

22nd Century Group, Inc.  
Form 10-Q  
August 07, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE**

**COMMISSION WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the Quarterly Period Ended June 30, 2018**

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

For the Transition Period From \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36338

**22nd Century Group, Inc.**

*(Exact name of registrant as specified in its charter)*

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

**8560 Main Street, Williamsville, New York 14221**

Edgar Filing: 22nd Century Group, Inc. - Form 10-Q

(Address of principal executive offices)

**(716) 270-1523**

*(Registrant's telephone number, including area code)*

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

Yes  No

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

Yes  No

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

(Do not check if smaller reporting company)

Emerging growth company

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

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

Yes  No

Edgar Filing: 22nd Century Group, Inc. - Form 10-Q

As of August 7, 2018, there were 124,374,919 shares of common stock issued and outstanding.

**22nd CENTURY GROUP, INC.**

**INDEX**

	<b>Page</b>
	<b>Number</b>
<b>PART I. FINANCIAL INFORMATION</b>	
<b>Item 1. Financial Statements</b>	
<u>Consolidated Balance Sheets as of June 30, 2018 (unaudited) and December 31, 2017</u>	<u>3</u>
<u>Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended June 30, 2018 and 2017 (unaudited)</u>	<u>4</u>
<u>Consolidated Statements of Operations and Comprehensive Loss for the Six Months Ended June 30, 2018 and 2017 (unaudited)</u>	<u>5</u>
<u>Consolidated Statement of Changes in Shareholders' Equity for the Six Months Ended June 30, 2018 (unaudited)</u>	<u>6</u>
<u>Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2018 and 2017 (unaudited)</u>	<u>7</u>
<u>Notes to Consolidated Financial Statements (unaudited)</u>	<u>8</u>
<b>Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b><u>26</u></b>
<b>Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	<b><u>36</u></b>
<b>Item 4. <u>Controls and Procedures</u></b>	<b><u>37</u></b>
<b><u>PART II.</u></b> <b><u>OTHER INFORMATION</u></b>	<b><u>38</u></b>
<b>Item 1. <u>Legal Proceedings</u></b>	<b><u>38</u></b>
<b><u>Item 1A.</u></b> <b><u>Risk Factors</u></b>	<b><u>39</u></b>
<b>Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	<b><u>39</u></b>

<u>Item 3. Default Upon Senior Securities</u>	<u>39</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>39</u>
<u>Item 5. Other Information</u>	<u>39</u>
<u>Item 6. Exhibits</u>	<u>39</u>
<u>SIGNATURES</u>	<u>40</u>

**22nd CENTURY GROUP, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****June 30, 2018 with Comparative Figures at December 31, 2017**

	June 30, 2018	December 31, 2017
	<b>(unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$3,373,388	\$3,659,534
Short-term investment securities	50,081,013	58,975,513
Accounts receivable	1,283,094	957,066
Inventory, net	2,942,967	3,282,537
Prepaid expenses and other assets	1,321,550	746,805
Total current assets	59,002,012	67,621,455
 Machinery and equipment, net	 3,417,162	 3,316,047
Other assets:		
Intangible assets, net	8,640,302	7,435,411
Investment	7,513,581	1,366,493
Total other assets	16,153,883	8,801,904
 Total assets	 \$78,573,057	 \$79,739,406
 <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of note payable	\$390,016	\$-
Accounts payable	3,049,808	2,080,691
Accrued expenses	1,920,816	1,987,675
Deferred revenue	249,972	28,350
Warrant liability	167,779	216,490
Total current liabilities	5,778,391	4,313,206
 Long-term portion of note payable	 285,210	 -
Total liabilities	6,063,601	4,313,206
 Commitments and contingencies (Note 10)	 -	 -
Shareholders' equity		
10,000,000 preferred shares, \$.00001 par value		

Edgar Filing: 22nd Century Group, Inc. - Form 10-Q

300,000,000 common shares, \$.00001 par value

Capital stock issued and outstanding:

124,311,087 common shares (123,569,367 at December 31, 2017)	1,243	1,236
Capital in excess of par value	169,056,133	166,592,536
Accumulated other comprehensive loss	(28,184 )	-
Accumulated deficit	(96,519,736 )	(91,167,572 )
Total shareholders' equity	72,509,456	75,426,200
Total liabilities and shareholders' equity	\$78,573,057	\$79,739,406

See accompanying notes to consolidated financial statements.

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

	<b>2018</b>	<b>2017</b>
<b>Revenue:</b>		
Sale of products, net	\$6,914,913	\$3,897,206
<b>Cost of goods sold (exclusive of depreciation shown separately below):</b>		
Products	6,753,199	4,062,261
<b>Gross profit (loss)</b>	161,714	(165,055 )
<b>Operating expenses:</b>		
Research and development (including equity-based compensation of \$1,344,317 and \$18,250, respectively)	4,781,407	813,287
General and administrative (including equity-based compensation of \$291,599 and \$105,277, respectively)	1,914,971	1,805,118
Sales and marketing (including equity-based compensation of \$46,312 and \$30,477, respectively)	203,629	267,591
Depreciation	131,294	88,464
Amortization	170,925	143,010
	7,202,226	3,117,470
<b>Operating loss</b>	(7,040,512 )	(3,282,525 )
<b>Other income (expense):</b>		
Warrant liability loss - net	-	(77,583 )
Realized loss on short-term investment securities	(42,384 )	-
Unrealized gain on short-term investment securities	92,574	-
Interest income, net	251,670	12,125
Interest expense	-	(7,641 )
	301,860	(73,099 )
<b>Loss before income taxes</b>	(6,738,652 )	(3,355,624 )
<b>Income taxes</b>	-	-



<b>Net loss</b>			
			\$(6,738,652 ) \$(3,355,624 )
<b>Other comprehensive loss:</b>			
Unrealized loss on short-term investment securities, net		(28,184 )	-
<b>Comprehensive loss</b>			\$(6,766,836 ) \$(3,355,624 )
<b>Net loss per common share - basic and diluted</b>			\$(0.05 ) \$(0.04 )
<b>Common shares used in basic and diluted net loss per share calculation</b>		124,311,087	91,577,688

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****Six Months Ended June 30,****(unaudited)**

	<b>2018</b>	<b>2017</b>
<b>Revenue:</b>		
Sale of products, net	\$ 13,030,952	\$ 6,128,723
<b>Cost of goods sold (exclusive of depreciation shown separately below):</b>		
Products	12,797,660	6,567,675
<b>Gross profit (loss)</b>	233,292	(438,952 )
<b>Operating expenses:</b>		
Research and development (including equity-based compensation of \$1,564,730 and \$32,200, respectively)	7,298,176	1,364,138
General and administrative (including equity-based compensation of \$599,087 and \$233,726, respectively)	3,947,363	3,425,597
Sales and marketing (including equity-based compensation of \$82,287 and \$57,057, respectively)	402,738	563,304
Depreciation	255,822	176,585
Amortization	338,477	283,898
	12,242,576	5,813,522
<b>Operating loss</b>	(12,009,284 )	(6,252,474 )
<b>Other income (expense):</b>		
Warrant liability gain (loss) - net	48,711	(82,927 )
Realized loss on short-term investment securities	(42,189 )	-
Unrealized gain on investment	6,147,088	346,180
Interest income, net	503,510	27,880
Interest expense	-	(15,560 )
	6,657,120	275,573
<b>Loss before income taxes</b>	(5,352,164 )	(5,976,901 )
<b>Income taxes</b>	-	-

<b>Net loss</b>			\$(5,352,164 )	\$(5,976,901 )
<b>Other comprehensive loss:</b>				
Unrealized loss on short-term investment securities, net		(28,184 )	-	
<b>Comprehensive loss</b>			\$(5,380,348 )	\$(5,976,901 )
<b>Net loss per common share - basic and diluted</b>			\$(0.04 )	\$(0.07 )
<b>Common shares used in basic and diluted net loss per share calculation</b>			124,166,321	91,165,770

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY****Six Months Ended June 30, 2018****(unaudited)**

	Common Shares Outstanding	Par Value of Common Shares	Capital in Excess of Par Value	Accumulated Other Comprehensive Loss	Accumulated Deficit	Shareholders' Equity
Balance at December 31, 2017	123,569,367	\$ 1,236	\$ 166,592,536	\$ -	\$(91,167,572)	\$ 75,426,200
Stock issued in connection with warrant exercises	426,180	4	(4 )	-	-	-
Stock issued in connection with option exercises	315,540	3	217,497	-	-	217,500
Equity based compensation	-	-	2,246,104	-	-	2,246,104
Unrealized loss on short-term investment securities, net	-	-	-	(28,184 )	-	(28,184 )
Net loss	-	-	-	-	(5,352,164 )	(5,352,164 )
Balance at June 30, 2018	124,311,087	\$ 1,243	\$ 169,056,133	\$(28,184 )	\$(96,519,736)	\$ 72,509,456

See accompanying notes to consolidated financial statements.

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

	2018	2017
Cash flows from operating activities:		
Net loss	\$(5,352,164 )	\$(5,976,901 )
Adjustments to reconcile net loss to cash used in operating activities:		
Amortization and depreciation	545,288	411,472
Amortization of license fees	49,011	49,011
Unrealized gain on investment	(6,147,088 )	(346,180 )
Realized loss on short-term investment securities	42,189	-
Warrant liability (gain) loss	(48,711 )	82,927
Accretion of interest on note payable and accrued severance	-	15,560
Equity-based employee compensation expense	2,246,104	322,983
Decrease in allowance for doubtful accounts	-	(10,000 )
(Decrease) increase in inventory reserve	(35,000 )	95,000
(Increase) decrease in assets:		
Accounts receivable	(326,028 )	(666,927 )
Inventory	374,570	(1,290,331 )
Prepaid expenses and other assets	(574,745 )	(355,368 )
Increase (decrease) in liabilities:		
Accounts payable	681,026	754,236
Accrued expenses	(66,860 )	(24,339 )
Accrued severance	-	(112,500 )
Deferred revenue	221,622	-
Net cash used in operating activities	(8,390,786 )	(7,051,357 )
Cash flows from investing activities:		
Acquisition of patents and trademarks	(137,761 )	(133,059 )
Acquisition of machinery and equipment	(299,227 )	(13,710 )
Sales and maturities of short-term investment securities	42,183,538	-
Purchase of short-term investment securities	(33,359,410)	-
Net cash provided by (used in) investing activities	8,387,140	(146,769 )
Cash flows from financing activities:		
Net proceeds from exercise of warrants	-	6,212,712
Payment on note payable	(500,000 )	-
Proceeds from exercise of stock options	217,500	-
Net cash (used in) provided by financing activities	(282,500 )	6,212,712

Edgar Filing: 22nd Century Group, Inc. - Form 10-Q

Net decrease in cash	(286,146 )	(985,414 )
Cash - beginning of period	3,659,534	13,468,188
Cash - end of period	\$3,373,388	\$12,482,774

Supplemental disclosures of cash flow information:

Net cash paid for:

Cash paid during the period for interest	\$-	\$2,943
Cash paid during the period for income taxes	\$-	\$-

Non-cash transactions:

Patent and trademark additions included in accounts payable and accrued expenses	\$230,381	\$204,669
Machinery and equipment additions included in accounts payable	\$57,710	\$-
License acquired with note payable	\$1,175,226	\$-

See accompanying notes to consolidated financial statements.

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2018**

**(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 six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. The balance sheet as of December 31, 2017 has been derived from the audited consolidated financial statements at that date, but does not include all the information and footnotes required by GAAP for complete financial statements.

These interim consolidated financial statements should be read in conjunction with the December 31, 2017 audited consolidated financial statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on March 7, 2018.

***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 Heracles Pharmaceuticals, LLC (“Heracles 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 (i) for the level of nicotine and other nicotinic alkaloids in tobacco plants to be decreased or increased through genetic

engineering and plant breeding and (ii) the levels of cannabinoids in hemp plants to be decreased or increased through genetic engineering and plant breeding. Goodrich Tobacco and Heracles Pharma are business units for the Company's (i) 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 subsequent participating member under the tobacco Master Settlement Agreement ("MSA") between the tobacco industry and the settling states under the MSA and operates the Company's tobacco products manufacturing business in North Carolina. Botanical Genetics is a wholly-owned subsidiary of 22nd Century Group and was incorporated to facilitate an investment in Anandia Laboratories, Inc. more fully described in Note 6.

**Reclassifications** – Certain items in the 2017 financial statements have been reclassified to conform to the 2018 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.

**Concentration of Credit Risk** - Financial instruments that potentially subject the Company to concentration of credit risk consist of cash accounts in financial institutions. Although the cash accounts exceed the federally insured deposit amount, management does not anticipate nonperformance by the financial institutions. Management reviews the financial viability of these institutions on a periodic basis.



**Cash and cash equivalents** – The Company considers all highly liquid investments with maturities of three months or less at the date of acquisition to be cash equivalents. Cash equivalents included in this category consist of a bank certificate of deposit. Cash and cash equivalents are stated at cost, which approximates fair value.

**Short-term investment securities** – The Company’s short-term investment securities are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. The Company’s short-term investment securities are carried at fair value within current assets on the Company’s Consolidated Balance Sheets, with fair value based on either quoted market prices or pricing models maximizing the use of observable inputs for similar securities. The Company views its available-for-sale securities as available for use in current operations regardless of the stated maturity date of the security. The Company’s investment policy states that all investment securities must have a maximum maturity of twenty-four (24) months or less and the maximum weighted maturity of the investment securities must not exceed twelve (12) months. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as other comprehensive income or loss on the Company’s Consolidated Statements of Operations and Comprehensive Loss. Realized gains and losses on short-term investment securities are recorded in the other income (expense) portion of the Company’s Consolidated Statements of Operations and Comprehensive Loss. Interest earned, net of investment fees, on the short-term investment securities are included in interest income.

**Accounts receivable** - The Company periodically reviews aged account balances for collectability. The Company established an allowance for doubtful accounts of \$0 at both June 30, 2018 and December 31, 2017.

**Inventory** - Inventories are valued at the lower of cost or net realizable value. Cost is determined using an average cost method for tobacco leaf inventory and raw materials inventory and standard cost is primarily used for finished goods inventory. Inventories are evaluated to determine whether any amounts are not recoverable based on slow moving or obsolete condition and are written off or reserved as appropriate. Inventories at June 30, 2018 and December 31, 2017 consisted of the following:

	June 30, 2018	December 31, 2017
Inventory - tobacco leaf	\$1,582,976	\$ 1,552,474
Inventory - finished goods		
Cigarettes and filtered cigars	205,617	289,004
Inventory - raw materials		
Cigarette and filtered cigar components	1,314,374	1,636,059
	3,102,967	3,477,537
Less: inventory reserve	160,000	195,000
	\$2,942,967	\$ 3,282,537

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

**Intangible Assets** - Intangible assets are recorded at cost and consist primarily of (1) expenditures incurred with third-parties related to the processing of patent claims and trademarks with government authorities, as well as costs to acquire patent rights from third-parties, (2) license fees paid for third-party intellectual property, (3) costs to become a signatory under the tobacco MSA, and (4) license fees paid to acquire a predicate cigarette brand. The amounts capitalized relate to intellectual property that the Company owns or to which it has exclusive rights. The Company's intellectual property capitalized costs are amortized using the straight-line method over the remaining statutory life of the granted patent assets in each of the Company's patent families, which have estimated expiration dates ranging from 2018 to 2034. 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 2019 through 2034. The Company believes costs associated with becoming a signatory to the MSA and acquiring a predicate cigarette brand have an indefinite life and as such, no amortization is taken. Total intangible assets at June 30, 2018 and December 31, 2017 consisted of the following:

	June 30, 2018	December 31, 2017
Intangible assets, net		
Patent and trademark costs	\$6,695,610	\$ 6,327,467
Less: accumulated amortization	2,806,932	2,517,465
Patent and trademark costs, net	3,888,678	3,810,002
License fees, net (see Note 10)	2,625,226	1,450,000
Less: accumulated amortization	375,602	326,591
License fees, net	2,249,624	1,123,409
MSA signatory costs	2,202,000	2,202,000
License fee for predicate cigarette brand	300,000	300,000
	\$8,640,302	\$ 7,435,411

Amortization expense relating to the above intangible assets for the three and six months ended June 30, 2018 and 2017 amounted to \$170,925 and \$338,477, respectively (\$143,010 and \$283,898 for the three and six months ended June 30, 2017, respectively).

The estimated annual average amortization expense for the next five years is approximately \$355,000 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 six months ended June 30, 2018 or 2017, respectively.

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

Considering the Company's history of cumulative net operating losses and the uncertainty of their future utilization, the Company has established a valuation allowance to fully offset its net deferred tax assets as of June 30, 2018 and December 31, 2017.

The Company's federal and state tax returns for the years ended December 31, 2014 through December 31, 2016 are currently open to audit under the statutes of limitations. There were no pending audits as of June 30, 2018.

The Tax Cuts and Jobs Act of 2017 (the "TCJA") was signed into law on December 22, 2017. The TCJA includes significant changes to the U.S. corporate income tax system, including a Federal corporate rate reduction from 35% to 21%. In accordance with a question and answer document issued by the Financial Accounting Standards Board ("FASB") staff on January 18, 2018, the Company is applying the guidance in Securities and Exchange Commission Staff Accounting Bulletin ("SAB") 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, which provides guidance on applying FASB Accounting Standards Codification ("ASC") 740, Income Taxes, if the accounting for certain income tax effects of the TCJA are incomplete by the time the financial statements are issued for a reporting period. Specifically, SAB 118 permits companies to use reasonable estimates and provisional amounts for some line items for taxes when preparing year-end 2017 financial statements. The Company completed the accounting under the TCJA, and accordingly, has reported the effects in the Company's consolidated financial statements for the

year ended December 31, 2017.

***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*** - On January 1, 2018, the Company adopted ASC 606, Revenue from Contracts with Customers and all related amendments (the “new revenue standard”) for all contracts using the modified retrospective method. Under the modified retrospective method, the Company was required to record a cumulative-effect adjustment to the opening balance of retained earnings on January 1, 2018. The Company has determined that the adoption of the new revenue standard did not require a cumulative-effect adjustment. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the product to a customer. The Company's customer contracts consist of obligations to manufacture the customer's branded filtered cigars and cigarettes. For certain contracts, the performance obligation is satisfied over time as the Company determines, due to contract restrictions, it does not have an alternative use of the product, and it has an enforceable right to payment as the product is manufactured. The Company recognizes revenue under those contracts at the unit price stated in the contract based on the units manufactured. The manufacturing process is completed on a daily basis and, therefore, there were no performance obligations partially satisfied at June 30, 2018. For the contract where the performance obligation is satisfied at a point in time, the Company recognizes revenue when the product is transferred to the customer. Revenue from the sale of the Company's products is recognized net of cash discounts, sales returns and allowances. There was no allowance for discounts or returns and allowances at June 30, 2018 and December 31, 2017.

The Company generally requires a down payment from its customers prior to commencement of manufacturing the product. Amounts received in advance of satisfying the performance obligations are recorded as deferred revenue. Customer payment terms vary depending on the terms of each customer contract, but payment is generally due prior to product shipment or within extended credit terms up to twenty-one (21) days after shipment.

The Company's net sales revenue is derived from customers located primarily in the United States of America and is disaggregated by the timing of revenue recognition. For the three and six months ended June 30, 2018, net sales revenue from products transferred over time amounted to approximately \$4,569,000 and \$8,492,000, respectively, and net sales revenue from products transferred at a point in time amounted to approximately \$2,346,000 and \$4,539,000, respectively.

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

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

**Advertising** - The Company expenses advertising costs as incurred. Advertising expense was approximately \$4,000 and \$16,000 for the three and six months ended June 30, 2018, respectively (\$12,000 and \$43,000 for the three and six months ended June 30, 2017, 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 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** - The Company's financial instruments include cash and cash equivalents, short-term investment securities, accounts receivable, accounts payable, accrued expenses and warrant liability. Other than for cash equivalents, short-term investment securities and 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 cash equivalents, short-term investment securities and warrant liability are discussed in Note 7.

**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 of the other entity 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. If the Company's equity investment in other entities is less than 20%, and the Company has no significant influence over the operating or financial policies of the entity, and such equity investment does not have a readily determinable market value, then the Company accounts for such equity investments in accordance with FASB

ASU 2016-01, which the Company adopted in the first quarter of 2018 with respect to the Company's investment in Anandia Laboratories, Inc. in Canada (see Note 6 for a further discussion). The Company used the cost method of accounting with respect to its investment in Anandia Laboratories for prior periods.

***Accounting Pronouncements*** - 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. – OCTOBER 2017 REGISTERED DIRECT OFFERING**

On October 10, 2017, the Company closed a registered direct offering (the “Offering”) with institutional investors purchasing an aggregate of 20,570,000 shares of the Company’s common stock at a price of \$2.6250 per share generating net cash proceeds for the Company of \$50,732,200, after deducting expenses associated with the transaction. The securities purchase agreement entered into with the institutional investors provides that, subject to certain exceptions, for a period of one year following the closing of the Offering, the Company will be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of common stock or common stock equivalents (or a combination of units thereof) involving a variable rate transaction, which generally includes any transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of common stock either (A) at a conversion price or exchange rate that is based upon and/or varies with the trading prices of or quotations for the shares of common stock at any time after the initial issuance of such securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the common stock or (ii) enters into any agreement, whereby the Company may issue securities at a future determined price.

## **NOTE 3. – JUNE 2017 WARRANT EXERCISE AGREEMENTS**

On June 19, 2017, the Company entered into Warrant Exercise Agreements (the “Agreements”) with all of the holders (the “Holders”) of outstanding warrants to purchase up to 7,043,211 shares of common stock of the Company at \$1.00 per share and warrants to purchase up to 4,250,000 shares of common stock of the Company at \$1.45 per share (collectively, the “Warrants”). These Warrants to purchase shares of the Company’s common stock were acquired by the Holders in registered direct offerings in October of 2016 and in July of 2016, respectively. The Company and the Holders agreed that the Holders would, subject to beneficial ownership limitations on exercise contained in the Warrants, exercise all the Warrants for cash. In June 2017, the Holders exercised 3,229,711 Warrants at \$1.00 per share and 2,354,948 Warrants at \$1.45 per share, resulting in net proceeds to the Company in the amount of \$6,169,212, after deducting expenses associated with the transaction. In July and August of 2017, the Holders exercised 3,813,500 Warrants at \$1.00 per share and 1,895,052 Warrants at \$1.45 per share, resulting in net proceeds to the Company in the amount of \$6,167,646, after deducting expenses associated with the transaction.

In consideration for the Holders exercising their Warrants for cash, the Company issued to each Holder a new warrant (the “New Warrants”) to purchase shares of common stock of the Company equal to the number of shares of common stock received by each Holder upon the cash exercise of the Holder’s Warrants. The terms of the New Warrants are substantially similar to the terms of the Warrants exercised, except the New Warrants (i) have an exercise price equal to \$2.15 per share and (ii) are exercisable six months from the date of issuance of the New Warrants for a period of five (5) years. Accordingly, the Company issued an aggregate of 11,293,211 New Warrants to the Holders, upon exercise of the Holder’s Warrants as described above. The New Warrants had a fair value of \$16,049,031 at issuance

and have been recorded as an adjustment to capital in excess of par value.

#### **NOTE 4. - MANUFACTURING FACILITY**

The Company's manufacturing operations at its North Carolina factory began approaching production capacity during the six months ended June 30, 2018. The Company significantly expanded capacity during the second and third quarters of 2017 in order to fulfill anticipated new manufacturing contracts. In mid-May of 2017, the Company began the first phase of a manufacturing contract for an existing brand of filtered cigars under a new contract manufacturing agreement (the "New Agreement") with a third-party and continued manufacturing a third-party MSA cigarette brand and other filtered cigars on a contract basis. The production volume under the New Agreement continued to increase during the first and second quarters of 2018, has resulted in an increase in the utilization of production capacity, required the hiring of additional personnel, and investment in additional manufacturing equipment for the factory. 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 \$318,511 and \$629,439 for the three and six months ended June 30, 2018, respectively (\$215,941 and \$334,691 for the three and six months ended June 30, 2017, respectively).

**NOTE 5. - MACHINERY AND EQUIPMENT**

Machinery and equipment at June 30, 2018 and December 31, 2017 consisted of the following:

	<b>Useful Life</b>	<b>June 30, 2018</b>	<b>December 31, 2017</b>
Cigarette manufacturing equipment	3 - 10 years	\$4,522,479	\$ 4,302,299
Office furniture, fixtures and equipment	5 years	135,909	110,499
Laboratory equipment	5 years	86,609	32,193
Leasehold improvements	6 years	163,359	106,429
		4,908,356	4,551,420
Less: accumulated depreciation		1,491,194	1,235,373
Machinery and equipment, net		\$3,417,162	\$ 3,316,047

Depreciation expense was \$131,294 and \$255,822 for the three and six months ended June 30, 2018, respectively (\$88,464 and \$176,585 for the three and six months ended June 30, 2017, respectively).

**NOTE 6. - INVESTMENT**

The Company (through its wholly-owned subsidiary, Botanical Genetics), holds a 14.8% equity investment in Anandia Laboratories, Inc., a Canadian plant biotechnology company (“Anandia”). At June 30, 2018 and December 31, 2017, the Company’s investment balance in Anandia was \$7,513,581 and \$1,366,493, respectively, and is classified within Other assets on the accompanying Consolidated Balance Sheets. During the first quarter of 2018, the Company began accounting for its equity investment in Anandia in accordance with Financial Accounting Standards Board ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. This guidance changes how entities account for equity investments that do not result in consolidation and are not accounted for under the equity method of accounting. Under ASU 2016-01, the Company is required to measure its investment in Anandia at fair value at the end of each reporting period and recognize changes in fair value in net income. A practical expedient is available for equity investments that do not have readily determinable fair values, however; the exception requires the Company to adjust the carrying amount for impairment and observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Accordingly, and as a result of, an equity issuance by Anandia during December of 2017 and January of 2018 (orderly transactions), the Company recorded an unrealized gain on its investment in Anandia in the amount of \$6,147,088 during the three months ended March 31, 2018. There was no change in the fair value of the Company’s equity investment in Anandia during the three months ended June 30, 2018.

During the first quarter of 2017, a dilutive event occurred bringing the Company's investment percentage in Anandia below 20%, a threshold for the use of the equity method of accounting that the Company had previously used to account for its investment in Anandia. Accordingly, the Company discontinued applying the equity method of accounting for its investment in Anandia. After the dilutive event, the Company accounted for its investment in Anandia under the cost method of accounting until it adopted ASU 2016-01, as described above. The Company's gain on the investment in Anandia was \$346,180 for the three months ended March 31, 2017.

On July 15, 2018, Anandia signed a binding Arrangement Agreement to be acquired by Aurora Cannabis, Inc. ("Aurora"), a Canadian company (TSX: ACB.TO). When this transaction closes, which is expected to occur in August of 2018, Aurora will acquire 100% of the outstanding shares of Anandia in exchange for (i) free trading shares of Aurora common stock based on the 20-day volume weighted average trading price of the Aurora stock for the 20 trading days immediately prior to June 11, 2018, and (ii) warrants with a five-year term to purchase one-half of a share of Aurora common stock for each whole share of Aurora common stock received as part of the transaction. The number and value of the shares of Aurora common stock and warrants that will be issued to 22nd Century in consideration for our Company's approximately 14.8% equity ownership of Anandia will not be known until the closing of the transaction, which is currently scheduled to occur in August 2018. There is no guarantee that the transaction will be consummated.

**NOTE 7. – FAIR VALUE MEASUREMENTS**

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 following table presents information about our assets and liabilities measured at fair value at June 30, 2018 and December 31, 2017, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	<b>Asset and Liabilities at Fair Value</b>			
	<b>As of June 30, 2018</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Cash equivalents:				
Certificate of deposit	\$-	\$3,000,000	\$-	\$3,000,000
Short-term investment securities:				
Money market funds	5,272,629	-	-	5,272,629
Corporate bonds	-	27,610,232	-	27,610,232
Commercial paper	-	2,443,160	-	2,443,160
U.S. treasury securities	-	5,985,640	-	5,985,640
U.S. government agency bonds	-	8,769,352	-	8,769,352
Total cash equivalents and short-term investment securities	\$5,272,629	\$47,808,384	\$-	\$53,081,013
<b>Liabilities</b>				

Edgar Filing: 22nd Century Group, Inc. - Form 10-Q

Warrant liability	\$-	\$-	\$167,779	\$167,779
-------------------	-----	-----	-----------	-----------

Asset and Liabilities at Fair Value

As of December 31, 2017

	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Cash equivalents:				
Certificate of deposit	\$-	\$3,000,000	\$-	\$3,000,000
Short-term investment securities:				
Certificates of deposit	-	6,000,000	-	6,000,000
Money market funds	41,526,540	-	-	41,526,540
Corporate bonds	-	9,450,933	-	9,450,933
U.S. government agency bonds	-	1,998,040	-	1,998,040
Total cash equivalents and short-term investment securities	\$41,526,540	\$20,448,973	\$-	\$61,975,513
<b>Liabilities</b>				
Warrant liability	\$-	\$-	\$216,490	\$216,490

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.

#### **NOTE 8. – NOTE PAYABLE FOR LICENSE FEE**

On June 22, 2018, the Company entered into the Second Amendment to the License Agreement (the "Second Amendment") with North Carolina State University ("NCSU") that amended an original License Agreement between the Company and NCSU, dated December 8, 2015, and the First Amendment, dated February 14, 2018, to the original License Agreement. Under the terms of the Second Amendment, the Company is obligated to pay NCSU milestone payments totaling \$1,200,000, of which amount \$500,000 was payable upon execution of the Second Amendment, \$400,000 will be payable on the first anniversary of the execution of the Second Amendment, and \$300,000 will be payable on the second anniversary of the execution of the Second Amendment. The Company has recorded the present value of the obligations under the Second Amendment as a note payable that originally amounted to \$1,175,226. After the initial payment of \$500,000, the balance remaining as of June 30, 2018 amounted to \$675,226, with \$390,016 and \$285,210 reported as current and long-term portion of the note payable, respectively, on the Company's Consolidated Balance Sheets.

The cost of the of acquired license amount to \$1,175,226 and is included in Intangible assets, net on the Company's Consolidated Balance Sheets, and will be amortized on a straight-line basis over the last-to-expire patent, which is expected to be in 2036.

#### **NOTE 9. - WARRANTS FOR COMMON STOCK**

At June 30, 2018, the Company had outstanding warrants to purchase 11,387,932 shares of common stock of the Company, of which warrants to purchase 94,721 shares contain an anti-dilution feature. In July of 2018, the 94,721 warrants containing an anti-dilution feature were exercised on a cashless basis resulting in the issuance of 63,832 shares of the Company's common stock.

During the three and six months ended June 30, 2018, warrant holders exercised 0 and 700,148 warrants, respectively, on a cashless basis, resulting in the issuance of 0 and 426,180 shares, respectively.

## Edgar Filing: 22nd Century Group, Inc. - Form 10-Q

During the year ended December 31, 2017, the Company issued 11,293,211 warrants in conjunction with the June 2017 warrant exchange agreements. These warrants have an exercise price equal to \$2.15 per share and are exercisable for a period of six months from the date of issuance for a period of five (5) years. See Note 3 for additional details.

During the year ended December 31, 2017, warrant holders exercised 12,763,238 warrants, with 1,286,277 of such warrants being exercised on a cashless basis, resulting in the issuance of an aggregate of 12,249,327 shares. Additionally, 223,814 warrants expired unexercised during the year ended December 31, 2017.



Outstanding warrants at June 30, 2018 consisted of the following:

Warrant Description	Number of Warrants	Exercise Price	Expiration
August 2012 convertible NP warrants <sup>(1)</sup> <sup>(2)</sup>	94,721	\$0.9310	August 8, 2018
June 2017 warrants pursuant to warrant exercise agreements	11,293,211	\$2.1500	December 20, 2022
Total warrants outstanding	11,387,932		

(1) Includes anti-dilution features.

(2) Exercised on a cashless basis in July of 2018.

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.

The following table is a roll-forward summary of the warrant liability since December 31, 2016:

Fair value at December 31, 2016	\$58,681
Loss as a result of change in fair value	157,809
Fair value at December 31, 2017	216,490
Gain as result of change in fair value	(48,711 )
Fair value at June 30, 2018	\$167,779

The aggregate net gain (loss) as a result of the Company's warrant liability for the three and six months ended June 30, 2018 amounted to \$0 and \$48,711, respectively (the aggregate net loss for the three and six months ended June 30, 2017 amounted to \$77,583 and \$82,927, respectively), which are included in Other income (expense) under Warrant liability gain (loss) - net in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

The following table summarizes the Company's warrant activity since December 31, 2016:

	<b>Number of Warrants</b>
<b>Warrants outstanding at December 31, 2016</b>	<b>13,781,921</b>
Warrants exercised during 2017	(1,470,027 )
Warrants expired during 2017	(223,814 )
Warrants issued pursuant to June 2017 warrant exercise agreements	11,293,211
Warrants exercised pursuant to June 2017 warrant exercise agreements	(11,293,211)
<b>Warrants outstanding at December 31, 2017</b>	<b>12,088,080</b>
Warrants exercised during 2018	(700,148 )
<b>Warrants outstanding at June 30, 2018</b>	<b>11,387,932</b>
 <b>Composition of outstanding warrants:</b>	
Warrants containing anti-dilution feature	94,721
Warrants without anti-dilution feature	11,293,211
	<b>11,387,932</b>

**NOTE 10. - COMMITMENTS AND CONTINGENCIES**

***License agreements and sponsored research*** – The Company has entered into various license agreements and sponsored research and development agreements. The costs associated with the following three agreements 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 and Comprehensive Loss. The amounts expensed during the three and six months ended June 30, 2018 were \$83,838 and \$221,070, respectively (\$56,250 and \$119,640 for the three and six months ended June 30, 2017, respectively).

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 is \$225,000. The license agreement continues through the life of the last-to-expire patent, which is expected to be 2022. The license agreement also requires a milestone payment of \$150,000 upon FDA approval or clearance of a product that uses the NCSU licensed technology. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. These costs vary from year to year and the Company has certain rights to direct the activities that result in these costs. During the three and six months ended June 30, 2018, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$4,845 and \$34,107, respectively (\$4,866 and \$31,709 for the three and six months ended June 30, 2017, 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 royalty beginning on December 31, 2018 in the amount of \$10,000. The minimum annual royalty payment increases to \$15,000 in 2019, \$25,000 in 2020 and 2021, and \$50,000 per year thereafter for the remaining term of the License. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the three and six months ended June 30, 2018, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$79 and \$79, respectively (\$199 and \$29,866 for the three and six months ended June 30, 2017). 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 had extended the Agreement through January 31, 2017 at an additional cost of \$85,681. In February 2018, the Company finalized an additional extension to this Agreement through April 30, 2018 at a cost of \$88,344. In May 2018, the Company finalized an additional extension to this Agreement through April 30, 2019 at a total cost of \$121,357.

**License agreements** - Additionally, the Company has entered into the following four license agreements and the costs associated with these license agreements 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 \$24,505 and \$49,011 for the three and six months ended June 30, 2018, respectively (\$24,505 and \$49,011 for the three and six months ended June 30, 2017), and was included in Amortization expense on the Company's Consolidated Statements of Operations and Comprehensive Loss.

On June 22, 2018, the Company entered into the Second Amendment to the License Agreement (the "Second Amendment") with NCSU that amended an original License Agreement between the Company and NCSU, dated December 8, 2015. Under the terms of the Second Amendment, the Company is obligated to pay NCSU a non-refundable, non-creditable license fee of \$1,200,000. The license fee is payable in accordance with a note payable more fully described in Note 8 – Note Payable for License Fee. The present value of the payments in the amount of \$1,175,226 are included in Intangible assets, net on the Company's Consolidated Balance Sheets, and will be amortized on a straight-line basis over the last-to-expire patent, which is expected to be in 2036.

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. 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, and the Company must pay to NCSU an additional non-refundable, non-creditable lump sum fee of \$75,000 upon issuance of a U.S. utility patent included in the patent rights. A patent was issued during the first quarter of 2017 under this clause, and accordingly, the \$75,000 was due and payable to NCSU. The \$75,000 cost was included in Research and development costs on the Company's Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2017 and the six months ended June 30, 2017. 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. The Company is obligated to pay to NCSU an annual minimum royalty fee of \$20,000 in 2018, \$30,000 in 2019, and \$50,000 per year thereafter for the remaining term of the License Agreement. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the three and six months ended June 30, 2018, the aggregated costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$4,995 and \$9,465, respectively (\$5,173 and \$24,242 for the three and six months ended June 30, 2017, 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. The Anandia Sublicense required an up-front fee of \$75,000, an annual license fee of \$10,000, the payment of patent filing and maintenance costs, a running royalty on future net sales of products made from such sublicensed intellectual property, and a sharing of future sublicensing consideration received from sublicensing to third-parties such sublicensed intellectual property. The Anandia Sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035.

***Other research agreements*** - Further, the Company has entered into the following three agreements relating to sponsored research. Costs associated with these agreements are expensed when incurred in Research and development costs on the Company’s Consolidated Statements of Operations and Comprehensive Loss.

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 is conducting research on behalf of the Company relating to the hemp/cannabis plant. The Agreement had an initial term of twelve (12) months from the date of the Agreement and could be extended at the sole option of the Company for two (2) additional periods of twelve (12) months each (of which the option on the first twelve (12) month period has been extended). The Company paid Anandia \$379,800 over the initial term of the Agreement. On March 13, 2017, the Company entered into Amendment No. 1 to the Agreement (the “Amendment”). The Amendment has a term of twelve (12) months and calls for the Company to pay Anandia a total of \$785,100 in equal monthly installments of \$65,425. During the three and six months ended June 30, 2018, expenses related to the Agreement amounted to \$0 and \$130,850, respectively (\$196,275 and \$261,700 for the three and six months ended June 30, 2017, respectively), and are included in Research and development costs on the Company’s Consolidated Statements of Operations and Comprehensive Loss. 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. The Amendment expired on March 12, 2018 and the Company is in negotiations with Anandia regarding exercising its option on the second of the additional twelve (12) month extensions.

The Company had an R&D agreement with the University of Virginia (“UVA”) relating to nicotine biosynthesis in tobacco plants. The extended term of the R&D agreement with UVA expired on October 31, 2016. In December 2016, the Company entered into a new sponsored research agreement with UVA and an exclusive license agreement with the University of Virginia Patent Foundation d/b/a University of Virginia Licensing & Ventures Group (“UVA LVG”) pursuant to which the Company will invest approximately \$1,000,000 over a three-year period with UVA to create unique industrial hemp plants with guaranteed levels of THC below the legal limits and optimize other desirable hemp plant characteristics to improve the plant’s suitability for growing in Virginia and other legacy tobacco regions of the United States. This work with UVA will also involve the development and study of medically important cannabinoids

to be extracted by UVA from the Company's hemp plants. UVA and the Company will conduct all activities in this scientific collaboration within the parameters of state and federal licenses and permits held by UVA for such work. The agreements with UVA and UVA LVG grant the Company exclusive rights to commercialize all results of the collaboration in consideration of royalty payments by the Company to UVA LVG. During the three and six months ended June 30, 2018, expenses related to the agreements amounted to \$76,211 and \$180,178, respectively (\$70,729 and \$111,574 for the three and six months ended June 30, 2017, respectively), and are included in Research and development costs on the Company's Consolidated Statements of Operations and Comprehensive Loss.

On May 1, 2018, the Company entered into a University Growing and Evaluation Agreement (the "Agreement") with the University of Kentucky Research Foundation ("UKRF") whereby UKRF will provide the Company with services relating to growing certain tobacco breeding lines of the Company. Under the Agreement, the Company is obligated to pay \$75,000 to UKRF in three installments of \$25,000 each through January 31, 2019. During the second quarter of 2018, the Company recorded a R&D expense related to this Agreement in the amount of \$25,000.

**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 second two-year lease extension term that will expire on October 31, 2019. The lease expense for the three and six months ended June 30, 2018 amounted to approximately \$42,000 and \$85,000, respectively (approximately \$38,000 and \$77,000 for the three and six months ended June 30, 2017, respectively). The future minimum annual lease payments if the Company exercises each of the additional extensions are approximately as follows:

Year ended December 31, 2018 -	\$85,000
Year ended December 31, 2019 -	\$169,000
Year ended December 31, 2020 -	\$169,000
Year ended December 31, 2021 -	\$141,000

On August 14, 2017, the Company entered into a lease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment, to store the Company's proprietary tobacco leaf and to store inventory used in the Company's contract manufacturing business. The lease calls for a monthly payment of \$4,665, expires on August 14, 2018 and contains twelve-month renewal options as long as the Company continues to lease the warehouse. Future minimum lease payments will be approximately \$56,000 per year for each subsequent year the warehouse space is leased by the Company.

On October 4, 2017, the Company entered a lease for office space at a location in Williamsville, New York with an initial three-year term and with a monthly lease payment of \$6,375. The Company moved into the leased space in February of 2018. Future minimum annual lease payments under the new office lease will be approximately \$38,000, \$76,000 and \$76,000 for the years ending on December 31, 2018, 2019 and 2020, respectively.

On May 1, 2016, the Company entered into a sublease for laboratory space in Buffalo, New York. The sublease called for a monthly payment of \$1,471 through April 30, 2018. Additionally, on February 1, 2017, the Company entered into an amendment to the initial sublease calling for the sublease of additional lab space at a cost of \$1,219 per month, bringing the total monthly sublease obligation to \$2,690. On April 26, 2017, the Company entered into an amendment to the sublease to extend the term of the sublease for an additional twelve (12) months, commencing on May 1, 2017 at a total cost of \$2,770 per month for the total lease obligation. On February 21, 2018, the Company entered into a new sublease amendment that further increased the lab space, extended the sublease term through June 30, 2019 and calls for a monthly sublease payment of \$5,706 beginning on March 1, 2018. Future minimum sublease payments for the years ending on December 31, 2018 and 2019 will be approximately \$34,000 and \$34,000, respectively.

***Modified Risk Tobacco Product Application (“MRTP Application”)*** – In connection with the Company’s MRTP Application for its *Brand A* Very Low Nicotine Content (“VLNC”) cigarettes with the FDA, the Company has entered in various contracts with third-party service providers to fulfill various requirements of the MRTP Application. Such contracts include services for clinical trials, perception studies, legal guidance, product testing, and consulting expertise. During the three and six months ended June 30, 2018, the Company incurred expenses relating to these contracts in the approximate amount of \$2,725,000 and \$4,021,000, respectively. There were no expenses incurred relating to the MRTP Application for the three and six months ended June 30, 2017. Future financial commitments under these contracts are estimated to amount to approximately an additional \$7,500,000 and are expected to be completed over the next six to nine months.



**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 related expenses. The Company will then continue to monitor the matter for further developments that could affect the amount of any such accrued liability.

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

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

Following such ruling, on July 11, 2016, the Company filed a motion to sever the Crede lawsuit into two separate cases, requesting all claims relating to the Tranche 1A warrant and the securities purchase agreement to stay in the SDNY Court and all claims relating to the China joint venture agreement to be transferred to the United States District Court for the Western District of New York (the “WDNY Court”), where the Company’s headquarters office is located. On January 20, 2017, the SDNY Court granted the Company’s motion.

On February 14, 2017, Crede voluntarily dismissed its lawsuit against the Company in the WDNY Court.

On February 21, 2017, the SDNY Court granted the Company's request to file a motion for summary judgment for the claims remaining in the SDNY Court, with all discovery in the case being deferred until after the SDNY Court issued its decision on the summary judgment motion of the Company.

On March 20, 2017, the Company filed its motion for summary judgment for the claims remaining in the SDNY Court. The response by Crede to the Company's summary judgment motion was filed by Crede on May 1, 2017. On May 15, 2017, the Company filed its response to Crede's filing.

On December 28, 2017, the SDNY Court issued its decision in response to the Company's motion for summary judgment, with such decision (i) granting the Company's motion for summary judgment relating to Count II of the Amended Complaint, which eliminated Crede's claim to rescind the prior securities purchase agreement, dated September 17, 2014, and denied Crede's claim for the return of any money from the Company under that securities purchase agreement, and (ii) denying the Company's motion for summary judgment on the remaining Counts of the Amended Complaint. In this decision, the SDNY Court also found that Crede breached the Activity Restrictions as defined and contained in the Tranche 1A warrant. As a result of this decision by the SDNY Court, the parties then proceeded with discovery in the case in preparation for a trial on the remaining Counts III, IV and V of the Amended Complaint, which relate to Crede's claim (i) to exchange the Tranche 1A warrant for 2,077,555 shares of our common stock even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant, (ii) for an unquantified additional amount of shares of our common stock that allegedly still remains under the Tranche 1A warrant even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant; and (iii) for alleged damages for the alleged breach of the Tranche 1A warrant in an amount in excess of \$18 million, plus costs and interest, even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant.

On July 13, 2018, the SDNY Court denied Crede's request to extend the discovery deadline. As a result of such ruling, the discovery in the Crede case has now been concluded. On July 20, 2018, the SDNY Court granted the request by the Company to file a motion for partial summary judgment to substantially limit the various damage claims by Crede, with the remaining schedule in the case being deferred until after the SDNY Court rules on such motion. The Company is to file its partial summary judgment motion by August 20, 2018, after which Crede is required to file its response by September 20, 2018, after which the Company will then be required to file its reply to Crede's response by October 14, 2018.

The Company believes that the claims are frivolous, meritless and that the Company has substantial legal and factual defenses to the claims. The Company has defended and intends to continue to defend against these claims vigorously.

**NOTE 11. - LOSS PER COMMON SHARE**

The following table sets forth the computation of basic and diluted loss per common share for the three-month periods ended June 30, 2018 and 2017, respectively:

	June 30, 2018	June 30, 2017
Net loss attributed to common shareholders	\$(6,738,652 )	\$(3,355,624 )
Denominator for basic loss per share-weighted average shares outstanding	124,311,087	91,577,688
Effect of dilutive securities: Warrants and options outstanding	-	-
Denominator for diluted loss per common share-weighted average shares adjusted for dilutive securities	124,311,087	91,577,688
Net loss per common share - basic and diluted	\$(0.05 )	\$(0.04 )

The following table sets forth the computation of basic and diluted loss per common share for the six-month periods ended June 30, 2018 and 2017, respectively:

	June 30, 2018	June 30, 2017
Net loss attributed to common shareholders	\$(5,352,164 )	\$(5,976,901 )
Denominator for basic loss per share-weighted average shares outstanding	124,166,321	91,165,770
Effect of dilutive securities: Warrants and options outstanding	-	-
Denominator for diluted loss per common share-weighted average shares adjusted for dilutive securities	124,166,321	91,165,770
Net loss per common share - basic and diluted	\$(0.04 )	\$(0.07 )

Edgar Filing: 22nd Century Group, Inc. - Form 10-Q

Dilutive securities outstanding at June 30, 2018 and 2017, respectively, are presented below. Securities outstanding were excluded from the computation of loss per share because they would have been anti-dilutive.

	<b>June 30, 2018</b>	<b>June 30, 2017</b>
Warrants	11,387,932	12,445,247
Options	8,756,560	6,965,688
	20,144,492	19,410,935

## NOTE 12. – EQUITY BASED COMPENSATION

On April 12, 2014, the stockholders of the Company approved the 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (the “OIP”) and the authorization of 5,000,000 shares to be reserved for issuance thereunder. On April 29, 2017, the stockholders approved an amendment to the OIP to increase the number of shares available for issuance by an additional 5,000,000 shares. 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 an aggregate of 10,000,000 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 the OIP and the number of shares of common stock to underlie each such award under the OIP. As of June 30, 2018, the Company had available 1,802,115 shares remaining for future awards under the OIP.

During the six months ended June 30, 2018, the Company issued stock option awards from the OIP for 1,431,841 shares to eligible individuals. Stock options issued to acquire 1,131,841 shares of Company common stock have vesting periods ranging from one to three years from the date of the award, and stock options issued to acquire 300,000 shares of Company common stock were scheduled to vest upon the attainment of various milestones. During the six months ended June 30, 2017, the Company issued stock option awards from the OIP for 1,372,000 shares to eligible individuals having vesting periods ranging from one to three years 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.

For the three and six months ended June 30, 2018, the Company recorded compensation expense related to stock option awards granted under the OIP of \$1,682,228 and \$2,246,104, respectively (\$154,004 and \$322,983 for the three and six months ended June 30, 2017, respectively).

As of June 30, 2018, unrecognized compensation expense related to non-vested stock options amounted to approximately \$3,644,000, which is expected to be recognized as follows: \$943,000, \$1,113,000, \$698,000 and \$98,000 during 2018, 2019, 2020 and 2021, respectively. Approximately \$792,000 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 milestones.

The Company’s Senior Vice President of Science and Regulatory Affairs, James E. Swauger, Ph.D., died on April 19, 2018. As a result, stock options to purchase a total of 900,000 shares of the Company’s common stock with an exercise price of \$2.12 per share granted to Dr. Swauger on October 31, 2017 vested upon his death and are exercisable by Dr. Swauger’s beneficiaries for a period of one year from the date of his death. Additional stock options to purchase a total of 300,000 shares of the Company’s common stock with an exercise price of \$2.12 per share granted to Dr. Swauger on October 31, 2017 were to vest based on the achievement of certain milestones by Dr. Swauger, and accordingly,

Edgar Filing: 22nd Century Group, Inc. - Form 10-Q

will not vest and were cancelled. The unrecognized fair value of Dr. Swauger's subject stock options to purchase 900,000 shares at the time of his death was \$1,226,825 and was recognized as equity-based compensation during the second quarter of 2018. The unrecognized fair value of Dr. Swauger's subject stock options to purchase 300,000 shares was \$443,006.

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 six months ended June 30, 2018 and 2017:

	2018		2017	
Risk-free interest rate (weighted average)	2.97	%	2.12	%
Expected dividend yield	0	%	0	%
Expected stock price volatility	90	%	90	%
Expected life of options (weighted average)	5.55 years		5.13 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, 2016 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
<b>Outstanding at December 31, 2016</b>	5,650,679	\$ 1.04		
Granted in 2017	2,692,000	\$ 1.76		
Exercised in 2017	(85,988 )	\$ 0.79		
Expired in 2017	(100,000 )	\$ 1.43		
<b>Outstanding at December 31, 2017</b>	8,156,691	\$ 1.28		
Granted in 2018	1,431,841	\$ 2.66		
Exercised in 2018	(327,781 )	\$ 0.81		
Expired / cancelled in 2018	(504,191 )	\$ 1.71		
<b>Outstanding at June 30, 2018</b>	8,756,560	\$ 1.50	6.2 years	\$8,516,505
<b>Exercisable at June 30, 2018</b>	5,237,804	\$ 1.32	4.8 years	\$5,693,556

The weighted average grant date fair value of options issued during the six months ended June 30, 2018 and 2017 was \$1.80 and \$0.97, respectively. The total fair value of options that vested during the six months ended June 30, 2018 and 2017 amounted to \$2,306,867 and \$684,265, respectively. There were 327,781 options exercised on a cash and cashless basis during the six months ended June 30, 2018 resulting in the issuance of 315,540 shares and proceeds of \$217,500 to the Company. There were 56,991 options exercised on a cashless basis during the six months ended June 30, 2017 resulting in the issuance of 34,953 shares of the Company's common stock.

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

### Forward-Looking Statements

*This Quarterly Report on Form 10-Q contains "forward-looking statements" that reflect, when made, the Company's expectations or beliefs concerning future events that involve risks and uncertainties. Forward-looking statements frequently are identified by the words "believe," "anticipate," "expect," "estimate," "intend," "project," "will be," "will continue," "likely result," or other similar words and phrases. Similarly, statements herein that describe the Company's objectives, plans or goals also are forward-looking statements. Actual results could differ materially from those projected, implied or anticipated by the Company's forward-looking statements. Some of the factors that could cause actual results to differ include: our ability to continue to monetize the licensing of our technology and products; our ability to achieve profitability; our ability to manage our growth effectively; the lack of implementation of the plan by the FDA to regulate nicotine content in cigarettes; our ability to have a Modified Risk Tobacco Product approved by the FDA; our ability to obtain FDA clearance for our Modified Risk Cigarettes; 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, 2017, which is available on the SEC's website at [www.sec.gov](http://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) developing reduced risk tobacco cigarettes 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 hemp/cannabis plants through genetic engineering and plant breeding to alter levels of cannabinoids to be used for potential new medicines and improved agricultural uses. We have an extensive intellectual property portfolio of issued patents and patent applications relating to the tobacco and hemp/cannabis plants. Our management team is focused on monetizing our intellectual property portfolio; facilitating the timely implementation of the plan by the U.S. Food and Drug Administration ("FDA") to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine; resubmitting our Modified Risk Tobacco Product ("MRTP") application to the FDA to obtain a reduced exposure



marketing authorization for our *BRAND A* Very Low Nicotine Content (“VLNC”) cigarettes to be marketed in the United States as “less addictive” and/or containing 95% less nicotine than conventional tobacco cigarettes; seeking licensing agreements for our tobacco technology and/or our proprietary tobaccos; establishing international strategic partnerships to sell and distribute our proprietary tobacco and products; and developing and commercializing unique plant varieties of hemp for important new medicines and agricultural crops.

In tobacco, we have developed proprietary VLN<sup>TM</sup> tobacco that grows with at least 95% less nicotine than conventional cigarette tobacco. We collectively refer to all of our various types of very low nicotine tobacco under the Company’s trademark name: VLN<sup>TM</sup> tobacco. Since 2011, we have produced more than 24 million SPECTRUM® research cigarettes containing our proprietary tobaccos for the National Institute on Drug Abuse (“NIDA”), which is part of the National Institutes of Health (“NIH”). To date, agencies of the United States federal government have invested more than \$100 million in independent clinical studies using our SPECTRUM® research cigarettes. The results of these studies, as published in peer-reviewed publications, show that our proprietary VLNC cigarettes are associated with: (1) reduced smoking, (2) lower nicotine exposure, and (3) lessened nicotine dependence, all with minimal evidence of nicotine withdrawal symptoms, compensatory smoking, or serious adverse events. A list of completed and published clinical studies using cigarettes made with 22nd Century’s VLN<sup>TM</sup> tobacco is shown on the Company’s website at <http://www.xxiicentury.com/published-clinical-studies/>. A list of on-going clinical studies using 22nd Century’s SPECTRUM® research cigarettes is shown on the Company’s website at <http://www.xxiicentury.com/on-going-clinical-studies/>. The numerous independent clinical studies on VLNC cigarettes provides strong scientific support for the FDA’s announcement on July 28, 2017 that the FDA plans to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. After we obtain all necessary regulatory approvals, we plan to offer our proprietary VLNC cigarettes for domestic sale, for international sale, and for licensing by third parties.

In hemp, we are developing proprietary hemp strains for important new medicines and agricultural crops. Our current activities involve only work with legal hemp in full compliance with federal and state laws. The hemp plant and the cannabis/marijuana plant are both part of the same *cannabis sativa* genus/species of plant, except that hemp has less than 0.3% dry weight content of delta-9-tetrahydrocannabinol (“THC”) and is legal under federal and state laws. The same plant, with a higher THC content, is cannabis/marijuana, which is legal under certain state laws, but which is currently not legal under federal law. We work only with legal hemp in full compliance with federal and state laws. We have developed hemp plants with zero (-0-) amounts of THC (“ZERO-THC”). We believe that our ZERO-THC hemp plants are a potential solution to one of the biggest challenges facing the legal hemp industry because, currently, hemp crops that grow with THC levels above the legal limit of 0.3% THC are required to be destroyed and hemp farmers cannot obtain crop insurance to protect against this risk. However, our ZERO-THC hemp plants can be a potential solution to this risk since our ZERO-THC hemp plants will not develop THC above the legal limits for hemp. In the United States, we are working with the University of Virginia (“UVA”) to (i) create unique industrial hemp plants with guaranteed levels of THC below 0.3% the legal limit that defines hemp for optimal growth in Virginia (thus eliminating the risk to growers of having to destroy non-conforming hemp crops), (ii) optimize other desirable hemp plant characteristics to improve the plant’s suitability for growing in Virginia and in similar legacy tobacco regions of the United States, (iii) utilize high-value medical cannabinoid hemp varieties and specialized cannabinoid extraction processes for use in human therapeutics, and (iv) use our unique hemp plants for phytoremediation to clean up and reclaim polluted soils. We have also obtained a license in the State of New York to research and grow hemp. In Canada, we conduct sponsored research on the hemp plant with Anandia Laboratories in Vancouver, British Columbia, in full compliance with Canadian regulations.

Additional information about our business and operations is contained in our Annual Report on Form 10-K for the year ended December 31, 2017.

## Strategic Objectives

Our strategic objectives include the following:

- Facilitating the timely implementation of the plan announced by the FDA to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine;

- Resubmitting our MRTP application to the FDA to obtain a reduced exposure marketing authorization for our *BRAND A VLNC* cigarettes to be marketed in the United States as “less addictive” and/or containing 95% less nicotine than conventional tobacco cigarettes;

- Seeking licensing agreements for our VLN™ tobacco technology and/or our VLN™ proprietary tobaccos;

· Producing *SPECTRUM*® research cigarettes for the National Institute on Drug Abuse (“NIDA”), which is part of the National Institutes of Health (“NIH”), for use in independent clinical studies;

· Researching and developing other novel tobacco plant varieties;

· Exploring opportunities outside of the United States for the use of our VLN™ tobacco in potential over-the-counter cigarettes, such as *BRAND A*, or in a potential prescription-based, smoking cessation aid;

· Expanding our legal hemp activities and development of unique plant varieties of hemp, including (i) hemp plants with other desirable agronomic traits in addition to low to no amounts of THC for the legal hemp industry, and (ii) hemp plants with high levels of cannabidiol (“CBD”) and other non-THC cannabinoids for the legal medical cannabinoid markets;

· Exploring opportunities outside of the United States for the sale of our branded proprietary tobacco products; and

· Growing our contract manufacturing business for third-party branded tobacco products.

**For the second quarter of 2018, our accomplishments and notable events include:**

On April 23, 2018, we announced that the Food and Drug Law Institute (“FDLI”) published an article by Dr. James Swauger, who was then the Senior Vice President of Science and Regulatory Affairs at 22nd Century. In that public policy analysis, Dr. Swauger pointed out that since it is universally accepted that nicotine is the primary addictive component of cigarettes, the tobacco industry and public health officials should logically support the nicotine reduction plan proposed by the FDA. Dr. Swauger described VLNC cigarettes as “well-studied by a diverse group of scientists” and linked these results to the FDA’s planned mandate to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. In establishing the importance of the FDA’s mandate, Dr. Swauger cited an editorial in the October 2015 edition of *The New England Journal of Medicine* in which Drs. Michael Fiore and Timothy Baker wrote: “*Reducing the nicotine content of combustible tobacco to levels that will not sustain dependence seems to us to be the most promising regulatory policy option for preventing [at least] 20 million premature deaths.*” Sadly, shortly before publication of his article in FDLI, Dr. Swauger passed away unexpectedly on April 19, 2018.

On April 25, 2018, we announced that we are committed to working collaboratively with the FDA on the FDA’s planned new rule to require that all cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. In contrast, earlier that same month, Altria Group, Inc., and Reynolds American Inc. (a subsidiary of British American Tobacco) petitioned the FDA for a 90-day extension beyond the original public comment period for the FDA’s Advance Notice of Proposed Rulemaking (“ANPRM”) that was then set to end on June 14, 2018. The FDA subsequently extended the public comment period for the ANPRM, but by only an additional 30 days, to July 16, 2018.

The FDA’s ANPRM is an important step in the FDA’s official rule-making process. The ANPRM describes the independent science that supports the FDA’s proposed nicotine reduction mandate. Although the ANPRM indicates that the FDA desires to receive input on a maximum allowable nicotine level, the ANPRM already references previously completed research that found: “an absolute limit of 0.4 to 0.5 mg of nicotine per cigarette should be adequate to prevent or limit the development of addiction in most young people. At the same time, it may provide enough nicotine for taste and sensory stimulation.” The ANPRM also cites the results of independent clinical studies, including the clinical trial by Dr. Eric Donny, *et al.*, that was published in the October 2015 issue of *The New England Journal of Medicine*, that found: “Those participants using cigarettes with the lowest nicotine content (0.4 mg per gram nicotine/gram of tobacco filler), demonstrated reduced dependence... with minimal evidence of withdrawal-related discomfort or safety concerns.” 22nd Century provided all of the proprietary VLNC cigarettes that made this study possible. We submitted our response to the FDA’s ANPRM on July 16, 2018. See the more detailed disclosure regarding our response to the FDA’s ANPRM in the section below.

On May 24, 2018, we announced that 41 public health and medical organizations, including the American Heart Association, the American Cancer Association, the American Medical Association and dozens of other public health and medical organizations, wrote an open letter to FDA Commissioner Dr. Scott Gottlieb urging the FDA to quickly

implement its plan to reduce nicotine in cigarettes to minimally or non-addictive levels. In their letter, these well-known public health and medical organizations described the “massive public health benefits” that will result from the adoption of the FDA’s plan to reduce nicotine in cigarettes as follows: “Every day that passes means more kids moving from experimentation to addiction and more adults who want to quit and try to quit, but remain addicted to a lethal product. We urge FDA to issue a proposed rule within six months of its ANPRM (by September 16, 2018) and a final rule six months later (by March 16, 2019). We also urge that implementation of the rule be no later than the one-year period provided for in Section 907 of the Family Smoking Prevention and Tobacco Control Act, which would allow the rule to be implemented by March of 2020.”

On June 20, 2018, we announced that our Company had initiated three short-term studies investigating the behavioral and biochemical responses to our Company's proprietary VLN<sup>TM</sup> tobacco. We will submit the data collected from these studies as part of our revised and enhanced MRTP application to the FDA for "BRAND A" VLNC cigarettes.

On June 25, 2018, we announced that our Company was added to the Russell 2000, Russell 3000, and Russell Global Indexes when FTSE Russell ("Russell") reconstituted its U.S. and global equity indexes on June 22, 2018. The Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for investment strategies. In that same announcement, we also stated that our Company's research partner, Anandia Laboratories in Canada, had agreed to be acquired by Aurora Cannabis Inc. (TSX: ACB.TO). In consideration for units consisting of one share of Aurora common stock plus a warrant to purchase one-half of a share of Aurora common stock, for each share of Aurora that is issued to Anandia. The number and value of the shares of Aurora common stock and warrants that will be issued to 22nd Century in consideration for our Company's approximately 14.8% equity ownership of Anandia will not be known until the closing of the transaction, which is currently scheduled to occur in August 2018. There is no guarantee that the transaction will be consummated.

On June 26, 2018, we announced that our Company had exclusively licensed from North Carolina State University ("NCSU") several flue-cured and burley tobacco plant lines that grow with very low levels of nicotine. These new plants contain no foreign genetic material (non-GMO) and will compliment 22nd Century's existing VLN<sup>TM</sup> plants and technologies. The new, non-GMO, VLN<sup>TM</sup> tobacco plant lines are immediately commercially viable as they are the result of multiple generations of plantings that have yielded stable, true-breeding crop lines of flue-cured and burley tobacco plants. The addition of these non-GMO tobacco varieties represents a significant advancement for 22nd Century's next generation tobacco technology. Our new VLN<sup>TM</sup> plant varieties will provide options for 22nd Century and for potential licensees to more readily comply with the FDA's plan to dramatically reduce the nicotine in all combustible cigarettes sold in the United States. The non-GMO nature of these tobacco varieties will also facilitate the sale of 22nd Century's proprietary VLN<sup>TM</sup> tobacco in some foreign countries where the use of genetically modified crops is restricted.

**Subsequent to the close of the second quarter of 2018, we also announced:**

On July 17, 2018, we announced that our Company submitted our public comments to the FDA's ANPRM to develop a rule that will require that all cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. 22nd Century's public comments to the FDA's ANPRM describe how the FDA's proposed rule is (i) supported by rigorous independent science, (ii) exceedingly practical and urgently needed in the interests of public health and (iii) immediately feasible. We cited the facts that our Company has produced and delivered tens of millions of our proprietary VLNC SPECTRUM® research cigarettes since the year 2011 for use in numerous completed and on-going independent clinical studies funded by agencies of the United States federal government. The results of these independent clinical studies show that upon switching to 22nd Century's VLNC cigarettes, smokers: (1) reduce their cigarette consumption, (2) experience lessened withdrawal symptoms, and (3) increase their attempts to quit smoking. These peer-reviewed and published studies provide a solid scientific foundation for the FDA's proposed nicotine

reduction mandate. VLNC cigarettes are so promising that independent researchers estimate that in the first year after implementation of the FDA's rule to limit cigarettes to minimally or non-addictive levels of nicotine, approximately 5 million people would stop smoking and, in as few as five years after implementation of the FDA's plan, more than 13 million people would stop smoking.

To make VLNC cigarettes a prompt reality for all smokers, our ANPRM response announced that we are willing to license the use of our VLN™ technology and our VLN™ tobacco seeds/plants to all interested companies. The availability of this licensing opportunity negates any argument by other tobacco companies that contend it is somehow not possible to comply with the planned FDA nicotine reduction mandate.

### **Three Months Ended June 30, 2018 Compared to Three Months Ended June 30, 2017**

#### *Revenue - Sale of products, net*

In the three months ended June 30, 2018, we realized net sales revenue from the sale of products in the amount of \$6,914,913, an increase of \$3,017,707, or 77.4%, from net sales revenue of \$3,897,206 for the three months ended June 30, 2017. The increase in net sales revenue for the second quarter of 2018 was primarily the result of continued additional net sales revenue generated from a new contract to manufacture an existing brand of filtered cigars as compared to net sales revenue for the second quarter of 2017. Production under the new manufacturing contract began in mid-May of 2017.

#### *Cost of goods sold - Products*

During the three months ended June 30, 2018, cost of goods sold were \$6,753,199, or 97.7%, of net sales revenue. While our factory was still not at production capacity during the second quarter of 2018, we continued to make progress towards utilizing more capacity as a result of the new filtered cigar manufacturing agreement that commenced in mid-May of 2017. As a result of the increased capacity utilization, net sales revenues exceeded the cost of goods sold, which included the cost of raw material components, excise taxes and certain regulatory fees, direct manufacturing costs and an overhead allocation.

During the three months ended June 30, 2017, cost of goods sold were \$4,062,261, or 104.2%, of net sales revenue. We were not yet operating our factory at full production capacity during the second quarter of 2017, but we began utilizing a portion of the excess capacity as a result of the new filtered cigar contract manufacturing agreement that commenced in mid-May of 2017. As a result, the cost of goods sold relating to product sales, which included the cost of raw material components, excise taxes and certain regulatory fees, direct manufacturing costs and an overhead allocation, exceeded net sales revenue. We also recorded an increase in our inventory reserve by \$95,000 during the second quarter of 2017 that resulted in an increase in the cost of goods sold by the same amount.



*Research and development expense*

Research and development (“R&D”) expense was \$4,781,407 in the three months ended June 30, 2018, an increase of \$3,968,120, or 487.9%, from \$813,287 in the three months ended June 30, 2017. This increase was primarily the result of an increase in expenses relating to our MRTP application with the FDA for our VLNC cigarettes of approximately \$2,578,000, an increase in equity-based compensation of approximately \$1,326,000, an increase in payroll and related benefits of approximately \$92,000, an increase in costs related to our laboratory operations of approximately \$117,000, an increase in consulting fees of approximately \$18,000, and an increase in patent maintenance costs of approximately \$15,000, partially offset by a decrease in sponsored research costs of approximately \$183,000.

*General and administrative expense*

General and administrative expense was \$1,914,971 in the three months ended June 30, 2018, an increase of \$109,853, or 6.1%, from \$1,805,118 in the three months ended June 30, 2017. The increase was mainly due to an increase in payroll and related benefits of approximately \$89,000, an increase in equity-based compensation of approximately \$186,000, an increase in legal and accounting fees of approximately \$184,000, an increase in business insurance, primarily relating to Directors and Officers insurance, of approximately \$21,000, and a net increase in various other general and administrative expenses of approximately \$50,000, partially offset by a decrease in expenses relating to investor relations of approximately \$381,000, and a decrease in other professional services of approximately \$40,000.

*Sales and marketing expense*

During the three months ended June 30, 2018, we incurred sales and marketing expenses of \$203,629, a decrease of \$63,962, or 23.9%, from \$267,591 in the three months ended June 30, 2017. The decrease in sales and marketing expenses was primarily the result of a decrease in payroll and related benefit costs of approximately \$74,000, and a decrease in travel related expenses of approximately \$13,000, partially offset by an increase in equity-based compensation of approximately \$16,000, and an increase in costs related to industry trade shows of approximately \$11,000.

*Depreciation expense*

Depreciation expense for the three months ended June 30, 2018 amounted to \$131,294, an increase of \$42,830, or 48.4%, from \$88,464 for the three months ended June 30, 2017. The increase was primarily due to depreciable acquisitions of machinery and equipment during the year ended December 31, 2017 and the six months ended June 30, 2018 in the approximate amount of \$1,596,000, primarily consisting of equipment additions in our NASCO factory operations in North Carolina, equipment additions in our laboratory facility in Buffalo, New York, and leasehold improvements to our new corporate office in Williamsville, New York. These acquisitions were placed in service at various time intervals over the last eighteen (18) months.

*Amortization expense*

Amortization expense for the three months ended June 30, 2018 amounted to \$170,925, an increase of \$27,915, or 19.5%, from \$143,010 for the three months ended June 30, 2017. The amortization expense relates to amortization taken on capitalized patent costs and license fees. The increase was primarily due to amortization taken on additional patent costs incurred during the three months ended June 30, 2018 and the year ended December 31, 2017 in the amounts of \$334,230 and \$582,040, respectively.

*Warrant liability loss - net*

There was no material change in the fair value of our stock warrants during the three months ended June 30, 2018. As such, there was no gain or loss recorded on the change in the fair value of stock warrants during the three months ended June 30, 2018. Additionally, the remaining 94,721 stock warrants containing the anti-dilutive features that created the warrant liability were exercised on a cashless basis in July of 2018.

The warrant liability loss of \$77,583 for the second quarter of 2017 was due to an increase in the estimated fair value of the warrants during the period. The increase in the estimated fair value of the warrants was primarily attributable to an increase in our underlying stock price from \$1.18 per share at March 31, 2017 as compared to \$1.75 per share at June 30, 2017.

*Realized loss and unrealized gain on short-term investment securities*

In December of 2017, we funded a short-term investment account with excess capital raised from a registered direct offering in October of 2017. Investments in the short-term investment account are managed in accordance with our investment policy. The realized loss on short-term investment securities of \$42,384 for the three months ended June 30, 2018, was a loss resulting from the maturity of a corporate bonds in the short-term investment account.

During the first quarter of 2018, we recorded an unrealized loss on short-term investment securities in the amount of \$92,574 that should have been recorded as other comprehensive loss. Accordingly, during the second quarter of 2018, we corrected this by reversing the first quarter unrealized loss to comprehensive loss with the offsetting portion of the reversal recorded as an unrealized gain on short-term investment securities.

*Interest income, net*

Interest income, net for the three months ended June 30, 2018, was \$251,670, an increase of \$239,545 from interest income of \$12,125 for the three months ended June 30, 2017. The increase in net interest income (interest income less investment fees) was the result of net interest earned in our short-term investment account that was established in December of 2017. Interest income earned during the three months ended June 30, 2017 was the result of interest income generated from excess cash invested in a money market account.

*Interest expense*

Interest expense was \$0 and \$7,641 for the three months ended June 30, 2018 and 2017, respectively. We had no interest-bearing obligations during the three months ended June 30, 2018, and accordingly, we incurred no interest expense during that time period. Interest expense for the three months ended June 30, 2017 was derived from the interest component of severance payments made on accrued severance and the accretion of interest on a note payable.

*Net loss*

We had a net loss for the three months ended June 30, 2018 of \$6,738,652 as compared to a net loss of \$3,355,624 in the three months ended June 30, 2017. The increase in the net loss of \$3,383,028, or 100.8%, was primarily the result of an increase in operating expenses of approximately \$4,085,000, partially offset by an increase in gross profit on product sales of approximately \$327,000, and an increase in net other income of approximately \$375,000. The increase in operating expenses of \$4,085,000 was primarily the result of an increase in expenses relating to our MRTP application with the FDA for our VLNC cigarettes of approximately \$2,578,000, and an increase in R&D equity-based compensation of approximately \$1,326,000.

*Other comprehensive loss – unrealized loss on short-term investment securities, net*

We maintain an account for short-term investment securities that are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as Other comprehensive income or loss. We recorded an unrealized loss on short-term investment securities for the three months ended June 30, 2018 in the amount of \$28,184.

**Six Months Ended June 30, 2018 Compared to Six Months Ended June 30, 2017**

*Revenue - Sale of products, net*

In the six months ended June 30, 2018, we realized net sales revenue from the sale of products in the amount of \$13,030,952, an increase of \$6,902,229, or 112.62%, from net sales revenue of \$6,128,723 for the six months ended June 30, 2017. The increase in net sales revenue for the first six months of 2018 was primarily the result of continued additional net sales revenue generated from a new contract to manufacture an existing brand of filtered cigars as compared to net sales revenue for the first six months of 2017. Production under the new manufacturing contract began in mid-May of 2017.

*Cost of goods sold - Products*

During the six months ended June 30, 2018, cost of goods sold were \$12,797,660, or 98.2%, of net sales revenue. While our factory was still not at production capacity during the first six months of 2018, we continued to make progress towards utilizing more capacity as a result of the new filtered cigar manufacturing agreement that commenced in mid-May of 2017. As a result of the increased capacity utilization, net sales revenues exceeded the cost of goods sold, which included the cost of raw material components, excise taxes and certain regulatory fees, direct manufacturing costs and an overhead allocation.

During the six months ended June 30, 2017, cost of goods sold were \$6,567,675, or 107.2% of net sales revenue. We were not yet operating our factory at full production capacity during the six months ended June 30, 2017, but we began utilizing a portion of the excess capacity as a result of the new filtered cigar contract manufacturing agreement that commenced in mid-May of 2017. As a result, the cost of goods sold relating to product sales, which included the cost of raw material components, excise taxes and certain regulatory fees, direct manufacturing costs and an overhead allocation, exceeded net sales revenue. We also recorded an increase in our inventory reserve by \$95,000 during the second quarter of 2017 that resulted in an increase in the cost of goods sold by the same amount.

#### *Research and development expense*

Research and development (“R&D”) expense was \$7,298,176 in the six months ended June 30, 2018, an increase of \$5,934,038, or 435.0%, from \$1,364,138 in the six months ended June 30, 2017. This increase was primarily the result of an increase in expenses relating to our MRTP application with the FDA for our VLNC cigarettes of approximately \$3,822,000, an increase in equity-based compensation of approximately \$1,533,000, an increase in sponsored research costs of approximately \$79,000, an increase in payroll and related benefits of approximately \$286,000, an increase in costs related to our laboratory operations of approximately \$191,000, an increase in consulting fees of approximately \$39,000, an increase in travel related expenses of approximately \$29,000, and an increase in patent maintenance costs of approximately \$20,000, partially offset by a decrease in license and royalty fees of approximately \$60,000.

#### *General and administrative expense*

General and administrative expense was \$3,947,363 in the six months ended June 30, 2018, an increase of \$521,766, or 15.2%, from \$3,425,597 in the six months ended June 30, 2017. The increase was mainly due to an increase in payroll and related benefits of approximately \$266,000, an increase in equity-based compensation of approximately \$365,000, an increase in annual SEC and NYSE American compliance costs of approximately \$75,000, an increase in legal and accounting expenses of approximately \$201,000, and a net increase in various other general and administrative expenses of approximately \$85,000, partially offset by a decrease in expenses relating to investor relations of approximately \$471,000.

#### *Sales and marketing expense*

During the six months ended June 30, 2018, we incurred sales and marketing expenses of \$402,738, a decrease of \$160,566, or 28.5%, from \$563,304 in the six months ended June 30, 2017. The decrease in sales and marketing expenses was primarily the result of a decrease in payroll and related benefit costs of approximately \$154,000, a decrease in advertising and promotional costs of approximately \$27,000, and a decrease in travel related expenses of

approximately \$18,000, partially offset by an increase in equity-based compensation of approximately \$25,000, and an increase in costs related to industry trade shows of approximately 16,000.

*Depreciation expense*

Depreciation expense for the six months ended June 30, 2018 amounted to \$255,822, an increase of \$79,237, or 44.9%, from \$176,585 for the six months ended June 30, 2017. The increase was primarily due to depreciable acquisitions of machinery and equipment during the year ended December 31, 2017 and the six months ended June 30, 2018 in the approximate amount of \$1,596,000, primarily consisting of equipment additions in our NASCO factory operations in North Carolina, equipment additions in our laboratory facility in Buffalo, New York, and leasehold improvements to our new corporate office in Williamsville, New York. These acquisitions were placed in service at various time intervals over the last eighteen (18) months.

*Amortization expense*

Amortization expense for the six months ended June 30, 2018 amounted to \$338,477, an increase of \$54,579, or 19.2%, from \$283,898 for the six months ended June 30, 2017. The amortization expense relates to amortization taken on capitalized patent costs and license fees. The increase was primarily due to amortization taken on additional patent costs incurred during the six months ended June 30, 2018 and the year ended December 31, 2017 in the amounts of \$334,230 and \$582,040, respectively.

*Warrant liability gain (loss) - net*

The warrant liability gain of \$48,711 for the six months ended June 30, 2018 was due to a decrease in the estimated fair value of the warrants during the first quarter of 2018. We did not record any gain or loss during the second quarter of 2018 as discussed above. The decrease in the estimated fair value of the warrants during the first quarter of 2018 was primarily attributable to a decrease in our underlying stock price from \$2.80 per share at December 31, 2017 as compared to \$2.35 per share at March 31, 2018.

The warrant liability loss of \$82,927 for the six months ended June 30, 2017 was due to an increase in the estimated fair value of the warrants during the period. The increase in the estimated fair value of the warrants was primarily attributable to an increase in the Company's underlying stock price from \$1.09 per share at December 31, 2016 as compared to \$1.75 per share at June 30, 2017.

*Realized loss on short-term investment securities*

In December of 2017, we funded a short-term investment account with excess capital raised from a registered direct offering in October of 2017. Investments in the short-term investment account are managed in accordance with our investment policy. The realized loss on short-term investment securities of \$42,189 for the six months ended June 30, 2018, was a loss resulting from the maturity of a corporate bond in the short-term investment account.

*Unrealized gain on investment*

During the first quarter of 2018, we began accounting for our equity investment in Anandia in accordance with Financial Accounting Standards Board ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. This guidance changes how entities account for equity investments that do not result in consolidation and are not accounted for under the equity method of accounting. Under ASU 2016-01, we are required to measure our investment in Anandia at fair value at the end of each reporting period and recognize changes in fair value in net income. A practical expedient is available for equity investments that do not have readily determinable fair values, however; the exception requires us to adjust the carrying amount for impairment and observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Accordingly, and as a result of an equity issuance by Anandia during December of 2017 and January of 2018 (orderly transactions), we recorded an unrealized gain on our investment in Anandia in the amount of \$6,147,088 for the three months ended March 31, 2018. There was no change in the fair value our equity investment in Anandia during the second quarter of 2018.



During the first quarter of 2017, a dilutive event occurred bringing our investment percentage in Anandia below 20%, a threshold for the use of the equity method of accounting that we had previously used to account for our investment in Anandia. Accordingly, we discontinued applying the equity method of accounting for our investment in Anandia after such dilutive event. After the dilutive event, we accounted for our investment in Anandia under the cost method of accounting until we adopted ASU 2016-01, as described above. We recorded an unrealized gain on the investment in Anandia the amount of \$346,180 for the three months ended March 31, 2017. The cost method of accounting was being used for the equity investment in Anandia during the second quarter of 2017. Accordingly, no gain or loss was recorded for the six months ended June 30, 2017.

*Interest income, net*

Interest income, net for the six months ended June 30, 2018 was \$503,510, an increase of \$475,630 from interest income of \$27,880 for the six months ended June 30, 2017. The increase in net interest income (interest income less investment fees) was the result of net interest earned in our short-term investment account that was established in December of 2017. Interest income earned during the six months ended June 30, 2017 was the result of interest income generated from excess cash invested in a money market account.

*Interest expense*

Interest expense was \$0 and \$15,560 for the six months ended June 30, 2018 and 2017, respectively. We had no interest-bearing obligations during the six months ended June 30, 2018, and accordingly, we incurred no interest expense during that time period. Interest expense for the six months ended June 30, 2017 was derived from the interest component of severance payments made on accrued severance and the accretion of interest on a note payable.

*Net loss*

We had a net loss for the six months ended June 30, 2018 of \$5,352,164 as compared to a net loss of \$5,976,901 in the six months ended June 30, 2017. The decrease in the net loss of \$624,737, or 10.5%, was primarily the result of an increase in the gross profit on product sales of approximately \$672,000, and an increase in net other income of approximately \$6,382,000, partially offset by an increase in operating expenses of \$6,429,000. The increase in net other income of \$6,382,000 includes the unrealized gain on our investment in Anandia of approximately \$6,147,000, as discussed above. The increase in operating expenses of \$6,429,000 includes the increase in expenses relating to our MRTTP application with the FDA for our VLNC cigarettes of approximately \$3,822,000, and the increase in R&D equity-based compensation of approximately \$1,533,000.

*Other comprehensive loss – unrealized loss on short-term investment securities, net*

We maintain an account for short-term investment securities that are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as Other comprehensive income or loss. We recorded an unrealized loss on short-term investment securities for the three months ended June 30, 2018 in the amount of \$28,184.

**Liquidity and Capital Resources**

*Working Capital*

As of June 30, 2018, we had working capital of approximately \$53.2 million compared to working capital of approximately \$63.3 million at December 31, 2017, a decrease of approximately \$10.1 million. This decrease in working capital is due to a decrease in current assets of approximately \$8.6 million, which is primarily due to a net decrease in cash and cash equivalents and short-term investment securities of approximately \$9.2 million, offset by a net increase in all other current assets of approximately \$0.6 million, and an increase in net current liabilities of approximately \$1.5 million. The net decrease in cash and cash equivalents and short-term investment securities is primarily the result of cash used in operating activities during the six months ended June 30, 2018.

We must successfully execute our business plan to increase revenue in order to achieve positive cash flows from operations to sustain adequate liquidity without requiring additional funds from capital raises and other external sources to meet minimum operating requirements. On December 30, 2016, we filed a Form S-3, universal shelf registration statement with the U.S. Securities and Exchange Commission (“SEC”) that was declared effective by the SEC on January 17, 2017. The universal shelf registration statement will allow, but not compel, the Company to raise up to \$100 million of capital over a three-year period ending January 17, 2020 through a wide array of securities at times and in amounts to be determined by the Company. Following the October 2017 registered direct offering, the universal shelf registration has approximately \$46 million of remaining capacity. If required, there can be no assurance that additional capital will be available on acceptable terms or at all.

*Cash demands on operations*

We had cash and cash equivalents and short-term investment securities at June 30, 2018 of \$53,454,401. We believe this amount of cash and cash equivalents and short-term investment securities will be adequate to sustain normal operations and meet all current obligations as they come due for a number of years. During the six months ended June 30, 2018, we experienced an operating loss of approximately \$12,009,000 (including approximately \$4,021,000 in expenses relating to our MRTP application) and used cash in operations of approximately \$8,391,000. Excluding discretionary expenses relating to R&D, patent and trademark costs, contract growing of our proprietary tobacco, modified risk tobacco products and certain nonrecurring expenses relating to factory capital expenses, investor relations and marketing costs, our monthly cash expenditures are approximately \$850,000. In addition, we expect to incur an estimated amount of approximately an additional \$7,500,000 in expenses relating to our MRTP application over approximately the next six to nine months.

*Net cash used in operating activities*

In the six months ended June 30, 2018, \$8,390,785 of cash was used in operating activities as compared to \$7,051,357 of cash used in operating activities in the six months ended June 30, 2017, an increase of \$1,339,428. The increase in use of cash in operations was primarily due to an increase in the cash portion of the net loss in the amount of \$3,344,243, offset by a decrease in the use of cash used for working capital components related to operations in the amount of \$2,004,815 for the six months ended June 30, 2018 as compared to the six months ended June 30, 2017.

*Net cash provided by (used in) investing activities*

In the six months ended June 30, 2018, net cash provided by investing activities was \$8,387,140, as compared to \$146,769 of cash used in investing activities during the six months ended June 30, 2017, an increase in net cash provided by investing activities of \$8,533,909. The increase was primarily the result of an increase in net cash provided from transactions in our short-term investment account in the amount of \$8,824,128, offset by a net increase in cash used for the acquisition of patents and trademarks and in the acquisition of machinery and equipment in the aggregate amount of \$290,219.

*Net cash (used in) provided by financing activities*

During the six months ended June 30, 2018, \$282,500 of cash was used in financing activities, resulting from a \$500,000 payment on a note payable, partially offset by \$217,500 cash raised from the exercise of various stock options.

During the six months ended June 30, 2017, \$6,212,712 of cash was provided by financing activities and was the result of net cash raised from the exercise of stock warrants.

### **Critical Accounting Policies and Estimates**

There have been no material changes to the information set forth in our Annual Report on Form 10-K for the year ended December 31, 2017.

### **Inflation**

Inflation did not have a material effect on our operating results for the six months ended June 30, 2018 and 2017, respectively.

### **Off-Balance Sheet Arrangements**

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

There have been no material changes to the information set forth in our Annual Report on Form 10-K for the year ended December 31, 2017.

#### **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 effective as of the end of the period covered by this Form 10-Q to ensure information required to be disclosed is recorded, processed, summarized and reported within the time period specified by SEC rules, 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 controls over financial reporting during the second quarter of 2018 that have materially affected, or are reasonably likely to materially affect, the Company’s internal controls over financial reporting.

## Part II. OTHER INFORMATION

### Item 1. Legal Proceedings

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

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

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

Following such ruling, on July 11, 2016, the Company filed a motion to sever the Crede lawsuit into two separate cases, requesting all claims relating to the Tranche 1A warrant and the securities purchase agreement to stay in the SDNY Court and all claims relating to the China joint venture agreement to be transferred to the United States District Court for the Western District of New York (the “WDNY Court”), where the Company’s headquarters office is located. On January 20, 2017, the SDNY Court granted the Company’s motion.

On February 14, 2017, Crede voluntarily dismissed its lawsuit against the Company in the WDNY Court.

On February 21, 2017, the SDNY Court granted the Company's request to file a motion for summary judgment for the claims remaining in the SDNY Court, with all discovery in the case being deferred until after the SDNY Court issued its decision on the summary judgment motion of the Company.

On March 20, 2017, the Company filed its motion for summary judgment for the claims remaining in the SDNY Court. The response by Crede to the Company's summary judgment motion was filed by Crede on May 1, 2017. On May 15, 2017, the Company filed its response to Crede's filing.

On December 28, 2017, the SDNY Court issued its decision in response to the Company's motion for summary judgment, with such decision (i) granting the Company's motion for summary judgment relating to Count II of the Amended Complaint, which eliminated Crede's claim to rescind the prior securities purchase agreement, dated September 17, 2014, and denied Crede's claim for the return of any money from the Company under that securities purchase agreement, and (ii) denying the Company's motion for summary judgment on the remaining Counts of the Amended Complaint. In this decision, the SDNY Court also found that Crede breached the Activity Restrictions as defined and contained in the Tranche 1A warrant. As a result of this decision by the SDNY Court, the parties then proceeded with discovery in the case in preparation for a trial on the remaining Counts III, IV and V of the Amended Complaint, which relate to Crede's claim (i) to exchange the Tranche 1A warrant for 2,077,555 shares of our common stock even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant, (ii) for an unquantified additional amount of shares of our common stock that allegedly still remains under the Tranche 1A warrant even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant; and (iii) for alleged damages for the alleged breach of the Tranche 1A warrant in an amount in excess of \$18 million, plus costs and interest, even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant.

On July 13, 2018, the SDNY Court denied Crede's request to extend the discovery deadline. As a result of such ruling, the discovery in the Crede case has now been concluded. On July 20, 2018, the SDNY Court granted the request by the Company to file a motion for partial summary judgment to substantially limit the various damage claims by Crede, with the remaining schedule in the case being deferred until after the SDNY Court rules on such motion. The Company is to file its partial summary judgment motion by August 20, 2018, after which Crede is required to file its response by September 20, 2018, after which the Company will then be required to file its reply to Crede's response by October 14, 2018.

The Company believes that the claims are frivolous, meritless and that the Company has substantial legal and factual defenses to the claims. The Company has defended and intends to continue to defend against these claims vigorously.



**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, 2017, as filed with the SEC on March 7, 2018.

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

On July 6, 2018, we issued 63,832 shares of common stock to an investor from the cashless exercise of 94,721 warrants to purchase shares of our common stock.

The shares were offered and sold pursuant to exemptions from the registration requirements under Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

**Item 3. Default Upon Senior Securities.**

None

**Item 4. Mine Safety Disclosures**

None

**Item 5. Other Information**

None

**Item 6. Exhibits**

Exhibit 10.1    Second Amendment to License Agreement with North Carolina State University dated June 22, 2018 (filed herewith)

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: August 7, 2018 /s/ Henry Sicignano III  
Henry Sicignano III  
President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: August 7, 2018 /s/ John T. Brodfuehrer  
John T. Brodfuehrer  
Chief Financial Officer  
(Principal Accounting and Financial Officer)