Offering costs related to private equity offering	(1,416,786)		(1,416,786)	(1,729,242)
Proceeds from registered direct offering ($0.50/share)	7,551,031		7,566,165	11,291,419
Offering costs related to registered direct offering	(331,621)		(331,621)	(650,849)
Legal fees in connection with equity offerings	(166,222)		(166,222)	(344,886)
Interest expense related to conversion of notes payable	2,352,045		2,352,045	2,352,045
Interest expense related to warrant tender offer				
Stock issued for bonuses and tendered for income tax				
Stock issued for board compensation	260,190		260,190	260,190
Stock-based compensation	566,609		566,609	1,096,226
Interest expense related to warrant extension				826,252
Debt discount related to convertible notes payable				1,645,010
Net loss February 28, 2018		(17,950,100)	(17,950,100)	(40,526,058)
Balance February 28, 2018	$ 155,714,098	$ (163,515,773)	$ (7,592,679)	$ (7,592,679)
Fourth Quarter Fiscal Year Ended May 31, 2018				
Proceeds from warrant exercise ($0.50/share)	1,510,604		1,513,631	3,161,131
Offering costs related to warrant tender offer	(73,234)		(73,234)	(73,234)
Proceeds from private equity offering ($0.50/share)				17,642,948
Offering costs related to private equity offering				(1,729,242)
Proceeds from registered direct offering ($0.50/share)	2,315,360		2,320,000	13,611,419

Offering costs related to registered direct offering	(206,300)		(206,300)	(857,149)
Legal fees in connection with equity offerings	(188,548)		(188,548)	(533,434)
Interest expense related to conversion of notes payable				2,352,045
Interest expense related to warrant tender offer	393,686		393,686	393,686
Stock issued for bonuses and tendered for income tax	104,394		104,545	104,545
Stock issued for board compensation				260,190
Stock-based compensation	194,551		194,551	1,290,777
Interest expense related to warrant extension				826,252
Debt discount related to convertible notes payable				1,645,010
Net Loss May 31, 2018		(9,623,623)	(9,623,623)	(50,149,681)
Balance May 31, 2018	$ 159,764,611	$ (173,139,396)	$ (13,157,971)	$ (13,157,971)

See accompanying notes to consolidated financial statements

Table of Contents

CytoDyn Inc.

Consolidated Statement of Changes in Stockholders (Deficit)/ Equity

(Unaudited)

	Additional Paid-In Capital	Accumulated Deficit	Total	Fiscal Year To Date
Balance May 31, 2018	$ 159,764,611	$ (173,139,396)	$ (13,157,971)	$ (13,157,971)
First Quarter Fiscal Year Ended May 31, 2019				
Acquisition of ProstaGene LLC				
Issuance of stock payment shares				
Proceeds from registered direct offering ($0.50/share)	983,030		985,000	985,000
Offering costs related to registered direct offering	(75,151)		(75,151)	(75,151)
Proceeds from private equity offering ($0.50/share)	7,499,271		7,514,300	7,514,300
Offering costs related to private equity offering	(882,716)		(882,716)	(882,716)
Legal fees in connection with equity offerings	(50,544)		(50,544)	(50,544)
Stock-based compensation	283,346		283,346	283,346
Net Loss August 31, 2018		(14,413,569)	(14,413,569)	(14,413,569)
Balance August 31, 2018	$ 167,521,847	$ (187,552,965)	$ (19,797,305)	(19,797,305)
Second Quarter Fiscal Year Ended May 31, 2019				
Acquisition of ProstaGene LLC	11,539,342		11,558,000	11,558,000
Issuance of stock payment shares			8,342	8,342
Proceeds from registered direct offering ($0.50/share)				985,000
Offering costs related to registered direct offering				(75,151)
Proceeds from private equity offering ($0.50/share)	14,934,355		14,964,285	22,478,585
Offering costs related to private equity offering	(1,693,354)		(1,693,354)	(2,576,070)
Legal fees in connection with equity offerings	(25,652)		(25,652)	(76,195)
Stock-based compensation	1,227,140		1,227,140	1,510,486
Net Loss November 30, 2018		(14,305,380)	(14,305,380)	(28,718,950)
Balance November 30, 2018	$ 193,503,678	$ (201,858,345)	$ (8,063,924)	$ (8,063,924)

See accompanying notes to consolidated financial statements

11

Table of Contents

CYTODYN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2018

(UNAUDITED)

Note 1 Organization

CytoDyn Inc. (the Company , we or us) was originally incorporated under the laws of Colorado on May 2, 2002 under the name RexRay Corporation (its previous name) and, effective August 27, 2015, reincorporated under the laws of Delaware. Effective November 16, 2018, we implemented a holding company reorganization, as a result of which, we became the successor issuer and reporting company to the former CytoDyn Inc. (now our wholly owned subsidiary, CytoDyn Operations Inc.). 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, leronlimab (PRO 140), belongs to a class of HIV therapies known as entry inhibitors that block HIV from entering into and infecting certain cells.

The Company is developing a class of therapeutic monoclonal antibodies to address unmet medical needs in the areas of HIV and graft-versus-host disease (GvHD). In addition, we are expanding the clinical focus of leronlimab (PRO 140) to include the evaluation of certain cancer and immunological indications where CCR antagonism has shown initial promise.

Note 2 Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and reflect all adjustments, which consist solely of normal recurring adjustments, needed to fairly present the financial results for these periods. The consolidated financial statements and notes thereto are presented as prescribed by Form 10-Q. Accordingly, certain information and note disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been omitted. The accompanying consolidated financial statements should be read in conjunction with the financial statements for the fiscal years ended May 31, 2018 and 2017 and notes thereto in the Company s Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended May 31, 2018, filed with the Securities and Exchange Commission on July 27, 2018 and September 28, 2018, respectively. Operating results for the three months ended November 30, 2018 are not necessarily indicative of the results that may be expected for the entire year. In the opinion of management, all adjustments have been made, which consist only of normal recurring adjustments necessary for a fair statement of (a) the results of operations for the three and six months ended November 30, 2018 and November 30, 2017, (b) the financial position at November 30, 2018 and (c) cash flows for the six month periods ended November 30, 2018 and November 30, 2017.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, CytoDyn Operations Inc., Advanced Genetic Technologies, Inc. (AGTI) and CytoDyn Veterinary Medicine LLC

(CVM), of which both AGTI and CVM are dormant entities. All intercompany transactions and balances are eliminated in consolidation.

Reclassifications

Certain prior year amounts shown in the accompanying consolidated financial statements have been reclassified to conform to the 2018 presentation. These reclassifications did not have any effect on total current assets, total assets, total current liabilities, total liabilities, total stockholders (deficit) equity, net loss or loss per share.

Going Concern

The consolidated accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company had losses for all periods presented. The Company incurred a net loss of $28,718,950 for the six months ended November 30, 2018 and has an accumulated deficit of $201,858,345 as of November 30, 2018. These factors, among others, raise substantial doubt about the Company s ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company s continuation as a going concern is dependent upon its ability to obtain additional operating capital, complete development of its product candidates, obtain U.S. Food & Drug Administration (FDA) approval, outsource manufacturing of the product candidates, and ultimately achieve initial revenues and attain profitability. The Company is currently engaging in significant research and development activities related to these product candidates, and expects to incur significant research and development expenses in the future primarily related

Table of Contents

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 November 30, 2018 and May 31, 2018 approximated $0.5 million and $1.1 million, respectively.

Identified Intangible Assets

The Company follows the provisions of Financial Accounting Standards Board (FASB) ASC Topic 350 Intangibles-Goodwill and Other, which establishes accounting standards for the impairment of long-lived assets such as intangible assets subject to amortization. The Company reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. If the sum of the undiscounted expected future cash flows over the remaining useful life of a long-lived asset group is less than its carrying value, the asset is considered impaired. Impairment losses are measured as the amount by which the carrying amount of the asset group exceeds the fair value of the asset. There were no impairment charges for the six months ended November 30, 2018 and 2017. The value of the Company s patents would be significantly impaired by any adverse developments as they relate to the clinical trials pursuant to the patents acquired as discussed in Notes 7 and 9.

Research and Development

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

Pre-launch Inventory

The Company may scale-up and make commercial quantities of its product candidate prior to the date it anticipates that such product will receive final FDA approval. The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever. This risk notwithstanding, the Company may scale-up and build pre-launch inventories of product that have not yet received final governmental approval when the Company believes that such action is appropriate in relation to the commercial value of the product launch opportunity. The determination to capitalize is made once the Company (or its third party development partners) has filed a Biologics License Application (BLA) that has been acknowledged by the

FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely manner and management is reasonably certain that all regulatory and legal requirements will be satisfied. This determination is based on the particular facts and circumstances relating to the expected FDA approval of the drug product being considered. As of November 30, 2018 and May 31, 2018, the Company did not have pre-launch inventory that qualified for capitalization pursuant to U.S. GAAP ASC 330 Inventory.

Fair Value of Financial Instruments

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.

Table of Contents

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.

Liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of November 30, 2018 and May 31, 2018 is as follows:

	Fair Value Measurement at November 30, 2018 (1)		Fair Value Measurement at May 31, 2018 (1)	
	Using Level 3	Total	Using Level 3	Total
Liabilities:				
Derivative liability - warrants	$ 1,789,066	$ 1,789,066	$ 1,323,732	$ 1,323,732
Derivative liability - convertible note redemption provision	1,286,076	1,286,076		
Total liabilities	$ 3,075,142	$ 3,075,142	$ 1,323,732	$ 1,323,732

(1) The Company did not have any assets or liabilities measured at fair value using Level 1 or 2 of the fair value hierarchy as of November 30, 2018 and May 31, 2018.

A financial instrument s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurements. These instruments are not quoted on an active market. The Company uses a Binomial Lattice Model to estimate the value of the warrant derivative liability and a Monte Carlo Simulation to value the derivative liability of the redemption provision within a convertible promissory note. These valuation models were used because management believes they reflect all the assumptions that market participants would likely consider in negotiating the transfer of the instruments. The Company s derivative liabilities are classified within Level 3 of the fair value hierarchy because certain unobservable inputs were used in the valuation models. The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the six months ended November 30, 2018 and the year ended May 31, 2018:

Investor warrants issued with registered direct equity offering	$ 4,360,000
Placement agent warrants issued with registered direct equity offering	819,200
Fair value adjustments	(3,855,468)
Balance at May 31, 2018	1,323,732
Inception date value of redemption provision	1,284,998
Fair value adjustments	466,412
Balance at November 30, 2018	$ 3,075,142

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. Periodically, the Company will issue restricted common stock to third parties as compensation for services rendered. Such stock awards are valued at fair market value on the effective date of the Company s obligation.

Table of Contents

Common Stock

On August 24, 2017, at the 2017 Annual Meeting of Stockholders, a proposal was approved to increase the total number of authorized shares of common stock from 350,000,000 to 375,000,000. On June 7, 2018, at a special meeting of stockholders, a proposal was approved to increase the total number of authorized shares of common stock of the Company from 375,000,000 to 450,000,000. Subsequent to each stockholders meeting, an amendment to the Company s Certificate of Incorporation was filed with the Secretary of State of the State of Delaware to give effect to each authorized share increase.

On November 8, 2018 at the 2018 Annual Meeting of Stockholders, a proposal was approved to increase the total number of authorized shares of common stock from 450,000,000 to 600,000,000. Subsequent to the meeting, an amendment to the Company s Certificate of Incorporation was filed with the Secretary of State of the State of Delaware to give effect to the authorized share increase.

Preferred Stock

The Company s Board of Directors is authorized to issue up to 5,000,000 shares of preferred stock without stockholder approval. As of November 30, 2018, the Company has authorized the issuance of 400,000 shares of Series B Convertible Preferred Stock, of which 92,100 shares were outstanding. The remaining preferred shares authorized have no specified rights.

Treasury Stock

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

Debt Discount

During the six months ended November 30, 2018 and the year ended May 31, 2018, the Company incurred approximately $0.6 million and $1.5 million of debt discount related to the issuance of convertible notes, as described in Note 4. The discount is amortized over the life of the convertible promissory notes. During the six months ended November 30, 2018 and November 30, 2017, the Company recorded approximately $117,500 and $1.2 million of related amortization.

Debt Issuance Cost

During the six months ended November 30, 2018 and the year ended May 31, 2018, the Company incurred direct costs associated with the issuance of convertible notes, as described in Note 4, and recorded approximately $0.1 million and $0.4 million, respectively of debt issuance costs. In connection with the debt issuance costs, the Company recognized approximately $20,000 and $0.3 million of related amortization for the six months ended November 30, 2018 and November 30, 2017, respectively.

Offering Costs

The Company incurred direct incremental costs associated with the sale of equity securities, as described in Notes 10 and 11. The costs were approximately $3.5 million for the year ended May 31, 2018, and approximately $2.7 million

and $0.6 million for the six months ended November 30, 2018 and November 30, 2017, respectively. The offering costs were recorded as a component of equity upon receipt of proceeds.

Stock for Services

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

Loss per Common Share

Basic loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share would include the weighted average number of shares of common stock outstanding and potentially dilutive common stock equivalents. Because of the net losses for all periods presented, the basic and diluted weighted average shares outstanding are the same since including the additional shares would have an anti-dilutive effect on the loss per share. For this reason, common stock options and warrants to purchase 155,836,676 and 87,551,801 shares of common stock were not included in the computation of basic and diluted weighted average number of shares of common stock outstanding for the six months ended November 30, 2018 and November 30, 2017, respectively. Additionally, as of November 30, 2018, shares of Series B convertible preferred stock in the aggregate of 92,100 shares can potentially convert into 921,000 shares of common stock.

Table of Contents

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

The Tax Cuts and Jobs Act (the Act) was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21% effective as of January 1, 2018. In accordance with Section 15 of the Internal Revenue Code, we utilized a blended rate of 28.62% for our fiscal 2018 tax year, by applying a prorated percentage of the number of days prior to and subsequent to the January 1, 2018 effective date. For the fiscal year ended May 31, 2018, we recorded provisional charges for the re-measurement of the deferred tax assets and reduced our deferred taxes before the valuation allowance by $17,497,051 to our income tax expense. The net tax expense for the year ended May 31, 2018, is zero, due to the reduction in the deferred tax valuation allowance. For the year ending May 31, 2019 a deferred tax rate of 21% is being utilized and a corresponding valuation allowance adjustment is being recorded for the generation of deferred tax assets reversing in the future. For the three months ending November 30, 2018 the Company recorded a $2,826,919 deferred income tax benefit from a reduction in the Company s deferred tax valuation allowance resulting from recording a deferred tax liability of $2,826,919 in connection with the acquisition of assets in the ProstaGene LLC transaction (see Note 7) . The deferred tax liability represents the tax effect of the difference in the carrying value of the assets and their tax basis at acquisition. The Company has a full valuation allowance on the Company s net deferred tax assets as of November 30, 2018 and May 31, 2018, as management does not consider it more than likely than not that the benefits from the deferred taxes will be realized.

Note 3 Recent Accounting Pronouncements

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

In August 2018, FASB issued Accounting Standards Update (ASU) No. 2018-13 *Fair Value Measurement (Topic 820) Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement.* The amendments in this Update provides guidance that remove, modify and add to the disclosure requirements related to fair value measurements. The guidance removes the requirements to disclose the amount and reasons for transfers between Level 1 and Level 2 assets, the policy for timing and transfers between levels and the valuation process for Level 3 fair value measurements. The guidance modifies disclosure requirements for investments in certain entities that calculate net asset value and clarifies the purpose of the measurement uncertainty disclosure. The guidance adds requirements to disclose changes in unrealized gains or losses included in other comprehensive income for recurring Level 3 fair value measurements and to disclose the range and weighted average used to develop significant

unobservable inputs for Level 3 fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The Company does not expect the adoption to have a material impact on its consolidated financial statements.

In June 2018, FASB issued ASU No. 2018-07, *Compensation Stock Compensation (Topic 718)*, *Improvements to Nonemployee Share Based Payment Accounting.* The amendments in this Update expand the scope of stock compensation to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance in this Update does not apply to transactions involving equity instruments granted to a lender or investor that provides financing to the issuer. The guidance is effective for fiscal years beginning after December 31, 2018 including interim periods within the fiscal year. The Company is currently assessing the impact this Update may have on its consolidated financial statements.

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

Table of Contents

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

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

In January 2017, the FASB issued ASU 2017-01, *Clarifying the Definition of a Business*, which narrows the definition of a business and clarifies that to be considered a business, the fair value of gross assets acquired (or disposed of) should not be concentrated in a single identifiable asset or a group of similar identifiable assets. In addition, to be considered a business, an acquisition would have to include an input and a substantive process that together will significantly contribute to the ability to create an output. Also, the amendments narrow the definition of the term output so that it is consistent with how outputs are defined in ASC Topic 606, *Revenue from Contracts with Customers*. This ASU was effective for the Company on June 1, 2018. Adoption of this new guidance must be applied on a prospective basis. The adoption of this ASU did not have a significant impact on the Company s consolidated financial statements.

Business combinations are accounted for by applying the acquisition method in accordance with ASC 805, *Business Combinations*. Under the acquisition method, identifiable assets acquired and liabilities assumed are measured at their fair values as of the date of acquisition and are recognized separately from goodwill. The results of operations of the acquired entity are included in the consolidated statement of income from the date of acquisition. Customers recognize goodwill when the acquisition price exceeds the estimated fair value of the net assets acquired.

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 November 30, 2018. Each share of the Series B is convertible into ten shares of the Company s $0.001 par value common stock, including any accrued dividends, with an effective fixed conversion price of $0.50 per share. The holders of the Series B can only convert their shares to common shares provided the Company has sufficient authorized common shares at the time of conversion. Accordingly, the conversion option was contingent upon the Company increasing its authorized common shares, which occurred in April 2010, when the Company s stockholders approved an increase in the authorized shares of common stock to 100,000,000. At the commitment date, which occurred upon such stockholder approval, the conversion option related to the Series B was beneficial. The intrinsic value of the conversion option at the commitment date resulted in a constructive dividend to the Series B holders of approximately $6,000,000. The constructive dividend increased and decreased additional paid-in capital by identical amounts. The Series B has liquidation

Table of Contents

preferences over the common shares at $5.00 per share plus any accrued dividends. Dividends are payable to the Series B holders when declared by the board of directors at the rate of $0.25 per share per annum. Such dividends are cumulative and accrue whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available. The Series B holders have no voting rights. As of November 30, 2018 and May 31, 2018, the undeclared, accrued dividends were approximately $205,000 and $199,000, respectively, or 410,000 and 387,000 shares of common stock, respectively.

Short-term Convertible Notes

During the fiscal year ended May 31, 2018, the Company issued approximately $4.89 million in aggregate principal of short-term Convertible Notes, with a maturity date of January 31, 2018, and related warrants to investors for cash. The principal amount of the short-term Convertible Notes, including any accrued but unpaid interest thereon, was convertible at the election of the holder at any time into shares of common shares at any time prior to maturity at a conversion price of $0.75 per share. The short-term Convertible Notes bore simple interest at the annual rate of 7%. Principal and accrued interest, to the extent not previously paid or converted, is due and payable on the maturity date. At the commitment date, the Company determined that the conversion feature related to these short-term Convertible Notes to be beneficial to the investors. As a result, the Company determined the intrinsic value of the beneficial conversion feature utilizing the fair value of the underlying common stock on the commitment dates and the effective conversion price after discounting the short-term Convertible Notes for the fair value of the related warrants.

In connection with the sale of the short-term Convertible Notes, detachable common stock warrants to purchase a total of 4,025,656 common shares, with an exercise price of $1.00 per share and a five-year term were issued to the investors. The Company determined the fair value of the warrants at issuance using the Black-Scholes option pricing model utilizing certain weighted average assumptions, such as expected stock price volatility, expected term of the warrants, risk-free interest rates and expected dividend yield at the grant date.

	2018
Expected dividend yield	0%
Stock price volatility	69.80%
Expected term	5 year
Risk-free interest rate	1.77-1.93%
Grant-date fair value	$0.30-$0.39

The fair value of the warrants, coupled with the beneficial conversion features, were recorded as a debt discount to the short-term Convertible Notes and a corresponding increase to additional paid-in capital was amortized over the term of the short-term Convertible Notes. The Company incurred debt discount of approximately $1.5 million related to the beneficial conversion feature and detachable warrants issued with the short-term Convertible Notes during the year ended May 31, 2018. Accordingly, the Company recognized approximately $-0- and $1.2 million of non-cash debt discount during the six months ended November 30, 2018 and November 30, 2017. In connection with the short-term Convertible Notes, the Company incurred direct issuance costs of approximately $0.4 million during the year ended May 31, 2018. The issuance costs were amortized over the term of the short-term Convertible Notes and accordingly, the Company recognized approximately $-0- and $0.3 million of debt issuance costs during the six months ended November 30, 2018 and November 30, 2017, respectively.

On January 31, 2018, in connection with a registered direct equity offering, as fully described in Note 11, the short-term Convertible Notes in an aggregate principal amount of $5,788,500, plus accrued unpaid interest of approximately $243,000 were sold for 12,062,728 shares of common stock. The short-term Convertible Note investors

also received warrants to purchase 7,718,010 shares of common stock. The securities were sold at a combined purchase price of $0.50 per share of common stock and related warrants, for aggregate gross proceeds to the Company of approximately $6.0 million. The Company repaid one short-term Convertible Note, including accrued interest in the aggregate of approximately $259,000. During the six months ended November 30, 2018 and November 30, 2017, the Company recognized approximately $-0- and $75,000, of interest expense related to the short-term Convertible Notes.

Table of Contents

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

	November 30, 2018	May 31, 2018
Face amount of short-term Convertible Notes	$	$ 6,038,500
Unamortized discount		
Registered direct equity offering		(5,788,500)
Note repayment		(250,000)
Carrying value of short-term Convertible Notes	$	$

Long-term Convertible Note

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

In connection with the Note, the Company recorded debt discount of $0.6 million and debt issuance costs of $0.1 million. The discount and issuance costs will be amortized over the life of the Note, and accordingly, the Company recognized approximately $20,000 and $-0- amortization of debt issuance costs for the six months ended November 30, 2018 and November 30, 2017, respectively and approximately $118,000 and $-0- of amortization of debt discount for the six months ended November 30, 2018 and November 30, 2017, respectively.

Effective November 15, 2018, the Note was amended to allow the Investor to redeem the monthly redemption amount of $350,000 in cash or stock, at the lesser of (i) $0.55, or (ii) the lowest closing bid price of the Company s common stock during the 20 days prior to the conversion, multiplied by a conversion factor of 85%. The variable rate redemption provision meets the definition of a derivative instrument and subsequent to the amendment, it no longer meets the criteria to be considered indexed to the Company s own stock. As of November 15, 2018, the redemption provision requires bifurcation as a derivative liability at fair value under the guidance in ASC Topic No. 815, Derivatives and Hedging.

The amendment of the Note was also evaluated under ASC Topic 470-50-40, Debt Modifications and Extinguishments. Based on the guidance, the instruments were determined to be substantially different, and debt extinguishment accounting was applied. We recorded approximately $1.5 million as an extinguishment loss, which was the difference in the net carrying value of the Note prior to the amendment of approximately $5.4 million, and the fair value of the Note and embedded derivatives after the amendment of approximately $6.9 million. The extinguishment loss includes a write-off of unamortized debt issuance costs and the debt discount associated with the original Note. During the six months ended November 30, 2018 and November 30, 2017, the Company recognized

approximately $248,000 and $-0-, of interest expense related to the Notes.

Activity related to the Note was as follows:

	November 30, 2018			
	Short term	Long term	Total	May 31, 2018
Face amount of convertible promissory note	$	$	$	$
June 26, 2018 convertible promissory note	2,100,000	3,600,000	5,700,000	
Monthly redemption	700,000	(700,000)		
Unamortized discount at August 31, 2018	(344,614)	(281,628)	(626,242)	
Carrying value of convertible notes at August 31, 2018	$ 2,455,386	$ 2,618,372	$ 5,073,758	$
Carrying value of convertible notes at November 30, 2018	$ 4,200,000	$ 1,396,974	$ 5,596,974	$

Table of Contents

Note 5 Derivative Liabilities

The investor and placement agent warrants, issued in connection with a registered direct offering in September 2016, contained 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, whereby such other Person or group acquires more than 50% of the outstanding common stock). If a fundamental transaction occurs in which the consideration issued consists principally of cash or stock in a successor entity, then the warrantholder has the option to receive cash equal to the fair value of the remaining unexercised portion of the warrant. Due to this contingent cash settlement provision, the investor and placement agent warrants require liability classification as derivatives in accordance with ASC 480 and ASC 815 and are recorded at fair value.

The following tables summarize the fair value of the warrant derivative liability and related common shares as of inception date September 15, 2016, May 31, 2018, August 31, 2018 and November 30, 2018:

	Shares Indexed	Derivative Liability
Inception date September 15, 2016	7,733,334	$ 5,179,200
Balance May 31, 2018	7,733,334	$ 1,323,732
Balance August 31, 2018	7,733,334	$ 2,071,199
Balance November 30, 2018	7,733,334	$ 1,789,066

The Company recognized approximately $466,000 of non-cash loss and approximately $467,000 of non-cash gain, due to the changes in the fair value of the liability associated with such classified warrants during the six months ended November 30, 2018 and November 30, 2017, respectively.

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

The Company estimated the fair value of the warrant derivative liability as of inception date September 15, 2016, May 31, 2018 and November 30, 2018, using the following assumptions:

	September 15, 2016	May 31, 2018	November 30, 2018
Fair value of underlying stock	$ 0.78	$ 0.49	$ 0.58
Risk free rate	1.20%	2.63%	2.83%
Expected term (in years)	5	3.3	2.79
Stock price volatility	106%	64%	62%
Expected dividend yield			
Probability of Fundamental Transaction	50%	50%	95%
Probability of holder requesting cash payment	50%	50%	50%

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

As described above in Note 4, the redemption provision embedded in the Note required bifurcation and measurement at fair value as a derivative. The fair value of the convertible note redemption provision derivative liability was calculated using a Monte Carlo Simulation which uses randomly generated stock-price paths obtained through a Geometric Brownian Motion stock price simulation. Various assumptions used in the valuation model included: annual volatility of 58.8%, risk free rate of 2.78%, an exercise factor of 2x and an expected term of 1.61 years.

The fair value of the derivative liability resulting from the redemption provision was approximately $1.28 million as of its inception date, November 15, 2018 and November 30, 2018. The fair value of the redemption provision will be significantly influenced by the fair value of the Company s stock price, stock price volatility, changes in interest rates and management s assumptions related to the redemption factor. The Company recognized approximately $1,100 of non-cash loss, due to the changes in the fair value of the liability associated with such classified redemption provision between the inception date and November 30, 2018.

Table of Contents

The following table summarizes the fair value of the convertible note redemption provision derivative liability as of inception date November 15, 2018 and November 30, 2018:

	Net Proceeds	Derivative Liability
Inception date, November 15, 2018	$ 5,000,000	$ 1,284,998
Balance November 30, 2018	$ 5,000,000	$ 1,286,076

The Company estimated the fair value of the redemption provision using the following assumptions on the closing date of November 15, 2015 and November 30, 2018:

	November 15, 2018	November 30, 2018
Fair value of underlying stock	$ 0.57	$ 0.58
Risk free rate	2.78%	2.78%
Expected term (in years)	1.61	1.61
Stock price volatility	58.8%	58.8%
Expected dividend yield		
Discount factor	85%	85%

Note 6 Stock Options and Warrants

The Company has one active stock-based equity plan at November 30, 2018, the CytoDyn Inc. 2012 Equity Incentive Plan, as amended (the 2012 Plan) and one stock-based equity plan that is no longer active, but under which certain prior awards remain outstanding, the CytoDyn Inc. 2004 Stock Incentive Plan (the 2004 Plan and, together with the 2012 Plan, the Incentive Plans). The 2012 Plan was approved by stockholders at the Company s 2012 annual meeting to replace the 2004 Plan. The 2012 Plan was amended by stockholder approval in February 2015 to increase the number of shares available for issuance from 3,000,000 to 5,000,000 shares of common stock and in March 2016 to increase the number of shares available for issuance from 5,000,000 to 7,000,000 shares of common stock. At the annual meeting of stockholders held on August 24, 2017, the stockholders approved an amendment to the 2012 Plan to increase the number of shares available for issuance from 7,000,000 to 15,000,000 shares of common stock. As of November 30, 2018, the Company had 553,048 shares available for future stock-based grants under the 2012 Plan.

Stock Options

During the six months ended November 30, 2018, the Company granted annual stock option awards to directors to purchase a total of 680,822 shares of common stock. The exercise price of the stock option awards is $0.49 per share, except for one stock option award covering 80,822 shares of common stock, which has an exercise price of $0.47 per share. These stock option awards vest quarterly over one year and have a ten-year term. The grant date fair value related to these stock options was $0.31 per share, except the stock option award covering 80,822 shares of common stock, which was $0.30 per share. These awards reflect an increase in the annual non-employee director stock option award from 75,000 to 100,000 shares per year, effective for fiscal year 2019.

During the six months ended November 30, 2018, the Company granted a stock option award covering 950,000 shares of common stock with an exercise price of $0.49 per share, to its Executive Chairman. This stock option award vests ratably over 24 months, has a ten-year term and a grant date fair value of $0.41 per share.

During the six months ended November 30, 2018, the Company granted stock options, covering an aggregate of 875,000 shares of common stock, to executive management and employees with exercise prices of $0.49 per share. The stock option awards vest annually over three years, with a ten-year term and grant date fair values of $0.31 per share. Additionally, the Company granted a stock option covering an aggregate of 1,000,000 shares of common stock, to an officer with an exercise price of $0.565 per share. The stock option award vests 50% upon grant and 50% on April 8, 2019; it has a ten-year term and grant date fair value of $0.30 per share. The Company also granted stock options, covering an aggregate of 500,000 shares of common stock to directors for consulting services with an exercise price of $0.565 per share. The stock option awards vest upon grant, have a ten-year term and grant date fair value of $0.30 per share.

During the six months ended November 30, 2018, the Company granted a stock option award covering 350,000 shares of common stock with an exercise price of $0.551 per share to Dr. Richard G. Pestell, M.D., Ph.D., in connection with his employment agreement as Chief Medical Officer and the closing of the ProstaGene transaction described in Note 7. The stock option award vests annually over three years, with a ten-year term and grant date fair value of $0.30 per share.

Table of Contents

Warrants

On June 15, 2018, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued warrants covering 1,970,000 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.75 per share. In connection with the registered direct offering, the Company also issued warrants covering 133,600 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of $0.55 per share.

During the six months ended November 30, 2018, in connection with a private equity offering, as fully described in Note 10, the Company issued common stock warrants covering a total of 22,478,585 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.75 per share. In connection with this offering, the Company also issued common stock warrants covering 4,245,117 shares of common stock to the placement agent. The placement agent warrants have a five-year term, an exercise price of $0.50 per share and a cashless exercise provision.

During the six months ended November 30, 2018, the Company issued compensable warrants covering an aggregate of 300,000 shares of common stock to consultants. The warrants have a five-year term, an exercise price of $0.56 per share and a grant date fair value of $0.30 per share.

During the year ended May 31, 2018, the Company determined to extend the expiration dates of certain warrants from May 31, 2017 to June 30, 2017 covering 3,295,000 shares of common stock. The warrants were originally issued in connection with 2012 convertible promissory notes and had an amended exercise price of $1.00 per share. The extension to June 30, 2017 was contingent upon immediate exercise of the warrants at a reduced exercise price of $0.50 per share. The Company received proceeds of approximately $1.6 million and, pursuant to U.S. GAAP, the Company recognized non-cash inducement interest expense of approximately $0.8 million, which represented the incremental increase in the fair value of the extended warrants.

Compensation expense related to stock options, compensatory warrants and common stock reserved for advisory services, for the three and six months ended November 30, 2018 and November 30, 2017 was approximately $1.2 million and $275,000 and $1.5 million and $530,000, respectively. The grant date fair value of options and compensatory warrants vested during the three and six month periods ended November 30, 2018 and November 30, 2017 was approximately $485,000 and $127,000 and $1.2 million and $574,000, respectively. As of November 30, 2018, there was approximately $5.7 million of unrecognized compensation expense related to share-based payments for unvested options, which is expected to be recognized over a weighted average period of 2.69 years.

The following table represents stock option and warrant activity as of and for the six months ended November 30, 2018:

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

Granted	33,483,124		0.69			
Exercised						
Forfeited/expired/cancelled	(10,031,717)		0.75			
Options and warrants outstanding - November 30, 2018	155,836,676		0.78	3.97		769,360
Outstanding exercisable - November 30, 2018	150,960,607	$	0.78	3.80	$	565,356

Note 7 Acquisition of Patents and Intangibles

As discussed in Note 9 below, the Company consummated an asset purchase on October 16, 2012, and paid $3,500,000 for certain assets, including intellectual property, certain related licenses and sublicenses, FDA filings and various forms of the leronlimab (PRO 140) drug substance. The Company followed the guidance in Financial Accounting Standards Topic 805 to determine if the Company acquired a business. Based on the prescribed accounting, the Company acquired assets and not a business. As of November 30, 2018, the Company has recorded and is amortizing $3,500,000 of intangible assets in the form of patents. The Company estimates the acquired patents have an estimated life of ten years. Subsequent to the acquisition date, the Company has continued to expand, amend and file new patents central to its current clinical trial strategies, which, in turn, have extended the protection period for certain methods of using leronlimab (PRO 140) and formulations comprising leronlimab (PRO 140) out through at least 2031 and 2038, respectively, in various countries.

Table of Contents

On November 16, 2018, the Company completed the acquisition of substantially all of the assets of ProstaGene, LLC (ProstaGene), a biotechnology start-up company, which included patents related to clinical research, a proprietary CCR5 technology for early cancer diagnosis, and a noncompetition agreement with ProstaGene s founder and Chief Executive Officer, Richard G. Pestell, M.D., Ph.D. The acquisition of ProstaGene s assets expands the Company s clinical development of leronlimab (PRO 140) into cancer indications and commercialization of certain cancer diagnostic tests.

The aggregate purchase price paid for the ProstaGene acquisition was $11,558,000 based on the issuance of 20,278,000 shares of common stock of CytoDyn at $0.57 per share, including 1,620,000 shares earned, but not yet issued, by the investment bank for advisory services. In connection with the purchase, the Company entered into a Stock Restriction Agreement (Agreement), restricting the transfer of 8,342,000 shares of common stock payable to Dr. Pestell for a three-year period from the closing date of the transaction. In the event Dr. Pestell s employment with the Company is terminated, as defined in the employment agreement, the Company will have an option to repurchase such Restricted Shares from Dr. Pestell at a purchase price of $0.001 per shares. The Restricted Shares will vest and be released from the Agreement in three equal annual installments commencing one year after the closing date of the acquisition of ProstaGene.

A summary of the net purchase price and allocation to the acquired assets is as follows:

	ProstaGene, LLC
CytoDyn Inc. Equity	$ 11,558,000
Acquisition Expenses	741,297
Release of Deferred Tax Asset	2,826,919
Total Cost of Acquisition	$ 15,126,216
Intangible assets	$ 15,126,216
Other	
Allocation of Acquisition Costs	$ 15,126,216

Assets acquired from ProstaGene include (1) patents issued in the United States and Australia related to Prostate Cancer Cell Lines, Gene Signatures and Uses Thereof and Use of Modulators of CCR5 in the Treatment of Cancer and Cancer Metastasis, (2) an algorithm used to identify a 14-gene signature to predict the likelihood and severity of cancer diagnoses, and (3) a noncompetition agreement in connection with an employment agreement with Dr. Pestell as Chief Medical Officer of the Company. The fair value of the assets acquired approximates the consideration paid. The Company did not assume any liabilities. The Company accounted for the ProstaGene acquisition as an asset acquisition under ASC 805-10-55 Business Combinations because the assets retained from ProstaGene do not include an assembled workforce, and the gross value of the assets acquired meets the screen test in ASC 805-10-55-5A related to substantially all of the fair value being concentrated in a single asset or group of assets (i.e., the proprietary technology and patents) and, thus, is not considered a business. Thus, management concluded that the acquisition did not include both an input and substantive processes that together significantly contribute to the ability to create outputs.

The fair value of the technology acquired is identified using the Income Approach. The fair value of the patents acquired is identified using the Cost to Reproduce Method. The fair value of noncompetition agreement acquired is

identified using the Residual Value Method. Goodwill is not recorded as the transaction represents an asset acquisition in accordance with ASU 2017-01. Acquisition costs for asset acquisitions are capitalized and included in the total cost of the transaction. In addition, pursuant to ASC 805, the net tax effect of the deferred tax liability arising from the book to tax basis differences is recorded as a cost of the acquisition.

Table of Contents

The following presents intangible assets activity:

	November 30, 2018	May 31, 2018
Gross carrying amounts	$ 3,500,000	$ 3,500,000
Intangible asset acquisition:		
ProstaGene, LLC	15,126,216	
Accumulated amortization	(2,209,254)	(1,968,846)
Total amortizable intangible assets, net	16,416,962	1,531,154
Patents currently not amortized	35,989	35,989
Carrying value of intangibles, net	$ 16,452,951	$ 1,567,143

Amortization expense related to intangible assets patents was approximately $152,900 and $240,400 and $87,500 and $175,000 for the three and six months ended November 30, 2018 and 2017, respectively. The estimated aggregate future amortization expense related to the Company s intangible assets with finite lives is estimated, on average, to be approximately $1.6 million per year for the next five years.

Note 8 License Agreements

The Company has a license agreement with a third-party licensor covering the licensor s system know-how technology with respect to the Company s use of proprietary cell lines to manufacture new leronlimab (PRO 140) material. The Company accrues an annual license fee of £300,000 (approximately US$400,000 utilizing current exchange rates), which is payable annually in December, except for the December 2017 and 2018 payments, which were extended to March 15, 2018 and March 15, 2019, respectively. Future annual license fees and royalty rate will vary depending on whether the Company manufactures leronlimab (PRO 140), utilizes the third-party licensor as a contract manufacturer, or utilizes an independent party as a contract manufacturer. The licensor does not charge an annual license fee when it serves as the manufacturer. In addition, the Company will incur royalties of up to 0.75% to 2% of net sales, depending upon who serves as the manufacturer, when the Company commences their first commercial sale, which will continue as long as the license agreement is maintained.

Note 9 Commitments and Contingencies

Under the Progenics Purchase Agreement, the Company acquired rights to the HIV viral-entry inhibitor drug candidate leronlimab (PRO 140), a humanized anti-CCR5 monoclonal antibody, as well as certain other related assets, including the existing inventory of bulk leronlimab (PRO 140) drug product, intellectual property, certain related licenses and sublicenses, and FDA regulatory filings. In connection with purchase, the Company has two remaining milestone payments, (i) $0.5 million upon filing a BLA with the FDA or non-U.S. equivalent regulatory body and (ii) $5.0 million, which will become due at the time of the first U.S. new drug application approval by the FDA or other non-U.S. approval for the sale of leronlimab (PRO 140). In addition, the Company will incur royalty payments of up to 5% on net sales during the period beginning on the date of the first commercial sale of leronlimab (PRO 140) until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years, in each case determined on a country-by country basis. During the year ended May 31, 2016 the Company paid a milestone obligation of $1.5 million owed to Progenics as a result of the first dosing in a U.S. Phase 3 trial. To the extent that the remaining milestone payment and royalties are not timely made, under the terms of the Progenics Purchase Agreement, Progenics has certain repurchase rights relating to the assets sold to the Company thereunder. As of the

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

Payments to the third-party licensor and to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the PDL License), between Protein Design Labs (now AbbVie Inc.) (PDL) and Progenics, which was assigned to the Company in the Progenics Purchase Agreement, pursuant to which the Company has an exclusive worldwide license to develop, make, have made, import, use, sell, offer to sell or have sold products that incorporate the humanized form of the leronlimab (PRO 140) antibody developed by PDL under the agreement the Company has paid various milestone obligations, with one remaining milestone payment of $0.5 million, which will become due upon FDA approval or approval by another non-U.S. equivalent regulatory body. In addition, the Company will incur royalties of up to 3.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of $150,000 or until annual royalties paid exceed that amount. To the extent the remaining milestone payment and royalties are not timely made, under the terms of the PDL License, AbbVie Inc. has certain termination rights relating to the Company s license of leronlimab (PRO 140) thereunder. As of the date of this filing, it is management s conclusion that the probability of achieving the subsequent future scientific research milestones is not reasonably determinable, thus the future milestone payments payable to PDL, Progenics and its sub-licensors are deemed contingent consideration and, therefore, are not currently accruable.

Table of Contents

The Company has entered into project work orders, as amended, for each of its clinical research organization (CRO) and related laboratory vendors. Under the terms of these agreements, the Company incurs execution fees for direct services costs, which are recorded as a current asset. In the event the Company were to terminate any trial, it may incur certain financial penalties which would become payable to the CRO. Conditioned upon the form of termination of any one trial, the financial penalties may range up to $0.2 million. In the remote circumstance that the Company would terminate all clinical trials, the collective financial penalties may range from an approximate low of $0.5 million to an approximate high of $1.1 million. During the year ended May 31, 2017, the Company entered into agreements with contract manufacturing companies. Under the terms of the agreements, the Company incurred approximately $2.1 million of execution fees for process validation and manufacturing activities, which have been utilized. In the event the Company were to terminate any of the agreements, it may incur certain financial penalties which would become payable to the manufacturers. Conditioned on the timing of termination, the financial penalties may range up to an approximate high of $0.3 million. From time to time, the Company is involved in routine litigation that arises in the ordinary course of business. There are no pending significant legal proceedings to which the Company is a party for which management believes the ultimate outcome would have a material adverse effect on the Company s financial position.

Note 10 Private Securities Offerings

During the six months ended November 30, 2018, the Company conducted a private equity offering, in which accredited investors purchased unregistered common stock at $0.50 per share with warrant coverage rate of 50%. Pursuant to the offering, the Company sold a total of 44,957,170 shares of common stock, $0.001 par value, for aggregate gross proceeds of approximately $22.5 million and issued to the investors five-year warrants covering 22,478,585 shares of common stock with an exercise price of $0.75 per share. The Company received net proceeds from the offering of approximately $19.9 million. In addition, the placement agent received warrants covering 4,245,117 shares of common stock (or 10% of total shares sold to investors) with a per share exercise price of $0.50, a five-year term and include a cashless exercise provision. The Company also paid a one-time non-accountable expense fee of $25,000 to the placement agent for its services in connection with the offering.

Note 11 Registered Direct Equity Offerings

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

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

On June 15, 2018, the Company entered into subscription agreements with certain investors for the sale of 1,970,000 shares of common stock at a purchase price of $0.50 per shares in a registered direct offering, pursuant to a registration statement on Form S-3. The investors in the offering also received warrants to purchase 1,970,000 shares of common stock with an exercise price of $0.75 per share and a five-year term. The Company received net proceeds from the offering of approximately $0.9 million. In addition, the placement agent received warrants covering 133,600 shares of common stock (or 8% of total shares sold to investors) with a per share exercise price of $0.55, a five-year term and include a cashless exercise provision.

Note 12 Employee Benefit Plan

The Company has an employee savings plan (the Plan) pursuant to Section 401(k) of the Internal Revenue Code (the Code), covering all of its employees. The Company makes a qualified non-elective contribution of 3%, which consequently vests immediately. In addition, participants in the Plan may contribute a percentage of their compensation, but not in excess of the maximum allowed under the Code. During the three and six months ended November 30, 2018 and 2017, the Company incurred an expense of approximately $15,200 and $31,000 and $10,800 and $21,500, respectively, for qualified non-elective contributions.

Table of Contents

Note 13 Related Party Transactions

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

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

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

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

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

On July 12, 2018, the Company announced certain leadership changes in connection with the strategic expansion and entry into certain cancer and immunologic indications. In connection with such leadership changes and effective July 11, 2018, Denis R. Burger, Ph.D. and A. Bruce Montgomery, M.D., resigned as members of the Company s board of directors. Dr. Burger also resigned as Chief Science Officer of the Company, which was not an executive officer position. On July 10, 2018, In connection with the resignations of Dr. Burger and Dr. Montgomery, the Company s board of directors determined to accelerate the vesting of all outstanding and unvested stock options held by Dr. Burger and Dr. Montgomery. Upon the effectiveness of their resignations, stock options covering 500,000 shares 100,000 shares, held by Dr. Burger and Dr. Montgomery, respectively became fully vested. The stock options retained their exercise period through their respective expiration dates and the terms of the stock options remained otherwise unchanged.

On November 16, 2018, the Company closed its acquisition of ProstaGene, as described in Note 7. In connection with the closing of the acquisition, the Company hired Dr. Pestell as its Chief Medical Officer. As previously disclosed by the Company, Dr. Pestell is the holder of approximately 77.2% of the outstanding equity interests in ProstaGene and consequently holds an indirect interest in approximately (i) 8,611,427 of 13,258,000 shares of the Company s common stock, currently pending distribution by ProstaGene to its members, and (ii) 4,171,013 of 5,400,000 shares of common stock, currently held in escrow for the benefit of ProstaGene and its members, which are subject to forfeiture to satisfy certain indemnity obligations of ProstaGene and will be released ratably every six months over the eighteen-month period following the closing date. In addition, as specified in a Stock Restriction Agreement with the Company entered into on the closing date, 8,342,000 additional shares of common stock previously distributed to Dr. Pestell in

the ProstaGene acquisition are currently subject to transfer restrictions and forfeiture obligations, subject to certain continuing employment obligations of Dr. Pestell, which will vest ratably each year over the three-years period following the closing date.

As specified in a Confidential Information, Inventions and Noncompetition Agreement between the Company and Dr. Pestell, which was entered into on the closing date of the ProstaGene acquisition, the Company may participate in the development and license of certain intellectual property created by Dr. Pestell, in connection with Dr. Pestell s ongoing research obligations to outside academic institutions. The Company also has the right to work with Dr. Pestell to manage any potential conflict between the Company s clinical development activities and such ongoing research obligations.

Table of Contents

Note 14 Subsequent Events

Between December 7, 2018 and December 11, 2018, the Company conducted a private equity offering, in which accredited investors purchased common stock at $0.50 per share with warrant coverage ratio of 50%. Pursuant to the offering, the Company sold a total of 2,018,000 shares of common stock, $0.001 par value, for aggregate gross proceeds of approximately $1.0 million and issued to the investors five-year warrants covering 1,009,000 shares of common stock with an exercise price of $0.75 per share. In connection with the equity offering, the Company paid an aggregate cash fee of approximately $0.1 million to the placement agent and issued warrants covering an aggregate of 201,800 shares of common stock to the placement agent as additional compensation. The placement agent warrants have a five-year term and an exercise price of $0.50 per share and a cashless exercise provision.

On December 10, 2018, Anthony D. Caracciolo resigned as the Chairman of the Board, but remains a director and Scott A. Kelly, M.D., was named Chairman of the Board. On December 19, 2018, the Compensation Committee of the Board approved an amendment to certain compensation arrangements for Anthony D. Caracciolo, pursuant to which his employment with the Company would be extended through April 16, 2019, at a salary reduced from $16,667 to $5,000 per month, with continuing benefits. In addition, the Compensation Committee approved an extension to 10-years of the expiration terms of certain previously awarded stock options covering an aggregate of 150,000 shares of the Company s common stock, provided that such stock options are out-of-the-money upon the date of such extension. These arrangements were conditioned upon Mr. Caracciolo s agreement to resign from the Board upon identification by the Company of an appropriately qualified candidate to fill the vacancy. Mr. Caracciolo has agreed to the foregoing terms. These arrangements were not the result of any disagreement with the Company on any matter relating to the Company s operations, policies or practices.

On December 22, 2018 the board of directors appointed Nitya G. Ray, Ph.D., as Chief Technology Officer Head of Process Sciences, Manufacturing and Supply Chain. In connection with Dr. Ray s appointment, the Company and Dr. Ray entered into an Employment Agreement that provides for (i) an annual base salary of $335,000, (ii) a target annual bonus equal to 50% of base salary, (iii) an initial signing bonus of $100,000 to be paid in two equal installments of $50,000 over the course of six months from the date of signing and (iv) other customary benefits described in the form of employment agreement. In connection with the appointment of Dr. Ray, the Company also issued Dr. Ray a stock option award under the Company s equity incentive plan, covering 400,000 shares of the Company s common stock, vesting in three equal annual installments from the grant date.

On December 27, 2018, the Company received a redemption notice from the holder of the Company s convertible note issued on June 26, 2018, requesting the redemption of $100,000 of the outstanding balance thereof. In satisfaction of the redemption notice, the Company issued 255,532 shares of common stock to the note holder in accordance with the terms of the convertible note. Following the redemption, the outstanding balance of the convertible note, including accrued but unpaid interest, was approximately $5.9 million.

Beginning December 28, 2018 through January 8, 2019, the Company issued $3.1 million (of which $0.5 million was purchased by Michael A. Klump, a director, on terms identical to all other investors) in aggregate principal amount of unsecured convertible promissory notes (the Notes) and related warrants (the Warrants) to purchase common stock of the Company (the Common Stock), to accredited investors (the Private Placements) pursuant to subscription agreements entered into with each investor (collectively, the Subscription Agreements), in exchange for cash in an equal amount. The proceeds of the Private Placements are anticipated to be used for general working capital and to fund clinical trials.

The principal amount of the Notes plus unpaid accrued interest at an annual rate of 10.0% is convertible at the election of the holders into shares of Common Stock at any time prior to maturity, at an initial conversion price of $0.50 per

share, with an aggregate of 6,200,000 shares of the Company s Common Stock initially underlying the Notes. As part of the investment in the Notes, the Company also issued Warrants exercisable for 50% of the shares into which the Notes are convertible, with Warrants for an aggregate of 3,100,000 shares of Common Stock issued in the Private Placements. The Warrants are exercisable at a price of $0.30 per share. The Warrants are currently exercisable in full and will expire five years from the date of issuance. The Subscription Agreements contain certain piggyback registration rights relating to resales of shares of Common Stock underlying the Notes and the Warrants.

As a result of the issuance of the Notes, pursuant to the terms of the Placement Agent Agreement, dated July 26, 2018, entered into in connection with a recently completed private securities offering, the placement agent in that offering earned a tail fee comprising warrants exercisable for 620,000 shares of Common Stock (the Placement Agent Warrants) and a cash fee of $372,000. The Placement Agent Warrants are exercisable at a price of $0.50 per share and will expire five years from the date of issuance. The Placement Agent Warrants provide for cashless exercise.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

This filing, contains forward-looking statements. The words anticipate, believe, expect, intend, predict, plan, estimate, project, continue, could, may, and similar terms and expressions are intended to identify forward-looki statements. These statements include, among others, information regarding future operations, future capital expenditures and future net cash flows. Such statements reflect current views with respect to future events and financial performance and involve risks and uncertainties, including, without limitation, regulatory initiatives and compliance with governmental regulations, the sufficiency of the Company s cash position and the ability to raise additional capital, clinical priorities, the results of clinical trials for the Company s drug candidate, and various other matters, many of which are beyond our 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 our financial condition and results of operations should be read in conjunction with the other sections of this Quarterly Report, including our 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 our financial condition, operations, plans, objectives and performance that involve risk, uncertainties and assumptions. The actual results may differ materially from those anticipated and set forth in such forward-looking statements.

Results of Operations

Clinical Trials Update

Phase 2b Extension Study for HIV, as Monotherapy

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

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

This is a pivotal 25-week trial for leronlimab (PRO 140) as a combination therapy to a highly active antiretroviral therapy (HAART) drug regimens. This trial was a double blind, placebo controlled trial. In late February 2018, we reported that we had enrolled 52 patients and the trial s primary endpoint was achieved with a p-value of 0.0032. The primary endpoint for efficacy was defined as 0.5log reduction in viral load after one week of therapy with leronlimab (PRO 140) in combination with the patient s failing HAART regimen. Following the achievement of primary endpoint, the trial is continuing to enroll under an open label for safety analysis. Forty-seven out of fifty-two patients have successfully completed this trial and most of the patients have transitioned into an FDA-cleared rollover study, as described below, in order to provide continued access to leronlimab (PRO 140) therapy, at the request of their treating physician. Management projects that the total costs of this trial, including the open label portion, may range from $12 million to $14 million. The successful results of this trial will serve as the basis for our BLA filing, which is expected to be completed in the first half of 2019.

Rollover Study for HIV, as Combination Therapy

This study is designed for patients who successfully complete the Phase 2b/3 Combination Therapy trial and for whom the treating physicians request a continuation of leronlimab (PRO 140) therapy in order to maintain suppressed viral load. If this study enrolls 40 patients from the Phase 2b/3 trial and all patients remain in the rollover study for one year, management estimates the cost of this study to be approximately $3 million to $4 million.

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

This is a trial of over 370 patients that assesses using leronlimab (PRO 140) subcutaneously as a long-acting single-agent maintenance therapy for 48 weeks in patients with suppressed viral load with CCR5-tropic HIV-1 infection. The primary endpoint is the proportion of participants with a suppressed viral load to those who experienced virologic failure. The secondary endpoint is the length of time to virologic failure. Enrollment of the first several patients was announced in December 2016. We are currently evaluating two higher-dose arms, one with 525 mg dose (a 50% increase from the original dosage of 350 mg), as well as a 700 mg dose. We believe that a higher dose of 700 mg will result in a much higher response rate, which is supported by preliminary data and

Table of Contents

most likely be the dose used for leronlimab (PRO 140) in the future. The estimates for the total cost of this trial currently range from $22 million to $25 million, with an expected $8 million to $9 million remaining in connection with maintaining patients to provide safety data for the BLA filing. We expect enrollment to be completed in 2019. Subject to the continuation of a high responder rate from preliminary data from the 700 mg dose arm, this trial may be discontinued if and when we successfully file a protocol for a pivotal Phase 3 trial for monotherapy and receives clearance from the FDA to initiate such a trial.

Phase 2 Trial for Graft-versus-Host Disease

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

Cancer and Immunological Applications for Leronlimab (PRO 140)

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

The target of leronlimab (PRO 140) is the important G protein coupled receptor CCR5. CCR5 is more than the pathway to HIV replication; it is also a crucial component of inflammatory responses and is a key mediator in many cancer metastasis. We believe this opens the potential for multiple pipeline opportunities for leronlimab (PRO 140). CCR5 is a protein located on the surface of white blood cells and cancer epithelial cells that serves as a receptor for attractants called chemokines. Chemokines are the key orchestrators of leukocyte trafficking by attracting immune cells to the sites of inflammation.

At the site of an inflammatory reaction, chemokines are released. These chemokines are specific for CCR5 and cause the migration of T-cells to these sites promoting further inflammation. We believe the mechanism of action of leronlimab (PRO 140) has the potential to block the movement of T-cells to inflammatory sites, which could be instrumental in diminishing or eliminating inflammatory responses. CCR5 is also expressed on the surface of epithelial cells in certain cancers. Some disease processes that we believe could benefit from CCR5 blockade include many types of common cancers, GvHD (a reaction occurring in some patients after bone marrow transplantation), autoimmunity and chronic inflammation, such as rheumatoid arthritis and psoriasis. Recent published data by Richard G. Pestell, M.D., Ph.D., our Chief Medical Officer, has shown that the cancer cells within the tumor consist of two types of cells-one with CCR5 and others without them. The published data clearly indicated that cancer cells that can metastasize express CCR5. Metastases are the cause of death in the vast majority of cancer patients. Moreover,

Dr. Pestell s prior publication indicates that CCR5 antagonists can turn off certain calcium signaling and reduce the migration of CCR5 positive cancer cells. Inhibition of CCR5 signaling blocks the guided migration and reduces the metastasis. Leronlimab (PRO 140) has demonstrated (in an in-vitro study) that it also turns off calcium signaling and blocks breast cancer cellular invasion. Furthermore, published studies showed current chemotherapy induces CCR5, and CCR5 antagonists enhance the effectiveness of current chemotherapies, potentially allowing a reduction in chemotherapy, which may provide an improved quality of life for patients.

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

Table of Contents

As a result of the foregoing, we are expanding the clinical focus with leronlimab (PRO 140) to include the evaluation in certain cancer and immunological indications where CCR5 antagonism has shown initial promise. We recently filed an investigational new drug application (IND) with the FDA and received approval in late November 2018 to begin a clinical trial with leronlimab (PRO 140) for metastatic triple-negative breast cancer. We also previously initiated our first clinical trial with leronlimab (PRO 140) in an immunological indication a Phase 2 clinical trial with leronlimab (PRO 140) for GvHD in patients with AML or MDS who are undergoing bone marrow stem cell transplantation. As noted above, enrollment under the amended protocol for the GvHD trial has been delayed subject to increased capital resources. In addition, we also intend to explore potential strategic partnerships with certain pharmaceutical companies, including for the development of follow-on technologies involving the use of leronlimab (PRO 140) alongside their existing products.

The Company will require a significant amount of additional capital to complete the foregoing clinical trials for HIV and make its BLA submission, as well as to advance its trials for GvHD and certain cancer indications. See Liquidity and Capital Resources below.

ProstaGene Transaction

On November 16, 2018, we completed an acquisition with ProstaGene, LLC, a Delaware limited liability company (ProstaGene). The ProstaGene transaction was consummated pursuant to the Transaction Agreement (the Transaction Agreement), dated as of August 27, which provided for the purchase of substantially all of the assets and rights, and the assumption of certain liabilities and obligations, associated with ProstaGene. In order to achieve certain tax efficiencies for the selling members of ProstaGene, as an initial step in the transaction, we effected a holding company reorganization under Section 251(g) of the Delaware General Corporation Law. The terms of the ProstaGene transaction were previously reported in our Current Reports on Form 8-K filed with the Securities and Exchange Commission on November 19, 2018 and August 28, 2018. As described in Note 7 to the accompanying financial statements, the aggregate purchase price paid in the ProstaGene transaction was approximately $11.6 million, which was recorded as intangibles, including a certain proprietary technology in an algorithm, noncompetition agreements and patents. Such intangibles have estimated amortizable lives from three years to 13 years.

We are currently evaluating strategic opportunities with respect to the assets acquired in the ProstaGene transaction, including potential licensing or other opportunities to monetize intellectual property assets relating to prostate cancer diagnostics. As an integral part of the acquisition of ProstaGene, we acquired a proprietary technology that demonstrated in a retrospective clinical trial assessing patients for more than 10 years that its prostate cancer prognostic test (PCa Test) provides substantial additive discriminate value for predicting outcomes of patients diagnosed with prostate cancer compared to the intermediate Gleason score, the current standard for prostate cancer diagnosis. The clinical objective is to more precisely guide therapeutic options for men thereby avoiding unnecessary surgery (prostatectomy) and radiation and/or chemotherapy with its attendant side effects.

Results of Operations for the three months ended November 30, 2018 and 2017 are as follows:

For the three months ended November 30, 2018 and November 30, 2017, the Company had no activities that produced revenues from operations.

For the three months ended November 30, 2018, the Company incurred a net loss of approximately $14.3 million, as compared to a net loss of approximately $10.9 million for the similar period in 2017. The increase in net loss of approximately $3.4 million related primarily to increases in research and development expenses of approximately $3.8 million and increases in general and administrative expenses of approximately $1.1 million and a decrease in the non-cash benefit from change in derivative liabilities of approximately $0.6 million, a non-comparable non-cash loss

on extinguishment of debt of approximately $1.5 million, offset by a reduction in interest expenses of approximately $0.8 million and a deferred tax benefit of approximately $2.8 million, which arose from the recognition of a deferred income tax benefit from a reduction in the Company s deferred tax valuation allowance resulting from recording a deferred tax liability of $2,826,919 in connection with the acquisition of assets in the ProstaGene transaction. The deferred tax liability represents the tax effect of the difference in the carrying value of the assets and their tax basis at acquisition. The loss per share for the quarters ended November 30, 2018 and November 30, 2017 was $(0.06) and $(0.07), respectively, with the reduction in loss per share (despite an increase in aggregate net loss) caused by a significant increase in the number of shares outstanding from the prior period.

For the three months ended November 30, 2018 and November 30, 2017, operating expenses totaled approximately $15.7 million and $10.8 million, respectively, consisting of research and development, general and administrative expenses, and amortization and depreciation. The increase in operating expenses of approximately $4.9 million, or 45.6%, was attributable to increases in research and development expenses of approximately $3.8 million and increased general and administrative expenses of approximately $1.1 million. General and administrative expenses, which totaled approximately $2.7 million for the three months ended November 30, 2018, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The increase in general and administrative expenses of approximately $1.1 million, or 66%, for the three months ended November 30, 2018 was due to an increase in non-cash stock-based compensation expenses of approximately $1.0 million, in connection stock issued for advisory services and employee awards, coupled with increased insurance and investor relations expenses, offset by a reduction in expenses for professional services.

Table of Contents

Research and development (R&D) expenses, which totaled approximately $12.7 million for the three months ended November 30, 2018, increased approximately $3.8 million, or 42%, over the comparable 2017 quarter principally due to higher manufacturing-related expenses in connection with the preparation of our BLA filing. For the quarter ended November 30, 2018, R&D expenditures continue to be primarily devoted to: (1) increased CMC (chemistry, manufacturing and controls) activities to address regulatory compliance requirements of a future BLA filing and to advance the preparations for manufacturing new quantities of leronlimab (PRO 140), (2) our pivotal Phase 2b/3 combination therapy trial and our investigative Phase 2b/3 monotherapy trial, and (3) continuing activities necessary to complete the BLA filing with the FDA.

We expect R&D expenses in future periods to level off modestly to reflect completion of manufacturing activities in preparation for an anticipated BLA filing in the first half of 2019, followed by a potential strategic advancement in clinical priorities for a pivotal monotherapy trial and cancer indications, all of which are subject to the availability of sufficient additional capital. Any acceleration in clinical activities would increase R&D expenses.

For the three months ended November 30, 2018, the Company recognized a non-cash benefit associated with the decrease in fair value of derivative liabilities of approximately $0.3 million, as compared to a non-cash benefit of approximately $0.8 in the similar 2017 quarter. The warrants that contain a provision which gives rise to a derivative liability originated in September 2016. For each reporting period, we determine the fair value of the derivative liabilities and record a corresponding non-cash benefit or non-cash charge, as a consequence of a decrease or increase, respectively, in the calculated derivative liabilities.

Interest expense for the three months ended November 30, 2018 totaled approximately $1.7 million, as compared to approximately $1.0 million for the similar quarter in 2017. The components of interest expense include a loss on extinguishment of a long-term convertible note, accrued interest on a convertible note, along with the amortization of debt discount and debt issuance costs. On November 15, 2018, as previously reported, the Company amended the convertible note to include an additional feature which allows the holder to receive the redemption amount (a) in cash or (b) by converting the redemption amount into shares of common stock. The amendment caused the embedded redemption provision to require bifurcation as a liability at fair value under ASC 815 (Topic 815). In addition, management also considered the accounting for the amendment under the accounting guidance in ASC 470, Debt (Topic 470), and determined that the amendment was substantive and extinguishment accounting applied. Accordingly, the carrying value of the original debt on the modification date is derecognized and the new debt is recorded at fair value. The difference was recorded as an extinguishment loss of approximately $1.5 million.

The future trends in all expenses will be driven, in large part, by the future outcomes of clinical trials and their correlative effect on research and development expenses, as well as general and administrative expenses, in addition to manufacturing of new additional quantities of commercial leronlimab (PRO 140), along with the necessary regulatory processes to confirm its qualification for future sale, if approved. The Company requires a significant amount of additional capital and its ability to continue to fund operations will continue to depend on its ability to raise such capital. See in particular, Liquidity and Capital Resources below and Item 1A Risk Factors in our Annual Report on Form 10-K for the year ended May 31, 2018 and in our Form 10-Q for the quarterly period ended August 31, 2018 in the section titled Risk Factors in Part II, Item 1A.

Results of Operations for the six months ended November 30, 2018 and 2017 are as follows:

For the six months ended November 30, 2018 and November 30, 2017, the Company had no activities that produced revenues from operations.

For the six months ended November 30, 2018, the Company incurred a net loss of approximately $28.7 million, as compared to a net loss of approximately $22.6 million for the similar period in 2017. The increase in net loss of approximately $6.1 million related primarily to increases in research and development expenses of approximately $7.1 million, increases in general and administrative expenses of approximately $1.4 million, non-cash expense from change in derivative liabilities of approximately $0.9 million, offset by a deferred tax benefit approximately $2.8 million, and a reduction in interest expenses of approximately $0.6 million. The credit for taxes on income arose from the recognition of a deferred income tax benefit from a reduction in the Company s deferred tax valuation allowance resulting from recording a deferred tax liability of $2,826,919 in connection with the acquisition of assets in the ProstaGene LLC transaction. The deferred tax liability represents the tax effect of the difference in the carrying value of the assets and their tax basis at acquisition. The loss per share for the six months ended November 30, 2018 and November 30, 2017 was $(0.12) and $(0.15), respectively, with the reduction in loss per share (despite an increase in aggregate net loss) caused by a significant increase in the number of shares outstanding from the prior period.

For the six months ended November 30, 2018 and November 30, 2017, operating expenses totaled approximately $29.2 million and $20.6 million, respectively, consisting of research and development, general and administrative expenses, and amortization and depreciation. The increase in operating expenses of approximately $8.6 million, or 42%, was attributable to increases in research and development expenses of approximately $7.1 million and an increase in general and administrative expenses of approximately $1.4 million.

Table of Contents

General and administrative expenses, which totaled approximately $4.6 million for the six months ended November 30, 2018, were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The increase in general and administrative expenses of approximately $1.4 million, or 45%, for the six months ended November 30, 2018 over the comparable period a year ago was primarily due to an increase in non-cash stock-based compensation expenses of approximately $1.0 million in connection with common stock issued for advisory services and an employee awards.

Research and development (R&D) expenses, which totaled approximately $24.3 million for the six months ended November 30, 2018, increased approximately $7.1 million, or 41%, over the comparable 2017 period principally due to higher manufacturing-and clinical trial elated expenses. For the six-month period ended November 30, 2018, R&D expenditures continue to be primarily devoted to: (1) increased CMC (chemistry, manufacturing and controls) activities to address regulatory compliance requirements of a future BLA filing and to advance the preparations for manufacturing new quantities of leronlimab (PRO 140), (2) our pivotal Phase 2b/3 combination therapy trial and our investigative Phase 2b/3 monotherapy trial, and (3) continuing activities necessary to complete the BLA filing with the FDA.

We expect R&D expenses in future periods to level off modestly to reflect completion of manufacturing activities preparation for an anticipated BLA filing in the first half of 2019 followed by a potential strategic advancement in clinical priorities for a pivotal monotherapy trial and cancer indications, all of which are subject to the availability of sufficient additional capital. Any acceleration in clinical activities would increase R&D expenses.

For the six months ended November 30, 2018, the Company recognized a non-cash charge associated with the increase in fair value of derivative liabilities of approximately $0.5 million, as compared to a non-cash benefit of approximately $0.5 in the similar 2017 period. The warrants that contain a provision which gives rise to a derivative liability originated in September 2016. For each reporting period, we determine the fair value of the derivative liabilities and record a corresponding non-cash benefit or non-cash charge, as a consequence of a decrease or increase, respectively, in the calculated derivative liabilities.

Interest expense for the six months ended November 30, 2018 totaled approximately $1.9 million, as compared to approximately $2.5 million for the similar period in 2017. The components of interest expense include a loss on extinguishment of a long-term convertible note, accrued interest on a convertible note, along with the amortization of debt discount and debt issuance costs. On November 15, 2018, as previously reported, the Company amended the convertible note to include an additional feature which allows the holder to receive the redemption amount (a) in cash or (b) by converting the redemption amount into shares of common stock. The amendment caused the embedded redemption provision to require bifurcation as a liability at fair value under ASC 815 (Accounting Standards Codification Derivatives and Hedging (Topic 815). In addition, management also considered the accounting for the amendment under the accounting guidance in ASC 470, Debt (Topic 470), and determined that the amendment was substantive and extinguishment accounting applied. Accordingly, the carrying value of the original debt on the modification date is derecognized and the new debt is recorded at fair value. The difference was recorded as an extinguishment loss of approximately $1.5 million.

The future trends in all expenses will be driven, in large part, by the future outcomes of clinical trials and their correlative effect on research and development expenses, as well as general and administrative expenses, in addition to manufacturing of new additional quantities of commercial leronlimab (PRO 140), along with the necessary regulatory processes to confirm its qualification for future sale, if approved. The Company requires a significant amount of additional capital and its ability to continue to fund operations will continue to depend on its ability to raise such capital. See in particular, Liquidity and Capital Resources below and Item 1A Risk Factors in our Annual Report on Form 10-K for the year ended May 31, 2018 and in our Form 10-Q for the quarterly period ended August 31, 2018 in

the section titled Risk Factors in Part II, Item 1A

Liquidity and Capital Resources

The Company s cash position at November 30, 2018 decreased approximately $0.4 million to approximately $0.8 million, as compared to a balance of approximately $1.2 million as of May 31, 2018. The net decrease in cash for the six months ended November 30, 2018 was attributable to net cash used in operating activities of approximately $26.2 million, offset in part by net cash provided by financing activities of approximately $25.7 million.

As of November 30, 2018, the Company had significant negative working capital of approximately $20.1 million compared to negative working capital of approximately $13.4 million at May 31, 2018, an increase in negative working capital of approximately $6.7 million attributable primarily to cash used in operations.

Table of Contents

Cash Flows

Net cash used in operating activities totaled approximately $26.2 million during the six months ended November 30, 2018, which reflects an increase of approximately $13.3 million of net cash used in operating activities over the six months ended November 30, 2017. The increase in net cash used in operating activities was due to an increase in net loss of approximately $6.1 million, coupled with an increase in working capital components totaling approximately $5.7 million, a non-cash loss on extinguishment of debt of approximately $1.5 million and increased stock based compensation of approximately $1.0 million, which was mitigated in part by non-cash deferred income tax benefit of approximately $2.8 million, a reduction in amortization of approximately $2.1 million and a non-cash credit of approximately $1 million due to the change in derivative liabilities.

Net cash used in investing activities was immaterial during the six months ended November 30, 2018, and there was no activity during the six months ended November 30, 2017.

Net cash provided by financing activities of approximately $25.7 million during the six months ended November 30, 2018, increased approximately $13.3 million over the $12.4 million of net cash provided by financing activities during the six months ended November 30, 2017. The increase in net cash provided from financing activities was attributable to net proceeds from the sale of common stock and warrants of approximately $23.5 million, an increase of approximately $16.4 million in net proceeds from the sale of similar securities, offset by an increase of approximately $1.6 million in offering costs. During the 2017 six-month period the Company realized non-comparable proceeds of approximately $1.6 million from the exercise of warrants.

Capital Requirements

We have not generated revenue to date, and will not generate product revenue in the foreseeable future, although revenues are anticipated to be realized following approval of the Company s BLA. We expect to continue to incur significant operating losses as expenses continue as we proceed with clinical trials with respect to leronlimab (PRO 140) and continue to advance it through the product development and regulatory process. The future trends of all expenses will be driven, in large part, by the future outcomes of the clinical trials and their correlative effect on general and administrative expenses, in addition to the manufacturing of new commercial leronlimab (PRO 140), along with the increasing activities to prepare and file a BLA for leronlimab (PRO 140) as a combination therapy. We will require a significant amount of additional capital in the future for our clinical trials and to advance our manufacturing activities of leronlimab (PRO 140) necessary for completion of our BLA filing.

In connection with this undertaking, we have entered into an arrangement with a third party contract manufacturing organization (the CMO) to provide process transfer, validation and manufacturing services for leronlimab (PRO 140). Management believes the CMO will best serve our strategic objectives for the anticipated BLA filing and, if approved, the long-term commercial manufacturing capabilities for leronlimab (PRO 140). Management will continue to assess manufacturing capacity requirements as new market information becomes available regarding anticipated demand, subject to FDA approval. In the event that we terminate the agreement with our CMO, we may incur certain financial penalties which would become payable to the CMO. Conditioned on the timing of termination, the financial penalties may range up to an approximate high of $0.3 million. These CMO undertakings are anticipated to require approximately $9 million of additional capital over the next several fiscal quarters, including the estimated costs to fill, label, and package product into the final commercial package for commercial sale.

We have entered into project work orders for each of our clinical trials with our CRO and related laboratory vendors. Under the terms of these agreements, we have prepaid certain execution fees for direct services costs. In connection with our clinical trials, we have entered into separate project work orders for each trial with our CRO. In the event that

we terminate any trial, we may incur certain financial penalties which would become payable to the CRO. Conditioned upon the form of termination of any one trial, the financial penalties may range up to $0.2 million. In the remote circumstance that we terminate all clinical trials, the collective financial penalties may range from an approximate low of $0.5 million to an approximate high of $1.1 million.

Under the Progenics Purchase Agreement, we are required to pay Progenics the following ongoing milestone payments and royalties: (i) $5.0 million at the time of the first U.S. new drug application approval by the FDA or other non-U.S. approval for the sale of leronlimab (PRO 140); and (ii) royalty payments of up to five percent (5%) on net sales during the period beginning on the date of the first commercial sale of leronlimab (PRO 140) until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years, in each case determined on a country-by country basis. In addition, under a Development and License Agreement, dated April 30, 1999 (the PDL License), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was previously assigned to us, we are required to pay AbbVie Inc. additional milestone payments and royalties as follows: (i) $0.5 million upon filing a BLA with the FDA or non-U.S. equivalent regulatory body; (ii) $0.5 million upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iii) royalties of up to 3.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of $150,000 until royalties paid exceed that amount.

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

Table of Contents

Going Concern

As reported in the accompanying consolidated financial statements, for the six months ended November 30, 2018 and November 30, 2017, we incurred net losses of approximately $28.7 million and $22.6 million, respectively. We have no activities that produced revenue in the periods presented and have sustained operating losses since inception.

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

Since inception, we have financed our activities principally from the sale of public and private equity securities and proceeds from convertible notes payable and related party notes payable. We intend to finance our future operating activities and our working capital needs largely from the sale of equity and debt securities, combined with additional funding from other traditional financing sources. As of the date of this filing, we have approximately 124 million shares of common stock authorized and available for issuance under our certificate of incorporation, as amended, and approximately $166 million available for future registered offerings of securities under our universal shelf registration statement on Form S-3, which was declared effective on March 9, 2018 (assuming the full exercise of outstanding warrants, at the currently applicable exercise prices, that were previously issued in registered transactions thereunder).

The sale of equity and convertible debt securities to raise additional capital may result in dilution to stockholders and those securities may have rights senior to those of common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these activities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangements could require us to relinquish valuable rights. We may require additional capital beyond currently anticipated needs. Additional capital, if available, may not be available on reasonable or non-dilutive terms. Please refer to the matters discussed under the heading Risk Factors above.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred losses for all periods presented and have a substantial accumulated deficit. As of November 30, 2018, these factors, among several others, raise substantial doubt about our ability to continue as a going concern.

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

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

Under the supervision and with the participation of management, including the Chief Executive Officer and the Chief Financial Officer of the Company, the Company has evaluated the effectiveness of its disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of November 30, 2018. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective as of November 30, 2018.

Table of Contents

Internal Control Over Financial Reporting

Changes in Control Over Financial Reporting

No changes occurred during the quarter ended November 30, 2018, that materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

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 Securities and Exchange Commission on July 27, 2018, as amended on September 28, 2018, as supplemented by the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on October 9, 2018.

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.

Table of Contents

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits:

2.1	Transaction Agreement by and among CytoDyn Inc., Point NewCo, Inc., Point Merger Sub, Inc., ProstaGene, LLC, and Dr. Richard Pestell, dated August 27, 2018 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K, as amended, filed August 28, 2018).
3.1	Amended and Restated Certificate of Incorporation of CytoDyn Inc. (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K12G3 filed November 19, 2018).
3.2	Amended and Restated Bylaws of CytoDyn Inc. (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K12G3 filed November 19, 2018).
4.1	Form of Warrant Agreement (September 2018 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed September 4, 2018).
4.2	Amended and Restated Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K12G3 filed November 19, 2018).
10.1	Form of Subscription Agreement (September 2018 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed September 4, 2018).
10.2	Convertible Promissory Note Amendment and Restatement, dated November 15, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K12G3 filed November 19, 2018).
10.3	Escrow Agreement, dated as of November 16, 2018, by and among ProstaGene, LLC, CytoDyn Inc., and Computershare Trust Company, N.A. (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K12G3 filed November 19, 2018).
10.4	Stock Restriction Agreement, dated as of November 16, 2018, by and among CytoDyn Inc., ProstaGene, LLC and Dr. Richard G. Pestell (incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K12G3 filed November 19, 2018).
10.5	Confidential Information, Inventions and Noncompetition Agreement, dated as of November 16, 2018, by and among CytoDyn Inc., CytoDyn Operations Inc. and Dr. Richard G. Pestell (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K12G3 filed November 19, 2018).
10.6	Employment Agreement, dated as of November 16, 2018, by and among CytoDyn, Inc., CytoDyn Operations Inc. and Dr. Richard G. Pestell (incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K12G3 filed November 19, 2018).
31.1*	Rule 13a-14(a) Certification by CEO of Registrant.
31.2*	Rule 13a-14(a) Certification by CFO of the Registrant.
32.1*	Certification of CEO of the Registrant pursuant to 18 U.S.C. Section 1350.
32.2*	Certification of CFO of the Registrant pursuant to 18 U.S.C. Section 1350.

101.INS * XBRL Instance Document.

101.SCH * XBRL Taxonomy Extension Schema Document.

101.CAL * XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF * XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB * XBRL Taxonomy Extension Label Linkbase Document.

101.PRE * XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

Table of Contents

SIGNATURES

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

CYTODYN INC.

(Registrant)

Dated: January 9, 2019

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

Dated: January 9, 2019

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