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

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the Quarterly Period Ended March 31, 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 of incorporation) | (IRS Employer 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 x 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 x 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 x |
| 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 x

As of May 9, 2016, there were 76,015,273 shares of common stock issued and outstanding.

**22nd CENTURY GROUP, INC.**

**INDEX**


| | | Page Number |
|---|---|---|
| PART I. | FINANCIAL INFORMATION | |
| Item 1. | Financial Statements | |
| | Consolidated Balance Sheets as of March 31, 2016 (unaudited) and December 31, 2015 | 3 |
| | Consolidated Statements of Operations for the Three Months Ended March 31, 2016 and 2015 (unaudited) | 4 |
| | Consolidated Statement of Changes in Shareholders' Equity for the Three Months Ended March 31, 2016 (unaudited) | 5 |
| | Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2016 and 2015 (unaudited) | 6 |
| | Notes to Consolidated Financial Statements (unaudited) | 7 |
| Item 2. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 20 |
| Item 3. | Quantitative and Qualitative Disclosures About Market Risk | 26 |
| Item 4. | Controls and Procedures | 26 |
| PART II. | OTHER INFORMATION | 27 |
| Item 1. | Legal Proceedings | 27 |
| Item 1A. | Risk Factors | 27 |
| Item 2. | Unregistered Sales of Equity Securities and Use of Proceeds | 27 |
| Item 3. | Default Upon Senior Securities | 27 |
| Item 4. | Mine Safety Disclosures | 27 |

| | | |
|---|---|---|
| Item 5. | Other Information | 27 |
| Item 6. | Exhibits | 27 |
| SIGNATURES | | 28 |

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

| | March 31, 2016 (unaudited) | December 31, 2015 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash | $6,051,593 | $3,760,297 |
| Accounts receivable, net | 102,913 | 51,230 |
| Inventory, net | 2,920,883 | 2,706,330 |
| Prepaid expenses and other assets | 529,296 | 635,998 |
| Total current assets | 9,604,685 | 7,153,855 |
| | | |
| Machinery and equipment, net | 2,476,716 | 2,555,793 |
| | | |
| Other assets: | | |
| Intangible assets, net | 7,383,107 | 7,364,120 |
| Equity investment | 1,135,419 | 1,222,651 |
| Total other assets | 8,518,526 | 8,586,771 |
| | | |
| Total assets | 20,599,927 | $18,296,419 |
| | | |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Current portion of note payable | $314,710 | 308,582 |
| Accounts payable | 1,729,129 | 1,283,346 |
| Accrued expenses | 1,222,697 | 1,349,438 |
| Accrued severance | 218,834 | 220,661 |
| Total current liabilities | 3,485,370 | 3,162,027 |
| | | |
| Long-term portion of note payable | 307,938 | 307,938 |
| Long-term portion of accrued severance | 145,153 | 199,658 |
| Warrant liability | 17,231 | 2,898,296 |
| Total liabilities | 3,955,692 | 6,567,919 |
| | | |
| Commitments and contingencies (Note 11) | - | - |
| | | |
| 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: | | |
| 76,015,273 common shares (71,006,844 at December 31, 2015) | 760 | 710 |
| Capital in excess of par value | 86,452,952 | 78,284,815 |

| | | |
|---|---|---|
| Accumulated deficit | (69,809,477) | (66,557,025) |
| Total shareholders' equity | 16,644,235 | 11,728,500 |
| Total liabilities and shareholders' equity | $20,599,927 | $18,296,419 |

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**Three Months Ended March 31,**
**(unaudited)**

| | 2016 | 2015 |
|---|---|---|
| Revenue: | | |
| Sale of products | $3,019,056 | $616,138 |
| Cost of goods sold (exclusive of depreciation shown separately below): | | |
| Products | 2,895,410 | 632,580 |
| Gross profit (loss) | 123,646 | (16,442) |
| Operating expenses: | | |
| Research and development (including equity based compensation of $45,056 and $45,563, respectively) | 597,391 | 158,469 |
| General and administrative (including equity based compensation of $226,175 and $2,390,821, respectively) | 1,846,607 | 3,651,721 |
| Sales and marketing (including equity based compensation of $11,636 and $4,821, respectively) | 702,614 | 115,229 |
| Depreciation | 80,597 | 78,810 |
| Amortization | 124,841 | 106,587 |
| | 3,352,050 | 4,110,816 |
| Operating loss | (3,228,404) | (4,127,258) |
| Other income (expense): | | |
| Warrant liability gain - net | 71,065 | 59,213 |
| Loss on equity investment | (87,232) | (50,981) |
| Interest income | 2,493 | 7,795 |
| Interest expense | (10,374) | (5,508) |
| | (24,048) | 10,519 |
| Loss before income taxes | (3,252,452) | (4,116,739) |
| Income taxes | - | - |
| Net loss | $(3,252,452) | $(4,116,739) |
| Loss per common share - basic and diluted | $(0.04) | $(0.06) |
| Common shares used in basic earnings per share calculation | 74,031,148 | 64,187,656 |

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY**
**Three Months Ended March 31, 2016**
**(unaudited)**

| | Common Shares Outstanding | Par value of Common Shares | Contributed Capital | Accumulated Deficit | Shareholders' Equity (Deficit) |
|---|---|---|---|---|---|
| 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 | 5,000,000 | 50 | 5,091,741 | - | 5,091,791 |
| Reclassification of warrant liability to capital in excess of par (see Note 4) | - | - | 2,810,000 | - | 2,810,000 |
| Stock based compensation | 5,811 | - | $ 266,200 | - | 266,200 |
| Stock issued in connection with warrant exercise | 2,618 | - | $ 196 | - | 196 |
| Net loss | - | - | $ - | (3,252,452) | (3,252,452) |
| Balance at March 31, 2016 | 76,015,273 | $ 760 | $ 86,452,952 | $ (69,809,477) | $ 16,644,235 |

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**Three Months Ended March 31,**
**(unaudited)**

| | 2016 | 2015 |
|---|---|---|
| Cash flows from operating activities: | | |
| Net loss | $(3,252,452) | $(4,116,739) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Amortization and depreciation | 180,932 | 160,891 |
| Amortization of license fees | 24,506 | 24,506 |
| Loss on equity investment | 87,232 | 50,981 |
| Accretion of interest on note payable and accrued severance | 10,374 | - |
| Warrant liability gain | (71,065) | (59,213) |
| Equity based employee compensation expense | 259,994 | 354,087 |
| Equity based payments for outside services | 22,873 | 2,087,118 |
| Increase in inventory reserve | - | 60,000 |
| (Increase) decrease in assets: | | |
| Accounts receivable | (51,684) | (209,028) |
| Inventory | (214,553) | (558,537) |
| Prepaid expenses and other assets | 90,036 | (151,711) |
| Increase (decrease) in liabilities: | | |
| Accounts payable | 301,955 | 316,746 |
| Accrued expenses | (126,741) | (448,865) |
| Accrued severance | (60,578) | (30,856) |
| Net cash used in operating activities | (2,799,171) | (2,520,620) |
| | | |
| Cash flows from investing activities: | | |
| Acquisition machinery and equipment | (1,520) | (3,720) |
| Net cash used in investing activities | (1,520) | (3,720) |
| | | |
| Cash flows from financing activities: | | |
| Proceeds from exercise of warrants | 196 | - |
| Net proceeds from February 2016 registered direct offering | 5,091,791 | - |
| Stock cancellation | - | (34,500) |
| Net cash provided by (used in) financing activities | 5,091,987 | (34,500) |
| | | |
| Net increase (decrease) in cash | 2,291,296 | (2,558,840) |
| Cash - beginning of period | 3,760,297 | 6,402,687 |
| Cash - end of period | $6,051,593 | $3,843,847 |
| | | |
| Supplemental disclosures of cash flow information: | | |
| Net cash paid for: | | |
| Cash paid during the period for interest | $10,374 | $5,508 |
| Cash paid during the period for income taxes | $- | $- |
| Non-cash transactions: | | |

| | | |
|---|---|---|
| Patent and trademark additions included in accounts payable | $143,828 | $194,329 |
| Machinery and equipment additions included in accounts payable | $- | $18,076 |
| Reclassification of warrant liability to capital in excess of par due to voiding of exchange rights clause in Crede Tranche 1A warrant | $2,810,000 | $- |
| Issuance of common stock in satisfaction of accrued expense | $- | $325,000 |
| Issuance of common stock for services recorded as prepaid expense | $- | $91,667 |

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 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 of 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 three months ended March 31, 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 of 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 7.

***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 March 31, 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 the first-in, first-out (FIFO) method on all other inventories. 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 March 31, 2016 and December 31, 2015 consisted of the following:

| | March 31, 2016 | December 31, 2015 |
|---|---|---|
| Inventory - tobacco leaf | $ 1,830,675 | $ 1,816,857 |
| Inventory - finished goods | | |
| Cigarettes and filtered cigars | 371,414 | 342,707 |
| Inventory - raw materials | | |
| Cigarette and filtered cigar components | 829,417 | 657,389 |
| | 3,031,506 | 2,816,953 |
| Less: inventory reserve | 110,623 | 110,623 |
| | $ 2,920,883 | $ 2,706,330 |

***Fixed assets*** - Fixed assets 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 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 March 31, 2016 and December 31, 2015 consisted of the following:

| | March 31, 2016 | December 31, 2015 |
|---|---|---|
| Intangible assets, net | | |
| Patent and trademark costs | $5,290,387 | $ 5,146,559 |
| Less: accumulated amortization | 1,704,228 | 1,603,893 |
| Patent and trademark costs, net | 3,586,159 | 3,542,666 |

| | | |
|---|---|---|
| License fees, net (see Note 11) | 1,450,000 | 1,450,000 |
| Less: accumulated amortization | 155,052 | 130,546 |
| License fees, net | 1,294,948 | 1,319,454 |
| | | |
| MSA signatory costs | 2,202,000 | 2,202,000 |
| | | |
| License fee for predicate cigarette brand | 300,000 | 300,000 |
| | | |
| | $7,383,107 | $ 7,364,120 |

8

Amortization expense relating to the above intangible assets for the three months ended March 31, 2016 and 2015 amounted to $124,841 and $106,587, respectively.

The estimated annual average amortization expense for the next five years is approximately $358,000 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 months ended March 31, 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.

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 March 31, 2016 and December 31, 2015.

The Company's federal and state tax returns for the years ended December 31, 2012 to December 31, 2014 are currently open to audit under the statutes of limitations.  There were no pending audits as of March 31, 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 $1,735,000 and $325,000 are included in net sales and accounts receivable billed to customers for the three months ended March 31, 2016 and 2015, respectively, except on sales of *SPECTRUM* research cigarettes, exported cigarettes and exported filtered cigars, 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.

***Derivatives* -** The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates 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 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 whether or not 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 as incurred. Advertising expense was approximately $208,000 and $51,000 for the three months ended March 31, 2016 and 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, demand bank loan 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 10.

***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). The Company is currently evaluating the impact of the pending adoption of ASU 2014-09 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 of 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. - 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 are exercisable for a period of sixty-six (66) months after issuance, are 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.

**NOTE 3. - 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 are 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.

**NOTE 4. - 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 months ended March 31, 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 stocks, Tranche IB 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 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 has reclassified the warrant liability associated with the Tranche 1A warrant to Capital in excess of par on its Consolidated Balance Sheets at March 31, 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 5. - MANUFACTURING FACILITY**

The Company's manufacturing operations at its North Carolina factory were not at full production capacity during the first quarter of 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 $135,267 and 131,518 for the three months ended March 31, 2016 and 2015, respectively.

**NOTE 6. - MACHINERY AND EQUIPMENT**

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

| | March 31, 2016 | December 31, 2015 |
|---|---|---|
| Cigarette manufacturing equipment | $3,016,246 | $ 3,016,246 |
| Office furniture, fixtures and equipment | 96,881 | 95,361 |

| | | |
|---|---|---|
| | 3,113,127 | 3,111,607 |
| Less: accumulated depreciation | 636,411 | 555,814 |
| Machinery and equipment, net | $2,476,716 | $ 2,555,793 |

Depreciation expense was $80,597 and $78,810 for the three months ended March 31, 2016 and 2015, respectively.

**NOTE 7. - 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.

11

The Company uses the equity method of accounting to record its 25% ownership interest in Anandia. As of March 31, 2016 and December 31, 2015, the Company's equity investment balance in Anandia was $1,135,419 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 for each of the three months ended March 31, 2016 and 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 $72,820 and $36,569 for the three months ended March 31, 2016 and 2015, respectively, representing 25% of Anandia's net losses, resulting in a total loss on equity investment of $87,232 and $50,981 for the three months ended March 31, 2016 and 2015, respectively.

**NOTE 8. - NOTES PAYABLE AND PATENT ACQUISITION**

On December 22, 2014, the Company entered into a Purchase Agreement (the "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 payment. 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 required 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 amount to $622,648; with $314,710 and $307,938 recorded as the current and long-term portion of the note payable, respectively, at March 31, 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 9. - 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. 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 first quarter of 2016, the discounted current and long-term balance of the severance liability amounted to $218,834 and $145,153, respectively, at March 31, 2016 ($220,661 and $199,658, respectively, at December 31, 2015).

**NOTE 10. - WARRANTS FOR COMMON STOCK**

At March 31, 2016, the Company had outstanding warrants to purchase 10,326,621 shares of common stock of the Company, of which only 92,632 warrants contain an anti-dilution feature. The Crede Tranche 2 and Tranche 3 warrants are excluded from the outstanding warrant total of 10,326,621 (see Note 4 for additional discussion).

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 February 5, 2016, and discussed in Note 2, the Company issued warrants to purchase 2,500,000 shares of common stock with an exercise price of $1.21 per share. These warrants have a term of sixty-six (66) months, are not exercisable for six months immediately following the date of issuance, do not contain an anti-dilution feature, and had a fair value of approximately $1,940,000 at issuance.

Pursuant to the registered direct offering that closed on June 2, 2015, and discussed in Note 3, the Company issued warrants to purchase 3,000,000 shares of common stock with an exercise price of $1.25 per share. These warrants have a term of sixty-six (66) months, were not exercisable for six months immediately following the date of issuance, do not contain an anti-dilution feature, and had a fair value of approximately $2,067,000 at issuance.

Outstanding warrants at March 31, 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] | 92,632 | $0.9520 | August 8, 2018 |
| August 2012 convertible NP warrants | 92,244 | $0.9060 | August 8, 2018 |
| Crede Tranche 1A warrants | 1,250,000 | $3.3600 | September 29, 2016 |
| Crede Tranche 1B warrants | 1,000,000 | $2.5951 | September 29, 2016 |
| June 2015 registered direct offering warrants | 3,000,000 | $1.2500 | December 2, 2020 |
| February 2016 registered direct offering warrants | 2,500,000 | $1.2100 | August 5, 2021 |
| Total warrants outstanding [2],[3],[4] | 10,236,621 | | |

(1) Includes anti-dilution features.

(2) Includes warrants to purchase 533,000 shares of common stock (5.2%) held by officers and directors that have had the anti-dilution feature removed.

(3) Includes warrants to purchase 312,730 shares of common stock (3.1%) held by a former officer and director that have had the anti-dilution feature removed.

(4) Excludes the Crede Tranche 2 and Tranche 3 warrants to purchase 2,000,000 shares of common stock because the warrants will never be exercisable (see Note 4 for additional discussion).

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, 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 | (71,065) |
| Fair value at March 31, 2016 | $17,231 |

The aggregate net gain as a result of the Company's warrant liability for the three months ended March 31, 2016 and 2015 amounted to $71,065 and $59,213, respectively, which are included in Other income (expense) under Warrant liability 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 ) |
| Warrants outstanding at March 31, 2016 | 10,236,621 |
| | |
| Composition of outstanding warrants: | |
| Warrants containing anti-dilution feature | 92,632 |
| Warrants without anti-dilution feature | 10,143,989 |
| | 10,236,621 |

(1) Crede Tranche 2 Warrants and Tranche 3 Warrants are not exercisable (see Note 4 for additional discussion).

**NOTE 11. - 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 increases 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 months ended March 31, 2016 and 2015, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to $3,980 and $17,328, 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 months ended March 31, 2016 and 2015, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to $6,075 and $0, respectively. 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 months ended March 31, 2016 and 2015 were $114,797 and $39,051, 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 months ended March 31, 2016 and 2015, the aggregated costs incurred related to capitalized patent costs and patent maintenance expense amounted to $27,956 and $3,682, 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 7). 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 royalties 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 amounted to $24,506 in each of the three months ended March 31, 2016 and 2015, and was included in Amortization expense 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 will pay Anandia $379,800 over the initial term of the Agreement, of which $116,400 was paid in October 2015, and additional amounts of $95,000, $84,200 and $84,200 are due on January 1, 2016, April 1, 2016 and July 1, 2016, respectively. The $95,000 incurred during the first quarter of 2016 is 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 one-year lease extension term that will expire on October 31, 2016. The lease expense for the three months ended March 31, 2016 and 2015 amounted to $36,131 and $30,750, respectively. The future minimum lease payments if the Company exercises each of the additional extensions are approximately as follows:

| | |
|---|---|
| Year ended December 31, 2016 - | $110,000 |
| 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 that expires on August 31, 2016, with the Company having the option to extend this 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 $34,000 and $31,000, respectively, if the Company exercises the optional renewal period.

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 $33,750, $45,000, $45,000 and $37,500, respectively, if the Company exercises the optional renewal period.

***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.

**NOTE 12. - 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 March 31, 2016 and 2015:

| | March 31, 2016 | March 31, 2015 |
|---|---|---|
| Net loss attributed to common shareholders | $(3,252,452 ) | $(4,116,739 ) |
| Denominator for basic earnings per share-weighted average shares outstanding | 74,031,148 | 64,187,656 |
| Effect of dilutive securities: | | |
| Warrants, restricted stock and options outstanding | - | - |
| Denominator for diluted earnings per common share-weighted average shares adjusted for dilutive securities | 74,031,148 | 64,187,656 |
| Loss per common share - basic and diluted | $(0.04 ) | $(0.06 ) |

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

| | March 31, 2016 | March 31, 2015 |
|---|---|---|
| Warrants | 10,236,621 | 13,674,409 |
| Restricted stock | - | 250,000 |
| Options | 4,795,679 | 2,599,999 |
| | 15,032,300 | 16,524,408 |

16

**NOTE 13. - 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 months ended March 31, 2016, the Company issued stock option awards from the OIP for 1,634,037 shares to eligible individuals having vesting periods ranging from one to three years from the date of the award. During the three months ended March 31, 2015, the Company issued restricted stock and stock options awards from the OIP for 20,000 shares and 1,559,999 shares, respectively, to eligible individuals having vesting periods ranging from six months to one year from the date of the award. 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 months ended March 31, 2016 and 2015, the Company recorded compensation expense related to restricted stock and stock option awards granted under the EIP and OIP of $259,994 and $354,087, respectively. During the three months ended March 31, 2016, the Company issued stock to third-party service providers in the amount of 5,811 shares. During the three months ended March 31, 2015, the Company also issued restricted stock and stock options to third-party service providers in the amount of 189,196 and 100,000 shares, respectively. The Company recorded equity based compensation related to the third-party providers for the three months ended March 31, 2016 and 2015 in the amount of $23,873 and $108,333, respectively.

As of March 31, 2016, unrecognized compensation expense related to non-vested restricted shares and stock options amounted to approximately $1,429,000, which is expected to be recognized approximately as follows: $571,000, $344,000, $253,000 and $42,000 during 2016, 2017, 2018 and 2019, respectively. Approximately $218,000 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 three months ended March 31, 2016 and 2015:

| | 2016 | | 2015 | |
|---|---|---|---|---|
| Risk-free interest rate (weighted average) | 1.37 | % | 1.52 | % |
| Expected dividend yield | 0 | % | 0 | % |
| Expected stock price volatility | 90 | % | 90 | % |
| Expected life of options (weighted average) | 4.98 years | | 5.17 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 | 1,634,037 | $ 0.95 | | |
| Outstanding at March 31, 2016 | 4,795,679 | $ 1.05 | 7.9 years | $ 67,100 |
| Exercisable at March 31, 2016 | 2,349,999 | $ 1.09 | 7.3 years | $ 43,100 |

There were stock options granted during the three months ended March 31, 2016 and 2015, to purchase a total of 1,634,037 shares and 1,659,999 shares, respectively. The weighted average grant date fair value of options issued during the three months ended March 31, 2016 was $0.65 ($0.59 for the three months ended March 31, 2015). The total fair value of options that vested during the three months ended March 31, 2016 amounted to $909,319. No options vested during the three months ended March 31, 2015. No options were exercised during the three months ended March 31, 2016 and 2015.

**NOTE 14. - SUBSEQUENT EVENTS**

On April 26, 2016, Crede CG III, LTD. (“Crede”) filed a complaint against us in the United States District Court for the Southern District of New York entitled Crede CG III, LTD. v. 22nd Century Group, Inc., alleging, among other things, that we breached certain agreements entered into with the plaintiff, including the joint venture arrangement relating to efforts to sell our proprietary tobacco into China, the Tranche 1A Warrant and the prior securities purchase agreement with Crede. The complaint seeks, among other relief, an injunction prohibiting us from selling tobacco into China without plaintiff’s involvement and compensatory damages, fees and such other relief as the court may deem just and proper. We believe that the claims are frivolous, meritless and that we have substantial legal and factual defenses to the claims and allegations contained in the complaint. We intend to defend against these claims vigorously and file counterclaims against Crede and its principal, Terren Peizer, if the case continues.

**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 co 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 strategic objectives include:**

- pursuit of reduced exposure authorization from the U.S. Food and Drug Administration (FDA) for our Very Low Nicotine *BRAND A* modified risk cigarette in development (an application for which was submitted to the FDA on December 31, 2015). The Company's Modified Risk Tobacco Product (MRTP) application to the FDA seeks a reduced exposure order so that 22nd Century 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 the Company's 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,

- contracting with a strategic joint venture partner to fund a Phase III smoking cessation clinical trial for X-22, our tobacco-based smoking cessation aid in development,

- research and development of unique cannabis plants through genetic engineering and plant breeding,

- commercialization of *RED SUN* super-premium cigarettes in the United States and internationally,

- commercialization of *MAGIC* super-premium, Very Low Nicotine cigarettes internationally,

- expansion of a base of third-party cigarette and filtered cigar contract manufacturing business at our manufacturing facility in Mocksville, North Carolina, and

- establishment of substantial multi-year sales contracts for our proprietary tobacco leaf and/or finished tobacco products internationally.

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

- The Company met with administrators and scientific reviewers at the FDA to review the Company's MRTP application for *BRAND A* VLN cigarettes. The FDA contacted 22nd Century upon receiving the Company's MRTP application and facilitated – fewer than 14 days after the Company's MRTP submission – a meeting at FDA headquarters to discuss the application and the review process. Not long after, FDA formally acknowledged receipt of the Company's MRTP application for *BRAND A* Very Low Nicotine tobacco cigarettes and assigned two Submission Tracking Numbers (STN) to 22nd Century's historic MRTP application: MR0000047 and MR0000048.

- Independent scientific researchers at the 22nd Annual Meeting of the *Society for Research on Nicotine & Tobacco* (SRNT) presented more than fifteen (15) independent scientific studies involving the Company's *SPECTRUM®* research cigarettes. The annual event was highly attended by participants from around the world, including acclaimed university scientists, FDA and other regulators, and industry professionals. The initial results of the independent scientific studies involving the Company's proprietary reduced nicotine tobacco cigarettes demonstrates that once again the Company's Very Low Nicotine cigarettes reduce cigarette consumption and assist in smoking cessation.

- The Company shipped the remaining 2.85 million of a 4.95 million SPECTRUM® research cigarette order for the National Institute on Drug Abuse (NIDA), a department of the National Institutes of Health (NIH). The main SPECTRUM® product line consists of a series of cigarette styles that have a fixed "tar" yield but varying nicotine yields over a 50-fold range – from very low to high. Altogether, SPECTRUM® features 24 styles, 11 regular and 13 menthol versions, with 8 different levels of nicotine content. SPECTRUM® is strictly for research purposes and is not sold as a commercial cigarette. However, the Company has begun outreach efforts to independent scientists and researchers who are seeking research cigarettes with varying levels of nicotine for use in their own smoking cessation studies and other clinical trials.

**More recent notable accomplishments include:**

- The Company received an initial purchase order from Australian tobacco distributor, Quay Tobacco Trading PTY, LTD for both Very Low Nicotine *MAGIC* brand cigarettes and "Extreme Nicotine" *RED SUN* cigarettes. This purchase order represents 22nd Century's first sale of product to the Asia-Pacific region. Starting this summer, Quay Tobacco will introduce 22nd Century's unique cigarette brands to adult Australian smokers.

- The Company entered into a supply arrangement with Celanese Corporation. Through this arrangement, 22nd Century will combine many of its proprietary tobaccos with Celanese's revolutionary CelFX® carbon filter in new cigarette designs for select markets around the world. The Celanese CelFX® filter is a highly efficient cigarette filter that delivers an extraordinary taste experience while significantly reducing many toxic compounds in smoke.

*Annual Report on Form 10-K*

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

**Three Months Ended March 31, 2016 Compared to Three Months Ended March 31, 2015**

*Revenue - Sale of products*

In the three months ended March 31, 2016, we realized net sales revenue from the sale of products in the amount of $3,019,056, an increase of $2,402,918 over sales of $616,138 for the three months ended March 31, 2015. The revenue for the first quarter of 2016 included sales of *SPECTRUM* research cigarettes in the amount of $329,321. There were no sales of *SPECTRUM* research cigarettes during the first quarter of 2015. The remainder of the first quarter 2016 increase in net sales revenue of $2,073,597 resulted from increased product sales when compared to sales for the first quarter of 2015.

*Cost of goods sold - Products*

During the three months ended March 31, 2016, cost of goods sold were $2,895,410 or 95.9% 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 $2,840,391 or 105.6% of related net sales revenue. Excise taxes and certain regulatory fees in the approximate amount of $1,735,000 are included in the cost of goods sold for the three months ended March 31, 2016. We were not operating the factory at full production capacity during the first quarter 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 three months ended March 31, 2015, cost of goods sold were $632,580 or 102.7% of net sales revenue. Excise taxes and certain regulatory fees in the approximate amount of $325,000 are included in the cost of goods sold for the three months ended March 31, 2015.

*Research and development expense*

Research and development ("R&D") expense was $597,391 in the three months ended March 31, 2016, an increase of $438,922, or 277.0%, from $158,469 in the three months ended March 31, 2015. This increase was primarily a result of increases in licensed research and royalty expenses in the approximate amount of $130,000, an increase in sponsored research contract costs of approximately $126,000, an increase of approximately $98,000 in payroll and related benefit costs, an increase associated with our *Brand A* modified risk application filed with the FDA in the approximate amount of $35,000 and an increase in R&D travel related expenses in the approximate amount of $52,000.

*General and administrative expense*

General and administrative expense was $1,846,607 in the three months ended March 31, 2016, a decrease of $1,805,114, or 49.4%, from $3,651,721 in the three months ended March 31, 2015. The decrease was mainly due to a decrease in equity based compensation to third-party service providers in the approximate amount of $2,070,000 (approximately $1,979,000 of the decrease pertained to the Crede consulting fee), a decrease in legal fees of approximately $174,000 and a decrease in employee related equity compensation of approximately $88,000, partially offset by an increase in investor relations costs of approximately $410,000, an increase in consulting fees of approximately $60,000 and an increase in travel related expenses of approximately $40,000.

*Sales and marketing expense*

During the three months ended March 31, 2016, we incurred sales and marketing expenses of $702,614, an increase of $587,385, or 509.8%, from $115,229 in the three months ended March 31, 2015. The increase in sales and marketing expenses are primarily the result of costs incurred to promote and advertise our proprietary cigarette brand, *RED SUN*. Expenses include *RED SUN* advertising and promotional expenses of approximately $400,000 (the majority of this increase relates to the cost of one-time promotional campaigns), an increase in payroll and related benefits in the approximate amount of $151,000 and an increase in travel expenses in the approximate amount of $24,000.

*Depreciation expense.*

Depreciation expense for the three months ended March 31, 2016 amounted to $80,597, an increase of $1,787, or 2.3%, from $78,810 for the three months ended March 31, 2015.

*Amortization expense.*

Amortization expense for the three months ended March 31, 2016 amounted to $124,841, an increase of $18,254, or 17.1%, from $106,587 for the three months ended March 31, 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 three months ended March 31, 2016 and the year ended December 31, 2015 in the amounts of $120,825 and $654,069, respectively.

*Warrant liability gain - net*

The warrant liability gain of $71,065 for the first quarter of 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 a decrease in the Company's underlying stock price from $1.40 per share at December 31, 2015, as compared to $0.78 per share at March 31, 2016, and as a result of certain warrants aging closer to their expiration dates with the passage of time.

The warrant liability gain of $59,213 for the first 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 the Company's underlying stock price from $1.65 per share at December 31, 2014, as compared to $0.86 per share at March 31, 2015, and as a result of certain warrants aging closer to their expiration dates with the passage of time.

*Loss on equity investment*

The loss on equity investment of $87,232 and $50,981 for the three months ended March 31, 2016 and 2015, respectively, consists of (i) our 25% share of Anandia's net loss for the respective three month periods ending March 31, 2016 and 2015 in the amount of $72,820 and $36,569, 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 March 31, 2016 was $2,493, a decrease of $5,302 from interest income of $7,795 for the three months ended March 31, 2015. The interest income earned in the three months ended March 31, 2016 and 2015 was generated from excess cash invested in a money market account.

*Interest expense*

Interest expense increased in the three months ended March 31, 2016 to $10,374 from $5,508 in the three months ended March 31, 2015. This increase of $4,866 was derived from the interest component of severance payments made during the three months ended March 31, 2016, where the severance accrual 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 March 31, 2016 of $3,252,452 as compared to a net loss of $4,116,739 in the three months ended March 31, 2015. The decrease in the net loss of $864,287, or 21.0%, was primarily the result of the decrease in operating expenses of approximately $759,000 and an increase in gross profit of approximately $140,000, partially offset by a decrease in the other income (expense) of approximately $35,000.

**Liquidity and Capital Resources**

*Working Capital*

As of March 31, 2016, we had positive working capital of approximately $6.12 million compared to positive working capital of approximately $3.99 million at December 31, 2015, an increase of approximately $2.13 million. The increase in our working capital position was mainly a result of the net proceeds received from a February 2016 registered direct offering of approximately $5.10 million, offset by cash used in our operating activities of approximately $2.80 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. The Company's Form S-3 universal shelf registration statement was filed with the U.S. Securities and Exchange Commission ("SEC") on April 18, 2014, and became effective on June 5, 2014. The universal shelf registration statement will allow, but not compel, the Company to raise up to approximately $27 million of capital over a three-year period ending June 5, 2017 through a wide array of securities at times and in amounts to be determined by the Company. We will likely 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 first quarter of 2016, we experienced an operating loss of approximately $3,230,000 and used cash in operations of approximately $2,800,000. Excluding contract growing of our proprietary tobacco with farmers, costs associated with an additional modified risk application with the FDA, patent and trademark costs, discretionary expenses such as potential clinical trials, capital expenses for our factory, and possible sponsored research, our monthly cash expenditures are approximately $650,000. Including cash on hand at March 31, 2016 of $6,051,593 and revenues from ongoing product sales, but not including potential milestone payments of up to $7,000,000 from BAT, we believe resulting cash balances will be adequate to sustain operations and meet all current obligations as they come due through at least October 2016.

*Net Cash used in Operating Activities*

In the first three months of 2016, $2,799,171 of cash was used in operating activities as compared to $2,520,620 of cash used in operating activities in the first three months of 2015; an increase of $278,551. 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 $1,299,238, and a decrease in the use of cash used for working capital components related to operations in the amount of $1,020,687, for the first three months of 2016 as compared to the first three months of 2015.

*Net Cash used in Investing Activities*

In the first three months of 2016, net cash used in investing activities was $1,520, as compared to $3,720 of cash used in investing activities during the first three months of 2015.

*Net Cash provided by (used in) Financing Activities*

During the first three months of 2016, $5,091,987 of cash was provided by financing activities primarily as a result of net cash proceeds received from a February 2016 registered direct offering. During the three months ended March 31, 2015, we used $34,500 from our financing activities as a result of cash used in connection with a stock option reinstatement and stock cancellation.

**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 the First-in, First-out (FIFO) method on all other inventories. 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 and accounts receivable billed to customers, except on sales of *SPECTRUM* and exported cigarettes 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* research cigarettes delivered during the three months ended March 31, 2015.

*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 months ended March 31, 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 March 31, 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 March 31, 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 whether or not 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 ended March 31, 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**

Not applicable.

**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:**

There were no changes in the Company's internal control over financial reporting during the first 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 affect on us.

On April 26, 2016, Crede CG III, LTD. ("Crede") filed a complaint against us in the United States District Court for the Southern District of New York entitled Crede CG III, LTD. v. 22nd Century Group, Inc., alleging, among other things, that we breached certain agreements entered into with the plaintiff, including the joint venture arrangement relating to efforts to sell our proprietary tobacco into China, the Tranche 1A Warrant and the prior securities purchase agreement with Crede. The complaint seeks, among other relief, an injunction prohibiting us from selling tobacco into China without plaintiff's involvement and compensatory damages, fees and such other relief as the court may deem just and proper. We believe that the claims are frivolous, meritless and that we have substantial legal and factual defenses to the claims and allegations contained in the complaint. We intend to defend against these claims vigorously and to file counterclaims against Crede and its principal, Terren Peizer, if the case continues.

### 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 |

**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: May 10, 2016 | /s/ Henry Sicignano III<br>Henry Sicignano III<br>President, Chief Executive Officer and Director<br>(Principal Executive Officer) |
| Date: May 10, 2016 | /s/ John T. Brodfuehrer<br>John T. Brodfuehrer<br>Chief Financial Officer<br>(Principal Accounting and Financial Officer) |