

CytoDyn Inc.
Form 10-Q
April 09, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended February 28, 2019

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

For the transition period from _____ to _____

Commission File Number: 000-49908

CYTODYN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

1111 Main Street, Suite 660

Vancouver, Washington
(Address of principal executive offices)

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

83-1887078
(I.R.S. Employer or
Identification No.)

98660

(Zip Code)

(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

Non-accelerated Filer

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 March 31, 2019, there were 305,490,094 shares outstanding of the registrant's \$0.001 par value common stock.

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CytoDyn Inc.

Consolidated Balance Sheets

(Unaudited)

| | February 28, 2019 (unaudited) | May 31, 2018 |
|--------------------------------------------------------|----------------------------------|---------------|
| Assets | | |
| Current assets: | | |
| Cash | \$ 1,593,629 | \$ 1,231,445 |
| Prepaid expenses | 232,541 | 227,173 |
| Prepaid service fees | 2,641,301 | 1,862,009 |
| Total current assets | 4,467,471 | 3,320,627 |
| Furniture and equipment, net | 8,713 | 11,228 |
| Intangibles, net | 15,951,361 | 1,567,143 |
| Total assets | \$ 20,427,545 | \$ 4,898,998 |
| Liabilities and Stockholders (Deficit) Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 14,941,523 | \$ 15,841,859 |
| Accrued liabilities and compensation | 252,825 | 757,778 |
| Accrued license fees | 517,600 | 133,600 |
| Accrued interest on convertible notes | 75,154 | |
| Convertible notes payable, net | 2,271,823 | |
| Current portion of long term convertible notes payable | 4,200,000 | |
| Total current liabilities | 22,258,925 | 16,733,237 |
| Long-term liabilities: | | |
| Convertible notes payable, net | 1,225,416 | |
| Derivative liabilities | 3,192,243 | 1,323,732 |
| Total long-term liabilities | 4,417,659 | 1,323,732 |
| Total liabilities | 26,676,584 | 18,056,969 |
| Commitments and Contingencies | | |
| Stockholders (Deficit) equity | | |
| | 92 | 92 |

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Series B convertible preferred stock, \$0.001 par value; 400,000 shares authorized, 92,100 shares issued and outstanding at February 28, 2019 and May 31, 2018, respectively

| | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---------------------|
| Common stock, \$0.001 par value; 600,000,000 and 375,000,000 shares authorized, 304,679,081 and 216,881,790 issued and 304,520,070 and 216,722,779 outstanding at February 28, 2019 and May 31, 2018, respectively | 304,680 | 216,881 |
| Additional paid-in capital | 207,878,504 | 159,764,611 |
| Accumulated (deficit) | (214,432,156) | (173,139,396) |
| Less: treasury stock, at par (159,011 shares at \$0.001) | (159) | (159) |
| Total stockholders (deficit) | (6,249,039) | (13,157,971) |
| Total liabilities and stockholders (deficit) equity | \$ 20,427,545 | \$ 4,898,998 |

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Operations

(Unaudited)

| | Three Months Ended February 28, | | Nine Months Ended February 28, | |
|--------------------------------------------------------------|------------------------------------|------------------------|-----------------------------------|------------------------|
| | 2019 | 2018 | 2019 | 2018 |
| Operating expenses: | | | | |
| General and administrative | \$ 3,345,179 | \$ 1,974,915 | \$ 8,005,346 | \$ 5,153,336 |
| Research and development | 9,022,223 | 12,076,460 | 33,294,771 | 29,301,808 |
| Amortization and depreciation | 503,922 | 89,132 | 747,693 | 267,414 |
| Total operating expenses | 12,871,324 | 14,140,507 | 42,047,810 | 34,722,558 |
| Operating loss | (12,871,324) | (14,140,507) | (42,047,810) | (34,722,558) |
| Interest income | 19 | 662 | 2,021 | 1,870 |
| Change in fair value of derivative liabilities | 1,347,907 | (741,066) | 881,495 | (274,132) |
| Interest expense: | | | | |
| Amortization of discount on convertible notes | (559,383) | (493,022) | (676,917) | (1,666,017) |
| Amortization of debt issuance costs | (155,435) | (153,480) | (175,024) | (435,609) |
| Loss on extinguishment of convertible note | | | (1,519,603) | |
| Inducement interest related to warrant exercise | | | | (826,252) |
| Inducement interest related to convertible debt | | (2,352,045) | | (2,352,045) |
| Interest on convertible note payable | (335,595) | (70,642) | (583,842) | (251,315) |
| Total interest expense | (1,050,413) | (3,069,189) | (2,955,386) | (5,531,238) |
| Loss before income taxes | (12,573,811) | (17,950,100) | (44,119,680) | (40,526,058) |
| Income tax benefit | | | 2,826,919 | |
| Net loss | \$ (12,573,811) | \$ (17,950,100) | \$ (41,292,761) | \$ (40,526,058) |
| Basic and diluted loss per share | \$ (0.04) | \$ (0.10) | \$ (0.16) | \$ (0.25) |
| Basic and diluted weighted average common shares outstanding | 295,637,023 | 178,088,905 | 257,491,288 | 162,460,451 |

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Cash Flows

(Unaudited)

| | Nine Months Ended February 28, | |
|-----------------------------------------------------------------------------|-----------------------------------|-----------------|
| | 2019 | 2018 |
| Cash flows from operating activities: | | |
| Net loss | \$ (41,292,761) | \$ (40,526,058) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Amortization and depreciation | 747,693 | 267,414 |
| Amortization of debt issuance costs | 676,917 | 435,609 |
| Amortization of discount on convertible notes | 175,024 | 1,666,017 |
| Interest expense associated with extension of warrant expirations | | 826,252 |
| Interest expense associated with conversion of notes | | 2,352,045 |
| Interest expense associated with accretion of convertible notes payable | 283,442 | |
| Change in fair value of derivative liabilities | (881,495) | 274,132 |
| Stock-based compensation | 2,891,548 | 1,096,226 |
| 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 | (1,525,956) | 2,674,850 |
| (Decrease) increase in accounts payable and accrued expenses | (720,889) | 8,014,522 |
| Net cash used in operating activities | (40,953,793) | (22,918,991) |
| Cash flows from investing activities: | | |
| Furniture and equipment purchases | (3,182) | |
| Net cash used in investing activities | (3,182) | |
| Cash flows from financing activities: | | |
| Proceeds from sale of common stock and warrants | 29,836,826 | 22,903,710 |
| Proceeds from warrant exercises | | 1,647,500 |
| Proceeds from convertible notes payable, net | 15,460,000 | 4,888,500 |
| Repayment on convertible note | | (259,157) |
| Payment of debt issuance costs | (583,200) | |
| Payment of offering costs | (3,394,467) | (3,090,203) |
| Net cash provided by financing activities | 41,319,159 | 26,090,350 |
| Net change in cash | 362,184 | 3,171,359 |
| Cash, beginning of period | 1,231,445 | 1,775,583 |

| | | |
|---------------------|--------------|--------------|
| Cash, end of period | \$ 1,593,629 | \$ 4,946,942 |
|---------------------|--------------|--------------|

See accompanying notes to consolidated financial statements.

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CytoDyn Inc.

Consolidated Statements of Cash Flows

(Unaudited)

| | Nine Months Ended February 28, | |
|----------------------------------------------------------------------------------|-----------------------------------|--------------|
| | 2019 | 2018 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid during the period for interest | \$ | \$ 9,157 |
| Non-cash investing and financing transactions: | | |
| Accrued interest converted into note payable | \$ 225,245 | \$ |
| Common stock issued for acquisition of ProstaGene, LLC | \$ 11,558,000 | \$ |
| Derivative liability associated with convertible notes payable | \$ 2,750,006 | \$ |
| Beneficial conversion feature and fair value of warrant issued with note payable | \$ 3,534,992 | \$ |
| Common stock issued in connection with an employment agreement | \$ 8,342 | \$ |
| Common stock issued for conversion redemption | \$ 455,000 | \$ |
| Financing costs associated with placement agent warrants | \$ 260,635 | \$ 70,383 |
| Debt discount associated with convertible notes payable | \$ 3,059,159 | \$ 1,574,628 |
| Common stock issued upon conversion of convertible debt | \$ | \$ 5,788,500 |
| Common stock issued for accrued interest payable | \$ | \$ 242,158 |
| Common stock issued for board compensation | \$ | \$ 260,190 |

See accompanying notes to consolidated financial statements.

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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 | | | | | | |
| Issuance of stock for note payable redemption | | | | | | |
| 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 | | | | | | |
| Offering costs related to debt offering | | | | | | |
| Debt discount and issuance costs related to offering | | | | | | |
| Beneficial conversion feature on note payable and relative fair value associated with warrants | | | | | | |
| 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 | | |
| Issuance of stock for note payable redemption | | | | | | |
| 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 | | | | | | |
| Offering costs related to debt offering | | | | | | |
| Debt discount and issuance costs related to offering | | | | | | |
| Beneficial conversion feature on note payable and relative fair value associated with warrants | | | | | | |
| 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

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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, 2019 | | | | | | |
| Acquisition of ProstaGene LLC | | | | | | |
| Issuance of stock payment shares | | | | | | |
| Issuance of stock for note payable redemption | | | 1,123,641 | 1,124 | | |
| Proceeds from registered direct offering (\$0.50/share) | | | 10,728,480 | 10,728 | | |
| Offering costs related to registered direct offering | | | | | | |
| Proceeds from private equity offering (\$0.50/share) | | | 2,018,000 | 2,018 | | |
| Offering costs related to private equity offering | | | | | | |
| Offering costs related to debt offering | | | | | | |
| Debt discount and issuance costs related to debt offering | | | | | | |
| Beneficial conversion feature on note payable and relative fair value associated with warrants | | | | | | |
| Legal fees in connection with equity offerings | | | | | | |
| Stock-based compensation | | | | | | |
| Net Loss February 28, 2019 | | | | | | |
| Balance February 28, 2019 | 92,100 | 92 | 304,679,081 | 304,680 | 159,011 | (159) |

See accompanying notes to consolidated financial statements

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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 | | | | |
| Issuance of stock for note payable redemption | | | | |
| 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) |
| Offering costs related to debt offering | | | | |
| Debt discount and issuance costs related to offering | | | | |
| Beneficial conversion feature on note payable and relative fair value associated with warrants | | | | |
| 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 |
| Issuance of stock for note payable redemption | | | | |
| 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 | | 14,964,284 | 22,478,584 |
| Offering costs related to private equity offering | (1,693,354) | | (1,693,354) | (2,576,070) |

| | | | | |
|------------------------------------------------------------------------------------------------|--------------------|-------------------------|-----------------------|-----------------------|
| Offering costs related to debt offering | | | | |
| Debt discount and issuance costs related to offering | | | | |
| Beneficial conversion feature on note payable and relative fair value associated with warrants | | | | |
| Legal fees in connection with equity offerings | (25,652) | | (25,652) | (76,196) |
| Stock-based compensation | 1,227,140 | | 1,227,140 | 1,510,486 |
| Net Loss November 30, 2018 | | (14,305,380) | (14,305,381) | (28,718,950) |
| Balance November 30, 2018 | 193,503,678 | \$ (201,858,345) | \$ (8,063,926) | \$ (8,063,926) |

See accompanying notes to consolidated financial statements

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CytoDyn Inc.

Consolidated Statement of Changes in Stockholders (Deficit)/ Equity

(Unaudited)

| | Additional Paid-In Capital | Accumulated Deficit | Total | Fiscal Year To Date |
|------------------------------------------------------------------------------------------------|----------------------------------|-------------------------|-----------------------|------------------------|
| Third Quarter Fiscal Year Ended May 31, 2019 | | | | |
| Acquisition of ProstaGene LLC | | | | 11,558,000 |
| Issuance of stock payment shares | | | | |
| Issuance of stock for note payable redemption | 453,876 | | 455,000 | 455,000 |
| Proceeds from registered direct offering (\$0.50/share) | 5,353,511 | | 5,364,241 | 6,349,241 |
| Offering costs related to registered direct offering | (545,970) | | (545,970) | (621,121) |
| Proceeds from private equity offering (\$0.50/share) | 1,006,982 | | 1,009,000 | 23,487,584 |
| Offering costs related to private equity offering | (121,079) | | (121,079) | (2,697,149) |
| Offering costs related to debt offering | 260,636 | | 260,636 | 260,636 |
| Debt discount and issuance costs related to debt offering | 3,059,159 | | 3,059,159 | 3,059,159 |
| Beneficial conversion feature on note payable and relative fair value associated with warrants | 3,534,992 | | 3,534,992 | 3,534,992 |
| Legal fees in connection with equity offerings | | | | (76,196) |
| Stock-based compensation | 1,372,719 | | 1,372,719 | 2,891,547 |
| Net Loss February 28, 2019 | | (12,573,811) | (12,573,811) | (41,292,761) |
| Balance February 28, 2019 | \$ 207,878,504 | \$ (214,432,156) | \$ (6,249,039) | \$ (6,249,039) |

See accompanying notes to consolidated financial statements

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CYTODYN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF FEBRUARY 28, 2019

(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 and nine months ended February 28, 2019 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 nine months ended February 28, 2019 and February 28, 2018, (b) the financial position at February 28, 2019 and (c) cash flows for the nine month periods ended February 28, 2019 and February 28, 2018.

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 2019 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 \$41,292,761 for the nine months ended February 28, 2019 and has an accumulated deficit of \$214,432,156 as of February 28, 2019. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

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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 candidate, obtain U.S. Food & Drug Administration (FDA) approval, outsource manufacturing of the product candidate, and ultimately achieve initial revenues and attain profitability. The Company is currently engaging in significant research and development activities related to its product candidate for multiple indications, and expects to incur significant research and development expenses in the future primarily related to its clinical trials. These research and development activities are subject to significant risks and uncertainties. The Company intends to finance its future development activities and its working capital needs largely from the sale of equity and debt securities, combined with additional funding from other traditional sources. There can be no assurance, however, that the Company will be successful in these endeavors.

Use of Estimates

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

Cash

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. Balances in excess of federally insured limits at February 28, 2019 and May 31, 2018 approximated \$1.3 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 nine months ended February 28, 2019 and 2018. 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 February 28, 2019 and May 31, 2018, the Company did not have pre-launch inventory that qualified for capitalization pursuant to U.S. GAAP ASC 330 Inventory.

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

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

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

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

Liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of February 28, 2019 and May 31, 2018 is as follows:

| | Fair Value Measurement at February 28, 2019 (1) | | Fair Value Measurement at May 31, 2018 (1) | |
|--------------------------------------------------------------|-------------------------------------------------------|--------------|--------------------------------------------------|--------------|
| | Using Level 3 | Total | Using Level 3 | Total |
| Liabilities: | | | | |
| Derivative liability - warrants | \$ 793,866 | \$ 793,866 | \$ 1,323,732 | \$ 1,323,732 |
| Derivative liability - convertible note redemption provision | 2,398,377 | 2,398,377 | | |
| Total liabilities | \$ 3,192,243 | \$ 3,192,243 | \$ 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 February 28, 2019 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.

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The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the nine months ended February 28, 2019 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 provisions | 2,750,006 |
| Fair value adjustments - warrants | (529,867) |
| Fair value adjustments - convertible notes | (351,628) |
| Balance at February 28, 2019 | \$ 3,192,243 |

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.

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 February 28, 2019, 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. See Note 14 Subsequent Events

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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 nine months ended February 28, 2019 and the year ended May 31, 2018, the Company incurred approximately \$4.2 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. Due to accounting under ASC 815, \$0.6 million will be accounted for as interest expense and an accretion to convertible notes payable. During the nine months ended February 28, 2019 and February 28, 2018, the Company recorded approximately \$0.7 million and \$1.6 million of related amortization, respectively.

Debt Issuance Cost

During the nine months ended February 28, 2019 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 \$1.0 million and \$0.4 million, respectively of debt issuance costs. Due to accounting under ASC 815, \$0.1 million will be accounted for as interest expense and an accretion to convertible notes payable. During the nine months ended February 28, 2019 and February 28, 2018, the Company approximately \$0.2 million and \$0.4 million of related amortization for the nine months ended February 28, 2019 and February 28, 2018, respectively.

Offering Costs

During the nine months ended February 28, 2019 and the year ended May 31, 2018, the Company incurred direct incremental costs associated with the sale of equity securities, as described in Notes 10 and 11. The costs were approximately \$3.3 million and \$3.5 million for the nine months ended February 28, 2019 and year ended May 31, 2018, 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 175,043,638 and 130,457,331 shares of common stock were not included in the computation of basic and diluted weighted average number of shares of common stock outstanding for the nine months ended

February 28, 2019 and February 28, 2018, respectively. Additionally, as of February 28, 2019, shares of Series B convertible preferred stock in the aggregate of 92,100 shares can potentially convert into 921,000 shares of common stock.

Income Taxes

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

The Company follows the provisions of FASB 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.

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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, was 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 nine months ending February 28, 2019, 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 February 28, 2019 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.

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

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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 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 February 28, 2019. Each share of the Series B is convertible into ten shares of the Company's \$0.001 par value common stock, including any accrued dividends, with an effective fixed conversion price of \$0.50 per share. The holders of the Series B can only convert their shares to common shares provided the Company has sufficient authorized common shares at the time of conversion. Accordingly, the conversion option was contingent upon the Company increasing its authorized common shares, which occurred in April 2010, when the Company's stockholders approved an increase in the authorized shares of common stock to 100,000,000. At the commitment date, which

occurred upon such stockholder approval, the conversion option related to the Series B was beneficial. The intrinsic value of the conversion option at the commitment date resulted in a constructive dividend to the Series B holders of approximately \$6,000,000. The constructive dividend increased and decreased additional paid-in capital by identical amounts. The Series B has liquidation preferences over the common shares at \$5.00 per share plus any accrued dividends. Dividends are payable to the Series B holders when declared by the Board of Directors at the rate of \$0.25 per share per annum. Such dividends are cumulative and accrue whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available. The Series B holders have no voting rights. As of February 28, 2019 and May 31, 2018, the undeclared, accrued dividends were approximately \$210,000 and \$199,000, respectively, or 421,000 and 387,000 shares of common stock, respectively.

2018 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, (the 2018 Short-term Convertible Notes) with a maturity date of January 31, 2018, and related warrants to investors for cash. The principal amount of the 2018 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

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price of \$0.75 per share. The 2018 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 2018 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 2018 Short-term Convertible Notes for the fair value of the related warrants.

In connection with the sale of the 2018 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 2018 Short-term Convertible Notes and a corresponding increase to additional paid-in capital was amortized over the term of the 2018 Short-term Convertible Notes. The Company incurred debt discount of approximately \$1.6 million related to the beneficial conversion feature and detachable warrants issued with the notes during the year ended May 31, 2018. Accordingly, the Company recognized approximately \$-0- and \$1.6 million of non-cash debt discount during the nine months ended February 28, 2019 and February 28, 2018, respectively. In connection with the 2018 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 2018 Short-term Convertible Notes and accordingly the Company recognized approximately \$-0- and \$0.4 million of debt issuance costs during the nine months ended February 28, 2019 and February 28, 2018, respectively.

On January 31, 2018, in connection with a registered direct equity offering, as fully described in Note 11, the 2018 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 2018 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 2018 Short-term Convertible Note, including accrued interest in the aggregate of approximately \$259,000. During the nine months ended February 28, 2019 and February 28, 2018, the Company recognized approximately \$-0- and \$75,000, of interest expense related to the note.

Activity related to the 2018 Short-term Convertible Notes was as follows:

| | |
|-------------------|-----------------|
| February 28, 2019 | May 31, 2018 |
|-------------------|-----------------|

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| | | |
|------------------------------------------------|----|--------------|
| 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 | \$ | \$ |

2019 Short-term Convertible Notes

During the nine months ended February 28, 2019, the Company issued approximately \$5.5 million of nine-month unsecured Convertible Notes (the 2019 Short-term Convertible Notes) and related warrants to investors for cash. The principal amount of the 2019 Short-term Convertible Notes, including any accrued but unpaid interest thereon, is convertible at the election of the holder at any time into shares of common stock at any time prior to maturity at a conversion price of \$0.50 per share. The 2019 Short-term Convertible Notes bear simple interest at the annual rate of 10%. Principal and accrued interest, to the extent not previously paid or converted, is due and payable on the maturity date. At the commitment dates, the Company determined that the conversion feature

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related to these 2019 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 2019 Short-term Convertible Notes for the fair value of the related warrants.

In connection with the sale of the 2019 short-term Notes, detachable common stock warrants to purchase a total of 5,460,000 common shares, with an exercise price of \$0.30 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 - 2019 |
| Expected dividend yield | 0% |
| Stock price volatility | 55.8 - 55.88% |
| Expected term | 5 year |
| Risk-free interest rate | 2.48 - 2.56% |
| Grant-date fair value | \$0.30 - \$0.38 |

The fair value of the warrants, coupled with the beneficial conversion features, were recorded as a debt discount to the 2019 Short-term Convertible Notes and a corresponding increase to additional paid-in capital and will be amortized over the life of the 2019 Short-term Convertible Notes. In connection with the 2019 Short-term Convertible Notes, the placement agent earned a tail fee comprised of warrants covering 972,000 shares of common stock and a cash fee of \$583,200. The placement agent warrants are exercisable at a price of \$0.50 per share and will expire five years from the date of issuance and include a cashless exercise provision. During the nine months ended February 28, 2019, and in connection with the 2019 Short-term Convertible Notes, the Company incurred debt discount and issuance costs of approximately \$3.0 million, related to the beneficial conversion feature and detachable warrants issued with the 2019 Short-term Convertible Notes and approximately \$0.8 in issuance costs. The debt discount and issuance costs will be amortized over the term of the 2019 Short-term Convertible Notes. Accordingly, the Company recognized approximately \$0.6 million and \$0.2 million of debt discount and issuance costs, respectively, during the nine months ended February 28, 2019.

Activity related to the 2019 Short-term Convertible Notes was as follows:

| | | |
|------------------------------------------------|-------------------|--------------|
| | February 28, 2019 | May 31, 2018 |
| Face amount of Short-term Convertible Notes | \$ 5,460,000 | \$ |
| Unamortized discount | (2,499,776) | |
| Unamortized issuance costs | (688,401) | |
| Carrying value of Short-term Convertible Notes | \$ 2,271,823 | \$ |

The Company recognized approximately \$75,000 and \$0- of interest expense during the nine months ended February 28, 2019 and the year ended May 31, 2019, respectively.

Long-term Convertible Notes

June 2018 Note

On June 26, 2018, the Company entered into a securities purchase agreement, pursuant to which the Company issued a convertible promissory note (the June 2018 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 June 2018 Note bears interest of 10% and is convertible into common stock, at \$0.55 per share. The June 2018 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 June 2018 Note. The Investor may redeem any portion of the June 2018 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. As a result of the entry into the January 2019 Note (as defined below), the Company's obligations under the June 2018 Note are now secured by all of the assets of the Company, excluding the Company's intellectual property.

In connection with the June 2018 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 June 2018 Note, and accordingly, the Company recognized approximately \$20,000 and \$-0- amortization of debt issuance costs for the nine months ended February 28, 2019 and February 28, 2018, respectively and approximately \$118,000 and \$-0- of amortization of debt discount for the nine months ended February 28, 2019 and February 28, 2018, respectively.

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Effective November 15, 2018, the June 2018 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 June 2018 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 June 2018 Note prior to the amendment of approximately \$5.4 million, and the fair value of the June 2018 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 the June 2018 Note. During the nine months ended February 28, 2019 and February 28, 2018, the Company recognized approximately \$440,000 and \$0-, of interest expense related to the June 2018 Note.

During the nine months ended February 28, 2019 the Company received redemption notices from the holder of the Company's June 2018 Note, requesting an aggregate redemption of \$455,000 of the outstanding balance thereof. In satisfaction of the redemption notices, the Company issued shares of common stock totaling 1,123,641 to the June 2018 Note holder in accordance with the terms of the June 2018 Note. Following the redemptions, the outstanding balance of the convertible June 2018 Note, including accrued but unpaid interest, was approximately \$5.4 million.

January 2019 Note

On January 30, 2019, the Company entered into a securities purchase agreement, pursuant to which the Company issued a convertible promissory note (the January 2019 Note) with a two-year term to the holder of the June 2018 Note in the initial principal amount of \$5.7 million. In connection with the issuance of the January 2019 Note, the Company granted a lien against all of the assets of the Company, excluding the Company's intellectual property, to secure all obligations owed to the investor by the Company (including those under both the January 2019 Note and the June 2018 Note). The investor gave consideration of \$5.0 million to the Company, reflecting original issue discount of \$0.6 million and issuance costs of \$0.1 million. The January 2019 Note bears interest of 10% and is convertible into common stock, at \$0.50 per share. The January 2019 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 Company analyzed the conversion option for derivative accounting treatment under ASC 815 and determined that the embedded conversion option did not qualify for derivative accounting.

The Investor may redeem any portion of the January 2019 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 monthly redemption amount may be paid in cash or stock, at the Company's election, at the lesser of (i) \$0.50, 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 redemption provision meets the definition of a derivative instrument and does not meet the criteria to be considered indexed to the Company's own stock. Therefore, the redemption provision requires bifurcation as a derivative liability at fair value under the guidance in ASC Topic No. 815 (ASC 815). The securities purchase agreement requires the Company to reserve 20,000,000 shares for future conversions or redemptions.

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In conjunction with the January 2019 Note, the investor received a warrant to purchase 5,000,000 shares of common stock with an exercise price of \$0.30 which is exercisable until the 5-year anniversary of the date of issuance. The warrant achieved equity classification at inception. The net proceeds of \$5.0 million were allocated first to the redemption provision at its fair value, then to the warrants at their relative fair value and the beneficial conversion feature at its intrinsic value as follows:

| | January 30, 2019 |
|---------------------------------------------------|------------------|
| Fair value of redemption provision | \$ 1,465,008 |
| Relative fair value of equity classified warrants | 858,353 |
| Beneficial conversion feature | 2,676,639 |
| Proceeds | \$ 5,000,000 |

Under the guidance of ASC 815, after allocation of proceeds to the redemption provision, relative fair value of equity classified warrants and the beneficial conversion feature, there were no proceeds remaining to allocate to convertible note payable. Therefore, principal, accrued interest, debt discount and offering costs will be recognized as interest expense, which represents the accretion of

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the convertible note payable and related debt discount and issuance costs. During the nine months ended February 28, 2019 and year ended May 31, 2018, the Company recognized approximately \$69,000 and \$-0- of interest expense related to the January 2019 Note.

Activity related to the June 2018 Note and the January 2019 Note is as follows:

| | February 28, 2019 | | | May 31, 2018 |
|----------------------------------------------|-------------------|--------------|--------------|--------------|
| | Short term | Long term | Total | |
| June 2018 Note | \$ 2,100,000 | \$ 3,600,000 | \$ 5,700,000 | |
| Monthly redemption provision | 2,100,000 | (2,100,000) | | |
| Note amendment, net | | 111,410 | 111,410 | |
| Redemptions | | (455,000) | (455,000) | |
| January 2019 Note | | 69,006 | 69,006 | |
| Carrying value of Notes at February 28, 2019 | \$ 4,200,000 | \$ 1,225,416 | \$ 5,425,416 | \$ |

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 warrant holder 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 and February 28, 2019:

| | 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 February 28, 2019 | 7,733,334 | \$ 793,866 |

The Company recognized approximately \$530,000 of non-cash gain and approximately \$274,000 of non-cash loss, due to the changes in the fair value of the liability associated with such classified warrants during the nine months ended February 28, 2019 and February 28, 2018, 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.

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The Company estimated the fair value of the warrant derivative liability as of inception date September 15, 2016, May 31, 2018 and February 28, 2019, using the following assumptions:

| | September 15, 2016 | May 31, 2018 | February 28, 2019 |
|-----------------------------------------------|-----------------------|-----------------|----------------------|
| Fair value of underlying stock | \$ 0.78 | \$ 0.49 | \$ 0.50 |
| Risk free rate | 1.20% | 2.63% | 2.51% |
| Expected term (in years) | 5 | 3.3 | 2.54 |
| Stock price volatility | 106% | 64% | 60% |
| Expected dividend yield | | | |
| Probability of Fundamental Transaction | 50% | 50% | 50% |
| Probability of holder requesting cash payment | 50% | 50% | 50% |

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

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As described in Note 4 above, the redemption provision embedded in the June 2018 and January 2019 Notes required bifurcation and measurement at fair value as a derivative. The fair value of the Note redemption provision derivative liabilities was calculated using a Monte Carlo Simulation which uses randomly generated stock-price paths obtained through a Geometric Brownian Motion stock price simulation. 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 estimated the fair value of the redemptive provision using the following assumptions on the closing date of November 15, 2018, January 30, 2019 and February 28, 2019:

| | November 15, 2018 | November 30, 2018 | January 30, 2019 | February 28, 2019 | |
|--------------------------------|----------------------|----------------------|---------------------|-------------------|--------------|
| | | | | June Note | January Note |
| Fair value of underlying stock | \$ 0.57 | \$ 0.58 | \$ 0.49 | \$ 0.50 | \$ 0.50 |
| Risk free rate | 2.78% | 2.78% | 2.52% | 2.54% | 2.52% |
| Expected term (in years) | 1.61 | 1.61 | 2 | 1.33 | 1.92 |
| Stock price volatility | 58.8% | 58.8% | 61% | 61% | 61.3% |
| Expected dividend yield | | | | | |
| Discount factor | 85% | 85% | 85% | 85% | 85% |

The following table summarizes the fair value of the convertible note redemption provision derivative liability as of inception dates November 15, 2018, January 30, 2019 and February 28, 2019:

| | Derivative Liability | | |
|-------------------------------------------------------|----------------------|----------------|-------------------|
| | Net Proceeds | Inception Date | February 28, 2019 |
| Inception date June 2018 Note, November 15, 2018 | \$ 5,000,000 | \$ 1,284,988 | \$ 1,065,646 |
| Inception date January 2019 Note, January 30, 2019 | 5,000,000 | 1,465,008 | 1,332,731 |
| | | | \$ 2,398,377 |

The Company recognized approximately \$352,000 of non-cash gain, due to the changes in the fair value of the liability associated with such classified redemption provision between the inception date and February 28, 2019.

Note 6 Stock Options and Warrants

The Company has one active stock-based equity plan at February 28, 2019, 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 February 28, 2019, the Company had 164,144 shares available for future stock-based grants under the 2012 Plan.

Stock Options

During the nine months ended February 28, 2019, 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 nine months ended February 28, 2019, the Company granted a pro-rata stock option award to a director, covering 38,904 shares of common stock, which has an exercise price of \$0.50 per share. This stock option award vests 13,904 shares on March 1, 2019 and 25,000 shares on June 1, 2019. The grant date fair value of this stock option award was \$0.27 per share.

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During the nine months ended February 28, 2019, 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 nine months ended February 28, 2019, 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 certain directors 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 nine months ended February 28, 2019, 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.

During the nine months ended February 28, 2019, the Company granted a stock option award covering 400,000 shares of common stock with an exercise price of \$0.48 per to the Company's Chief Technology Officer, in connection with his employment agreement. The stock option award vests annually over three years, has a ten-year term and grant date fair value of \$0.26 per share.

On January 4, 2019, in connection with the resignation of a director, the Company's Board of Directors approved a motion to accelerate all outstanding unvested stock options held by the director, to vest immediately upon the effectiveness of his resignation and to retain the stock options' exercise period through their respective expiration date. Stock options covering 1,145,834 shares of common stock were subject to acceleration. The other terms of the accelerated stock options remained otherwise unchanged. In addition, the expiration terms of certain other previously awarded stock options covering an aggregate of 150,000 shares common stock were extended from five years to 10 years. The other terms of the extended stock options remained otherwise unchanged.

Warrants

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.

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 nine months ended February 28, 2019, in connection with a private equity offering, as fully described in Note 10, the Company issued common stock warrants covering a total of 23,487,585 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 4,446,917 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 nine months ended February 28, 2019, 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. In addition the Company issued a warrant covering 500,000 shares of common stock to a director. The warrant has a ten-year term, an exercise price of \$0.51 per share and a grant date fair value of \$0.28 per share.

During the nine months ended February 28, 2019, in connection with the offering of 2019 Short-term Convertible Notes, as fully described in Note 4, the Company issued common stock warrants covering a total of 5,460,000 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of \$0.30 per share. In connection with this offering, the Company also issued common stock warrants covering 972,000 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.

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During the nine months ended February 28, 2019, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued common stock warrants covering a total of 5,364,240 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of \$0.50 per share. In connection with this offering, the Company also issued common stock warrants covering 965,563 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 nine months ended February 28, 2019, in connection with the issuance of the January 2019 Note, as fully described in Note 4, the Company issued a warrant covering a total of 5,000,000 shares of common stock to January investor. The warrant has a five-year term and an exercise price of \$0.30 per share.

Compensation expense related to stock options, compensatory warrants and common stock reserved for advisory services for the three and nine months ended February 28, 2019 and February 28, 2018 was approximately \$1.4 million and \$0.6 million and approximately \$2.9 million and \$1.1 million, respectively. The grant date fair value of options and compensatory warrants vested during the three and nine month periods ended February 28, 2019 and February 28, 2018 was approximately \$0.7 million and \$0.8 million and \$1.8 million \$1.3, respectively. As of February 28, 2019, there was approximately \$4.9 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 2.58 years.

The following table represents stock option and warrant activity as of and for the nine months ended February 28, 2019:

| | 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 | 53,394,631 | 0.58 | | |
| Exercised | | | | |
| Forfeited/expired/cancelled | (10,736,262) | 0.82 | | |
| Options and warrants outstanding - February 28, 2019 | 175,043,638 | 0.73 | 3.89 | 2,129,223 |
| Outstanding exercisable - February 28, 2019 | 171,069,400 | \$ 0.74 | 3.75 | \$ 2,108,816 |

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 February 28, 2019, 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.

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.

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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.

The following presents intangible assets activity:

| | February 28, 2019 | May 31, 2018 |
|------------------------------------------|-------------------|--------------|
| Gross carrying amounts | \$ 3,500,000 | \$ 3,500,000 |
| Intangible asset acquisition: | | |
| ProstaGene, LLC | 15,126,216 | |
| Accumulated amortization | (2,674,855) | (1,968,846) |
| | | |
| Total amortizable intangible assets, net | \$ 15,951,361 | \$ 1,531,154 |

| | | | |
|------------------------------------|----|------------|--------------|
| Patents currently not amortized | \$ | \$ | 35,989 |
| Carrying value of intangibles, net | \$ | 15,951,361 | \$ 1,567,143 |

Amortization expense related to intangible assets patents was approximately \$502,000 and \$87,500 and \$742,000 and \$265,000 for the three and nine months ended February 28, 2019 and 2018, 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 April 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.

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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.

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 \$0.3 million. In the remote circumstance that the Company would terminate all clinical trials, the collective financial penalties may range from an approximate low of \$0.5 million to an approximate high of \$1.2 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 Equity Offerings

During the nine months ended February 28, 2019, 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 46,975,170 shares of common stock, \$0.001 par value, for aggregate gross proceeds of approximately \$23.5 million and issued to the investors five-year warrants covering 23,487,585 shares of common stock with an exercise price of \$0.75 per share. In addition, the placement agent received warrants covering 4,446,917 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 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 (the June Offering), pursuant to a registration statement on Form S-3. The investors in the June 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.

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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.

Between January 31, 2019 and February 13, 2019 the Company entered into subscription agreements with certain investors for the sale of 10,728,480 shares of common stock at a purchase price of \$0.50 per share in a registered direct offering (the 2019 Offering), pursuant to a registration statement on Form S-3. The investors in the 2019 Offering also received warrants to purchase 5,364,240 shares of common stock with an exercise price of \$0.50 per share and a five-year term. The Company received net proceeds from the offering of approximately \$4.8 million. In addition, the placement agent received warrants covering 965,563 shares of common stock (or 9% of total shares sold to investors) with a per share exercise price of \$0.50 and 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 nine months ended February 28, 2019 and 2018, the Company incurred an expense of approximately \$18,600 and \$49,600 and \$30, 200 and \$51,700, respectively, for qualified non-elective contributions.

Note 13 Related Party Transactions

The Audit Committee of the Board of Directors, comprised of independent directors, reviews and approves all related party transactions. The below 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 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.

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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.

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 the 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 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.

On January 8, 2019, Argonne Trading LLC (Argonne), participated in the private placement of convertible promissory notes, as fully described in Note 4. Michael A. Klump, the manager of Argonne, is a director of the Company. Argonne purchased a convertible promissory note, bearing interest of 10% for \$500,000 in aggregate principal and received a warrant covering 500,000 shares of common stock at an exercise price of \$0.30 per share. The terms and conditions of the Argonne 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 December 10, 2018, Anthony D. Caracciolo resigned as the Chairman of the Board of Directors, but remained a director and Scott A. Kelly, M.D., was named Chairman of the Board of Directors. On December 19, 2018, the Compensation Committee of the Board of Directors 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 were out-of-the-money upon the date of such extension. These arrangements were conditioned upon Mr. Caracciolo's agreement to resign from the Board of Directors upon identification by the Company of an appropriately qualified candidate to fill the vacancy. Mr. Caracciolo had agreed to the foregoing terms and his resignation was effective January 10, 2019. These arrangements were not the result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices.

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Note 14 Subsequent Events

On March 12, March 14 and April 2, 2019, the Company received redemption notices from the holder of the Company's June 2018 Convertible Note, requesting redemptions of \$150,000, \$250,000 and \$125,000, respectively, of the outstanding balance thereof. In satisfaction of the redemption notices, the Company issued, in the aggregate, 1,281,194 shares of common stock to the note holder in accordance with the terms of the convertible note. Following the redemptions, the outstanding balance of the convertible note, including accrued but unpaid interest, was approximately \$5.3 million.

On March 20, 2019, the Company filed with the Secretary of State of the State of Delaware a Certificate of Designation of the Rights, Preferences, Privileges and Restrictions (the "Certificate of Designation") for Series C Convertible Preferred Stock, par value \$0.001 per share (the "Series C Preferred Stock"). The Certificate of Designation was previously authorized by the Board of Directors and provides for the issuance of up to 5,000 shares of Series C Preferred Stock.

The Certificate of Designation provides, among other things, that holders of Series C Preferred Stock shall be entitled to receive, at the option of the holder, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C Preferred Stock, to be paid per share of Series C Preferred Stock. Any dividends paid by the Company will first be paid to the holders of Series C Preferred Stock prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series C Preferred Stock are mandatory and cumulative and there are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. The stated value per share for the Series C Preferred Stock is \$1,000 (the "Stated Value").

In the event of any liquidation, dissolution or winding up of the Company, the Series C Preferred Stock will be paid, prior and in preference to any payment or distribution on any shares of common stock, currently outstanding series of preferred stock, or subsequent series of preferred stock, an amount per share equal to the Stated Value and the amount of any accrued and unpaid dividends. The holders of the Series C Preferred Stock will then receive distributions along with the holders of common stock on a *pari passu* basis according to the number of shares of common stock the Series C Preferred holders would be entitled if they converted their shares of Series C Preferred Stock at the time of such distribution.

If, at any time while the Series C Preferred Stock is outstanding, the Company effects any reorganization, merger or sale of the Company or substantially all of its assets (each a "Fundamental Transaction"), a holder of the Series C Preferred Stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series C Preferred Stock immediately prior to the Fundamental Transaction.

Each share of Series C Preferred Stock is convertible at any time at the holder's option into that number of fully paid and nonassessable shares of the Company's common stock determined by dividing the Stated Value by the conversion price of \$0.50 per share (subject to adjustment as set forth in the Certificate of Designation). No fractional shares will be issued upon the conversion of the Series C Preferred Stock.

Except as otherwise provided in the Certificate of Designation or as otherwise required by law, the Series C Preferred Stock has no voting rights.

On March 20, 2019 the Company, issued in private placements to accredited investors an aggregate of 3,246 shares of its Series C Preferred Stock, together with warrants to purchase an aggregate of up to 3,895,200 shares of its common stock, with an initial exercise price of \$0.50 per share, for aggregate gross proceeds to the Company of approximately

\$3.2 million. In connection with the private placement, the Company issued and sold to certain lead investors additional warrants to purchase an aggregate of up to 1,000,000 shares of Common Stock, on identical terms to the other warrants issued to investors. Pursuant to the subscription agreements entered into with each of the investors, the Company has agreed to use commercially reasonable efforts to prepare and file with the SEC within 120 days following the closing of the Series C Offering, but not later than August 31, 2019, a registration statement under the Securities Act of 1933, as amended, covering the resale of any common stock issuable to the investors upon the conversion of the Series C Preferred Stock and the exercise of their related warrants.

On March 29, 2019, the board of directors approved a stock option award covering 40,000 shares of common stock to an employee. The option has an exercise price of \$0.48 per share and a five-year term.

On April 1, 2019, the Company entered into a Master Services Agreement and Product Specific Agreement (together, the Samsung Agreement) with Samsung BioLogics Co., Ltd. (Samsung), pursuant to which Samsung will perform technology transfer, process validation, manufacturing and supply services for the commercial supply of the Company's leronlimab (PRO140) drug substance. Under the terms of the Samsung Agreement, the Company is obligated to make specified minimum purchases from Samsung pursuant to the Company's forecasted requirements. The first forecast will be delivered to Samsung by March 31, 2020. The Company must provide Samsung with a rolling forecast on a quarterly basis setting forth the total quantity that it expects to require in the following years.

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On April 5, 2019 the Company entered into subscription agreements with certain investors for the sale of 8,730,000 shares of common stock at a purchase price of \$0.50 per share in a registered direct offering, pursuant to a registration statement on Form S-3. The investors in the registered direct offering also received warrants to purchase 4,365,000 shares of common stock with an exercise price of \$0.50 per share and a five-year term. The Company received net proceeds from the offering of approximately \$4.0 million. In addition, the placement agent received warrants covering 785,700 shares of common stock (or 9% of total shares sold to investors) with a per share exercise price of \$0.50 and a five-year term and include a cashless exercise provision.

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-looking statements. These statements include, among others, information regarding future operations, future capital expenditures and future net cash flows. Such statements reflect current views with respect to future events and financial performance and involve risks and uncertainties, including, without limitation, regulatory initiatives and compliance with governmental regulations, the 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 approximately 4.5 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.

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

This is a pivotal 25-week trial for leronlimab 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 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 extension study, as described below, in order to provide continued access to leronlimab 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 our Biologics License Application (BLA) filing, of which, the first of three sections was filed in March 2019.

Extension 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 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 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 recently reported that interim data suggested that both the 525 mg and the 700 mg dosages are achieving a responder rate of approximately

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90% after the initial 10 weeks. 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 responders rate from preliminary data from the 525 mg and 700 mg dose arms, this trial may be discontinued, if and when we successfully file a protocol for a pivotal Phase 3 trial for monotherapy and initiate such a trial.

Cancer and Immunological Applications for Leronlimab

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

The target of leronlimab 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. 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 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 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.

Dr. Pestell's research has demonstrated three key properties of the CCR5's Mechanism of Action (MOA). The first is that the CCR5 receptor on cancer cells was responsible for the migration and invasion of cells into the blood stream, which leads to metastasis of breast, prostate, and colon cancer. The second is that blocking the CCR5 also turns on anti-tumor fighting properties restoring immune function. The third key finding was that blockage of the CCR5/CCL5 interaction had a synergistic effect with chemotherapeutic therapy and controlled cancer progression. Chemotherapy traditionally increased expression of CCR5 so blocking it is expected to reduce the levels of invasion and metastasis.

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

We also previously initiated our first clinical trial with leronlimab in an immunological indication—a Phase 2 clinical trial with leronlimab for GvHD in patients with AML or MDS who are undergoing bone marrow stem cell transplantation. As noted below, 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 alongside their existing products.

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

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Phase 1b/2 Trial for Triple-Negative Breast Cancer

We recently received clearance from the U.S. Food and Drug Administration (the FDA) for our IND submission to initiate a phase 1b/2 clinical trial for metastatic triple-negative breast cancer patients. We have identified five clinical trial sites and intend to dose its first several patients during the second quarter of calendar 2019. The change in circulating tumor cells (CTCs) number will be evaluated every 21 days during treatment and will be used as an initial prognostic marker for efficacy. Up to 48 patients are expected to be enrolled in this study.

Pre-clinical Studies for Multiple Cancer Indications

The Company recently announced that it was initiating eight pre-clinical studies with leronlimab for melanoma, pancreatic, breast, prostate colon, lung, liver and stomach cancers. An ongoing pre-clinical study conducted by the Company recently reported that leronlimab reduces by more than 98% human breast cancer metastasis in a murine xenograft model. Based upon these strong results, the Company filed for Orphan Drug Designation for its Phase 1b/2 triple negative breast cancer trial.

Phase 2 Trial for Graft-versus-Host Disease

This Phase 2 multi-center 100-day study with 60 patients is designed to evaluate the feasibility of the use of leronlimab 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. The amendments also provide for a 100% increase in the dose of leronlimab, 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.

Licensing Opportunities

We are currently evaluating strategic opportunities with respect to the assets acquired in our November 2018 acquisition of ProstaGene, LLC (ProstaGene), 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 discriminative 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.

In addition, we continue to conduct exploratory discussions with third parties who have expressed an interest in a licensing arrangement for leronlimab for HIV indications; such proposed arrangements are country or region specific.

Results of Operations for the three months ended February 28, 2019 and 2018 are as follows:

For the three months ended February 28, 2019 and February 28, 2018, the Company had no activities that produced revenues from operations.

For the three months ended February 28, 2019, the Company incurred a net loss of approximately \$12.6 million, as compared to a net loss of approximately \$18.0 million for the similar period in 2018. The decrease in net loss of approximately \$5.3 million related primarily to reduced research and development expenses of approximately \$3.1 million and a reduction in interest expense of approximately \$2.0 million, coupled with a non-cash benefit in the change in derivative liabilities of approximately \$2.1 million. These favorable trends were offset in part by an increase in general and administrative expenses of approximately \$1.4 million and amortization expenses of approximately \$0.4 million. The loss per share for the quarters ended February 28, 2019 and February 28, 2018 was \$(0.04) and \$(0.10), which reflects a comparatively lower net loss combined with a substantial increase in common shares outstanding.

For the three months ended February 28, 2019 and February 28, 2018, operating expenses totaled approximately \$12.9 million and \$14.1 million, respectively, consisting of research and development, general and administrative expenses, and amortization and

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depreciation. The reduction in operating expenses of approximately \$1.2 million, or 8.9%, was attributable to reductions in research and development expenses of approximately \$3.1 million, offset in part by increased general and administrative expenses and amortization of approximately \$1.4 million and \$0.4 million, respectively. General and administrative expenses, which totaled approximately \$3.3 million for the three months ended February 28, 2019, 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 69%, for the three months ended February 28, 2019 was due to increased salaries and benefits for new employees, and increased stock-based compensation for acceleration of vesting and stock awards related to an employment agreement, coupled with increases in other administrative expenses. . The increase in amortization expense of approximately \$0.4 million, or 465% was due to the increase in intangibles recognized with the acquisition of ProstaGene.

Research and development (R&D) expenses, which totaled approximately \$9.0 million for the three months ended February 28, 2019, decreased approximately \$3.1 million, or 25.3%, over the comparable 2018 quarter principally due to near completion of manufacturing-related expenses in connection with the preparation of our BLA filing. For the quarter ended February 28, 2019, R&D expenditures continue to be primarily devoted to: (1) increased CMC (chemistry, manufacturing and controls) activities to address regulatory compliance requirements for our BLA filing and leronlimab, (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 connection with the CMC portion of our BLA filing in mid-2019, followed by a potential strategic advancement in clinical priorities for a pivotal monotherapy trial and evaluation of several 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 February 28, 2019, the Company recognized a non-cash benefit associated with the decrease in fair value of derivative liabilities of approximately \$1.3 million, as compared to a non-cash charge of approximately \$0.7 in the similar 2018 quarter. The three months ended February 28, 2019 also includes two incremental derivatives relating to newly issued long-term convertible notes (see Note 4 to the accompanying financial statements) that represent approximately \$0.4 million and are not comparable to the same quarter in 2018. The warrants that contain a provision which gives rise to a derivative liability originated in September 2016. The two long-term convertible notes contain a provision for redemption at a variable price and originated in June 2018 and January 2019. 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 February 28, 2019 totaled approximately \$1.1 million, as compared to approximately \$3.1 million for the similar quarter in 2018. The components of interest expense include inducement interest related to convertible debt, accrued interest on convertible notes payable and amortization of debt discount and offering costs.

The future trends in all expenses will be driven, in large part, by the future outcomes of pre-clinical studies and clinical trials and their correlative effect on research and development expenses, as well as general and administrative expenses. 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 nine months ended February 28, 2019 and 2018 are as follows:

For the nine months ended February 28, 2019 and February 28, 2018, the Company had no activities that produced revenues from operations.

For the nine months ended February 28, 2019, the Company incurred a net loss of approximately \$41.3 million, as compared to \$40.5 million for the similar period in 2018. The increase in net loss of approximately \$0.8 million over the 2018 nine-month period was primarily attributable to a \$7.3 million increase in operating expenses, offset in part by an approximate decrease in interest expense of \$2.6 million, recognition of a \$2.8 million deferred income tax benefit and comparative increase in a non-cash benefit of the change in derivative liability of approximately \$1.2 million.

Operating expenses for the nine months ended February 28, 2019 increased by approximately \$7.3 million over the comparable 2018 period, due to increased general and administrative expenses of approximately \$2.9 million, increased R&D expenses of approximately \$4.0 million and amortization expense of approximately \$0.5 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 approximately \$2.8 million in connection with the acquisition of assets in the ProstaGene LLC

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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 nine months ended February 28, 2019 and February 28, 2018 was \$(0.16) and \$(0.25), respectively, with the reduction in loss per share (despite a small increase in aggregate net loss) caused by a significant increase in the number of shares outstanding from the prior period.

For the nine months ended February 28, 2019 and February 28, 2018, operating expenses totaled approximately \$42.0 million and \$34.7 million, respectively, consisting of research and development, general and administrative expenses, and amortization and depreciation. The increase in operating expenses of approximately \$7.3 million, or 21.7%, was attributable to increases in research and development expenses of approximately \$4.0 million and an increase in general and administrative expenses of approximately \$2.9 million and higher amortization of approximately \$0.5 million.

General and administrative expenses, which totaled approximately \$8.0 million for the nine months ended February 28, 2019, 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 \$2.9 million, or 55.3%, for the nine months ended February 28, 2019 over the comparable period a year ago was primarily due to an increase in non-cash stock-based compensation expenses of approximately \$1.8 million in connection with common stock issued related to an employment agreement, financial advisory services and employee stock option awards.

Research and development (R&D) expenses, which totaled approximately \$33.3 million for the nine months ended February 28, 2019, increased approximately \$4.0 million, or 13.6%, over the comparable 2018 period principally due to the completion of product manufacturing related to our BLA filing, and continuing clinical trial related expenses. For the nine-month period ended February 28, 2019, R&D expenditures continue to be primarily devoted to: (1) increased CMC (chemistry, manufacturing and controls) activities to satisfy regulatory compliance requirements for our BLA filing, (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 connection with BLA filing mid-2019 followed by a potential strategic advancement in clinical priorities for a pivotal monotherapy trial and evaluation of several 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 nine months ended February 28, 2019, the Company recognized a non-cash benefit associated with the decrease in fair value of derivative liabilities of approximately \$0.9 million, as compared to a non-cash charge of approximately \$0.3 in the similar 2018 period. The warrants that contain a provision which gives rise to a derivative liability originated in September 2016. The two long-term convertible notes contain a provision for redemption at a variable price and originated in June 2018 and January 2019. 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 nine months ended February 28, 2019 totaled approximately \$3.0 million, as compared to approximately \$5.5 million for the similar period in 2018. The components of interest expense include a loss on extinguishment of a long-term convertible note, accrued interest on a convertible note, inducement interest related to warrant exercise and convertible debt, along with the amortization of debt discount and debt issuance. On November 15, 2018, as previously reported, the Company amended one long-term convertible note to include an additional feature which allows the holder to receive the redemption amount at the Company's election (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. 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.

Table of Contents**Liquidity and Capital Resources**

The Company's cash position at February 28, 2019 increased approximately \$0.4 million to approximately \$1.6 million, as compared to a balance of approximately \$1.2 million as of May 31, 2018. The net increase in cash for the nine months ended February 28, 2019 was attributable to net cash provided by financing activities of approximately \$41.3 million, offset in part by cash used in operating activities of approximately \$41.0 million.

As of February 28, 2019, the Company had significant negative working capital of approximately \$17.8 million compared to negative working capital of approximately \$13.4 million at May 31, 2018, an increase in negative working capital of approximately \$4.4 million attributable primarily to cash used in operations.

Cash Flows

Net cash used in operating activities totaled approximately \$41.0 million during the nine months ended February 28, 2019, which reflects an increase of approximately \$18 million of net cash used in operating activities over the nine months ended February 28, 2018. The increase in net cash used in operating activities was due to an increase in net loss of approximately \$0.8 million, increased stock based compensation of approximately \$1.8 million, a non-cash loss on extinguishment of debt of approximately \$1.5 million, decrease of approximately \$1.2 million due to change in fair value of derivatives, increased amortization of approximately \$0.5 million, mitigated in part by a net decrease in working capital components totaling approximately \$12.9 million, and a reduction in interest expense of approximately \$2.9 million and non-cash deferred tax benefit of approximately \$2.8 million.

Net cash used in investing activities was immaterial during the nine months ended February 28, 2019, and there was no activity during the nine months ended February 28, 2018.

Net cash provided by financing activities of approximately \$41.3 million during the nine months ended February 28, 2019, increased approximately \$15.2 million over the \$26.1 million of net cash provided by financing activities during the nine months ended February 28, 2018. The increase in net cash provided from financing activities was attributable to net proceeds from the sale of common stock and warrants of approximately \$26.4 million, coupled with approximately \$14.9 million in net proceeds from convertible notes payable.

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 and continue to advance it through the regulatory process towards ultimate approval, concurrent with evaluating multiple cancer indications. 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, along with the increasing activities to complete the remaining two portions of our BLA filing for leronlimab as a combination therapy and will require a significant amount of additional capital in the future to complete these endeavors.

Contract Manufacturing

Subsequent to quarter end, on April 1, 2019, we entered into a Master Services Agreement and Product Specific Agreement with Samsung BioLogics Co., Ltd. (Samsung), pursuant to which Samsung will perform technology transfer, process validation, manufacturing and supply services for the commercial supply of leronlimab. Under the terms of the Agreement, we are obligated to make specified minimum purchases of leronlimab from Samsung

pursuant to our forecasted requirements. The first forecast will be delivered to Samsung by March 31, 2020. We must provide Samsung with a rolling forecast on a quarterly basis setting forth the total quantity that it expects to require in the following years. We estimate that initial ramp-up costs to manufacture commercial product at scale could aggregate approximately \$60 million, with approximately \$30 million payable over the course of calendar 2020 and approximately \$30 million more payable in the first quarter of 2021. Thereafter, we will pay Samsung per 15,000L batch according to the pricing terms specified in the agreement.

The agreement with Samsung has an initial term ending in December 2027 and shall be automatically extended for additional two year periods unless either party gives notice of termination at least six months prior to the then current term. Either party may terminate the agreement in the event of the other party's insolvency or uncured material breach, and we may terminate the agreement in the event of a voluntary or involuntary complete market withdrawal of leronlimab from commercial markets, with one and half year's prior notice. Neither party may assign the agreement without the consent of the other, except in the event of a sale of all or substantially all of the assets of a party to which the agreement relates.

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In addition to our manufacturing agreement with Samsung, we also have previously entered into an arrangement with another third party contract manufacturer to provide process transfer, validation and manufacturing services for leronlimab. In the event that we terminate the agreement with this manufacturer, we may incur certain financial penalties which would become payable to the manufacturer. Conditioned on the timing of termination, the financial penalties may range up to an approximate high of \$0.3 million. These undertakings are anticipated to require approximately \$5 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.

Management believes that two contract manufacturers may best serve our strategic objectives for the anticipated BLA filing and, if approved, the long-term commercial manufacturing capabilities for leronlimab. Management will continue to assess manufacturing capacity requirements as new market information becomes available regarding anticipated demand, subject to FDA approval.

Contract Research

We have entered into project work orders for each of our clinical trials with our contract research organization (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 \$0.3 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 \$1.2 million.

Licensing

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, while we have completed and filed the first of three portions of our BLA, it remains uncertain as to when the remaining two portions will be filed and when the BLA is accepted by the FDA, it is management's conclusion that the probability of achieving the subsequent future clinical development and regulatory milestones is not reasonably determinable, thus the future milestone payments payable to Progenics and its sub-licensors are deemed contingent consideration and, therefore, are not currently accruable.

Going Concern

As reported in the accompanying consolidated financial statements, for the nine months ended February 28, 2019 and February 28, 2018, we incurred net losses of approximately \$41.3 million and \$40.5 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 manufacturing 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 70 million shares of common stock authorized and available for issuance under our certificate of incorporation, as amended, and approximately \$153.2 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).

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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 February 28, 2019, 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 February 28, 2019. 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 February 28, 2019.

Internal Control Over Financial Reporting

No changes occurred during the quarter ended February 28, 2019, that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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PART II

Item 1. Legal Proceedings.

On February 1, 2019, the Securities and Exchange Commission entered a final settlement order regarding certain administrative charges stemming from alleged violations of federal securities laws pertaining to the disclosure of material weaknesses in our Internal Controls over Financial Reporting (ICFR) during the period from 2008 to 2016. The settlement was upon the terms previously reported in our Form 10-K for the fiscal year ended May 31, 2018. The settlement order noted that we had remediated our material weaknesses and determined that ICFR was effective as of May 31, 2017. Entry of the settlement order brought formal closure of the settlement previously negotiated with the Securities and Exchange Commission.

Other than the foregoing, we are not aware of any material pending legal proceedings, other than ordinary routine litigation incidental to the business, to which we are a party or of which any of our property is the subject.

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.

On February 14, 2019, the Company issued an unsecured convertible promissory note in the principal amount of \$250,000 and related warrants to purchase common stock of the Company in a private placement to an accredited investor, pursuant to a subscription agreement entered into with the investor, in exchange for cash in an equal amount. In connection with the offering the placement agent received a warrant covering 50,000 shares of common stock. The warrant has a five year term, an exercise of \$0.50 per share and has a cashless exercise provision. The terms of the private placement and of the notes and warrants were identical to those in the private placement that occurred on December 28, 2018, as described in Form 8-K filed with the Securities and Exchange Commission on January 3, 2019.

In addition, from February 4, 2019 through April 2, 2019, the Company received six redemption notices from the holder of the Company's convertible note issued on June 26, 2018 requesting redemptions in the aggregate amount of \$880,000 of the outstanding balance thereof. In satisfaction of the redemption notices, the Company issued 2,149,303 shares of Common Stock to the note holder in accordance with the terms of the convertible note. Following the redemptions, the outstanding balance of the convertible note, including accrued but unpaid interest, was approximately \$5.3 million.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

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Item 6. Exhibits.

(a) Exhibits:

- 3.1 Certificate of Designation, Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed March 20, 2019).
- 4.1 Form of Convertible Promissory Note (December 2018 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 3, 2019).
- 4.2 Convertible Promissory Note by and between CytoDyn Inc. and Iliad Research and Trading, L.P. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 30, 2019).
- 4.3 Convertible Promissory Note Warrant Agreement by and between CytoDyn Inc. and Iliad Research and Trading, L.P. (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed January 31, 2019).
- 4.4 Form of Warrant to Purchase Common Stock (December 2018 Offering) (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed January 3, 2019).
- 4.5 Form of Warrant Agreement (January/February 2019 Offering) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 31, 2019).
- 4.6 Form of Series C Warrant Agreement (Series C Convertible Preferred Stock Offering) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed March 20, 2019).
- 10.1* Employment Agreement by and between CytoDyn Inc. and Dr. Nitya G. Ray, dated December 22, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 26, 2018).
- 10.2 Form of Subscription Agreement (December 2018 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 3, 2019).
- 10.3 Securities Purchase Agreement by and between CytoDyn Inc. and Iliad Research and Trading, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 30, 2019).
- 10.4 Security Agreement by and between CytoDyn Inc. and Iliad Research and Trading, L.P. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed January 30, 2019).
- 10.5 Form of Subscription Agreement (January/February 2019 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 31, 2019).
- 10.6 Placement Agent Agreement (January/February 2019 Offering) (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed January 31, 2019).
- 10.7 Form of Subscription Agreement (Series C Convertible Preferred Stock Offering) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 20, 2019).
- 31.1** Rule 13a-14(a) Certification by CEO of Registrant.

31.2**

Rule 13a-14(a) Certification by CFO of the Registrant.

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| 32.1** | <u>Certification of CEO of the Registrant pursuant to 18 U.S.C. Section 1350.</u> |
| 32.2** | <u>Certification of CFO of the Registrant pursuant to 18 U.S.C. Section 1350.</u> |
| 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. |

* Management contract or compensatory plan or arrangement.

** Filed herewith.

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SIGNATURES

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

CYTODYN INC.

(Registrant)

Dated: April 9, 2019

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

Dated: April 9, 2019

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