

22nd Century Group, Inc.
Form 10-Q
November 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
X ACT OF 1934**

For the Quarterly Period Ended September 30, 2016

**..TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
OF 1934**

For the Transition Period From _____ to _____

Commission File Number: 001-36338

22nd Century Group, Inc.

(Exact name of registrant as specified in its charter)

Nevada **98-0468420**
(State or other jurisdiction (IRS Employer
of incorporation) Identification No.)

9530 Main Street, Clarence, New York 14031
(Address of principal executive offices)

(716) 270-1523

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Large Accelerated Filer Accelerated Filer

Non-accelerated Filer Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of November 8, 2016, there were 90,698,113 shares of common stock issued and outstanding.

22nd CENTURY GROUP, INC.

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22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
September 30, 2016 with Comparative Figures at December 31, 2015

| | September 30, 2016 (unaudited) | December 31, 2015 |
|--|---|-------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash | \$5,190,505 | \$3,760,297 |
| Accounts receivable, net | 16,454 | 51,230 |
| Inventory, net | 3,047,402 | 2,706,330 |
| Prepaid expenses and other assets | 414,691 | 635,998 |
| Total current assets | 8,669,052 | 7,153,855 |
| Machinery and equipment, net | 2,448,035 | 2,555,793 |
| Other assets: | | |
| Intangible assets, net | 7,400,713 | 7,364,120 |
| Equity investment | 1,050,583 | 1,222,651 |
| Total other assets | 8,451,296 | 8,586,771 |
| Total assets | \$19,568,383 | \$18,296,419 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Current portion of note payable | \$327,086 | \$308,582 |
| Accounts payable | 1,381,711 | 1,283,346 |
| Accrued expenses | 1,050,467 | 1,349,438 |
| Accrued severance | 227,553 | 220,661 |
| Total current liabilities | 2,986,817 | 3,162,027 |
| Long-term portion of note payable | 307,938 | 307,938 |
| Long-term portion of accrued severance | 30,195 | 199,658 |
| Warrant liability | 73,694 | 2,898,296 |
| Total liabilities | 3,398,644 | 6,567,919 |
| Commitments and contingencies (Note 12) | - | - |
| Shareholders' equity | | |
| Capital stock authorized: | | |
| 10,000,000 preferred shares, \$.00001 par value | | |
| 300,000,000 common shares, \$.00001 par value | | |
| Capital stock issued and outstanding: | | |
| 82,198,113 common shares (71,066,844 at December 31, 2015) | 822 | 710 |

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| | | |
|--|--------------|--------------|
| Capital in excess of par value | 91,560,736 | 78,284,815 |
| Accumulated deficit | (75,391,819) | (66,557,025) |
| Total shareholders' equity | 16,169,739 | 11,728,500 |
| | | |
| Total liabilities and shareholders' equity | \$19,568,383 | \$18,296,419 |

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months Ended September 30,
(unaudited)

| | 2016 | 2015 |
|---|----------------|----------------|
| Revenue: | | |
| Sale of products, net | \$3,097,648 | \$2,667,506 |
| Cost of goods sold (exclusive of depreciation shown separately below): | | |
| Products | 3,282,266 | 2,948,928 |
| Gross loss | (184,618) | (281,422) |
| Operating expenses: | | |
| Research and development (including equity based compensation of \$34,656 and \$37,269, respectively) | 691,970 | 505,084 |
| General and administrative (including equity based compensation of \$157,844 and \$358,829, respectively) | 1,230,967 | 1,303,104 |
| Sales and marketing costs (including equity based compensation of \$12,360 and \$16,614, respectively) | 277,096 | 470,621 |
| Depreciation | 81,354 | 81,700 |
| Amortization | 129,807 | 115,671 |
| | 2,411,194 | 2,476,180 |
| Operating loss | (2,595,812) | (2,757,602) |
| Other income (expense): | | |
| Warrant liability (loss) gain - net | (46,995) | 27,723 |
| Loss on equity investment | (29,997) | (33,211) |
| Interest income | 2,131 | 10,101 |
| Interest expense | (9,315) | (8,702) |
| | (84,176) | (4,089) |
| Loss before income taxes | (2,679,988) | (2,761,691) |
| Income taxes | - | - |
| Net loss | \$(2,679,988) | \$(2,761,691) |
| Loss per common share - basic and diluted | \$(0.03) | \$(0.04) |
| Common shares used in basic earnings per share calculation | 80,386,519 | 70,798,879 |

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Nine Months Ended September 30,
(unaudited)

| | 2016 | 2015 |
|---|----------------|----------------|
| Revenue: | | |
| Sale of products, net | \$8,944,362 | \$5,590,597 |
| Cost of goods sold (exclusive of depreciation shown separately below): | | |
| Products | 9,146,247 | 6,181,954 |
| Gross loss | (201,885) | (591,357) |
| Operating expenses: | | |
| Research and development (including equity based compensation of \$117,937 and \$114,745, respectively) | 1,799,289 | 947,153 |
| General and administrative (including equity based compensation of \$560,766 and \$3,064,184, respectively) | 4,799,349 | 6,251,889 |
| Sales and marketing costs (including equity based compensation of \$29,246 and \$32,646, respectively) | 1,230,816 | 876,625 |
| Depreciation | 243,018 | 239,140 |
| Amortization | 380,689 | 331,960 |
| | 8,453,161 | 8,646,767 |
| Operating loss | (8,655,046) | (9,238,124) |
| Other income (expense): | | |
| Warrant liability gain - net | 14,602 | 199,556 |
| Settlement proceeds | - | 1,000,000 |
| Loss on equity investment | (172,068) | (125,026) |
| Interest income | 6,729 | 24,424 |
| Interest expense | (29,011) | (27,963) |
| | (179,748) | 1,070,991 |
| Loss before income taxes | (8,834,794) | (8,167,133) |
| Income taxes | - | - |
| Net loss | \$(8,834,794) | \$(8,167,133) |
| Loss per common share - basic and diluted | \$(0.11) | \$(0.12) |
| Common shares used in basic earnings per share calculation | 76,826,949 | 67,225,308 |

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
Nine Months Ended September 30, 2016
(unaudited)

| | Common Shares Outstanding | Par value of Common Shares | Contributed Capital | Accumulated Deficit | Shareholders' Equity |
|--|---------------------------------|-------------------------------------|------------------------|------------------------|-------------------------|
| Balance at December 31, 2015 | 71,006,844 | \$ 710 | \$78,284,815 | \$(66,557,025) | \$ 11,728,500 |
| Common stock issued in February 2016 registered direct offering, net | 5,000,000 | 50 | 5,091,741 | - | 5,091,791 |
| Common stock issued in July 2016 registered direct offering, net | 6,172,840 | 62 | 4,682,702 | - | 4,682,764 |
| Reclassification of warrant liability to capital in excess of par | - | - | 2,810,000 | - | 2,810,000 |
| Stock based compensation | 15,811 | - | 691,282 | - | 691,282 |
| Stock issued in connection with warrant exercise | 2,618 | - | 196 | - | 196 |
| Net loss | - | - | - | (8,834,794) | (8,834,794) |
| Balance at September 30, 2016 | 82,198,113 | \$ 822 | \$91,560,736 | \$(75,391,819) | \$ 16,169,739 |

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months Ended September 30,
(unaudited)

| | 2016 | 2015 |
|---|---------------|---------------|
| Cash flows from operating activities: | | |
| Net loss | \$(8,834,794) | \$(8,167,133) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Amortization and depreciation | 550,191 | 497,583 |
| Amortization of license fees | 73,516 | 73,516 |
| Loss on equity investment | 172,068 | 125,026 |
| Accretion of interest on note payable and accrued severance | 29,011 | 18,034 |
| Warrant liability gain | (14,602) | (199,556) |
| Equity based employee compensation expense | 677,076 | 1,000,603 |
| Equity based payments for outside services | 30,873 | 2,210,972 |
| Increase in inventory reserve | 45,000 | 60,000 |
| Decrease (increase) in assets: | | |
| Accounts receivable | 34,776 | (225,399) |
| Inventory | (386,072) | (369,731) |
| Prepaid expenses and other assets | 204,641 | (203,565) |
| Increase (decrease) in liabilities: | | |
| Accounts payable | (91,945) | 98,807 |
| Accrued expenses | (298,970) | 248,683 |
| Accrued severance | (173,078) | (30,857) |
| Net cash used in operating activities | (7,982,309) | (4,863,017) |
| Cash flows from investing activities: | | |
| Acquisition of patents and trademarks | (236,723) | (316,879) |
| Acquisition machinery and equipment | (125,511) | (22,796) |
| Net cash used in investing activities | (362,234) | (339,675) |
| Cash flows from financing activities: | | |
| Proceeds from exercise of warrants | 196 | - |
| Net proceeds from June 2015 registered direct offering | - | 5,576,083 |
| Net proceeds from February 2016 registered direct offering | 5,091,791 | - |
| Net proceeds from July 2016 registered direct offering | 4,682,764 | - |
| Stock cancellation | - | (34,500) |
| Net cash provided by financing activities | 9,774,751 | 5,541,583 |
| Net increase in cash | 1,430,208 | 338,891 |
| Cash - beginning of period | 3,760,297 | 6,402,687 |
| Cash - end of period | \$5,190,505 | \$6,741,578 |
| Supplemental disclosures of cash flow information: | | |
| Net cash paid for: | | |
| Cash paid during the period for interest | \$10,507 | \$7,296 |
| Cash paid during the period for income taxes | \$- | \$- |
| Non-cash transactions: | | |

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| | | |
|---|--------------|------------|
| Patent and trademark additions included in accounts payable | \$ 180,560 | \$ 242,925 |
| Machinery and equipment additions included in accounts payable | \$ 9,749 | \$ 12,677 |
| Issuance of common stock in satisfaction of accrued expense | \$ - | \$ 325,000 |
| Reclassification of warrant liability to capital in excess of par | \$ 2,810,000 | \$ - |

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2016

(unaudited)

NOTE 1. - NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation - The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments consisting of normal recurring accruals considered necessary for a fair and non-misleading presentation of the financial statements have been included.

Operating results for the nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. The balance sheet at December 31, 2015 has been derived from the audited consolidated financial statements at that date, but does not include all the information and footnotes required by GAAP for complete financial statements. These interim consolidated financial statements should be read in conjunction with the December 31, 2015 audited consolidated financial statements and the notes thereto.

Principles of Consolidation - The accompanying consolidated financial statements include the accounts of 22nd Century Group, Inc. ("22nd Century Group"), its three wholly-owned subsidiaries, 22nd Century Limited, LLC ("22nd Century Ltd"), NASCO Products, LLC ("NASCO"), and Botanical Genetics, LLC ("Botanical Genetics"), and two wholly-owned subsidiaries of 22nd Century Ltd, Goodrich Tobacco Company, LLC ("Goodrich Tobacco") and Hercules Pharmaceuticals, LLC ("Hercules Pharma") (collectively, the "Company"). All intercompany accounts and transactions have been eliminated.

Nature of Business - 22nd Century Ltd is a plant biotechnology company specializing in technology that allows for the level of nicotine and other nicotinic alkaloids (e.g., nornicotine, anatabine and anabasine) in tobacco plants to be decreased or increased through genetic engineering and plant breeding. The Company currently owns or exclusively controls more than 200 issued patents and more than 50 pending patent applications around the world. Goodrich Tobacco and Hercules Pharma are business units for the Company's (i) premium cigarettes and potential modified risk tobacco products and (ii) smoking cessation product, respectively. The Company acquired the membership interests of NASCO on August 29, 2014. NASCO is a federally licensed tobacco products manufacturer, a participating member of the tobacco Master Settlement Agreement ("MSA") between the tobacco industry and the Settling States under the

MSA, and operates the Company's cigarette manufacturing business in North Carolina. Botanical Genetics is a wholly-owned subsidiary of 22nd Century Group, and was incorporated to facilitate an equity investment more fully described in Note 8.

Reclassifications - Certain items in the 2015 financial statements have been reclassified to conform to the 2016 classification.

Preferred stock authorized - The Company is authorized to issue "blank check" preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock.

Accounts receivable - The Company periodically reviews aged account balances for collectability. As of September 30, 2016, and December 31, 2015, the Company has established an allowance for doubtful accounts in the amount of \$10,000.

Inventory - Inventories are valued at the lower of cost or market. Cost is determined using an average cost method for tobacco leaf inventory and raw materials inventory and standard cost is primarily used for finished goods inventory. Inventories are evaluated to determine whether any amounts are not recoverable based on slow moving or obsolete condition and are written off or reserved as appropriate. Inventories at September 30, 2016 and December 31, 2015 consisted of the following:

| | September 30, 2016 | December 31, 2015 |
|---|--------------------------|-------------------------|
| Inventory - tobacco leaf | \$1,867,335 | \$1,816,857 |
| Inventory - finished goods | | |
| Cigarettes and filtered cigars | 424,960 | 342,707 |
| Inventory - raw materials | | |
| Cigarette and filtered cigar components | 910,730 | 657,389 |
| | 3,203,025 | 2,816,953 |
| Less: inventory reserve | 155,623 | 110,623 |
| | \$3,047,402 | \$2,706,330 |

Machinery and equipment - Machinery and equipment are recorded at their acquisition cost and depreciated on a straight-line basis over their estimated useful lives ranging from 3 to 10 years. Depreciation commences when the asset is placed in service.

Intangible Assets - Intangible assets are recorded at cost and consist primarily of (1) expenditures incurred with third parties related to the processing of patent claims and trademarks with government authorities, as well as costs to acquire patent rights from third parties, (2) license fees paid for third-party intellectual property, (3) costs to become a signatory under the tobacco MSA, and (4) license fees paid to acquire a predicate cigarette brand. The amounts capitalized relate to intellectual property that the Company owns or to which it has exclusive rights. The Company's intellectual property capitalized costs are amortized using the straight-line method over the remaining statutory life of the primary patent in each of the Company's two primary groupings of patent families, which expire in 2019 and 2028 (the assets' estimated lives, respectively). Periodic maintenance or renewal fees are expensed as incurred. Annual minimum license fees are charged to expense. License fees paid for third-party intellectual property are amortized on a straight-line basis over the last to expire patents, which patent expiration dates range from 2028 through 2035. The Company believes costs associated with becoming a signatory to the MSA and acquiring the predicate cigarette brand have an indefinite life and as such, no amortization is taken. Total intangible assets at September 30, 2016 and December 31, 2015 consisted of the following:

| September 30, | December 31, |
|------------------|-----------------|
|------------------|-----------------|

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| | 2016 | 2015 |
|---|-------------|-------------|
| Intangible assets, net | | |
| Patent and trademark costs | \$5,563,841 | \$5,146,559 |
| Less: accumulated amortization | 1,911,066 | 1,603,893 |
| Patent and trademark costs, net | 3,652,775 | 3,542,666 |
| License fees, net (see Note 12) | 1,450,000 | 1,450,000 |
| Less: accumulated amortization | 204,062 | 130,546 |
| License fees, net | 1,245,938 | 1,319,454 |
| MSA signatory costs | 2,202,000 | 2,202,000 |
| License fee for predicate cigarette brand | 300,000 | 300,000 |
| | \$7,400,713 | \$7,364,120 |

Amortization expense relating to the above intangible assets for the three and nine months ended September 30, 2016 amounted to \$129,807 and \$380,689, respectively (\$115,671 and \$331,960 for the three and nine months ended September 30, 2015, respectively).

The estimated annual average amortization expense for the next five years is approximately \$364,000 for patent costs and \$98,000 for license fees.

Impairment of Long-Lived Assets - The Company reviews the carrying value of its amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable. The Company assesses recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. There was no impairment loss recorded during the three and nine months ended September 30, 2016 or 2015.

Income Taxes - The Company recognizes deferred tax assets and liabilities for any basis differences in its assets and liabilities between tax and GAAP reporting, and for operating loss and credit carry-forwards.

Considering the Company's history of cumulative net operating losses and the uncertainty of their future utilization, the Company has established a valuation allowance to fully offset its net deferred tax assets as of September 30, 2016 and December 31, 2015.

The Company's federal and state tax returns for the years ended December 31, 2013 through December 31, 2015 are currently open to audit under the statutes of limitations. There were no pending audits as of September 30, 2016.

Stock Based Compensation - The Company uses a fair-value based method to determine compensation for all arrangements under which Company employees and others receive shares or options to purchase common shares of the Company. Stock based compensation expense is recorded over the requisite service period based on estimates of probability and time of achieving milestones and vesting. For accounting purposes, the shares will be considered issued and outstanding upon vesting.

Revenue Recognition - The Company recognizes revenue from product sales at the point the product is shipped to a customer and title has transferred. Revenue from the sale of the Company's products is recognized net of cash

discounts, sales returns and allowances. Cigarette and filtered cigar federal excise taxes and other regulatory fees in the approximate amount of \$1,810,000 and \$5,387,000 are included in net sales for the three and nine months ended September 30, 2016, respectively (approximately \$1,910,000 and \$3,838,000 for the three and nine months ended September 30, 2015, respectively), except on sales of *SPECTRUM* research cigarettes, exported cigarettes, exported filtered cigars and in-bond sales of filtered cigars to other federally licensed tobacco products manufacturers, to which such taxes do not apply. The Company recognizes revenue from the sale of its *MAGIC* brand cigarettes in Europe when the cigarettes are sold by the European distributors to the retailers and are sold net of cash discounts, sales returns and allowances, and all applicable taxes.

The Company was chosen to be a subcontractor for a 5-year government contract between RTI International (“RTI”) and the National Institute on Drug Abuse (“NIDA”) to supply NIDA with research cigarettes. These government research cigarettes are distributed under the Company’s mark *SPECTRUM*. In September 2015, the Company received a purchase order for approximately 5.0 million *SPECTRUM* research cigarettes. Approximately 40% of the order was shipped in December 2015, resulting in the recognition of revenue in the amount of \$242,658 during the fourth quarter of 2015. The remainder of the order was shipped in January 2016 and generated revenue of \$329,321. There were no *SPECTRUM* cigarettes delivered during the second and third quarters of 2016.

Derivatives - The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair market value and then is revalued at each reporting date, with changes in fair value reported in the Consolidated Statements of Operations. The methodology for valuing our outstanding warrants classified as derivative instruments utilizes a lattice model approach which includes probability weighted estimates of future events, including volatility of our common stock. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified on the balance sheet as current or non-current based on if the net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

Research and Development - Research and development costs are expensed as incurred.

Advertising - The Company expenses advertising costs as incurred. Advertising expense was approximately \$24,000 and \$259,000 for the three and nine months ended September 30, 2016, respectively (\$71,000 and \$186,000 for the three and nine months ended September 30, 2015, respectively).

Loss Per Common Share - Basic loss per common share is computed using the weighted-average number of common shares outstanding. Diluted loss per share is computed assuming conversion of all potentially dilutive securities. Potential common shares outstanding are excluded from the computation if their effect is anti-dilutive.

Commitment and Contingency Accounting - The Company evaluates each commitment and/or contingency in accordance with the accounting standards, which state that if the item is more likely than not to become a direct liability, then the Company will record the liability in the financial statements. If not, the Company will disclose any material commitments or contingencies that may arise.

Use of Estimates - The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

Fair Value of Financial Instruments - Financial instruments include cash, receivables, accounts payable, accrued expenses, accrued severance, note payable and warrant liability. Other than warrant liability, fair value is assumed to approximate carrying values for these financial instruments, since they are short term in nature, they are receivable or payable on demand, or had stated interest rates that approximate the interest rates available to the Company as of the reporting date. The determination of the fair value of the warrant liability includes unobservable inputs and is therefore categorized as a Level 3 measurement, as further discussed in Note 11.

Equity Investments - The Company accounts for investments in equity securities of other entities under the equity method of accounting if the Company's investment in the voting stock is greater than or equal to 20% and less than a majority, and the Company has the ability to have significant influence over the operating and financial policies of the investee.

Accounting Pronouncements - In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU 2014-09, “Revenue from Contracts with Customers,” which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. The revised effective date for the ASU is for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). In August 2015, the FASB issued ASU 2015-14, “Revenue from Contracts with Customers (Topic 606) - Deferral of the Effective Date,” which deferred the effective date of ASU 2014-09 to annual reporting periods beginning after December 15, 2017, with earlier application permitted as of annual reporting periods beginning after December 15, 2016. In March 2016, the FASB issued ASU No. 2016-08, “Revenue from Contracts with Customers (Topic 606) - Principal versus Agent Considerations,” to clarify the implementation guidance on principal versus agent. In April 2016, the FASB issued ASU No. 2016-10, “Revenue from Contracts with Customers (Topic 606) - Identifying Performance Obligations and Licensing,” which clarifies the identifying performance obligations and licensing implementation guidance. The Company is currently evaluating the impact of the pending adoption of these ASU’s on its consolidated financial statements and has not yet determined the method by which it will adopt the standard.

In August 2014, the FASB issued ASU 2014-15, “Presentation of Financial Statements - Going Concern,” which provides guidance on determining when and how to disclose going-concern uncertainties in the financial statements. The new standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued. An entity will be required to provide certain disclosures if conditions or events raise substantial doubt about the entity’s ability to continue as a going concern. The ASU applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU 2014-15 on our consolidated financial statements and have not yet determined when we will adopt the standard.

In February 2016, the FASB issued ASU 2016-02, "Leases," which supersedes existing lease guidance under GAAP. Under the new guidance, lessees will be required to recognize leases as right of use assets and liabilities for leases with lease terms of more than twelve months. The guidance will apply for both finance and operating leases. The effective date for the ASU is for annual periods beginning after December 15, 2018 and interim periods therein. The Company is currently evaluating the impact of the ASU on its consolidated financial statements.

NOTE 2. – JULY 2016 REGISTERED DIRECT OFFERING

On July 27, 2016, the Company closed a registered direct offering of common stock and warrants consisting of 6,172,840 shares of the Company's common stock and warrants to purchase 7,043,211 shares of the Company's common stock. The warrants provide for an exercise price of \$1.00 per share and 1,543,210 of the warrants were exercisable immediately and had a fair value of approximately \$858,000 at issuance and 5,500,001 of the warrants were exercisable six months from the date of issuance and had a fair value of approximately \$3,058,000 at issuance. All the warrants have a term of 5.5 years. The common stock and warrants were sold for \$0.81 per unit, resulting in net proceeds to the Company in the amount of \$4,682,764, after deducting expenses associated with the transaction. In addition, on July 27, 2016, the Company terminated an aggregate of 5.5 million warrants with exercise prices of \$1.21 and \$1.25 per share (see Note 3 – February 2016 Registered Direct Offering and Note 4 – June 2015 Registered Direct Offering for additional information).

NOTE 3. - FEBRUARY 2016 REGISTERED DIRECT OFFERING

On February 5, 2016, the Company closed a registered direct offering of common stock and warrants consisting of 5,000,000 shares of the Company's common stock and warrants to purchase 2,500,000 shares of the Company's common stock at an exercise price of \$1.21 per share. The warrants were exercisable for a period of sixty-six (66) months after issuance, were not exercisable for a period of six months immediately following the issuance and had a fair value of approximately \$1,940,000 at issuance. The common stock and warrants were sold for \$1.10 per unit, resulting in net proceeds to the Company in the amount of \$5,091,791, after deducting expenses associated with the transaction. The warrants associated with this transaction were terminated on July 27, 2016 (see Note 2 – July 2016 Registered Direct Offering for additional information).

NOTE 4. - JUNE 2015 REGISTERED DIRECT OFFERING

On June 2, 2015, the Company closed a registered direct offering of common stock and warrants consisting of 6,000,000 shares of the Company's common stock and warrants to purchase 3,000,000 shares of the Company's common stock at an exercise price of \$1.25 per share. The warrants were exercisable for a period of sixty-six (66)

months after issuance, were not exercisable for a period of six months immediately following the issuance and had a fair value of approximately \$2,067,000 at issuance. The common stock and warrants were sold for \$1.00 per unit, resulting in net proceeds to the Company in the amount of \$5,576,083, after deducting expenses associated with the transaction. The warrants associated with this transaction were terminated on July 27, 2016 (see Note 2 – July 2016 Registered Direct Offering for additional information).

NOTE 5. - JOINT VENTURE, CONSULTING AGREEMENT AND ASSOCIATED WARRANTS

On June 22, 2015, the Company terminated its joint venture arrangement with Crede CG III, Ltd. (“Crede”) and a third-party due to non-performance and other breaches of the arrangement by Crede and its principals. The Company also notified Crede that the Company reserved and did not waive any rights that the Company may have to assert any and all claims that it may have against Crede, its employees, agents, representatives or affiliates thereof, which are allowable by law or in equity, including claims for breach of the warrant agreements entered into with Crede.

The six-month Consulting Agreement (the “Consulting Agreement”), entered into with Crede on September 29, 2014, expired on March 29, 2015. The value of the warrants issued in conjunction with the Consulting Agreement in the aggregate amount of \$4,070,000 and initially recorded as prepaid consulting fees have been fully amortized. The amortization of the prepaid consulting fees amounted to \$1,978,785 for the three months ended March 31, 2015, and are included in General and administrative expenses in the Company’s Consolidated Statements of Operations. There was no amortization of prepaid consulting fees for the three and nine months ended September 30, 2016.

Four tranches of warrants were issued to Crede in conjunction with the Consulting Agreement as follows: Tranche 1A warrant to purchase 1,250,000 shares of Company common stock, Tranche 1B warrant to purchase 1,000,000 shares of Company common stock, Tranche 2 warrant to purchase 1,000,000 shares of Company common stock and Tranche 3 warrant to purchase 1,000,000 shares of Company common stock. The Tranche 1A warrant contained an exchange rights clause that required derivative liability treatment under FASB ASC 480 - "Distinguishing Liabilities from Equity." The Company valued the derivative liability associated with the Tranche 1A warrant at inception at \$2,810,000 and the liability was recorded on the Company's Consolidated Balance Sheets in Warrant liability. In March 2016, the Company provided notice to Crede that Crede repeatedly breached the activity restrictions contained in the warrants and because the terms of the Tranche 1A warrant provide that the availability of the exchange feature was subject to compliance with such activity restrictions, the exchange rights clause contained in the Tranche 1A warrant was no longer available and was thereafter void (although the remaining amount of shares underlying the warrant without the exchange feature remained fully exercisable at \$3.36 per share through the warrant expiration date of September 29, 2016). Accordingly, the Company reclassified the warrant liability associated with the Tranche 1A warrant to Capital in excess of par on its Consolidated Balance Sheets during March 2016. The Tranche 1A and Tranche 1B warrants all expired without exercise on September 29, 2016.

The Tranche 2 and Tranche 3 warrants were not exercisable unless and until certain revenue milestones were attained, as defined in the prior joint venture agreement between Crede and the Company. As stated above, the Company terminated the joint venture agreement on June 22, 2015. Accordingly, such revenue milestones will never be satisfied and the Tranche 2 and Tranche 3 warrants will never be exercisable.

NOTE 6. - MANUFACTURING FACILITY

The Company's manufacturing operations at its North Carolina factory were not at full production capacity during the nine months ended September 30, 2016, but the Company continued manufacturing a third-party MSA cigarette brand, filtered cigars on a contract basis, and the Company's own proprietary cigarette brand, *RED SUN*. Raw material component costs, direct manufacturing costs, and an overhead allocation are included in the Cost of goods sold and finished goods inventory. General and administrative expenses of the factory amounted to \$140,690 and \$422,626 for the three and nine months ended September 30, 2016, respectively (\$164,280 and \$448,399 for the three and nine months ended September 30, 2015, respectively).

NOTE 7. - MACHINERY AND EQUIPMENT

Machinery and equipment at September 30, 2016 and December 31, 2015 consisted of the following:

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| | September 30, 2016 | December 31, 2015 |
|--|--------------------------|-------------------------|
| Cigarette manufacturing equipment | \$3,125,657 | \$3,016,246 |
| Office furniture, fixtures and equipment | 102,134 | 95,361 |
| Laboratory equipment | 19,076 | - |
| | 3,246,867 | 3,111,607 |
| Less: accumulated depreciation | 798,832 | 555,814 |
| Machinery and equipment, net | \$2,448,035 | \$2,555,793 |

Depreciation expense was \$81,354 and \$243,018 for the three and nine months ended September 30, 2016, respectively (\$81,700 and \$239,140 for the three and nine months ended September 30, 2015, respectively).

NOTE 8. - EQUITY INVESTMENT

On April 11, 2014, the Company, through its wholly-owned subsidiary, Botanical Genetics, entered into an investment agreement (the “Agreement”) with Anandia Laboratories, Inc., a Canadian plant biotechnology company (“Anandia”). The Agreement provided for the Company to make an initial investment of \$250,000 in Anandia in return for (i) a ten percent (10%) equity interest in Anandia, and (ii) certain rights granted to the Company for four patent families (the “Intellectual Property”). The \$250,000 investment was made on April 14, 2014. On September 15, 2014, certain milestones were achieved triggering an additional cash investment in Anandia in the amount of \$450,000 in return for (i) an additional fifteen percent (15%) equity interest in Anandia, and (ii) a worldwide sublicense agreement to the Intellectual Property, including exclusive rights within the U.S. In addition, the Company issued 150,000 unregistered shares of the Company’s common stock to Anandia with a value on the day of issuance of September 15, 2014 in the amount of \$394,500, and on March 31, 2015, the Company issued to Anandia an additional 377,906 unregistered shares of the Company’s common stock with an aggregate market value of \$325,000 at the time of the issuance in accordance with the Agreement.

The Company uses the equity method of accounting to record its 24.4% ownership interest in Anandia (ownership was 25% prior to a dilutive event on September 8, 2016). As of September 30, 2016 and December 31, 2015, the Company's equity investment balance in Anandia was \$1,050,583 and \$1,222,651, respectively, and is classified within Other assets on the accompanying Consolidated Balance Sheets. As of December 31, 2014, the carrying value of our investment in Anandia was approximately \$1,199,000 in excess of our share of the book value of the net assets of Anandia, with such difference being attributable to intangible assets. This intangible asset is being amortized over the expected benefit period and this amortization expense of \$14,412 and \$43,236 for the three and nine months ended September 30, 2016, respectively (\$14,412 and \$43,236 for the three and nine months ended September 30, 2015, respectively), has been included in the Loss on equity investment in the accompanying Consolidated Statements of Operations. In addition, the Company has recorded an equity loss of \$15,585 and \$128,832 for the three and nine months ended September 30, 2016, respectively, representing the Company's portion of Anandia's net losses, resulting in a total loss on equity investment of \$29,997 and \$172,068 for the three and nine months ended September 30, 2016, respectively (the Company recorded an equity loss of \$18,799 and \$81,790 for the three and nine months ended September 30, 2015, respectively, resulting in a total loss on equity investment of \$33,211 and \$125,026 for the three and nine months ended September 30, 2015, respectively).

NOTE 9. - NOTES PAYABLE AND PATENT ACQUISITION

On December 22, 2014, the Company entered into a Purchase Agreement (the "Purchase Agreement") with the National Research Council of Canada ("NRC") to acquire certain patent rights that the Company had previously licensed from NRC under a license agreement between the parties. The Purchase Agreement provided for payment by the Company to NRC for the NRC patent rights a total amount of \$1,213,000, of which \$213,000 was paid in cash at the closing on December 23, 2014, and with the remaining \$1,000,000 balance to be paid in three equal installments of \$333,333 in December of 2015, 2016 and 2017, respectively, with no interest on the installment payments unless the Company defaults on any such installment payments. As such, the Company computed the present value of the note payable using the Company's incremental borrowing rate. The resulting present value of the note payable amounted to \$925,730 at December 31, 2014. After the scheduled installment payment of \$333,333 made by the Company to NRC on December 22, 2015 and the accretion of interest, the remaining present value of the note payable amounts to \$635,024; with \$327,086 and \$307,938 recorded as the current and long-term portion of the note payable, respectively, at September 30, 2016 (\$616,520; with \$308,582 and \$307,938 as the current and long-term portion of the note payable, respectively, at December 31, 2015). The cost of the acquired patents in the amount of \$1,138,730 (cash of \$213,000 plus the original discounted notes payable in the amount of \$925,730) are included in Intangible assets, net on the Company's Consolidated Balance Sheets. All previous license agreements between NRC and the Company were terminated as a condition of the Purchase Agreement. NRC has a security interest in these patent rights acquired by the Company from NRC until the note payable has been satisfied.

NOTE 10. - SEVERANCE LIABILITY

The Company recorded an accrual for severance during the fourth quarter of 2014 in the initial amount of \$624,320 in accordance with FASB ASC 712 - "Compensation - Nonretirement Postemployment Benefits." The severance accrual relates to the October 25, 2014 termination of Joseph Pandolfino, the Company's former Chairman of the Board and Chief Executive Officer. The prior Employment Agreement with Mr. Pandolfino provided that in certain circumstances Mr. Pandolfino would receive severance payments in the gross amount of \$18,750 per month, subject to customary withholdings, over a term of 36 months. Amounts owed to Mr. Pandolfino have been discounted using the Company's incremental borrowing rate, resulting in current and long-term liabilities of \$212,012 and \$412,308, respectively, at December 31, 2014. Due to alleged breaches of the Employment Agreement by Mr. Pandolfino, payments were suspended by the Company on February 13, 2015. Resulting litigation between Mr. Pandolfino and the Company was settled on November 6, 2015, and pursuant to the settlement agreement Mr. Pandolfino's severance benefits were reinstated, including a catch-up payment through the date of the settlement. As a result of the severance benefit payments made through the third quarter of 2016, the discounted current and long-term balance of the severance liability amounted to \$227,553 and \$30,195, respectively, at September 30, 2016 (\$220,661 and \$199,658, respectively, at December 31, 2015).

NOTE 11. - WARRANTS FOR COMMON STOCK

At September 30, 2016, the Company had outstanding warrants to purchase 9,531,921 shares of common stock of the Company, of which only 94,721 warrants contain an anti-dilution feature. The Crede Tranche 2 and Tranche 3 warrants are excluded from the outstanding warrant total of 9,531,921 (see Note 5 – Joint Venture, Consulting Agreement and Associated Warrants for additional information).

On January 25, 2016, warrants to purchase 67,042 shares of common stock were exercised, primarily on a cashless basis, resulting in the issuance of 2,618 shares of the Company's common stock. On January 25, 2016, warrants to purchase 6,831,115 shares of common stock expired without being exercised.

Pursuant to the registered direct offering that closed on July 27, 2016, and discussed in Note 2, the Company issued warrants to purchase 7,043,211 shares of common stock. The warrants provide for an exercise price of \$1.00 per share and 1,543,210 of the warrants were exercisable immediately and had a fair value of approximately \$858,000 at issuance and 5,500,001 of the warrants were exercisable six months from the date of issuance and had a fair value of approximately \$3,058,000 at issuance. All the warrants have a term of 5.5 years and do not contain an anti-dilution feature. In addition, on July 27, 2016, the Company terminated an aggregate of 5.5 million warrants with exercise prices of \$1.21 and \$1.25 per share (see also Note 3 – February 2016 Registered Direct Offering and Note 4 – June 2015 Registered Direct Offering for additional information).

Pursuant to the registered direct offering that closed on February 5, 2016, and discussed in Note 3, the Company issued warrants to purchase 2,500,000 shares of common stock with an exercise price of \$1.21 per share. These warrants had a term of sixty-six (66) months, were not exercisable for six months immediately following the date of issuance, did not contain an anti-dilution feature, and had a fair value of approximately \$1,940,000 at issuance. The warrants associated with this transaction were terminated on July 27, 2016 (see Note 2 – July 2016 Registered Direct Offering for additional information).

Pursuant to the registered direct offering that closed on June 2, 2015, and discussed in Note 4, the Company issued warrants to purchase 3,000,000 shares of common stock with an exercise price of \$1.25 per share. These warrants had a term of sixty-six (66) months, were not exercisable for six months immediately following the date of issuance, did not contain an anti-dilution feature, and had a fair value of approximately \$2,067,000 at issuance. The warrants associated with this transaction were terminated on July 27, 2016 (see Note 2 – July 2016 Registered Direct Offering for additional information).

Outstanding warrants at September 30, 2016 consisted of the following:

| Warrant Description | Number of Warrants | Exercise Price | Expiration |
|--|--------------------|----------------|------------------|
| December 2011 convertible NP warrants | 172,730 | \$ 1.1984 | February 8, 2017 |
| December 2011 convertible NP warrants | 802,215 | \$ 1.3816 | February 6, 2018 |
| May 2012 PPO warrants | 401,700 | \$ 0.6000 | May 15, 2017 |
| November 2012 PPO warrants | 925,100 | \$ 0.6000 | November 9, 2017 |
| August 2012 convertible NP warrants ⁽¹⁾ | 94,721 | \$ 0.9310 | August 8, 2018 |
| August 2012 convertible NP warrants | 92,244 | \$ 0.9060 | August 8, 2018 |
| July 2016 registered direct offering warrants | 7,043,211 | \$ 1.0000 | January 27, 2021 |
| Total warrants outstanding ^{(2),(3)} | 9,531,921 | | |

(1) Includes anti-dilution features.

- (2) Includes warrants to purchase 533,000 shares of common stock (5.6%) held by officers and directors that have had the anti-dilution feature removed.
- (3) Includes warrants to purchase 312,730 shares of common stock (3.3%) held by a former officer and director that have had the anti-dilution feature removed.

The Company estimates the value of warrant liability upon issuance of the warrants and at each balance sheet date using the binomial lattice model to allocate total enterprise value to the warrants and other securities in the Company's capital structure. Volatility was estimated based on historical observed equity volatilities and implied (forward) or expected volatilities for a sample group of guideline companies and consideration of recent market trends.

As a result of the previously exercisable exchange rights contained in the Tranche 1A warrants, the financial instrument was previously considered a liability in accordance with FASB Accounting Standards Codification Topic 480 - "Distinguishing Liabilities from Equity" ("ASC 480"). More specifically, ASC 480 requires a financial instrument to be classified as a liability if such financial instrument contains a conditional obligation that the issuer must or may settle by issuing a variable number of its equity securities if, at inception, the monetary value of the obligation is based on a known fixed monetary amount. As a result of the actions by Crede that caused the exchange rights feature to be voided (see Note 5 - Joint Venture, Consulting Agreement and Associated Warrants for additional information), the Company reclassified the Tranche 1A warrant liability to Capital in excess of par.

The following table is a roll-forward summary of the warrant liability:

| | |
|--|-------------|
| Fair value at December 31, 2013 | \$3,779,522 |
| Reclassification of warrant liability to equity resulting from Warrant Amendments - Q1 2014 | (7,367,915) |
| Cost of inducement from Warrant Amendments - Q1 2014 | 144,548 |
| Fair value of warrant liability resulting from issuance of Crede Tranche 1A Warrants - Q3 2014 | 2,810,000 |
| Loss as a result of change in fair value | 3,676,691 |
| Fair value at December 31, 2014 | \$3,042,846 |
| Gain as a result of change in fair value | (144,550) |
| Fair value at December 31, 2015 | \$2,898,296 |
| Reclassification of warrant liability to capital in excess of par | (2,810,000) |
| Gain as a result of change in fair value | (14,602) |
| Fair value at September 30, 2016 | \$73,694 |

The aggregate net (loss) gain as a result of the Company's warrant liability for the three and nine months ended September 30, 2016 amounted to (\$46,995) and \$14,602, respectively (the aggregate net gain for the three and nine months ended September 30, 2015 amounted to \$27,723 and \$199,556, respectively), which are included in Other income (expense) under Warrant liability (loss) gain - net in the accompanying Consolidated Statements of Operations.

FASB ASC 820 - "Fair Value Measurements and Disclosures" establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

·Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities;

·Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and

·Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value.

A financial asset's or a financial liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The warrant liability is measured at fair value using certain estimated factors such as volatility and probability which are classified within Level 3 of the valuation hierarchy. Significant unobservable inputs that are used in the fair value measurement of the Company's derivative warrant liabilities include volatility. Significant increases (decreases) in the volatility input would result in a significantly higher (lower) fair value measurement.

The following table summarizes the Company's warrant activity since December 31, 2013:

| | Number of Warrants |
|--|-----------------------|
| Warrants outstanding at December 31, 2013 | 10,653,469 |
| Warrants issued in conjunction with consulting agreement | 4,250,000 |
| Warrants exercised during 2014 | (1,247,443) |
| Additional warrants due to anti-dilution provisions | 18,383 |
| Warrants outstanding at December 31, 2014 | 13,674,409 |
| Warrants issued in conjunction with registered direct offering | 3,000,000 |
| Warrants exercised during 2015 | (40,000) |
| Additional warrants due to anti-dilution provisions | 369 |
| Warrants outstanding at December 31, 2015 | 16,634,778 |
| Warrants issued in conjunction with registered direct offering | 2,500,000 |
| Unexercisable warrants ⁽¹⁾ | (2,000,000) |
| Warrants exercised during January 2016 | (67,042) |
| Warrants expired during January 2016 | (6,831,115) |
| June 2015 registered direct offering warrants cancelled | (3,000,000) |
| February 2016 registered direct offering warrants cancelled | (2,500,000) |
| Warrants issued in conjunction with July 2016 registered direct offering | 7,043,211 |
| Additional warrants due to anti-dilution provisions | 2,089 |
| Warrants expired during September 2016 ⁽²⁾ | (2,250,000) |
| Warrants outstanding at September 30, 2016 | 9,531,921 |
| Composition of outstanding warrants: | |
| Warrants containing anti-dilution feature | 94,721 |
| Warrants without anti-dilution feature | 9,437,200 |
| | 9,531,921 |

(1)Crede Tranche 2 Warrants and Tranche 3 Warrants are not exercisable (see Note 5 for additional information).

(2)Crede Tranche 1A Warrants and Crede Tranche 1B Warrants expired unexercised on September 29, 2016.

NOTE 12. - COMMITMENTS AND CONTINGENCIES

License Agreements - Under its exclusive worldwide license agreement with North Carolina State University ("NCSU"), the Company is required to pay minimum annual royalty payments, which are credited against running royalties on sales of licensed products. The minimum annual royalty for 2015 was \$75,000 and in 2016 the minimum annual royalty increased to \$225,000. The license agreement continues through the life of the last-to-expire patent, which is expected to be 2022. The license agreement also requires a milestone payment of \$150,000 upon FDA approval or clearance of a product that uses the NCSU licensed technology. The Company is also responsible for

reimbursing NCSU for actual third-party patent costs incurred. These costs vary from year to year and the Company has certain rights to direct the activities that result in these costs. During the three and nine months ended September 30, 2016, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$62,303 and \$76,299, respectively (\$61,045 and \$84,651 during the three and nine months ended September 30, 2015, respectively).

On December 8, 2015, the Company entered into an additional license agreement (the "License") with NCSU. Under the terms of the License, the Company paid NCSU a non-refundable, non-creditable lump sum license fee of \$150,000. Additionally, the License calls for the Company to pay NCSU a non-refundable, non-creditable minimum annual royalties beginning on December 31, 2018 in the amount of \$10,000. The minimum annual royalty payment increases to \$15,000 in 2019, \$25,000 in 2020 and 2021, and \$50,000 per year thereafter for the remaining term of the License. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the three and nine months ended September 30, 2016, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$0 and \$6,075, respectively (\$0 for each of the three and nine months ended September 30, 2015). This License continues through the life of the last-to-expire patent, expected to be in 2036.

On February 10, 2014, the Company entered into a sponsored research and development agreement (the "Agreement") with NCSU. Under the terms of the Agreement, the Company paid NCSU \$162,408 over the two-year term of the Agreement, which grants certain licensed rights to the Company. The Company has extended the Agreement through January 31, 2017 at an additional cost of \$85,681.

All payments made under the above referenced license agreements and the sponsored research and development agreement are initially recorded as a Prepaid expense on the Company's Consolidated Balance Sheets and subsequently expensed on a straight-line basis over the applicable period and included in Research and development costs on the Company's Consolidated Statements of Operations. The amounts expensed during the three and nine months ended September 30, 2016 were \$115,170 and \$345,137, respectively (\$39,051 and \$117,153 for the three and nine months ended September 30, 2015, respectively).

On August 22, 2014, the Company entered into a Commercial License Agreement with Precision PlantSciences, Inc. (the "Precision License"). The Precision License grants the Company a non-exclusive, but fully paid up right and license to use technology and materials owned by Precision PlantSciences for a license fee of \$1,250,000. An initial cash payment of \$725,000 was made upon execution of the Precision License with an unconditional obligation to pay the remaining \$525,000 in \$25,000 increments as materials are provided to the Company. The remaining \$525,000 was paid during December 2014. The Precision License continues through the life of the last-to-expire patent, which is expected to be in 2028.

On August 27, 2014, the Company entered into an additional exclusive License Agreement (the "License Agreement") with NCSU. Under the License Agreement, the Company paid NCSU a non-refundable, non-creditable lump sum license fee of \$125,000. Additionally, the License Agreement calls for the Company to pay NCSU three non-refundable, non-creditable license maintenance fees in the amount of \$15,000 per annum in each of December 2015, 2016 and 2017. Beginning in calendar year 2018, the Company is obligated to pay to NCSU an annual minimum royalty fee of \$20,000 in 2018, \$30,000 in 2019, and \$50,000 per year thereafter for the remaining term of the License Agreement. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the three and nine months ended September 30, 2016, the aggregated costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$4,056 and \$37,995, respectively (\$11,218 and \$15,422 for the three and nine months ended September 30, 2015, respectively). The License Agreement continues through the life of the last-to-expire patent, which is expected to be in 2034.

On September 15, 2014, the Company entered into a Sublicense Agreement with Anandia Laboratories, Inc. (the "Anandia Sublicense"). Under the terms of the Anandia Sublicense, the Company was granted an exclusive sublicense in the United States and a co-exclusive sublicense in the remainder of the world, excluding Canada, to the licensed Intellectual Property (more fully discussed in Note 8). The Anandia Sublicense calls for an up-front fee of \$75,000, an annual license fee of \$10,000, the payment of patent filing and maintenance costs, and a running royalty on future net sales. The Anandia Sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035.

The Precision License, the License Agreement with NCSU and the Anandia Sublicense are included in Intangible assets, net in the Company's Consolidated Balance Sheets and the applicable license fees will be amortized over the term of the agreements based on their last-to-expire patent date. Amortization during the three and nine months ended September 30, 2016 amounted to \$24,505 and \$73,516, respectively (\$24,506 and \$73,517 for the three and nine months ended September 30, 2015, respectively), and was included in accumulated amortization on the Company's

Consolidated Statements of Operations.

On September 28, 2015, the Company's wholly-owned subsidiary, Botanical Genetics, entered into a Sponsored Research Agreement (the "Agreement") with Anandia Laboratories Inc. ("Anandia"). Pursuant to the Agreement, Anandia will conduct research on behalf of the Company relating to the cannabis plant. The Agreement has an initial term of twelve (12) months from the date of the Agreement and can be extended at the sole option of the Company for two (2) additional periods of twelve (12) months each. The Company is in the process of evaluating the first extension option. The Company has paid Anandia \$379,800 over the initial term of the Agreement. During the three and nine months ended September 30, 2016 expenses related to the Agreement amounted to \$84,200 and \$263,400, respectively (\$116,400 for each of the three and nine months ended September 30, 2015), and are included in Research and development costs on the Company's Consolidated Statements of Operations. Under the terms of the Agreement, the Company will have co-exclusive worldwide rights with Anandia to all the intellectual property resulting from the sponsored research between the Company and Anandia. The party that commercializes such intellectual property in the future will pay royalties in varying amounts to the other party, with the amount of such royalties being dependent upon the type of products that are commercialized in the future. If either party sublicenses such intellectual property to a third-party, then the Company and Anandia will share equally in such sublicensing consideration.

Lease Agreements - The Company leases a manufacturing facility and warehouse located in North Carolina on a triple net lease basis. The lease commenced on January 14, 2014, and had an initial term of twelve (12) months. The lease contains four (4) additional extensions; with one lease extension being for an additional one (1) year and with the other three (3) lease extensions each being for an additional two (2) years in duration, exercisable at the option of the Company. The Company is currently in the first two-year lease extension term that will expire on October 31, 2017. The lease expense for the three and nine months ended September 30, 2016 amounted to \$36,131 and \$108,393, respectively (\$30,750 and \$92,250 for the three and nine months ended September 30, 2015, respectively). The future minimum lease payments if the Company exercises each of the additional extensions are approximately as follows:

| | |
|--------------------------------|-----------|
| Year ended December 31, 2016 - | \$38,000 |
| Year ended December 31, 2017 - | \$156,000 |
| Year ended December 31, 2018 - | \$169,000 |
| Year ended December 31, 2019 - | \$169,000 |
| Year ended December 31, 2020 - | \$169,000 |
| Year ended December 31, 2021 - | \$141,000 |

The Company has a lease for its office space in Clarence, New York and extended the lease for an additional one-year renewal period expiring on August 31, 2017. Future minimum lease payments for the years ended December 31, 2016 and 2017 are approximately \$11,000 and \$31,000, respectively.

On November 1, 2015, the Company entered into a one-year lease for 25,000 square feet of warehouse space in North Carolina to store the Company's proprietary tobacco leaf. The lease calls for a monthly lease payment of \$3,750 and contains a three-year renewal option after the initial one-year term. Future minimum lease payments for the years ended December 31, 2016, 2017, 2018 and 2019 are \$11,250, \$45,000, \$45,000 and \$37,500, respectively, if the Company exercises the optional renewal period.

On May 1, 2016, the Company entered into a sublease for laboratory space in Buffalo, New York. The sublease calls for a monthly payment of \$1,471, expires on April 30, 2017 and contains an option to extend the lease for a period of one year through April 30, 2018. Future minimum sublease payments for the years ended December 31, 2016, 2017 and 2018 are approximately \$4,400, \$18,000 and \$6,000, respectively, if the Company exercises the optional renewal period.

On September 1, 2016, the Company entered into a sublease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment. The sublease calls for a monthly payment of \$1,200, expires on August 31, 2017 and contains twelve-month renewal options as long as the sublessor continues to sublease the warehouse. Future minimum sublease payments for the year ended December 31, 2016 are \$3,600 and future minimum sublease payments are \$14,400 per year for each subsequent year the warehouse space is sublet by the Company.

Litigation - In accordance with applicable accounting guidance, the Company establishes an accrued liability for litigation and regulatory matters when those matters present loss contingencies that are both probable and estimable. In such cases, there may be an exposure to loss in excess of any amounts accrued. When a loss contingency is not both probable and estimable, the Company does not establish an accrued liability. As a litigation or regulatory matter develops, the Company, in conjunction with any outside counsel handling the matter, evaluates on an ongoing basis whether such matter presents a loss contingency that is probable and estimable. If, at the time of evaluation, the loss contingency related to a litigation or regulatory matter is not both probable and estimable, the matter will continue to be monitored for further developments that would make such loss contingency both probable and estimable. When a loss contingency related to a litigation or regulatory matter is deemed to be both probable and estimable, the Company

will establish an accrued liability with respect to such loss contingency and record a corresponding amount of litigation-related expense. The Company will then continue to monitor the matter for further developments that could affect the amount of any such accrued liability.

On April 26, 2016, Crede CG III, LTD. (“Crede”) filed a complaint against the Company in the United States District Court for the Southern District of New York (the “SDNY Court”) entitled Crede CG III, LTD. v. 22nd Century Group, Inc. On May 19, 2016, Crede filed an Amended Complaint that includes seven counts, alleging among other things, that the Company allegedly breached and/or interfered with certain agreements entered into with Crede, including the joint venture agreement relating to efforts to sell the Company’s proprietary tobacco into China, the Tranche 1A warrant and the prior securities purchase agreement with Crede. The Amended Complaint seeks money damages, to rescind the stock purchase agreement, to obtain declaratory and injunctive relief to require the Company to issue to Crede 2,077,555 shares of the Company’s common stock under the exchange provision of the Tranche 1A warrant, and entry of an injunction prohibiting the Company from selling tobacco into China without the joint venture’s involvement. The Amended Complaint also seeks attorney’s fees and such other relief as the Court may deem just and proper. We believe that the claims are frivolous, meritless and that the Company has substantial legal and factual defenses to the claims. The Company has defended and intends to continue to defend against these claims vigorously, and has filed letter motions for the dismissal of the claims and for the transfer of certain of the claims to the United States District Court for the Western District of New York (the “WDNY Court”). The Company also intends to file counterclaims if the case continues.

On May 19, 2016, Crede filed a motion for preliminary injunction, asking the SDNY Court to require the Company to issue 2,077,555 shares of its common stock to Crede under the exchange provision of the Tranche 1A warrant. After conducting an evidentiary hearing on this motion on June 14, 2016, the SDNY Court denied Crede’s motion and held, among other things, that Crede did not prove the potential for irreparable harm or a likelihood of success on its claim for such 2,077,555 shares under the Tranche 1A warrant, and that there was a likelihood that Crede had violated the activity restrictions of the Tranche 1A warrant, which would bar Crede’s claim for such shares from the Company.

Following such ruling, the SDNY Court directed the parties to file briefs on the pending letter motion to transfer certain claims to the WDNY Court. On July 11, 2016, the Company filed its formal motion to sever the Crede lawsuit into two separate cases, with all claims relating to the Tranche 1A warrant to stay in the SDNY Court, and with the claims relating to the China joint venture agreement and the securities purchase agreement to be transferred to the WDNY Court, where the Company's headquarters is located. On July 29, 2016, Crede filed its response to the Company's motion and on August 5, 2016, the Company filed its reply to Crede's response. The SDNY Court has not yet ruled on such motions.

NOTE 13. - EARNINGS PER COMMON SHARE

The following table sets forth the computation of basic and diluted earnings per common share for the three month periods ended September 30, 2016 and 2015:

| | September 30, 2016 | September 30, 2015 |
|--|--------------------------|--------------------------|
| Net loss attributed to common shareholders | \$(2,679,988) | \$(2,761,691) |
| Denominator for basic earnings per share-weighted average shares outstanding | 80,386,519 | 70,798,879 |
| Effect of dilutive securities: Warrants, restricted stock and options outstanding | - | - |
| Denominator for diluted earnings per common share-weighted average shares adjusted for dilutive securities | 80,386,519 | 70,798,879 |
| Loss per common share - basic and diluted | \$(0.03) | \$(0.04) |

The following table sets forth the computation of basic and diluted earnings per common share for the nine month periods ended September 30, 2016 and 2015:

| | September 30, 2016 | September 30, 2015 |
|--|--------------------------|--------------------------|
| Net loss attributed to common shareholders | \$(8,834,794) | \$(8,167,133) |

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| | | |
|--|------------|------------|
| Denominator for basic earnings per share-weighted average shares outstanding | 76,826,949 | 67,225,308 |
| Effect of dilutive securities: | | |
| Warrants, restricted stock and options outstanding | - | - |
| Denominator for diluted earnings per common share-weighted average shares adjusted for dilutive securities | 76,826,949 | 67,225,308 |
| Loss per common share - basic and diluted | \$(0.11 |) \$(0.12 |

Securities outstanding that were excluded from the computation because they would have been anti-dilutive are as follows:

| | September 30, 2016 | September 30, 2015 |
|------------------|--------------------------|--------------------------|
| Warrants | 9,531,921 | 16,674,778 |
| Restricted stock | - | 100,000 |
| Options | 5,650,679 | 3,061,642 |
| | 15,182,600 | 19,836,420 |

NOTE 14. - EQUITY BASED COMPENSATION

On October 21, 2010, the Company established the 2010 Equity Incentive Plan (“EIP”) for officers, employees, directors, consultants and advisors to the Company and its affiliates, which consisted of 4,250,000 shares of common stock. During the first quarter of 2014, the Company issued restricted stock awards from the EIP for 850,000 restricted shares to employees and directors that vested on January 27, 2015. All awards were valued at the closing price of the Company’s common stock on the measurement date of the award. No additional awards are issuable under the EIP.

On April 12, 2014, the stockholders of the Company approved the 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (the “OIP”). The OIP allows for the granting of equity and cash incentive awards to eligible individuals over the life of the OIP, including the issuance of up to 5,000,000 shares of the Company’s common stock pursuant to awards under the OIP. The OIP has a term of ten years and is administered by the Compensation Committee of the Company’s Board of Directors to determine the various types of incentive awards that may be granted to recipients under this plan and the number of shares of common stock to underlie each such award under the OIP.

During the three and nine months ended September 30, 2016, the Company issued stock option awards from the OIP for 665,000 and 2,389,037 shares, respectively, to eligible individuals having vesting periods ranging from six months to three and one-half years from the date of the award. During the three and nine months ended September 30, 2015, the Company issued 100,000 and 1,721,642 stock option awards, respectively, from the OIP, and during the three and nine months ended September 30, 2015, the Company issued restricted stock from the OIP for 0 and 20,000 shares, respectively, to eligible individuals having vesting periods ranging from six months to one year from the date of the awards. All stock option awards were valued using the Black-Scholes option-pricing model on the date of the award, and all restricted stock awards were valued at the closing price of the Company’s common stock on the NYSE MKT on the date of the award.

For the three and nine months ended September 30, 2016, the Company recorded compensation expense related to restricted stock and stock option awards granted under the EIP and OIP of \$204,860 and \$677,076, respectively (\$314,743 and \$1,000,603 for the three and nine months ended September 30, 2015, respectively). During the three and nine months ended September 30, 2016, the Company issued stock to third-party service providers in the amount of 0 and 15,811 shares, respectively, and during the three and nine months ended September 30, 2016, the Company issued stock options in the amount of 0 and 100,000 shares, respectively, to a third-party service provider. During the three and nine months ended September 30, 2015, the Company issued restricted stock to third-party service providers in the amount of 90,000 and 279,196 shares, respectively. During the three and nine months ended September 30, 2015, the Company issued stock options to third-party service providers in the amount of 300,000 and 400,000 shares, respectively. The Company recorded equity based compensation expense related to the third-party providers for the three and nine months ended September 30, 2016 in the amount of \$0 and \$30,873, respectively (\$97,969 and \$232,187 for the three and nine months ended September 30, 2015, respectively).

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As of September 30, 2016, unrecognized compensation expense related to non-vested restricted shares and stock options amounted to approximately \$1,586,000, which is expected to be recognized approximately as follows: \$193,000, \$457,000, \$357,000 and \$112,000 during 2016, 2017, 2018 and 2019, respectively. Approximately \$467,000 of the unrecognized compensation expense relates to previously issued stock options, with the vesting of such stock options being based on the achievement of a certain milestone, and the attainment of such milestone cannot be determined at this time.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were used for the nine months ended September 30, 2016 and 2015:

| | 2016 | | 2015 | |
|---|------------|---|------------|---|
| Risk-free interest rate (weighted average) | 1.31 | % | 1.60 | % |
| Expected dividend yield | 0 | % | 0 | % |
| Expected stock price volatility | 90 | % | 90 | % |
| Expected life of options (weighted average) | 4.87 years | | 8.91 years | |

The Company estimated the expected volatility based on data used by a peer group of public companies. The expected term was estimated using the contract life of the option. The risk-free interest rate assumption was determined using yield of the equivalent U.S. Treasury bonds over the expected term. The Company has never paid any cash dividends and does not anticipate paying any cash dividends in the foreseeable future. Therefore, the Company assumed an expected dividend yield of zero.

A summary of all stock option activity since December 31, 2013 is as follows:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|-----------------------------------|------------------------------|--|--|--|
| Outstanding at December 31, 2013 | 660,000 | \$ 0.74 | | |
| Granted in 2014 | 300,000 | \$ 2.61 | | |
| Exercised in 2014 | (70,000) | \$ 0.69 | | |
| Outstanding at December 31, 2014 | 890,000 | \$ 1.38 | | |
| Reinstated in 2015 | 50,000 | \$ 0.69 | | |
| Granted in 2015 | 2,221,642 | \$ 1.00 | | |
| Outstanding at December 31, 2015 | 3,161,642 | \$ 1.10 | | |
| Granted in 2016 | 2,489,037 | \$ 0.97 | | |
| Outstanding at September 30, 2016 | 5,650,679 | \$ 1.04 | 7.7 years | \$2,641,281 |
| Exercisable at September 30, 2016 | 2,711,642 | \$ 1.07 | 7.0 years | \$1,158,762 |

There were stock options granted during the nine months ended September 30, 2016 and 2015, to purchase a total of 2,489,037 shares and 2,121,642 shares, respectively. The weighted average grant date fair value of options issued during the nine months ended September 30, 2016 was \$0.66 (\$0.56 for the nine months ended September 30, 2015). The total fair value of options that vested during the nine months ended September 30, 2016 amounted to \$1,242,110 (\$206,500 for the nine months ended September 30, 2015). No options were exercised during the nine months ended September 30, 2016 and 2015.

NOTE 15. - SUBSEQUENT EVENTS

On October 19, 2016, the Company closed a registered direct offering of units, with each unit consisting of one share of common stock and a warrant to purchase 0.5 shares of common stock. The purchase price per unit was \$1.3425 and two institutional investors purchased a total of \$11.4 million of units, consisting of an aggregate of 8,500,000 shares of common stock and warrants to purchase up to 4,250,000 shares of common stock. The warrants provide for an exercise price of \$1.45 per share and all the warrants are exercisable six months from the date of issuance and had a fair value of approximately \$3,380,000 at issuance. All the warrants have a term of 5.5 years. The exercise price of the warrants will also be adjusted in the event of stock splits, reverse stock splits and the like pursuant to their terms. The

holders of the warrants will not have the right to exercise any portion of the warrants if the holders, together with its respective affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's common stock (including securities convertible into common stock) outstanding immediately after the exercise; provided, however, that the holder may increase or decrease this limitation at any time, although any increase shall not be effective until the 61st day following the notice of increase and the holder may not increase this limitation in excess of 9.99%. The Securities Purchase Agreement executed with the investors provides that, subject to certain exceptions, for a period ending on the earlier of (i) 90 days after October 19, 2016 and (ii) the trading day following the day that the closing price of the Company's common stock exceeds \$2.00 per share for ten consecutive trading days, neither the Company nor any of its subsidiaries will issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents.

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that reflect, when made, the Company's expectations or beliefs concerning future events that involve risks and uncertainties. Forward-looking statements frequently are identified by the words "believe," "anticipate," "expect," "estimate," "intend," "project," "will be," "will continue," "likely result," or other similar words and phrases. Similarly, statements herein that describe the Company's objectives, plans or goals also are forward-looking statements. Actual results could differ materially from those projected, implied or anticipated by the Company's forward-looking statements. Some of the factors that could cause actual results to differ include: our ability to continue to monetize the licensing of our technology and products; our ability to raise capital; our ability to achieve profitability; our ability to manage our growth effectively; our ability to obtain FDA clearance for our Modified Risk Cigarettes; our ability to obtain FDA approval for our X-22 smoking cessation product; our ability to gain market acceptance for our products, our ability to prevail in litigation and our ability to maintain our rights to our intellectual property licenses. For a discussion of these and all other known risks and uncertainties that could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, which is available on the SEC's website at www.sec.gov. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update this Quarterly Report on Form 10-Q to reflect events or circumstances after the date hereof.

For purposes of this Management's Discussion and Analysis of Financial Condition and Results of Operations, references to the "Company," "we," "us" or "our" refer to the operations of 22nd Century Group, Inc. and its direct and indirect subsidiaries for the periods described herein.

Overview

We are a plant biotechnology company focused on (i) tobacco harm reduction products and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding, and (ii) research and development of unique cannabis plants through genetic engineering and plant breeding. We currently own or exclusively control more than 200 issued patents and more than 50 pending patent applications around the world. Our management team is focused on monetizing our intellectual property portfolio and obtaining regulatory approval to market our reduced exposure cigarettes and our smoking cessation product in development.

Our Annual Report on Form 10-K for the year ended December 31, 2015 provides additional information about our business, operations and financial condition.

Strategic Objectives

Our strategic objectives include the following:

pursuit of reduced exposure authorization from the U.S. Food and Drug Administration (FDA) for our Very Low Nicotine *BRAND A* reduced exposure cigarette in development for which a Modified Risk Tobacco Product (MRTP) application was submitted to the FDA on December 31, 2015. Our MRTP application to the FDA seeks a reduced exposure order so that we may introduce *Brand A* into commerce in the United States. The MRTP application requests that *BRAND A* packaging and marketing be allowed to disclose to consumers that our proprietary Very Low Nicotine (VLN) cigarettes have 95% less nicotine than conventional tobacco cigarettes, and therefore drastically reduce smokers' exposure to nicotine;

pursuit of FDA reduced exposure authorization for our low Tar-to-Nicotine *BRAND B* modified risk cigarette in development;

establishment of a strategic joint venture to conduct a Phase III smoking cessation clinical trial for *X-22*, our Very Low Nicotine tobacco smoking cessation aid in development;

establishment of substantial multi-year sales contracts around the world for our proprietary high and very low nicotine tobacco leaf;

research and development of unique medical marijuana and industrial hemp plants through genetic engineering and plant breeding;

commercialization of our proprietary brands, *RED SUN*, *MAGIC*, and *MOONLIGHT* super-premium cigarettes; and

expansion of our growing base of contract manufacturing business at our manufacturing facility in Mocksville, North Carolina.

For the third quarter of 2016, our accomplishments and notable events include:

In July, 2016, we announced that the World Health Organization (WHO) Study Group on Tobacco Product Regulation (TobReg) recommended “a policy of limiting the sale of cigarettes to brands with a nicotine content that is not sufficient to lead to the development and/or maintenance of addiction.” We are the only company in the world capable of producing combustible tobacco cigarettes with a nicotine content below the addictive level – without any artificial extraction or chemical processes. In the July 2016 issue of *Tobacco Control*, Drs. Dorothy Hatsukami, Ghazi Zaatari and Eric Donny stated that failure to act on the WHO recommendation of mandating nicotine reductions in cigarettes to non-addictive levels could lead to the loss of millions of lives.

On July 27, 2016, we raised \$5.0 million in gross proceeds through the sale of units consisting of shares of common stock and warrants in a financing transaction.

On September 6, 2016, we announced that our wholly-owned subsidiary, Botanical Genetics LLC, expanded its cannabis research program to include multiple new research projects in support of its core mission, which is to develop proprietary cannabis strains for important new medicines and commercially viable agricultural crops. More specifically, Botanical Genetics is now: (i) working to develop proprietary cannabis strains for novel, safe, and effective medical applications, and (ii) developing very low THC industrial hemp varieties that may be legally grown in the U.S. and around the world as commercial agricultural crops. To inform investors and to generate interest from potential research and commercial partners, Botanical Genetic launched a new website at www.botanicalgenetics.com (information on our website is not incorporated in this Form 10-Q).

On September 27, 2016, we announced results from two separate independent surveys showing that strong consumer demand mirrors physicians’ willingness to prescribe our X-22 smoking cessation aid in development. To assess consumer reaction to X-22, the first survey questioned 501 current smokers in the United States, who have tried to quit at least once, about their failed quit attempts. Participants were then given a brief overview of our X-22 Very Low Nicotine cigarettes designed for use as a prescription smoking cessation aid. Overall, the vast majority of smokers expressed strong enthusiasm for our X-22 product to become available at U.S. pharmacies. Of 501 smokers surveyed, if X-22 were currently available, 89% said X-22 would be their top or first choice to help them quit smoking.

We also commissioned surveys (conducted by Survata, an independent market research firm based in San Francisco, California, and by Dobrin Consulting in Richmond, Virginia) of 136 practicing physicians who have experience in helping patients to quit smoking. Physicians reviewed detailed information regarding the use and efficacy of X-22, including published results from several of the numerous independent clinical trials that have been conducted with cigarettes made with our proprietary Very Low Nicotine tobacco. The survey of 136 physicians revealed that 89% said that they would prescribe X-22 cigarettes to help their patients to quit smoking.

We have an active Investigational New Drug (IND) application on file with the U.S. Food and Drug Administration (FDA) relating to the X-22 smoking cessation product. We intend to meet with the FDA in the first quarter of 2017 to discuss the regulatory approval path for X-22.

On September 29, 2016, the Tranche 1A and Tranche 1B warrants previously issued by us to Crede CG III, Ltd. to purchase an aggregate of 2,250,000 shares of our common stock expired. As previously disclosed, on September 29, 2014, we also issued to Crede a Tranche 2 warrant and a Tranche 3 warrant to purchase an aggregate total of 2,000,000 additional shares of our common stock at an exercise price of \$3.3736 per share. Although the Tranche 2 and Tranche 3 warrants do not expire until September 29, 2019, these warrants are subject to certain vesting conditions related to our prior joint venture agreement with Crede. Since we terminated the joint venture agreement with Crede on June 22, 2015 due to non-performance by Crede, the vesting conditions for the Tranche 2 and Tranche 3 warrants will never be satisfied and, for that reason, will never become exercisable. Accordingly, we no longer recognize the Tranche 2 and Tranche 3 warrants in our financial statements and an aggregate of 4,250,000 shares of potential dilution from the exercise of all the Crede warrants has been avoided entirely.

Subsequent to the close of the third quarter of 2016, we also announced:

On October 19, 2016, we raised \$11.4 million in gross proceeds through the sale of units consisting of shares of common stock and warrants in a financing transaction.

On October 26, 2016, we announced the hiring of Michael Zercher as our Vice President of Business Development. Mr. Zercher previously headed Santa Fe Natural Tobacco Company's international business operations based in Zurich, Switzerland. Mr. Zercher will lead the our efforts to form strategic partnerships with companies capable of widely commercializing our proprietary brands. In addition, Mr. Zercher will pursue sales of our proprietary Very Low Nicotine tobacco leaf and high nicotine tobacco leaf.

Three Months Ended September 30, 2016 Compared to Three Months Ended September 30, 2015

Revenue - Sale of products

In the three months ended September 30, 2016, we realized net sales revenue from the sale of products in the amount of \$3,097,648, an increase of \$430,142, or 16.1%, over sales of \$2,667,506 for the three months ended September 30, 2015. The increase in net sales revenue for the third quarter of 2016 is primarily the result of increased net sales revenue generated from our contract manufacturing business when compared to net sales revenue for the third quarter of 2015.

Cost of goods sold - Products

During the three months ended September 30, 2016, cost of goods sold were \$3,282,266, or 106.0%, of net sales revenue. Excise taxes and certain regulatory fees in the approximate amount of \$1,810,000 are included in the cost of goods sold for the three months ended September 30, 2016. We were not operating our factory at full production capacity during the third quarter of 2016. As a result, the cost of goods sold relating to product sales, which included the cost of raw material components, direct manufacturing costs and an overhead allocation, was in excess of net sales revenue.

During the three months ended September 30, 2015, cost of goods sold were \$2,948,928, or 110.6%, of net sales revenue. Excise taxes and certain regulatory fees in the approximate amount of \$1,910,000 are included in the cost of goods sold for the three months ended September 30, 2015. We were not operating our factory at full production capacity during the third quarter of 2015. As a result, the cost of goods sold relating to product sales, which included the cost of raw material components, direct manufacturing costs and an overhead allocation, was in excess of net sales revenue.

Research and development expense

Research and development (“R&D”) expense was \$691,970 in the three months ended September 30, 2016, an increase of \$186,886, or 37.0%, from \$505,084 in the three months ended September 30, 2015. This increase was primarily a result of increases in license and royalty fees in the approximate amount of \$118,000, an increase in sponsored research contract costs of approximately \$45,000, an increase of approximately \$82,000 in payroll and related benefit costs and an increase in consulting fees of approximately \$20,000, partially offset by a net decrease in expenses

associated with our modified risk tobacco product application filed with the FDA and other modified risk related expenses in the approximate amount of \$67,000 and a decrease in patent maintenance cost in the approximate amount of \$13,000.

General and administrative expense

General and administrative expense was \$1,230,967 in the three months ended September 30, 2016, a decrease of \$72,137, or 5.5%, from \$1,303,104 in the three months ended September 30, 2015. The decrease was mainly due to a decrease in employee related equity based compensation of approximately \$106,000, a decrease in third-party equity compensation of approximately \$95,000 and a decrease in payroll and related benefit costs of approximately \$46,000, partially offset by an increase in director fees of approximately \$26,000, an increase in consulting and investor relations costs of approximately \$94,000, and an increase in legal and accounting expenses of approximately \$32,000.

Sales and marketing expense

During the three months ended September 30, 2016, we incurred sales and marketing expenses of \$277,096, a decrease of \$193,525, or 41.1%, from \$470,621 in the three months ended September 30, 2015. The decrease in sales and marketing expenses are primarily the result of a reduction in advertising and promotion costs, primarily related to our proprietary cigarette brand, *RED SUN*, in the approximate amount of \$216,000, partially offset by an increase in payroll and related benefits in the approximate amount of \$32,000.

Depreciation expense

Depreciation expense for the three months ended September 30, 2016 amounted to \$81,354, a decrease of \$346, or 0.4%, from \$81,700 for the three months ended September 30, 2015.

Amortization expense

Amortization expense for the three months ended September 30, 2016 amounted to \$129,807, an increase of \$14,136, or 12.2%, from \$115,671 for the three months ended September 30, 2015. The amortization expense relates to amortization taken on capitalized patent costs and license fees. The increase is primarily due to amortization on additional patent costs incurred during the nine months ended September 30, 2016 and the year ended December 31, 2015 in the amounts of \$317,525 and \$654,069, respectively.

Warrant liability (loss) gain - net

The warrant liability loss of \$46,995 for the third quarter of 2016 was due to an increase in the estimated fair value of the warrants during the period. The increase in the estimated fair value of the warrants was primarily attributable to an increase in our underlying stock price from \$0.81 per share at June 30, 2016, as compared to \$1.45 per share at September 30, 2016.

The warrant liability gain of \$27,723 for the third quarter of 2015 was due to the decrease in the estimated fair value of the warrants during the period. The decrease in the estimated fair value of the warrants was primarily attributable to a decrease in our underlying stock price from \$0.94 per share at June 30, 2015, as compared to \$0.84 per share at September 30, 2015.

Loss on equity investment

The loss on equity investment of \$29,997 and \$33,211 for the three months ended September 30, 2016 and 2015, respectively, consists of (i) our 24.4% (25.0% ownership prior to a dilutive event on September 8, 2016) share of Anandia's net loss for the three month periods ending September 30, 2016 and 2015 in the amount of \$15,585 and \$18,799, respectively, plus (ii) amortization of the intangible asset represented by the difference between our equity investment in Anandia and our portion of the net assets of Anandia in the amount of \$14,412.

Interest income

Interest income for the three months ended September 30, 2016 was \$2,131, a decrease of \$7,970, or 78.9%, from interest income of \$10,101 for the three months ended September 30, 2015. The interest income earned in the three months ended September 30, 2016 and 2015 was generated from excess cash invested in a money market account and the decrease in interest income was due to a lower average balance maintained in the money market account and an average lower rate of interest earned on such funds.

Interest expense

Interest expense increased \$613, or 7.0%, in the three months ended September 30, 2016 to \$9,315 from \$8,702 in the three months ended September 30, 2015 and is derived from the interest component of severance payments made on accrued severance that had previously been recorded on a discounted basis using our incremental borrowing rate and the accretion of interest on the NRC note payable.

Net loss

We had a net loss in the three months ended September 30, 2016 of \$2,679,988 as compared to a net loss of \$2,761,691 in the three months ended September 30, 2015. The decrease in the net loss of \$81,703, or 3.0%, was primarily the result of a decrease in the gross loss of approximately \$97,000 and a decrease in operating expenses of approximately \$65,000, partially offset by an increase in net other expenses of approximately \$80,000.

Nine Months Ended September 30, 2016 Compared to Nine Months Ended September 30, 2015

Revenue - Sale of products

In the nine months ended September 30, 2016, we realized net sales revenue from the sale of products in the amount of \$8,944,362, an increase of \$3,353,765, or 60%, over sales of \$5,590,597 for the nine months ended September 30, 2015. The increase in net sales revenue for the nine months ended September 30, 2016 resulted from sales of *SPECTRUM* research cigarettes as well as increased sales of other products when compared to sales for the nine months ended September 30, 2015.

Cost of goods sold - Products

During the nine months ended September 30, 2016, cost of goods sold were \$9,146,247, or 102.3%, of net sales revenue. Cost of goods sold relating to the sales *SPECTRUM* research cigarettes were \$55,019, or 16.7%, of related net sales revenue and the remaining cost of goods sold was \$9,091,228, or 105.5%, of related net sales revenue. Excise taxes and certain regulatory fees in the approximate amount of \$5,387,000 are included in the cost of goods sold for the nine months ended September 30, 2016. We were not operating the factory at full production capacity during the first three quarters of 2016. As a result, the cost of goods sold relating to product sales (exclusive of *SPECTRUM* research cigarettes), which included the cost of raw material components, direct manufacturing costs and an overhead allocation, was in excess of net sales revenue.

During the nine months ended September 30, 2015, cost of goods sold were \$6,181,954, or 110.6%, of net sales revenue. Excise taxes and certain regulatory fees in the approximate amount of \$3,838,000 are included in the cost of goods sold for the nine months ended September 30, 2015.

Research and development expense

R&D expense was \$1,799,289 in the nine months ended September 30, 2016, an increase of \$852,136, or 90.0%, from \$947,153 in the nine months ended September 30, 2015. This increase was primarily a result of increases in license and royalty fees in the approximate amount of \$303,000, an increase in sponsored research contract costs of approximately \$271,000, an increase of approximately \$273,000 in payroll and related benefit costs, an increase in R&D related travel expenses of approximately \$57,000 and an increase in consulting fees of approximately \$55,000, partially offset by a net decrease in expenses associated with our modified risk tobacco product application filed with the FDA and other modified risk related expenses in the approximate amount of \$90,000 and a decrease in patent maintenance cost in the approximate amount of \$26,000.

General and administrative expense

General and administrative expense was \$4,799,349 in the nine months ended September 30, 2016, a decrease of \$1,452,540, or 23.2%, from \$6,251,889 in the nine months ended September 30, 2015. The decrease was mainly due to a decrease in equity based compensation to third-party service providers in the approximate amount of \$2,190,000 (approximately \$1,979,000 of the decrease pertained to the Crede consulting fee), a decrease in legal and accounting fees of approximately \$43,000, a decrease in NYSE MKT related costs of approximately \$65,000, a decrease in employee related equity compensation of approximately \$321,000 and a decrease in payroll and related benefit costs of approximately \$75,000, partially offset by an increase in investor relations costs of approximately \$825,000, an

increase in consulting fees of approximately \$151,000, an increase in press release related costs of approximately \$64,000, an increase relating to information technology costs of approximately \$30,000, an increase in director fees of approximately \$68,000, an increase general business insurance costs of approximately \$12,000 and a net increase in various other general and administrative expenses of approximately \$92,000.

Sales and marketing expense

During the nine months ended September 30, 2016, we incurred sales and marketing expenses of \$1,230,816, an increase of \$354,191, or 40.4%, from \$876,625 in the nine months ended September 30, 2015. The increase in sales and marketing expenses are primarily the result of an increase in advertising and promotion costs, primarily related to our proprietary cigarette brand, *RED SUN*, in the approximate amount of \$104,000 and an increase in payroll and related benefits in the approximate amount of \$250,000.

Depreciation expense

Depreciation expense for the nine months ended September 30, 2016 amounted to \$243,018, an increase of \$3,878, or 1.6%, from \$239,140 for the nine months ended September 30, 2015.

Amortization expense

Amortization expense for the nine months ended September 30, 2016 amounted to \$380,689, an increase of \$48,729, or 14.7%, from \$331,960 for the nine months ended September 30, 2015. The amortization expense relates to amortization taken on capitalized patent costs and license fees. The increase is primarily due to amortization on additional patent costs incurred during the nine months ended September 30, 2016 and the year ended December 31, 2015 in the amounts of \$317,525 and \$654,069, respectively.

Warrant liability gain - net

The warrant liability gain of \$14,602 for the nine months ended September 30, 2016 was due to the decrease in the estimated fair value of the warrants during the period. The decrease in the estimated fair value of the warrants was primarily attributable to the expiration of certain warrants and the remaining outstanding warrants aging closer to their expirations date with the passage of time.

The warrant liability gain of \$199,556 for the nine months ended September 30, 2015 was due to the decrease in the estimated fair value of the warrants during the period. The decrease in the estimated fair value of the warrants was primarily attributable to a decrease in our underlying stock price from \$1.65 per share at December 31, 2014, as compared to \$0.84 per share at September 30, 2015.

Settlement proceeds

There were no settlement proceeds during the nine months ended September 30, 2016. During the second quarter of 2015 we entered into a settlement agreement with an unrelated third-party to which the third-party was required, and subsequently paid, \$1,000,000 to us.

Loss on equity investment

The loss on equity investment of \$172,068 and \$125,026 for the nine months ended September 30, 2016 and 2015, respectively, consists of (i) our 24.4% (25.0% ownership prior to a dilutive event on September 8, 2016) share of Anandia's net loss for the nine month periods ending September 30, 2016 and 2015 in the amount of \$128,832 and

\$81,790, respectively, plus (ii) amortization of the intangible asset represented by the difference between our equity investment in Anandia and our portion of the net assets of Anandia in the amount of \$43,236.

Interest income

Interest income for the nine months ended September 30, 2016 was \$6,729, a decrease of \$17,695, or 72.4%, from interest income of \$24,424 for the nine months ended September 30, 2015. The interest income earned in the nine months ended September 30, 2016 and 2015 was generated from excess cash invested in a money market account and the decrease in interest income was due to a lower average balance maintained in the money market account and an average lower rate of interest earned on such funds.

Interest expense

Interest expense increased \$1,048, or 3.7%, in the nine months ended September 30, 2016 to \$29,011 from \$27,963 in the nine months ended September 30, 2015 and is derived from the interest component of severance payments made on accrued severance that had previously been recorded on a discounted basis using our incremental borrowing rate and the accretion of interest on the NRC note payable.

Net loss

We had a net loss in the nine months ended September 30, 2016 of \$8,834,794 as compared to a net loss of \$8,167,133 in the nine months ended September 30, 2015. The increase in the net loss of \$667,661, or 8.2%, was primarily the result of a decrease in the one-time settlement proceeds in the amount of \$1,000,000 and a decrease in the remaining components of other income (expense) of approximately \$251,000, offset by a decrease in operating expenses of approximately \$194,000 and a decrease in the gross loss of approximately \$389,000.

Liquidity and Capital Resources

Working Capital

As of September 30, 2016, we had positive working capital of approximately \$5.68 million compared to positive working capital of approximately \$3.99 million at December 31, 2015, an increase of approximately \$1.69 million. The increase in our working capital position was mainly a result of the net proceeds received from registered direct

offerings in February and July of 2016 in the aggregate amount of approximately \$9.77 million, offset by cash used in our operating activities of approximately \$7.98 million.

We must successfully execute our business plan to increase revenue in order to achieve positive cash flows to sustain adequate liquidity without requiring additional funds from external sources to meet minimum operating requirements. In October 2016, we raised approximately \$10.7 million of net proceeds in a registered direct offering of units consisting of shares of common stock and warrants which utilized the balance remaining on our Form S-3 universal shelf registration statement that was filed with the U.S. Securities and Exchange Commission (SEC) on April 18, 2014, and became effective on June 5, 2014. We may need to raise additional capital to fund (i) our operations and (ii) FDA approval of our products. There can be no assurance that additional capital will be available on acceptable terms or at all.

Cash demands on operations

During the nine months ended September 30, 2016, we experienced an operating loss of approximately \$8,655,000 and used cash in operations of approximately \$7,982,000. Excluding discretionary expenses related to R&D, patent and trademark costs, contract growing of our proprietary tobacco, and certain nonrecurring expenses relating to factory capital expenses, investor relations, and marketing costs, our monthly cash expenditures are approximately \$700,000. Including cash on hand at September 30, 2016 of \$5,190,505, net cash raised in the October 2016 registered direct offering of approximately \$10,700,000 and revenues from ongoing product sales, but not including potential milestone payments of up to \$7,000,000 from British American Tobacco (BAT), we believe resulting cash balances will be adequate to sustain operations and meet all current obligations as they come due through at least July 2018.

Net Cash used in Operating Activities

In the nine months ended September 30, 2016, \$7,982,309 of cash was used in operating activities as compared to \$4,863,017 of cash used in operating activities in the nine months ended September 30, 2015; an increase of \$3,119,292. The increase in use of cash in operations was primarily due to the increase in the cash portion of the net loss in the amount of \$2,890,706 and an increase in the use of cash used for working capital components related to operations in the amount of \$228,586, for the first nine months of 2016 as compared to the first nine months of 2015.

Net Cash used in Investing Activities

In the first nine months of 2016, net cash used in investing activities was \$362,234, as compared to \$339,675 of cash used in investing activities during the first nine months of 2015.

Net Cash provided by Financing Activities

During the first nine months of 2016, \$9,774,751 of cash was provided by financing activities primarily as a result of net cash proceeds of \$9,774,555 received from registered direct offerings in February and July of 2016. During the nine months ended September 30, 2015, cash of \$5,541,583 was provided by financing activities, primarily consisting of net cash received in a June 2015 registered direct offering of \$5,576,083.

Critical Accounting Policies and Estimates

Accounting principles generally accepted in the United States of America, or GAAP, require estimates and assumptions to be made that affect the reported amounts in our consolidated financial statements and accompanying notes. Some of these estimates require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations.

Inventory

Inventories are valued at the lower of cost or market. Cost is determined using an average cost method for tobacco leaf inventory and raw materials inventory and standard cost is primarily used for finished goods inventory. Inventories are evaluated to determine whether any amounts are not recoverable based on slow moving or obsolete condition and are written off or reserved as appropriate.

Revenue Recognition

We recognize revenue at the point the product is shipped to a customer and title has transferred. Revenue from the sale of our products is recognized net of cash discounts, sales returns and allowances. Federal cigarette and filtered cigar excise taxes are included in net sales, except on sales of *SPECTRUM* research cigarettes exported cigarettes, exported filtered cigars and in-bond sales of filtered cigars to other federally licensed tobacco products manufacturers as to which such taxes do not apply. We recognize revenue from the sale of our *MAGIC* brand cigarettes in Europe when the cigarettes are sold by the European distributors to the retailers and are sold net of cash discounts, sales returns and allowances and all applicable taxes.

We were chosen to be a subcontractor for a 5-year government contract between RTI International (“RTI”) and the National Institute on Drug Abuse (“NIDA”) to supply NIDA with research cigarettes. These government research cigarettes are distributed under the Company’s mark *SPECTRUM*. In September 2015, the Company received a purchase order for approximately 5.0 million *SPECTRUM* research cigarettes. Approximately 40% of the order was shipped in December 2015, resulting in the recognition of revenue in the amount of \$242,658 during the fourth quarter of 2015. The remainder of the order was shipped in January 2016 and generated revenue of \$329,321. There were no *SPECTRUM* cigarettes delivered during the second and third quarters of 2016.

Impairment of Long-Lived Assets

We review the carrying value of amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be appropriate. We also assess recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset’s carrying value and its fair value.

Non-amortizing intangibles (e.g., patents and trademarks) are reviewed annually for impairment. We have not recognized any impairment losses during the three and nine months ended September 30, 2016 or 2015.

Amortization Estimates of Intangible Assets

We generally determine amortization based on the estimated useful lives of the assets and record amortization expense on a straight-line method over such lives. The remaining life of the patent is generally used to determine the estimated useful life of the related patent costs.

Valuation of our Equity Securities

We use a fair-value based method to determine compensation for all arrangements under which Company employees and others receive shares, options or warrants to purchase shares of our common stock. Stock based compensation expense is recorded over the requisite service period based on estimates of probability and time of achieving milestones and vesting. For accounting purposes, the shares will be considered issued and outstanding upon vesting.

Income taxes

We recognize deferred tax assets and liabilities for any basis differences in our assets and liabilities between tax and GAAP reporting, and for operating loss and credit carry-forwards. In light of the Company's history of cumulative net operating losses and the uncertainty of their future utilization, the Company has established a valuation allowance to fully offset its net deferred tax assets as of September 30, 2016 and December 31, 2015.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair market value and then is revalued at each reporting date, with changes in fair value reported in the Consolidated Statement of Operations. The methodology for valuing our outstanding warrants classified as derivative instruments utilizes a lattice model approach which includes probability weighted estimates of future events including volatility of our common stock. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The warrant liability is measured at fair value using certain estimated factors such as volatility and probability which are classified within Level 3 of the valuation hierarchy. Significant unobservable inputs are used in the fair value measurement of the Company's derivative warrant liabilities include volatility. Significant increases (decreases) in the volatility input would result in a significantly higher (lower) fair value measurement. A 10% increase or decrease in the volatility factor used as of September 30, 2016 would have the impact of increasing or decreasing the liability by approximately \$4,000.

The classification of derivative instruments, including whether such instruments should be recorded as liabilities or equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on if the net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

Inflation

Inflation did not have a material effect on our operating results for the three months and nine months ended September 30, 2016 and 2015.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by Item 303(a)(4) of Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no material changes to the information set forth in our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures:

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its Securities Exchange Act of 1934 (“Exchange Act”) reports are recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to the Company’s management, including the Company’s chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our chief executive officer and chief financial officer, after evaluating the effectiveness of the Company’s “disclosure controls and procedures” (as defined in the Exchange Act Rules 13a-15(e) or 15d-15(e)) as of the end of the period covered by this quarterly report, have concluded that our disclosure controls and procedures were not effective and that material weaknesses described in our Form 10-K for the year ended December 31, 2015 exist in our internal control over financial reporting based on their evaluation of these controls and procedures as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15.

(b) Changes in Internal Control over Financial Reporting:

During the third quarter of 2016, an additional accounting employee hired during the second quarter of 2016 was fully deployed and with the assistance of a third-party consultant, we developed and commenced the implementation of a remediation plan targeted at eliminating our previously reported material weakness in our internal controls over financial reporting primarily resulting from a lack of segregation of duties. Except as set forth herein, there were no changes in the Company's internal controls over financial reporting during the third quarter of 2016 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

We are subject to various claims and legal proceedings arising in the ordinary course of business. As of the date hereof, we are unable to currently assess whether the final resolution of any of such claims or legal proceedings may have a material adverse effect on us.

On April 26, 2016, Crede CG III, LTD. ("Crede") filed a complaint against the Company in the United States District Court for the Southern District of New York (the "SDNY Court") entitled Crede CG III, LTD. v. 22nd Century Group, Inc. On May 19, 2016, Crede filed an Amended Complaint that includes seven counts, alleging among other things, that the Company allegedly breached and/or interfered with certain agreements entered into with Crede, including the joint venture agreement relating to efforts to sell the Company's proprietary tobacco into China, the Tranche 1A warrant and the prior securities purchase agreement with Crede. The Amended Complaint seeks money damages, to rescind the securities purchase agreement, to obtain declaratory and injunctive relief to require the Company to issue to Crede 2,077,555 shares of the Company's common stock under the exchange provision of the Tranche 1A warrant, and entry of an injunction prohibiting the Company from selling tobacco into China without the joint venture's involvement. The Amended Complaint also seeks attorney's fees and such other relief as the Court may deem just and proper. We believe that the claims are frivolous, meritless and that the Company has substantial legal and factual defenses to the claims. The Company has defended and intends to continue to defend against these claims vigorously, and has filed letter motions for the dismissal of the claims and for the transfer of certain of the claims to the United States District Court for the Western District of New York (the "WDNY Court"). The Company also intends to file counterclaims if the case continues.

On May 19, 2016, Crede filed a motion for preliminary injunction, asking the SDNY Court to require the Company to issue 2,077,555 shares of its common stock to Crede under the exchange provision of the Tranche 1A warrant. After conducting an evidentiary hearing on this motion on June 14, 2016, the SDNY Court denied Crede's motion and held, among other things, that Crede did not prove the potential for irreparable harm or a likelihood of success on its claim for such 2,077,555 shares under the Tranche 1A warrant, and that there was a likelihood that Crede had violated the activity restrictions of the Tranche 1A warrant, which would bar Crede's claim for such shares from the Company.

Following such ruling, the SDNY Court directed the parties to file briefs on the pending letter motion to transfer certain claims to the WDNY Court. On July 11, 2016, the Company filed its formal motion to sever the Crede lawsuit into two separate cases, with all claims relating to the Tranche 1A warrant to stay in the SDNY Court, and with the claims relating to the China joint venture agreement and the securities purchase agreement to be transferred to the WDNY Court, where the Company's headquarters is located. On July 29, 2016, Crede filed its response to the Company's motion and on August 5, 2016, the Company filed its reply to Crede's response. The SDNY Court has not yet ruled on such motions.

Item 1A. Risk Factors

Our risk factors have not changed materially from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on February 18, 2016.

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

None

Item 3. Default Upon Senior Securities.

None

Item 4. Mine Safety Disclosures

None

Item 5. Other Information

None

Item 6. Exhibits

Exhibit
31.1 Section 302 Certification - Chief Executive Officer

Exhibit
31.2 Section 302 Certification - Chief Financial Officer

Exhibit
32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

101 Interactive data files formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, and (iv) the Notes to the Consolidated Financial Statements.

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

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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:

22nd CENTURY GROUP, INC.

Date: November 8, 2016 /s/ Henry Sicignano III
Henry Sicignano III
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 8, 2016 /s/ John T. Brodfuehrer
John T. Brodfuehrer
Chief Financial Officer
(Principal Accounting and Financial Officer)