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

UNITED STATES

SECURITIES AND EXCHANGE

COMMISSION WASHINGTON, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 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 of incorporation)	(IRS Employer Identification No.)

8560 Main Street, Williamsville, New York 14221
(Address of principal executive offices)

(716) 270-1523
(Registrant's telephone number, including area code)

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

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).

Yes x 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 x

Non-accelerated filer ¨ Smaller reporting company ¨

Emerging growth company ¨

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

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

Yes ¨ No x

As of November 7, 2018, there were 124,401,468 shares of common stock issued and outstanding.

22nd CENTURY GROUP, INC.

INDEX

		Page Number
PART I.	FINANCIAL INFORMATION	
Item 1.	Financial Statements	
	Consolidated Balance Sheets as of September 30, 2018 (unaudited) and December 31, 2017	3
	Consolidated Statements of Operations and Comprehensive Income (Loss) for the Three Months Ended September 30, 2018 and 2017 (unaudited)	4
	Consolidated Statements of Operations and Comprehensive Income (Loss) for the Nine Months Ended September 30, 2018 and 2017 (unaudited)	5
	Consolidated Statement of Changes in Shareholders' Equity for the Nine Months Ended September 30, 2018 (unaudited)	6
	Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017 (unaudited)	7
	Notes to Consolidated Financial Statements (unaudited)	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	27
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	38
Item 4.	Controls and Procedures	39
PART II.	OTHER INFORMATION	40
Item 1.	Legal Proceedings	40
Item 1A.	Risk Factors	42
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	42

Item 3. Default Upon Senior Securities 42

Item 4. Mine Safety Disclosures 42

Item 5. Other Information 42

Item 6. Exhibits 42

SIGNATURES 43

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

September 30, 2018 with Comparative Figures at December 31, 2017

	September 30, 2018 **(unaudited)**	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$759,210	$3,659,534
Short-term investment securities	61,362,113	58,975,513
Accounts receivable	936,225	957,066
Inventory, net	3,330,267	3,282,537
Prepaid expenses and other assets	1,280,087	746,805
Total current assets	67,667,902	67,621,455
Machinery and equipment, net	3,306,601	3,316,047
Other assets:		
Intangible assets, net	8,709,973	7,435,411
Investment	6,731,114	1,366,493
Total other assets	15,441,087	8,801,904
Total assets	$86,415,590	$79,739,406
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of note payable	$392,686	$-
Accounts payable	3,853,193	2,080,691
Accrued expenses	1,902,350	1,987,675
Deferred revenue	486,010	28,350
Warrant liability	-	216,490
Total current liabilities	6,634,239	4,313,206
Long-term portion of note payable	286,971	-
Total liabilities	6,921,210	4,313,206
Commitments and contingencies (Note 10)	-	-
Shareholders' equity		
10,000,000 preferred shares, $.00001 par value		
300,000,000 common shares, $.00001 par value		
Capital stock issued and outstanding:		

124,401,468 common shares (123,569,367 at December 31, 2017)	1,244	1,236
Capital in excess of par value	169,696,744	166,592,536
Accumulated other comprehensive income	11,474	-
Accumulated deficit	(90,215,082)	(91,167,572)
Total shareholders' equity	79,494,380	75,426,200
Total liabilities and shareholders' equity	$86,415,590	$79,739,406

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

Three Months Ended September 30,

(unaudited)

	2018	2017
Revenue:		
Sale of products, net	$6,260,158	$4,530,865
Cost of goods sold (exclusive of depreciation shown separately below):		
Products	6,109,209	4,871,234
Gross profit (loss)	150,949	(340,369)
Operating expenses:		
Research and development (including equity-based compensation of $140,692 and $26,851, respectively)	4,009,808	784,587
General and administrative (including equity-based compensation of $285,829 and $194,296, respectively)	1,759,254	1,635,226
Sales and marketing (including equity-based compensation of $46,312 and $38,268, respectively)	238,704	279,254
Depreciation	132,846	88,711
Amortization	219,171	145,934
	6,359,783	2,933,712
Operating loss	(6,208,834)	(3,274,081)
Other income (expense):		
Warrant liability loss, net	-	(55,886)
Realized loss on short-term investment securities	(6,272)	-
Realized gain on investments	8,345,880	-
Unrealized gain on investment	3,923,156	-
Interest income, net	255,155	20,317
Interest expense	(4,431)	(6,984)
	12,513,488	(42,553)
Income (loss) before income taxes	6,304,654	(3,316,634)
Income taxes	-	-
Net income (loss)	$6,304,654	$(3,316,634)

Other comprehensive income:		
Unrealized gain on short-term investment securities, net	39,658	-
Comprehensive income (loss)	$6,344,312	$(3,316,634)
Net income (loss) per common share - basic	$0.05	$(0.03)
Net income (loss) per common share - diluted	$0.04	$(0.03)
Common shares used in basic earnings per share calculation	124,376,061	100,673,834
Common shares used in diluted earnings per share calculation	144,382,479	100,673,834

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

Nine Months Ended September 30,

(unaudited)

	2018	2017
Revenue:		
Sale of products, net	$19,291,110	$10,659,588
Cost of goods sold (exclusive of depreciation shown separately below):		
Products	18,906,869	11,438,909
Gross profit (loss)	384,241	(779,321)
Operating expenses:		
Research and development (including equity-based compensation of $1,705,422 and $59,051, respectively)	11,307,984	2,148,725
General and administrative (including equity-based compensation of $884,916 and $428,022, respectively)	5,706,617	5,060,823
Sales and marketing (including equity-based compensation of $128,599 and $95,325, respectively)	641,442	842,558
Depreciation	388,668	265,296
Amortization	557,648	429,832
	18,602,359	8,747,234
Operating loss	(18,218,118)	(9,526,555)
Other income (expense):		
Warrant liability gain (loss), net	48,711	(138,813)
Realized loss on short-term investment securities	(48,461)	-
Realized gain on investments	8,345,880	-
Unrealized gain on investments	10,070,244	346,180
Interest income, net	758,665	48,197
Interest expense	(4,431)	(22,544)
	19,170,608	233,020
Income (loss) before income taxes	952,490	(9,293,535)
Income taxes	-	-
Net income (loss)	$952,490	$(9,293,535)

Other comprehensive income:		
Unrealized gain on short-term investment securities, net	11,474	-
Comprehensive income (loss)	$963,964	$(9,293,535)
Net income (loss) per common share - basic	$0.01	$(0.10)
Net income (loss) per common share - diluted	$0.01	$(0.10)
Common shares used in basic earnings per share calculation	124,237,003	94,369,953
Common shares used in diluted earnings per share calculation	144,243,421	94,369,953

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

Nine Months Ended September 30, 2018

(unaudited)

	Common Shares Outstanding	Par Value of Common Shares	Capital in Excess of Par Value	Accumulated Other Comprehensive Income	Accumulated Deficit	Shareholders' Equity
Balance at December 31, 2017	**123,569,367**	**$ 1,236**	**$166,592,536**	**$ -**	**$(91,167,572)**	**$75,426,200**
Stock issued in connection with warrant exercises	490,012	5	(5)	-	-	-
Stock issued in connection with option exercises	342,089	3	217,497	-	-	217,500
Equity-based compensation	-	-	2,718,937	-	-	2,718,937
Reclassification of warrant liability to capital in excess of par	-	-	167,779	-	-	167,779
Unrealized gain on short-term investment securities	-	-	-	11,474	-	11,474
Net income	-	-	-	-	952,490	952,490
Balance at September 30, 2018	**124,401,468**	**$ 1,244**	**$169,696,744**	**$ 11,474**	**$(90,215,082)**	**$79,494,380**

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Nine Months Ended September 30,

(unaudited)

	2018	**2017**
Cash flows from operating activities:		
Net income (loss)	$952,490	$(9,293,535)
Adjustments to reconcile net income (loss) to cash used in operating activities:		
Amortization and depreciation	856,931	621,612
Amortization of license fees	89,385	73,516
Unrealized gain on investments	(10,070,244)	(346,180)
Realized gain on the sale of investments	(8,345,880)	
Realized loss on short-term investment securities	48,461	-
Warrant liability (gain) loss	(48,711)	138,813
Accretion of interest on note payable and accrued severance	4,431	22,544
Equity-based employee compensation expense	2,718,937	582,398
Decrease in allowance for doubtful accounts	-	(10,000)
(Decrease) increase in inventory reserve	(35,000)	95,000
(Increase) decrease in assets:		
Accounts receivable	20,841	(75,205)
Inventory	(12,730)	(1,036,478)
Prepaid expenses and other assets	(533,282)	(347,384)
Increase (decrease) in liabilities:		
Accounts payable	1,420,417	53,740
Accrued expenses	(85,325)	(93,882)
Accrued severance	-	(164,423)
Deferred revenue	457,660	158,478
Net cash used in operating activities	(12,561,619)	(9,620,986)
Cash flows from investing activities:		
Acquisition of patents and trademarks	(318,773)	(312,804)
Acquisition of machinery and equipment	(365,349)	(892,186)
Proceeds from the sale of investments	13,051,503	-
Sales and maturities of short-term investment securities	30,465,534	-
Purchase of short-term investment securities	(32,889,120)	-
Net cash provided by (used in) investing activities	9,943,795	(1,204,990)
Cash flows from financing activities:		
Net proceeds from exercise of warrants	-	12,380,358
Payment on note payable	(500,000)	-
Proceeds from exercise of stock options	217,500	-
Net cash (used in) provided by financing activities	(282,500)	12,380,358
Net (decrease) increase in cash	(2,900,324)	1,554,382

Cash and cash equivalents - beginning of period	3,659,534	13,468,188
Cash and cash equivalents - end of period	$759,210	$15,022,570
Supplemental disclosures of cash flow information:		
Net cash paid for:		
Cash paid during the period for interest	$-	$3,558
Cash paid during the period for income taxes	$-	$-
Non-cash transactions:		
Patent and trademark additions included in accounts payable	$338,212	$196,014
Machinery and equipment additions included in accounts payable	$13,873	$38,061
License acquired with note payable	$1,175,226	$-
Reclassification of warrant liability to capital in excess of par	$167,779	$-

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 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 the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments consisting of normal recurring accruals considered necessary for a fair and non-misleading presentation of the financial statements have been included.

Operating results for the nine months ended September 30, 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 in the amount of $0 and $3,000,000 at September 30, 2018 and December 31, 2017, respectively. 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 Income (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 Income (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 September 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 September 30, 2018 and December 31, 2017 consisted of the following:

	September 30, 2018	December 31, 2017
Inventory - tobacco leaf	$ 1,714,923	$ 1,552,474
Inventory - finished goods		
Cigarettes and filtered cigars	237,995	289,004
Inventory - raw materials		
Cigarette and filtered cigar components	1,537,349	1,636,059
	3,490,267	3,477,537
Less: inventory reserve	160,000	195,000

$ 3,330,267	$ 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 September 30, 2018 and December 31, 2017 consisted of the following:

	September 30, 2018	December 31, 2017
Intangible assets, net		
Patent and trademark costs	$ 6,984,452	$ 6,327,467
Less: accumulated amortization	2,985,729	2,517,465
Patent and trademark costs, net	3,998,723	3,810,002
License fees, net (see Note 10)	2,625,226	1,450,000
Less: accumulated amortization	415,976	326,591
License fees, net	2,209,250	1,123,409
MSA signatory costs	2,202,000	2,202,000
License fee for predicate cigarette brand	300,000	300,000
	$ 8,709,973	$ 7,435,411

Amortization expense relating to the above intangible assets for the three and nine months ended September 30, 2018 amounted to $219,171 and $557,648, respectively ($145,934 and $429,832 for the three and nine months ended September 30, 2017, respectively).

The estimated annual average amortization expense for the next five years is approximately $434,000 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 nine months ended September 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 September 30, 2018 and December 31, 2017.

The Company's federal and state tax returns for the years ended December 31, 2015 through December 31, 2017 are currently open to audit under the statutes of limitations. There were no pending audits as of September 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 September 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 September 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 nine months ended September 30, 2018, net sales revenue from products transferred over time amounted to approximately $3,987,000 and $12,479,000, respectively, and net sales revenue from products transferred at a point in time amounted to approximately $2,273,000 and $6,812,000, 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 Income (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 $7,000 and $23,000 for the three and nine months ended September 30, 2018, respectively ($6,000 and $49,000 for the three and nine months ended September 30, 2017, respectively).

Income (Loss) Per Common Share - Basic income (loss) per common share is computed using the weighted-average number of common shares outstanding. Diluted income (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, investments (stock warrants), accounts payable, accrued expenses and warrant liability. Other than for cash equivalents, short-term investment securities, investments (stock warrants), 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, investments (stock warrants), 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.

The Company has an investment in stock warrants that are considered equity securities. The Company's investment in stock warrants are recorded at fair value with changes in fair value recorded in net income (loss).

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 has been evaluating its current lease contracts and will likely record a right-to-use asset and a corresponding lease liability, primarily relating to real estate leases, during the first quarter of 2019, but the Company believes the impact of the ASU on its consolidated financial statements will be not be material.

13

NOTE 2. – OCTOBER 2017 REGISTERED DIRECT OFFERING

On October 10, 2017, the Company closed a registered direct 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.

NOTE 3. – JUNE 2017 WARRANT EXERCISE AGREEMENTS

On June 19, 2017, the Company entered into Warrant Exercise Agreements (the "Agreements") with all 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. During the second and third quarters of 2017, the Holders exercised 7,043,211 Warrants at $1.00 per share and 4,250,000 Warrants at $1.45 per share, resulting in net proceeds to the Company in the amount of $12,336,858, 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 continued to utilize additional production capacity due to increased production and sales of the contract manufacturing of filtered cigars and cigarettes during the three months ended September 30, 2018. This improvement resulted in gross profit on sales of products in the amount of $150,949 and $384,241 for the three and nine months ended September 30, 2018, respectively, as compared to a gross loss on sales of products in the amount of $340,369 and $779,321 for the three and nine months ended September 30, 2017, respectively. 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 $311,918 and $941,357 for the three and nine months ended September 30, 2018, respectively ($300,824 and $635,514 for the three and nine months ended September 30, 2017, respectively).

NOTE 5. - MACHINERY AND EQUIPMENT

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

	Useful Life	September 30, 2018	December 31, 2017
Cigarette manufacturing equipment	3 - 10 years	$ 4,537,696	$ 4,302,299
Office furniture, fixtures and equipment	5 years	135,909	110,499
Laboratory equipment	5 years	93,109	32,193
Leasehold improvements	6 years	163,359	106,429
		4,930,073	4,551,420
Less: accumulated depreciation		1,623,472	1,235,373
Machinery and equipment, net		$ 3,306,601	$ 3,316,047

Depreciation expense was $132,846 and $388,668 for the three and nine months ended September 30, 2018, respectively ($88,711 and $265,296 for the three and nine months ended September 30, 2017, respectively).

NOTE 6. - INVESTMENT

The Company (through its wholly-owned subsidiary, Botanical Genetics) held a 14.8% equity investment in Anandia Laboratories, Inc., a Canadian plant biotechnology company (“Anandia”). On August 8, 2018, all of Anandia’s outstanding common stock was acquired by Aurora Cannabis, Inc. (“Aurora”), a Canadian company (TSX: ACB.TO), in exchange for (i) free trading shares of Aurora common stock, 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. As a result of the transaction, the Company received 1,947,943 shares of Aurora common stock and warrants to purchase 973,971 shares of Aurora common stock that had a fair value of $9,221,594 and $2,807,958, respectively. The Company recorded a realized gain on the transaction in the amount of $4,515,971 during the three months ended September 30, 2018. Subsequent to the transaction, the Company sold all of its Aurora common stock resulting in net sales proceeds to the Company of $13,051,503 and realized a gain on the sale of $3,829,909. The aggregate realized gains from the Anandia transaction and the sale of the Aurora common shares amount to $8,345,880 for the three and nine months ended September 30, 2018. As a result of the sale of the Aurora stock, the Company expects to utilize Federal and State net operating losses to minimize or eliminate the current income tax effect of the realized gain. Accordingly, the Company anticipates a corresponding reduction to the deferred tax assets and the associated valuation allowance recorded on the net operating losses.

The warrants to purchase 973,971 shares of Aurora common stock have a five-year contractual term, an exercise price of $9.37 per share (Canadian Dollars; approximately $7.26 per share U.S. Dollars at September 30, 2018), are currently exercisable, are considered an equity security, and are recorded at fair value. The Company recorded the fair value of the Aurora common stock warrants of $6,731,114 at September 30, 2018, using the Black-Scholes pricing model, and recorded an unrealized gain on the warrants in the amount of $3,923,156 for the three months ended September 30, 2018. The fair value of the warrants at September 30, 2018 in the amount of $6,731,114 was classified within Other assets on the Company's Consolidated Balance Sheets.

Effective January 1, 2018, the Company adopted 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. As allowed by ASU 2016-01, since the Company's investment in Anandia did not have readily determinable fair value, the Company elected to account for its investment at cost. The cost basis is required to be adjusted in the event of impairment, if any, and for any observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Accordingly, and as a result of, a prior equity issuance by Anandia that was considered an orderly transaction, 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 were no further changes in the fair value of the Company's equity investment in Anandia through the acquisition of Anandia by Aurora on August 8, 2018, as discussed above. As a result of the fair value recording for both the Aurora common stock warrants, discussed above, and the equity investment in Anandia, the Company recorded unrealized gains in the amount of $3,923,156 and $10,070,244 for the three and nine months ended September 30, 2018, respectively.

The Company's investment in Anandia was recorded using the equity method of accounting until the first quarter of 2017, when a dilutive event occurred bringing the Company's investment percentage in Anandia below 20%. Accordingly, the Company discontinued applying the equity method of accounting for its investment in Anandia and began accounting for its investment in Anandia under the cost method of accounting. The Company's unrealized gain on the investment in Anandia was $346,180 for the nine months ended September 30, 2017. At December 31, 2017, the Company's investment balance in Anandia was $1,366,493, and was classified within Other assets on the accompanying Consolidated Balance Sheets.

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 September 30, 2018 and December 31, 2017, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	Asset and Liabilities at Fair Value As of September 30, 2018			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Short-term investment securities:				
Money market funds	$ 17,024,020	$ -	$-	$ 17,024,020
Corporate bonds	-	30,348,270	-	30,348,270
Commercial paper	-	1,198,890	-	1,198,890
U.S. treasury securities	-	4,001,605	-	4,001,605
U.S. government agency bonds	-	8,789,328	-	8,789,328
Total cash equivalents and short-term investment securities	$ 17,024,020	$ 44,338,093	$ -	$ 61,362,113
Investments:				
Stock warrants	$ -	$ -	$ 6,731,114	$ 6,731,114

16

	Asset and Liabilities at Fair Value As of December 31, 2017			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
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
Liabilities				
Warrant liability	$-	$-	$216,490	$216,490

The investment in stock warrants are measured at fair value using the Black-Scholes pricing model and are classified within Level 3 of the valuation hierarchy. The unobservable input used in the Black-Scholes pricing model is the volatility factor and an estimated volatility factor of 85% was used at September 30, 2018. A 20% increase or decrease in the volatility factor used at September 30, 2018 would have the impact of increasing or decreasing the fair value measurement of the stock warrants by approximately $710,000.

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. A significant increases or decreases in the volatility input would result in a significantly higher or lower fair value measurement. The Company’s outstanding warrants at September 30, 2018 do not include anti-dilution features and therefore are not considered derivative instruments, and accordingly, do not have an associated warrant liability

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 and the accretion of interest during the third quarter of 2018 in the amount of $4,431, the balance remaining as of September 30, 2018 amounted to $679,657, with $392,686 and $286,971 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 amounted 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 September 30, 2018, the Company had outstanding warrants to purchase 11,293,211 shares of common stock of the Company with an exercise price of $2.15 per share and an expiration date of December 20, 2022.

During the three and nine months ended September 30, 2018, warrant holders exercised 94,721 and 794,869 warrants, respectively, on a cashless basis, resulting in the issuance of 63,832 and 490,012 shares, respectively.

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.

The Company estimates the value of warrant liability upon issuance of warrants that are considered derivative instruments 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 Company's outstanding warrants at September 30, 2018 do not include anti-dilution features and therefore are not considered derivative instruments, and accordingly, do not have an associated warrant liability.

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 a result of change in fair value	(48,711)
Reclassification of warrant liability to capital in excess of par	(167,779)
Fair value at September 30, 2018	$-

The aggregate net gain as a result of the Company's warrant liability for the three and nine months ended September 30, 2018 amounted to $0 and $48,711, respectively (the aggregate net loss for the three and nine months ended September 30, 2017 amounted to $55,886 and $138,813, respectively), which are included in Other income (expense) under Warrant liability gain (loss), net in the accompanying Consolidated Statements of Operations and Comprehensive Income (Loss).

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

	Number of Warrants
Warrants outstanding at December 31, 2016	13,781,921
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)

Warrants outstanding at December 31, 2017	12,088,080
Warrants exercised during 2018	(794,869)
Warrants outstanding at September 30, 2018	11,293,211

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 Income (Loss). The amounts expensed during the three and nine months ended September 30, 2018 were $86,589 and $307,659, respectively ($56,250 and $175,890 for the three and nine months ended September 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 nine months ended September 30, 2018, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to $38,394 and $72,502, respectively ($11,022 and $42,730 for the three and nine months ended September 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 nine months ended September 30, 2018, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to $81,505 and $81,584, respectively ($236 and $30,102 for the three and nine months ended September 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. The amounts expensed during the three and nine months ended September 30, 2018 were $30,339 and $50,565.

Other 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 $40,374 and $89,385 for the three and nine months ended September 30, 2018, respectively ($24,506 and $73,516 for the three and nine months ended September 30, 2017), and was included in Amortization expense on the Company's Consolidated Statements of Operations and Comprehensive Income (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. Amortization of the license fee began in the third quarter of 2018.

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 Income (Loss) for the three months ended March 31, 2017 and the nine months ended September 30, 2017. Additionally, under the License Agreement the Company paid NCSU a non-refundable, non-creditable license maintenance fee in the amount of $15,000 during the year ended December 31, 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 nine months ended September 30, 2018, the aggregated costs incurred related to capitalized patent costs and patent maintenance expense amounted to $2,140 and $11,605, respectively ($12,928 and $37,170 for the three and nine months ended September 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 Income (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 conducted research on behalf of the Company relating to the hemp/cannabis plant. During the three and nine months ended September 30, 2018, expenses related to the Agreement amounted to $0 and $130,850, respectively ($196,275 and $457,975 for the three and nine months ended September 30, 2017, respectively). 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. As discussed in Note 6, Anandia was purchased by Aurora Cannabis Inc. on August 8, 2018 and has become a wholly-owned subsidiary of Aurora Cannabis Inc. The Agreement is still currently in effect and the Company is in discussions with Anandia regarding an amendment to the Agreement to conduct additional research together.

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 nine months ended September 30, 2018, expenses related to the agreements amounted to $116,265 and $296,443, respectively ($113,942 and $225,516 for the three and nine months ended September 30, 2017, respectively).

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 three and nine months ended September 30, 2018, expenses related to the Agreement amounted to $25,000 and $50,000.

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 nine months ended September 30, 2018 amounted to approximately $42,000 and $127,000, respectively (approximately $38,000 and $115,000 for the three and nine months ended September 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 - $42,000
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, expired 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 $19,000, $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 $17,000 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 nine months ended September 30, 2018, the Company incurred expenses relating to these contracts in the approximate amount of $3,135,000 and $7,155,000, respectively. There were no expenses incurred relating to the MRTP Application for the three and nine months ended September 30, 2017. Future financial commitments under these contracts are estimated to amount to approximately an additional $4,000,000 and are expected to be completed over the next three to six 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 judgement, with such decision (i) granting the Company's motion for summary judgement relating to Count II of the Amended Compliant, 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 judgement on the remaining Counts of the Amended Compliant. 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 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 filed its partial summary judgment motion on August 20, 2018, after which Crede filed its response on September 27, 2018, after which the Company filed its reply to Crede's response on October 11, 2018. The Company is now awaiting the decision by the SDNY Court on the Company's motion for partial summary judgment to substantially limit the various damage claims by Crede.

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. - INCOME (LOSS) PER COMMON SHARE

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

	September 30, 2018	September 30, 2017
Net income (loss) attributed to common shareholders	$6,304,654	$(3,316,634)
Denominator for basic earnings (loss) per share-weighted average shares outstanding	124,376,061	100,673,834
Effect of dilutive securities:		
Warrants and options outstanding	20,006,418	-
Denominator for diluted earnings (loss) per common share-weighted average shares adjusted for dilutive securities	144,382,479	100,673,834
Net income (loss) per common share - basic	$0.05	$(0.03)
Net income (loss) per common share - diluted	$0.04	$(0.03)

The following table sets forth the computation of basic and diluted income (loss) per common share for the nine-month periods ended September 30, 2018 and 2017, respectively:

	September 30, 2018	September 30, 2017
Net income (loss) attributed to common shareholders	$952,490	$(9,293,535)
Denominator for basic earnings (loss) per share-weighted average shares outstanding	124,237,003	94,369,953
Effect of dilutive securities:		
Warrants and options outstanding	20,006,418	-
Denominator for diluted earnings (loss) per common share-weighted average shares adjusted for dilutive securities	144,243,421	94,369,953
Net income (loss) per common share - basic	$0.01	$(0.10)
Net income (loss) per common share - diluted	$0.01	$(0.10)

24

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

	September 30, 2018	September 30, 2017
Warrants	11,293,211	12,204,580
Options	8,713,207	6,856,691
	20,006,418	19,061,271

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 September 30, 2018, the Company had available 1,802,115 shares remaining for future awards under the OIP.

During the three and nine months ended September 30, 2018, the Company issued stock option awards from the OIP for 0 and 1,431,841 shares, respectively, 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 are scheduled to vest upon the attainment of various milestones. During the three and nine months ended September 30, 2017, the Company issued stock option awards from the OIP for 20,000 and 1,392,000 shares, respectively, 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 nine months ended September 30, 2018, the Company recorded compensation expense related to stock option awards granted under the OIP of $472,833 and $2,718,937, respectively ($259,415 and $582,398 for the three and nine months ended September 30, 2017, respectively). The compensation expense for the nine months ended September 30, 2018 includes compensation expense in the amount of $1,226,825 recognized in the second quarter of 2018 when 900,000 stock options vested upon of the death of the Company's Senior Vice President of Science and Regulatory Affairs on April 19, 2018.

As of September 30, 2018, unrecognized compensation expense related to non-vested stock options amounted to approximately $3,166,000, which is expected to be recognized as follows: approximately $468,000, $1,110,000, $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 fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were used for the nine months ended September 30, 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		5.14 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
Outstanding at December 31, 2016	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		
Outstanding at December 31, 2017	8,156,691	$ 1.28		
Granted in 2018	1,431,841	$ 2.66		
Exercised in 2018	(371,134)	$ 0.83		
Expired / cancelled in 2018	(504,191)	$ 1.71		
Outstanding at September 30, 2018	8,713,207	$ 1.50	6.0 years	$10,628,107
Exercisable at September 30, 2018	5,310,124	$ 1.33	4.6 years	$7,264,390

The weighted average grant date fair value of options issued during the nine months ended September 30, 2018 and 2017 was $1.80 and $0.98, respectively. The total fair value of options that vested during the nine months ended September 30, 2018 and 2017 amounted to $2,392,207 and $750,265, respectively. There were 371,134 options exercised on a cash and cashless basis during the nine months ended September 30, 2018 resulting in the issuance of 342,089 shares and proceeds of $217,500 to the Company. There were 85,988 options exercised on a cashless basis during the nine months ended September 30, 2017 resulting in the issuance of 51,927 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 cor 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 monetize our intellectual property portfolio; 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. 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 containing 95% less nicotine than conventional tobacco cigarettes and other related claims as may be approved by the FDA; 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™ 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™ tobacco. In the year 2011, 22nd Century developed its SPECTRUM® research cigarettes in collaboration with independent researchers and officials from the FDA, the National Institute on Drug Abuse ("NIDA"), which is part of the National Institutes of Health ("NIH"), the National Cancer Institute ("NCI"), and the Centers for Disease Control and Prevention ("CDC"). Since 2011, we have produced more than 24 million SPECTRUM® research cigarettes containing our proprietary VLN™ tobaccos for use in independent clinical studies sponsored by agencies of the U.S federal government. The main SPECTRUM® product line consists of a series of cigarette styles that vary nicotine yields over a range – from very low (97% less nicotine than tobacco contained in conventional cigarette brands) to relatively high nicotine yields. SPECTRUM® features 24 styles, in both regular and menthol versions, with 8 different levels of nicotine. 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 containing our unique VLN™ tobacco 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™ 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 in the United States involve only work with legal hemp in full compliance with U.S. 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"). Although the 2014 federal Farm Bill legalizing hemp in the U.S. has lapsed, we expect the 2018 Farm Bill to soon extend and broaden the legal status of hemp in the U.S. 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 U.S. federal law. We work only with legal hemp in full compliance with federal and local 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 that state. 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. Information on our website is not incorporated by reference into this Form 10-Q.

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 containing 95% less nicotine than conventional tobacco cigarettes and other related claims as may be approved by the FDA;

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

- Continuing to produce *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 third quarter of 2018, our accomplishments and notable events include:

On July 16, 2018, we submitted our public comments to the FDA's Advance Notice of Proposed Rulemaking ("ANPRM") to develop a proposed new 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 the March 2018 issue of *The New England Journal of Medicine* published a special report by Dr. Benjamin Apelberg, *et al.,* entitled "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States." Apelberg, *et al.* concluded 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. Our ANPRM response further stated that 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.

On July 24, 2018, we announced that an independent clinical study published in JAMA Psychiatry, a specialty journal of the American Medical Association, found that nondaily smokers who switch to 22nd Century's proprietary VLNC cigarettes reduced their smoking by 51%. The Company's proprietary SPECTRUM® VLNC cigarettes and standard nicotine content cigarettes were used in this 12-week, randomized, controlled, double-blind study of 297 adult U.S. nondaily smokers. This was the first published clinical study to focus on occasional, intermittent smokers, which comprise 25% to 33% of all U.S. smokers. The results of this study show that intermittent smokers assigned to VLNC cigarettes reduced both the overall number of cigarettes smoked and the number of days on which they smoked. The researchers reported that their study results did not vary by sex or race/ethnicity and since intermittent smokers responded to VLNC cigarettes in a manner similar to daily smokers, study researchers concluding that a universal nicotine reduction policy by the FDA is possible.

On July 31, 2018, we announced that *The Washington Examiner* newspaper published an op-ed article by James Vail, Director of Communications, and Juan Sanchez Tamburrino, Ph.D. Vice President of Research and Development, at 22nd Century. The article calls for the U.S. Congress, tobacco control advocates, and the American people to ensure that the FDA's nicotine reduction plan quickly becomes reality. The article cites the many completed clinical studies using VLNC cigarettes and summarizes the important results from these clinical studies, including that independent scientists have found that VLNC cigarettes reduce cravings, reduce consumption of cigarettes, and increase quit attempts. In addition, the benefits of VLNC cigarettes appear to extend to adolescents, nondaily smokers, and vulnerable population groups, including people with psychiatric disorders and opioid dependence. The article also cited independent clinical studies that confirm that "compensation" (smoking a greater number of cigarettes to obtain the level of nicotine desired by the smoker) does not occur with VLNC cigarettes.

On August 8, 2018, Aurora Cannabis, Inc. acquired 100% of the outstanding shares of common stock of Anandia Laboratories, Inc., including the 14.8% equity stake in Anandia owned by 22nd Century. In the closing of this transaction, Aurora issued to us a total of 1,947,943 shares of Aurora common stock and a currently exercisable warrant with a five-year term to purchase 973,971 shares of Aurora common stock at an exercise price equal to $9.37 per share (Canadian Dollars; approximately $7.26 per share U.S. Dollars at September 30, 2018). During the third quarter of 2018, we sold the 1,947,943 shares of Aurora common stock for total net cash proceeds of more than $13 million. We realized a tax basis gain of more than 800% on the sale of such shares of Aurora common stock since we originally acquired our equity ownership in Anandia for approximately $1.4 million in cash and common stock of 22nd Century. At this date we retain ownership of the warrant to purchase 973,971 shares of Aurora common stock.

We also retain rights to research and intellectual property developed through our collaboration with Anandia. Furthermore, we also retain rights to an exclusive sublicense in the United States and a co-exclusive sublicense in the remainder of the world, excluding Canada, to patents and patent applications that enable us to regulate the genes in the cannabis plant that produce cannabinoids. We also retain rights to our Zero-THC hemp plants and other important plant lines developed with Anandia. We are in discussions with Ananda to extend our research agreement.

On August 21, 2018, we announced that RTI International had submitted an order to 22nd Century for 3.6 million SPECTRUM® research cigarettes for use in further independent clinical studies funded by NIDA, NIH, FDA and other U.S. federal government agencies. Since the year 2011, we have produced and delivered more than 24 million SPECTRUM® research cigarettes containing our proprietary VLN™ tobaccos in addition to the most recent order of 3.6 million SPECTRUM® research cigarettes by RTI.

On September 5, 2018, we announced that the Journal of the American Medical Association (JAMA) published results of an independent clinical study investigating the effects of an immediate reduction in nicotine content of cigarettes versus a gradual reduction in nicotine content of cigarettes. In this randomized, parallel, double-blind clinical study, which is the largest clinical study using VLNC cigarettes conducted to date, lead researcher, Dr.

Dorothy Hatsukami, and other independent scientists, assigned the 1,250 participants to one of three groups: (1) smokers who were provided only with cigarettes containing VLNC tobacco with 0.4 mg of nicotine per gram of tobacco, (2) smokers who were provided with cigarettes with a gradual reduction of nicotine from 15.5 mg to 0.4 mg of nicotine per gram of tobacco, and (3) smokers who were provided with cigarettes containing a conventional nicotine level with 15.5 mg of nicotine per gram of tobacco. The results of this study showed that an immediate reduction in nicotine was superior to a gradual nicotine reduction, with an immediate nicotine reduction being associated with (i) lower toxicant exposure across time, (ii) fewer cigarettes smoked per day, (iii) greater reduction in nicotine dependence and (iv) more days in which participants smoked no cigarettes (cigarette-free days). In contrast, results from the study participants who were assigned to a gradual reduction in nicotine were nearly indistinguishable from the results of those assigned to cigarettes with a conventional level of nicotine in the areas of dependence, number of cigarette-free days, cigarettes smoked per day, and most of the biomarkers of nicotine and tobacco smoke exposure. In a companion article published by the University of Minnesota, Dr. Hatsukami, explained that the results of this study support “the benefits of rapidly reducing nicotine in all cigarettes, primarily because this approach helped smokers, who initially had no immediate intentions to quit, experience smoke-free days. This is good news because the majority of smokers want to quit smoking, but only a small percentage of smokers are successful.”

30

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

On October 12, 2018, we announced that on October 11, 2018, Dr. Lynn Hull, Lead Pharmacologist at the FDA's Center for Tobacco Products, held a public webcast summarizing the published science supporting the FDA's proposed new rule to require all cigarettes sold in the United States to contain only minimally or non-addictive levels of nicotine. Entitled "Science to Inform a Tobacco Product Standard for the Level of Nicotine in Combusted Cigarettes," Dr. Hull's presentation featured prominently many independent clinical trials conducted with 22nd Century's Very Low Nicotine Content (VLNC) SPECTRUM® research cigarettes. Dr. Hull contrasted VLNC cigarettes with so-called "light" cigarettes by clarifying that VLNC cigarettes contain minimally or non-addictive levels of nicotine as compared to traditional "light" cigarettes that contain just as much nicotine as traditional cigarettes. In discussing "light" cigarettes, Dr. Hull remarked: "They are designed to appear 'light' to the user, but can deliver as much nicotine as traditional cigarettes. These products have no benefit to public health." In contrast to the highly addictive tobacco cigarettes marketed by Big Tobacco companies, 22nd Century's proprietary VLN™ tobacco and technology make possible tobacco cigarettes with a nicotine content of just 0.4mg/g, which is more than 95% less nicotine than conventional cigarettes (conventional cigarettes contain approximately 20 mg nicotine per gram of tobacco).

Dr. Hull concluded her webcast by stating that it is FDA's belief that rendering cigarettes minimally addictive by reducing their nicotine content could help current users quit and prevent future users from becoming addicted and escalating to regular use.

Three Months Ended September 30, 2018 Compared to Three Months Ended September 30, 2017

Revenue - Sale of products, net

In the three months ended September 30, 2018, we realized net sales revenue from the sale of products in the amount of $6,260,158, an increase of $1,729,293, or 38.2%, from net sales revenue of $4,530,865 for the three months ended September 30, 2017. The increase in net sales revenue for the third quarter of 2018 was primarily the result of additional net sales revenue generated from our contract manufacturing business as compared to net sales revenue for the third quarter of 2017.

Cost of goods sold - Products / Gross profit (loss)

During the three months ended September 30, 2018, cost of goods sold were $6,109,209, or 97.6%, of net sales revenue, resulting in gross profit on sales of products in the amount of $150,949. During the three months ended September 30, 2017, cost of goods sold were $4,871,234, or 107.5%, of net sales revenue, resulting in a gross loss on sales of products in the amount of $340,369. The $491,318 improvement from a gross loss in the third quarter of 2017 to a gross profit in the third quarter of 2018 is primarily the result of increased factory utilization.

Research and development expense

Research and development ("R&D") expense was $4,009,808 in the three months ended September 30, 2018, an increase of $3,225,221, or 411.1%, from $784,587 in the three months ended September 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 $3,088,000, an increase in equity-based compensation of approximately $114,000, an increase in payroll and related benefits of approximately $82,000, an increase in costs related to our laboratory operations of approximately $116,000, an increase in consulting fees of approximately $19,000, and an increase in travel related expenses of approximately $18,000, partially offset by a decrease in sponsored research costs of approximately $137,000, and a decrease in patent maintenance cost of approximately $85,000.

General and administrative expense

General and administrative expense was $1,759,254 in the three months ended September 30, 2018, an increase of $124,028, or 7.6%, from $1,635,226 in the three months ended September 30, 2017. The increase was mainly due to an increase in payroll and related benefits of approximately $111,000, an increase in equity-based compensation of approximately $92,000, an increase in legal and accounting fees of approximately $110,000, an increase in business insurance costs of approximately $17,000, and an increase in Board of Director related expenses of approximately $36,000, partially offset by a decrease in expenses relating to investor relations of approximately $168,000, a decrease in other professional services of approximately $60,000, and a net decrease in various other general and administrative expenses of approximately $14,000.

Sales and marketing expense

During the three months ended September 30, 2018, we incurred sales and marketing expenses of $238,704, a decrease of $40,550, or 14.5%, from $279,254 in the three months ended September 30, 2017. The decrease in sales and marketing expenses was primarily the result of a decrease in payroll and related benefit costs of approximately $47,000, and a decrease in travel related expenses of approximately $8,000, partially offset by an increase in equity-based compensation of approximately $8,000, and a net increase in other sales and marketing costs approximately $6,000.

Depreciation expense

Depreciation expense for the three months ended September 30, 2018 amounted to $132,846, an increase of $44,135, or 49.8%, from $88,711 for the three months ended September 30, 2017. The increase was primarily due to depreciable acquisitions of machinery and equipment during the year ended December 31, 2017 and the nine months ended September 30, 2018 in the aggregate amount of approximately $1,614,000, 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.

Amortization expense

Amortization expense for the three months ended September 30, 2018 amounted to $219,171, an increase of $73,237, or 50.2%, from $145,934 for the three months ended September 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 nine months ended September 30, 2018 and the year ended December 31, 2017 of approximately $613,000 and $582,000, respectively, and amortization of approximately $16,000 on the cost of a new license with NCSU that began in the third quarter of 2018.

Warrant liability loss, net

During July of 2018, the remaining 94,721 stock warrants containing the anti-dilutive features that created the warrant liability were exercised on a cashless basis. Accordingly, there was no warrant liability gain (loss) for the third quarter of 2018 and there will be no warrant liability gain (loss) in future periods unless we issue securities containing anti-dilution features.

The warrant liability loss of $55,886 for the third 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 $1.75 per share at June 30, 2017 as compared to $2.77 per share at September 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 $6,272 for the three months ended September 30, 2018, was a loss resulting from the maturity of various debt instruments held in the short-term investment account.

Realized gain on investments

We held a 14.8% equity investment in Anandia Laboratories, Inc., a Canadian plant biotechnology company (“Anandia”). On August 8, 2018, all of Anandia’s outstanding common stock was acquired by Aurora Cannabis, Inc. (“Aurora”), a Canadian company (TSX: ACB.TO), in exchange for (i) free trading shares of Aurora common stock, 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. As a result of the transaction, we received 1,947,943 shares of Aurora common stock and warrants to purchase 973,971 shares of Aurora common stock that had a fair value of $9,221,594 and $2,807,958, respectively. The Company recorded a realized gain on the transaction in the amount of $4,515,971 during the three months ended September 30, 2018. Subsequent to the transaction, we sold all of our Aurora common stock resulting in net sales proceeds $13,051,503 and realized a gain on the sale of $3,829,909. The aggregate realized gains from the Anandia transaction and the sale of the Aurora shares amount to $8,345,880 for the three months ended September 30, 2018.

Unrealized gain on investment

The warrants to purchase 973,971 shares of Aurora common stock, described above and in Note 6 to our consolidated financial statements, are considered an equity security, and are recorded at fair value. The Company recorded the fair value of the stock warrants of $6,731,114 at September 30, 2018, using the Black-Scholes pricing model, and recorded an unrealized gain on the warrants in the amount of $3,923,156 for the three months ended September 30, 2018.

Interest income, net

Interest income, net for the three months ended September 30, 2018, was $255,155, an increase of $234,838 from interest income of $20,317 for the three months ended September 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 September 30, 2017 was the result of interest income generated from excess cash invested in a money market account.

Interest expense

Interest expense was $4,431 and $6,984 for the three months ended September 30, 2018 and 2017, respectively. The interest expense for the three months ended September 30, 2018 was derived from the accretion of interest on a note payable to NCSU. Interest expense for the three months ended September 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 income (loss)

We had net income for the three months ended September 30, 2018 of $6,304,654 as compared to a net loss of $3,316,634 in the three months ended September 30, 2017. The change from a net loss for the three months ended September 30, 2017 to net income for the three months ended September 30, 2018 amounted to an increase of $9,621,288, or 290.1%, and was primarily the result of an increase in a realized gain on investments of approximately $8,346,000 in connection with the Anandia transaction and the sale of Aurora shares, an increase in an unrealized gain on investment of approximately 3,923,000, an increase in interest income, net of approximately $235,000, an increase in gross profit on product sales of approximately $491,000, and an increase in various other income (expenses) of approximately $52,000, partially offset by an increase in operating expenses of approximately $3,426,000. The

increase in operating expenses of $3,426,000 was primarily the result of an increase in expenses relating to our MRTP application with the FDA for our VLNC cigarettes of approximately $3,088,000.

Other comprehensive income – unrealized gain 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 gain on short-term investment securities for the three months ended September 30, 2018 in the amount of $39,658.

Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2017

Revenue - Sale of products, net

In the nine months ended September 30, 2018, we realized net sales revenue from the sale of products in the amount of $19,291,110, an increase of $8,631,522, or 80.0%, from net sales revenue of $10,659,588 for the nine months ended September 30, 2017. The increase in net sales revenue for the nine months ended September 30, 2018 was primarily the result of additional net sales revenue generated from our contract manufacturing business as compared to net sales revenue for the nine months ended September 30, 2017.

Cost of goods sold – Products / Gross profit (loss)

During the nine months ended September 30, 2018, cost of goods sold were $18,906,869, or 98.0%, of net sales revenue, resulting in gross profit on sales of products in the amount of $384,241. During the nine months ended September 30, 2017, cost of goods sold were $11,438,909, or 107.3%, of net sales revenue, resulting in a gross loss on sales of products in the amount of $779,321. The $1,163,562 improvement from a gross loss for the nine months ended September 30, 2017 to a gross profit for the nine months ended September 30, 2018 is primarily the result of increased factory utilization.

Research and development expense

Research and development ("R&D") expense was $11,307,984 in the nine months ended September 30, 2018, an increase of $9,159,259, or 426.3%, from $2,148,725 in the nine months ended September 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 $6,909,000, an increase in equity-based compensation of approximately $1,646,000, an increase in payroll and related benefits of approximately $368,000, an increase in costs related to our laboratory operations of approximately $308,000, an increase in consulting fees of approximately $57,000, and an increase in travel related expenses of approximately $48,000, partially offset by a decrease in license and royalty fees of approximately $60,000, a decrease in sponsored research costs of approximately $59,000, and a decrease in patent maintenance costs of approximately $65,000.

General and administrative expense

General and administrative expense was $5,706,617 in the nine months ended September 30, 2018, an increase of $645,794, or 12.8%, from $5,060,823 in the nine months ended September 30, 2017. The increase was mainly due to an increase in payroll and related benefits of approximately $376,000, an increase in equity-based compensation of approximately $457,000, an increase in annual SEC and NYSE American compliance costs of approximately $71,000, an increase in legal and accounting expenses of approximately $312,000, an increase in Board of Director related expenses of approximately $36,000, an increase in business insurance of approximately $38,000, and a net increase in various other general and administrative expenses of approximately $98,000, partially offset by a decrease in expenses relating to investor relations of approximately $639,000, and a decrease in consulting fees of approximately $103,000.

Sales and marketing expense

During the nine months ended September 30, 2018, we incurred sales and marketing expenses of $641,442, a decrease of $201,116, or 23.9%, from $842,558 in the nine months ended September 30, 2017. The decrease in sales and marketing expenses was primarily the result of a decrease in payroll and related benefit costs of approximately $201,000, a decrease in advertising and promotional costs of approximately $23,000, and a decrease in travel related expenses of approximately $26,000, partially offset by an increase in equity-based compensation of approximately $33,000, and an increase in costs related to industry trade shows of approximately 18,000.

Depreciation expense

Depreciation expense for the nine months ended September 30, 2018 amounted to $388,668, an increase of $123,372, or 46.5%, from $265,296 for the nine months ended September 30, 2017. The increase was primarily due to depreciable acquisitions of machinery and equipment during the year ended December 31, 2017 and the nine months ended September 30, 2018 in the approximate amount of $1,614,000, 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.

Amortization expense

Amortization expense for the nine months ended September 30, 2018 amounted to $557,648, an increase of $127,816, or 29.7%, from $429,832 for the nine months ended September 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 nine months ended September 30, 2018 and the year ended December 31, 2017 of approximately $613,000 and $582,000, respectively, and amortization of approximately $16,000 on the cost of a new license with NCSU that began in the third quarter of 2018.

Warrant liability gain (loss), net

The warrant liability gain of $48,711 for the nine months ended September 30, 2018 was due to a decrease in the estimated fair value of the warrants during the first quarter of 2018. 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. There was no material change in the fair value of our stock warrants during the second quarter of 2018 and during July of 2018, the remaining 94,721 stock warrants containing the anti-dilutive features that created the warrant liability were exercised on a cashless basis. Accordingly, there was no warrant liability gain (loss) recorded for the second or third quarters of 2018 and there will be no warrant liability gain (loss) in future periods unless we issue securities with anti-dilution features.

The warrant liability loss of $138,813 for the nine months ended September 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 our underlying stock price from $1.09 per share at December 31, 2016 as compared to $2.77 per share at September 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 $48,461 for the nine months ended September 30, 2018, was a loss resulting from the maturity of various debt instruments held in the short-term investment account.

Realized gain on investments

We held a 14.8% equity investment in Anandia. On August 8, 2018, all of Anandia's outstanding common stock was acquired by Aurora (TSX: ACB.TO), in exchange for (i) free trading shares of Aurora common stock, 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. As a result of the transaction, we received 1,947,943 shares of Aurora common stock and warrants to purchase 973,971 shares of Aurora common stock that had a fair value of $9,221,594 and $2,807,958, respectively. The Company recorded a realized gain on the transaction in the amount of $4,515,971 during the three months ended September 30, 2018. Subsequent to the transaction, we sold all our Aurora common stock resulting in net sales proceeds $13,051,503 and realized a gain on the sale of $3,829,909. The aggregate realized gains from the Anandia transaction and the sale of the Aurora shares amount to $8,345,880 for the nine months ended September 30, 2018.

Unrealized gain on investments

The warrants to purchase 973,971 shares of Aurora common stock, described above and in Note 6 to our consolidated financial statements, are considered an equity security, and are recorded at fair value. The Company recorded the fair value of the stock warrants of $6,731,114 at September 30, 2018, using the Black-Scholes pricing model, and recorded an unrealized gain on the warrants in the amount of $3,923,156 for the nine months ended September 30, 2018.

In addition, 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 changed 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.

The aggregate unrealized gain for the two transactions discussed above amounted to $10,070,244 for the nine months ended September 30, 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 nine months ended September 30, 2017.

Interest income, net

Interest income, net for the nine months ended September 30, 2018 was $758,665, an increase of $710,468 from interest income of $48,197 for the nine months ended September 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 nine months ended September 30, 2017 was the result of interest income generated from excess cash invested in a money market account.

Interest expense

Interest expense was $4,431 and $22,544 for the nine months ended September 30, 2018 and 2017, respectively. The interest expense for the nine months ended September 30, 2018 was derived from interest accreted on a note payable to NCSU. Interest expense for the nine months ended September 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 income (loss)

We had net income for the nine months ended September 30, 2018 of $952,490 as compared to a net loss of $9,293,535 in the nine months ended September 30, 2017. The change from a net loss for the nine months ended September 30, 2017 to net income for the nine months ended September 30, 2018 amounted to an increase of $10,246,025, and was primarily the result of an increase in a realized gain on investments of approximately $8,346,000 in connection with the Anandia transaction and the sale of Aurora shares, an increase in unrealized gains on investments of approximately $9,724,000 an increase in interest income, net of approximately $710,000, an increase in gross profit on product sales of approximately $1,164,000, and an increase in various other income (expenses) of approximately $157,000, partially offset by an increase in operating expenses of approximately $9,855,000. The increase in operating expenses of $9,855,000 was primarily the result of an increase in expenses relating to our MRTP application with the FDA for our VLNC cigarettes of approximately $6,909,000, and an increase in R&D equity-based compensation of approximately $1,646,000.

Other comprehensive income – unrealized gain 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 gain on short-term investment securities for the nine months ended September 30, 2018 in the amount of $11,474.

Liquidity and Capital Resources

Working Capital

As of September 30, 2018, we had working capital of approximately $61.0 million compared to working capital of approximately $63.3 million at December 31, 2017, a decrease of approximately $2.3 million. This decrease in working capital was primarily due to an increase in net current liabilities of approximately $2.3 million. Net current assets were essentially unchanged, amounting to approximately $67.6 million at both September 30, 2018 and December 31, 2017. Cash, cash equivalents and short-term investment securities decreased by approximately $0.5 million and the remaining net current assets increased by a similar amount. We used approximately $12.6 million in operating activities during the nine months ended September 30, 2018, however, we were able to maintain a cash, cash equivalent, and short-term investment balance of approximately $62.1 million as a result of approximately $13.1 million in net cash proceeds from our sale of the common stock of Aurora.

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 September 30, 2018 of $62,121,323. 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 nine months ended September 30, 2018, we experienced an operating loss of approximately $18,218,000 (including approximately $7,155,000 in expenses relating to our MRTP application) and used cash in operations of approximately $12,562,000. 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 $4,000,000 in expenses relating to our MRTP application over approximately the next three to six months.

Net cash used in operating activities

In the nine months ended September 30, 2018, $12,561,619 of cash was used in operating activities as compared to $9,620,986 of cash used in operating activities in the nine months ended September 30, 2017, an increase of $2,940,633. 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 $5,713,368, offset by a decrease in the use of cash used for working capital components related to operations in the amount of $2,772,735 for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017.

Net cash provided by (used in) investing activities

In the nine months ended September 30, 2018, net cash provided by investing activities was $9,943,795, as compared to $1,204,990 of cash used in investing activities during the nine months ended September 30, 2017, an increase in net cash provided by investing activities of $11,148,785. The increase was primarily the result of an increase in net cash provided from our sale of the common stock of Aurora Cannabis Inc. in the amount of $13,051,503, and a net decrease in cash used for the acquisition of patents and trademarks and in the acquisition of machinery and equipment in the aggregate amount of $520,868, partially offset by net cash used in transactions relating to our short-term investment account in the amount of $2,423,586.

Net cash (used in) provided by financing activities

During the nine months ended September 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 nine months ended September 30, 2017, $12,380,358 of cash was provided by financing activities as 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 nine months ended September 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 third 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 judgement, with such decision (i) granting the Company's motion for summary judgement relating to Count II of the Amended Compliant, 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 judgement on the remaining Counts of the Amended Compliant. 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 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 filed its partial summary judgment motion on August 20, 2018, after which Crede filed its response on September 27, 2018, after which the Company filed its reply to Crede's response on October 11, 2018. The Company is now awaiting the decision by the SDNY Court on the Company's motion for partial summary judgment to substantially limit the various damage claims by Crede.

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.

None

Item 3. Default Upon Senior Securities.

None

Item 4. Mine Safety Disclosures

None

Item 5. Other Information

None

Item 6. Exhibits

Exhibit 31.1	Section 302 Certification - Chief Executive Officer

Exhibit 31.2	Section 302 Certification - Chief Financial Officer
Exhibit 32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive data files formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, and (iv) the Notes to the Consolidated Financial Statements.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

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

22nd CENTURY GROUP, INC.

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

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