

UNITED STATES
SECURITIES AND EXCHANGE
COMMISSION WASHINGTON, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2019

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
(State or other jurisdiction
of incorporation)

98-0468420
(IRS Employer
Identification No.)

8560 Main Street, Suite 4, 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 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 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

Securities registered under Section 12(b) of the Act:

Title of each class	Ticker symbol	Name of Exchange on Which Registered
Common Stock, \$0.00001 par value	XXII	NYSE American

As of May 7, 2019, there were 124,660,000 shares of common stock issued and outstanding.

22nd CENTURY GROUP, INC.

INDEX

	Page Number
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
Consolidated Balance Sheets as of March 31, 2019 (unaudited) and December 31, 2018	3
Consolidated Statements of Operations and Comprehensive (Loss) Income for the Three Months Ended March 31, 2019 and 2018 (unaudited)	4
Consolidated Statements of Changes in Shareholders' Equity for the Three Months Ended March 31, 2019 and 2018 (unaudited)	5
Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2019 and 2018 (unaudited)	6
Notes to Consolidated Financial Statements (unaudited)	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	30
Item 3. Quantitative and Qualitative Disclosures About Market Risk	39
Item 4. Controls and Procedures	40
PART II. OTHER INFORMATION	41
Item 1. Legal Proceedings	41
Item 1A. Risk Factors	44
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	44
Item 3. Default Upon Senior Securities	44
Item 4. Mine Safety Disclosures	44
Item 5. Other Information	44
Item 6. Exhibits	44
SIGNATURES	45

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
March 31, 2019 with Comparative Figures at December 31, 2018

	March 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 588,960	\$ 604,925
Short-term investment securities	51,263,895	55,748,939
Accounts receivable, net	1,474,876	871,293
Inventory, net	3,334,395	3,043,949
Prepaid expenses and other assets	885,815	928,420
Total current assets	57,547,941	61,197,526
Property, plant and equipment:		
Machinery and equipment, net	3,333,051	3,260,748
Operating leases right-of-use assets, net	759,596	-
	<u>4,092,647</u>	<u>3,260,748</u>
Other assets:		
Intangible assets, net	9,722,900	9,751,504
Investment	6,065,891	3,092,358
Total other assets	15,788,791	12,843,862
Total assets	\$ 77,429,379	\$ 77,302,136
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 698,048	\$ 689,148
Operating lease obligations	211,519	-
Accounts payable	3,330,245	2,574,840
Accrued expenses	1,697,960	1,826,481
Deferred income	274,066	83,075
Total current liabilities	6,211,838	5,173,544
Long-term liabilities:		
Notes payable	849,977	848,217
Operating lease obligations	548,077	-
Total liabilities	7,609,892	6,021,761
Commitments and contingencies (Note 8)	-	-
Shareholders' equity		
10,000,000 preferred shares, \$.00001 par value		
300,000,000 common shares, \$.00001 par value		
Capital stock issued and outstanding:		
124,660,000 common shares (124,642,593 at December 31, 2018)	1,247	1,246
Capital in excess of par value	170,841,153	170,392,249
Accumulated other comprehensive income	184,283	21,363
Accumulated deficit	(101,207,196)	(99,134,483)
Total shareholders' equity	69,819,487	71,280,375
Total liabilities and shareholders' equity	\$ 77,429,379	\$ 77,302,136

See accompanying notes to consolidated financial statements.

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

	<u>2019</u>	<u>2018</u>
Revenue:		
Sale of products, net	\$ 6,293,648	\$ 6,116,039
Cost of goods sold (exclusive of depreciation shown separately below):		
Products	6,396,558	6,044,461
Gross (loss) profit	(102,910)	71,578
Operating expenses:		
Research and development (including equity-based compensation of \$99,669 and \$220,413, respectively)	2,451,442	2,516,769
General and administrative (including equity-based compensation of \$299,530 and \$307,488 respectively)	2,242,502	2,032,392
Sales and marketing (including equity-based compensation of \$49,706 and \$35,975, respectively)	231,699	199,109
Depreciation	135,047	124,528
Amortization	215,559	167,552
	<u>5,276,249</u>	<u>5,040,350</u>
Operating loss	(5,379,159)	(4,968,772)
Other income (expense):		
Unrealized gain on investment	2,973,533	6,147,088
Realized (loss) gain on short-term investment securities	(16,021)	195
Unrealized loss on short-term investment securities	-	(92,574)
Gain on the sale of machinery and equipment	87,351	-
Warrant liability gain - net	-	48,711
Interest income, net	272,243	251,840
Interest expense	(10,660)	-
	<u>3,306,446</u>	<u>6,355,260</u>
(Loss) income before income taxes	(2,072,713)	1,386,488
Income taxes	-	-
Net (loss) income	<u>\$ (2,072,713)</u>	<u>\$ 1,386,488</u>
Other comprehensive income:		
Unrealized gain on short-term investment securities	146,899	-
Reclassification of losses to net loss	16,021	-
	<u>162,920</u>	<u>-</u>
Comprehensive (loss) income	<u>\$ (1,909,793)</u>	<u>\$ 1,386,488</u>
Net (loss) income per common share - basic	<u>\$ (0.02)</u>	<u>\$ 0.01</u>
Net (loss) income per common share - diluted	<u>\$ (0.02)</u>	<u>\$ 0.01</u>
Common shares used in basic earnings per share calculation	<u>124,644,721</u>	<u>124,019,946</u>
Common shares used in diluted earnings per share calculation	<u>124,644,721</u>	<u>144,164,438</u>

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Three Months Ended March 31, 2019 and 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, 2018	124,642,593	\$ 1,246	170,392,249	21,363	(99,134,483)	\$ 71,280,375
Stock issued in connection with option exercises	17,407	1	(1)	-	-	-
Equity-based compensation	-	-	448,905	-	-	448,905
Unrealized gain on short-term investment securities	-	-	-	146,899	-	146,899
Reclassification of losses to net loss	-	-	-	16,021	-	16,021
Net loss	-	-	-	-	(2,072,713)	(2,072,713)
Balance at March 31, 2019	124,660,000	\$ 1,247	\$ 170,841,153	\$ 184,283	\$ (101,207,196)	\$ 69,819,487
	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	426,180	4	(4)	-	-	-
Stock issued in connection with option exercises	315,540	3	217,497	-	-	217,500
Equity-based compensation	-	-	563,876	-	-	563,876
Net income	-	-	-	-	1,386,488	1,386,488
Balance at March 31, 2018	124,311,087	\$ 1,243	\$ 167,373,905	\$ -	\$ (89,781,084)	\$ 77,594,064

See accompanying notes to consolidated financial statements.

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

	2019	2018
Cash flows from operating activities:		
Net (loss) income	\$ (2,072,713)	\$ 1,386,488
Adjustments to reconcile net income (loss) to cash used in operating activities:		
Amortization and depreciation	291,059	267,575
Amortization of license fees	59,547	24,506
Lease expense	54,679	-
Unrealized gain on investment	(2,973,533)	(6,147,088)
Unrealized loss on short-term investment securities	-	92,574
Realized loss (gain) on short-term investment securities	16,021	(195)
Gain on the sale of machinery and equipment	(87,351)	-
Warrant liability gain - net	-	(48,711)
Accretion of interest on notes payable	10,660	-
Equity based compensation expense	448,905	563,876
(Increase) decrease in assets:		
Accounts receivable	(603,583)	280,836
Inventory	(290,446)	120,305
Prepaid expenses and other assets	42,605	(306,772)
Increase (decrease) in liabilities:		
Operating lease obligations	(54,679)	-
Accounts payable	414,569	989,360
Accrued expenses	(128,521)	(338,282)
Deferred income	190,991	(28,350)
Net cash used in operating activities	(4,681,790)	(3,143,878)
Cash flows from investing activities:		
Acquisition of patents and trademarks	(7,041)	(28,751)
Acquisition of machinery and equipment	(125,227)	(177,385)
Proceeds from the sale of machinery and equipment	166,150	-
Sales and maturities of short-term investment securities	8,405,829	41,937,515
Purchase of short-term investment securities	(3,773,886)	(36,919,291)
Net cash provided by investing activities	4,665,825	4,812,088
Cash flows from financing activities:		
Proceeds from exercise of stock options	-	217,500
Net cash provided by financing activities	-	217,500
Net (decrease) increase in cash and cash equivalents	(15,965)	1,885,710
Cash and cash equivalents - beginning of period	604,925	3,659,534
Cash and cash equivalents- end of period	\$ 588,960	\$ 5,545,244
Supplemental disclosures of cash flow information:		
Net cash paid for:		
Cash paid during the period for interest	\$ -	\$ -
Cash paid during the period for income taxes	\$ -	\$ -
Non-cash transactions:		
Patent and trademark additions included in accounts payable	\$ 179,913	\$ 180,070
Machinery and equipment additions included in accounts payable	\$ 160,922	\$ 68,559
Right-of-use assets and corresponding operating lease obligations	\$ 814,275	\$ -

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2019
(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 three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. The balance sheet as of December 31, 2018 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, 2018 audited consolidated financial statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on March 6, 2019.

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. 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 the original investment in Anandia Laboratories, Inc., more fully described in Note 4, and performs research and development related to the Company's hemp business.

Reclassifications - Certain items in the 2018 financial statements have been reclassified to conform to the 2019 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. However, the Company has elected to classify money market mutual funds as short-term investment securities. 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. 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. All of the Company's short-term investment securities are fixed-income debt instruments, and accordingly, all unrealized gains and losses incurred on the short-term investment securities (the adjustment to fair value) are recorded in 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 March 31, 2019 and December 31, 2018.

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 March 31, 2019 and December 31, 2018 consisted of the following:

	March 31, 2019	December 31, 2018
Inventory - tobacco leaf	\$ 1,688,619	\$ 1,556,581
Inventory - finished goods		
Cigarettes and filtered cigars	182,564	156,702
Inventory - raw materials		
Cigarette and filtered cigar components	<u>1,563,212</u>	<u>1,430,666</u>
	3,434,395	3,143,949
Less: inventory reserve	<u>100,000</u>	<u>100,000</u>
	<u>\$ 3,334,395</u>	<u>\$ 3,043,949</u>

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.

Right-of-use assets - On January 1, 2019, the Company adopted ASU 2016-02, Subtopic ASC 842, Leases, and as a result has recorded Right-to-use assets and corresponding Lease obligations as more fully discussed in Note 3.

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 2019 to 2036. 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 are expected to range from 2019 through 2036. 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 March 31, 2019 and December 31, 2018 consisted of the following:

	March 31, 2019	December 31, 2018
Intangible assets, net		
Patent and trademark costs	\$ 7,323,729	\$ 7,136,774
Less: accumulated amortization	3,350,577	3,194,565
Patent and trademark costs, net	<u>3,973,152</u>	<u>3,942,209</u>
License fees, net (see Note 8)	3,776,426	3,776,426
Less: accumulated amortization	528,678	469,131
License fees, net	<u>3,247,748</u>	<u>3,307,295</u>
MSA signatory costs	2,202,000	2,202,000
License fee for predicate cigarette brand	<u>300,000</u>	<u>300,000</u>
	<u>\$ 9,722,900</u>	<u>\$ 9,751,504</u>

Amortization expense relating to the above intangible assets for the three months ended March 31, 2019 and 2018 amounted to \$215,559 and \$167,552, respectively.

The estimated annual average amortization expense for the next five years is approximately \$460,000 for patent costs and \$238,000 for license fees.

Impairment of Long-Lived Assets - The Company reviews the carrying value of its amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable. The Company assesses recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. There was no impairment loss recorded during the three months ended March 31, 2019 and 2018, 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 losses and credit carry-forwards.

As a result of the Company's history of cumulative net operating losses and the uncertainty of their future utilization, the Company has established a valuation allowance to fully offset its net deferred tax assets as of March 31, 2019 and December 31, 2018. Additionally, because the Company has a full valuation allowance offsetting its deferred tax assets and as a result has an effective tax rate of zero, the Company has elected to present other comprehensive income items relating to net unrealized gains on short-term investment securities gross and not net of taxes.

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 March 31, 2019.

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 or risks of forfeiture expiring.

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 daily and, therefore, there were no performance obligations partially satisfied at March 31, 2019. 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 March 31, 2019 and December 31, 2018.

The Company generally requires a down payment from its customers prior to commencement of manufacturing a 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 months ended March 31, 2019 and 2018, net sales revenue from products transferred over time amounted to approximately \$4,215,000 and \$3,923,000, respectively, and net sales revenue from products transferred at a point in time amounted to approximately \$2,079,000 and \$2,193,000, respectively.

Derivatives - The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. Derivative financial instruments are initially recorded at fair market value and then are revalued at each reporting date, with changes in fair value reported in the Consolidated Statements of Operations and Comprehensive Income (Loss). The classification of derivative instruments are evaluated at the end of each reporting period. Derivative instruments 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 \$5,000 and \$12,000 for the three months ended March 31, 2019 and 2018, respectively.

(Loss) Income 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.

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, investment (stock warrants), accounts payable, accrued expenses, and notes payable. Other than for cash equivalents, short-term investment securities, and investment (stock warrants), fair value is assumed to approximate carrying values for these financial instruments, since they are short term in nature, they are receivable or payable on demand, or had stated interest rates that approximate the interest rates available to the Company as of the reporting date. The determination of the fair value of cash equivalents, short-term investment securities, and investment (stock warrants) are discussed in Note 6.

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 former investment in Anandia Laboratories, Inc. in Canada (see Note 4 for a further discussion).

The Company has an investment in stock warrants that are considered equity securities under ASC 321 – Investments – Equity Securities and a derivative instrument under ASC 815 – Derivatives and Hedging. The stock warrants are not designated as a hedging instrument, and in accordance with ASC 815, the Company's investment in stock warrants are recorded at fair value with changes in fair value recorded in the Company's Consolidated Statements of Operations and Comprehensive Income (Loss).

NOTE 2. - MACHINERY AND EQUIPMENT

Machinery and equipment at March 31, 2019 and December 31, 2018 consisted of the following:

	Useful Life	March 31, 2019	December 31, 2018
Cigarette manufacturing equipment	3 - 10 years	\$ 4,683,035	\$ 4,608,267
Office furniture, fixtures and equipment	5 years	143,062	135,909
Laboratory equipment	5 years	120,768	104,709
Leasehold improvements	6 years	215,446	169,362
		5,162,311	5,018,247
Less: accumulated depreciation		1,829,260	1,757,499
Machinery and equipment, net		\$ 3,333,051	\$ 3,260,748

Depreciation expense was \$135,047 and \$124,528 for the three months ended March 31, 2019 and March 31, 2018, respectively.

NOTE 3. - RIGHT-OF-USE ASSETS, LEASE OBLIGATIONS, AND OTHER LEASES

On January 1, 2019, the Company adopted ASU 2016-02, Subtopic ASC 842, Leases (the "new guidance"). Under the new guidance, the Company was required to evaluate its leases and record a Right-to-use ("ROU") asset and a corresponding Lease obligation for leases that qualified as either finance or operating leases. Prior to the adoption of the new guidance, the Company had various operating leases for real estate. The Company elected to use the practical expedient which allowed the Company to carry forward the historical lease classifications of the existing leases. The Company determined that its leases contained (1) no variable lease expenses, (2) no termination options, (3) no residual lease guarantees, and (4) no material restrictions or covenants. The new guidance calls for the Lease obligations to be recorded at the present value of the remaining lease payments under the leases and the ROU assets are recorded as the sum of the present value of the Lease obligations plus any initial direct costs minus lease incentives plus prepaid lease payments. All remaining renewal options have been included in the computation of the ROU assets and Lease obligations. The present value of the remaining lease payments was computed using a discount rate of 5.14%. The Company determined that two real estate leases qualified as operating leases under the new guidance as discussed below.

The Company leases a manufacturing facility and warehouse located in North Carolina on a triple net lease basis with a monthly lease payment of \$14,094. As of January 1, 2019, the lease had a remaining term of thirty-four (34) months including all renewal options. The lease expense for the three months ended March 31, 2018 amounted to approximately \$42,000. Under the new guidance, the Company recorded a ROU asset and a corresponding Lease obligation in the amount of \$446,950 on January 1, 2019 and recorded a lease expense for the three months ended March 31, 2019 of approximately \$42,000.

On October 4, 2017, the Company entered a lease for office space at a location in Williamsville, New York with an initial monthly lease payment of \$6,375 per month for the first three years of the lease. The monthly lease payment increases by 5% annually for the remainder of the lease. As of January 1, 2019, the lease had a remaining term of sixty-two (62) months including all renewal options. The lease expense for the three months ended March 31, 2018 amounted to \$6,375. Under the new guidance, the Company recorded a ROU asset and a corresponding Lease obligation in the amount of \$367,325 on January 1, 2019 and recorded a Lease expense for the three months ended March 31, 2019 of approximately \$20,000.

As a result of the new guidance, the Company initially recorded ROU assets and Lease obligations in the amount of \$814,275 on January 1, 2019 on the Company's Consolidated Balance Sheets. After amortizing the ROU assets and applying principal payments to the Lease obligations, the ROU assets and the Lease obligations each had a balance of \$759,596 at March 31, 2019, with \$211,519 and \$548,077 of the Lease obligations recorded as current and long-term at March 31, 2019, respectively.

Further, FASB issued ASU 2018-11, Re-Leases Targeted Improvements to ASC 842, to provide entities with relief from the costs of implementing certain aspects of the new guidance. Under ASU 2018-11, entities may elect not to recast comparative periods when transitioning to the new guidance. The Company has adopted ASU 2018-11, and accordingly, will (1) apply ASC 840 Lease Accounting (the “old guidance”) in comparative periods, (2) provide disclosures for all comparative periods presented in accordance with the old guidance, and (3) recognize the effects of applying the new guidance as a cumulative-effects adjustment to retained earnings as of January 1, 2019. No cumulative-effects adjustment was made as the Company determined it to be immaterial.

In addition, the Company has two leases that did not qualify as operating or financing leases under the new guidance as discussed below.

On August 14, 2017, the Company entered into a lease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment, to store the Company’s proprietary tobacco leaf and to store inventory used in the Company’s contract manufacturing business. The lease calls for a monthly payment of \$4,665, expires on August 14, 2019, and contains twelve-month renewal options if the Company continues to lease the warehouse under its current terms.

On May 1, 2016, the Company entered into a sublease for laboratory space in Buffalo, New York. After a series of sublease amendments that increased the subleased laboratory space and monthly sublease payment, the Company on February 21, 2018 entered into a new sublease amendment that further increased the lab space, extended the sublease term through June 30, 2019 and called for a monthly sublease payment of \$5,706 beginning on March 1, 2018. The lease expense for the three months ended March 31, 2019 and 2018 amounted to approximately \$17,000 and 11,000, respectively.

The Company is currently in discussions with the lessors of the above two leases concerning new leases for these facilities. Any new leases that may result from these discussions will be evaluated under the new lease guidance.

NOTE 4. – INVESTMENT

The Company (through its wholly-owned subsidiary, Botanical Genetics) held an equity investment in Anandia Laboratories, Inc. (“Anandia”), a Canadian plant biotechnology company. On August 8, 2018, all of Anandia’s outstanding common stock was acquired by Aurora Cannabis, Inc. (“Aurora”), a Canadian company (TSX: ACB.TO), and as a result the Company received in exchange for its Anandia equity: (i) 1,947,943 free trading shares of Aurora common stock, and (ii) a stock warrant to purchase 973,971 shares of Aurora common stock. The Company sold all the shares of Aurora common stock during the third quarter of 2018, but still retains ownership of the stock warrant to purchase 973,971 shares of Aurora common stock as of March 31, 2019. The stock warrant has a five-year contractual term, an exercise price of \$9.37 per share (Canadian Dollars; approximately \$7.01 per share U.S. Dollars at March 31, 2019), is currently exercisable, is considered an equity security, and is recorded at fair value (Level 3 of the valuation hierarchy). The Company recorded the fair value of the Aurora common stock warrant of \$6,065,891 and \$3,092,358 at March 31, 2019 and December 31, 2018, respectively, using the Black-Scholes pricing model and was classified within Other assets on the Company’s Consolidated Balance Sheets. The Company recorded an unrealized gain, the adjustment to fair value, in the amount of \$2,973,533 for the three months ended March 31, 2019.

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 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, 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, an equity issuance in January of 2018 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.

NOTE 5. – FAIR VALUE MEASUREMENTS AND SHORT-TERM INVESTMENTS

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 March 31, 2019 and December 31, 2018, 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 March 31, 2019			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets				
Short-term investment securities:				
Money market funds	\$ 13,838,984	\$ -	\$ -	\$ 13,838,984
Corporate bonds	-	31,308,838	-	31,308,838
U.S. treasury securities	-	1,982,187	-	1,982,187
U.S. government agency bonds	-	4,133,886	-	4,133,886
Total short-term investment securities	<u>\$ 13,838,984</u>	<u>\$ 37,424,911</u>	<u>\$ -</u>	<u>\$ 51,263,895</u>
Investment:				
Stock warrant	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 6,065,891</u>	<u>\$ 6,065,891</u>

**Asset and Liabilities at Fair Value
As of December 31, 2018**

	Level 1	Level 2	Level 3	Total
Assets				
Short-term investment securities:				
Money market funds	\$ 10,083,972	\$ -	\$ -	\$ 10,083,972
Corporate bonds	-	38,579,055	-	38,579,055
U.S. treasury securities	-	2,970,900	-	2,970,900
U.S. government agency bonds	-	4,115,012	-	4,115,012
Total short-term investment securities	<u>\$ 10,083,972</u>	<u>\$ 45,664,967</u>	<u>\$ -</u>	<u>\$ 55,748,939</u>
Investment:				
Stock warrant	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,092,358</u>	<u>\$ 3,092,358</u>

Money market mutual funds are valued at their daily closing price as reported by the fund. Money market mutual funds held by the Company are open-end mutual funds that are registered with the SEC that generally transact at a stable \$1.00 Net Asset Value (“NAV”) representing its estimated fair value. On a daily basis the fund’s NAV is determined by the fund based on the amortized cost of the funds underlying investments.

U.S. government agency bonds, U.S. treasury securities, and corporate bonds are valued using pricing models maximizing the use of observable inputs for similar securities.

The investment in the Aurora stock warrant is measured at fair value using the Black-Scholes pricing model and is classified within Level 3 of the valuation hierarchy. The unobservable input is an estimated volatility factor of 85% and 92% at March 31, 2019 and December 31, 2018, respectively. A 20% increase or decrease in the volatility factor used at March 31, 2019 would have the impact of increasing or decreasing the fair value measurement of the stock warrants by approximately \$691,000.

The following table sets forth a summary of the changes in fair value of the Company’s stock warrant (Level 3 asset) since December 31, 2017:

Fair value at December 31, 2017	\$ -
Fair value of stock warrants acquired on August 8, 2018	2,807,958
Unrealized gain as a result of change in fair value	284,400
Fair value at December 31, 2018	3,092,358
Unrealized gain as a result of change in fair value	2,973,533
Fair value at March 31, 2019	<u>\$ 6,065,891</u>

The following tables sets forth a summary of the Company’s available-for-sale securities in its short-term investment account from amortized cost basis to fair value at March 31, 2019 and December 31, 2018:

	Available-for-Sale Securities – March 31, 2019			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$ 31,174,276	\$ 149,833	\$ (15,271)	\$ 31,308,838
U.S. treasury securities	1,967,031	15,156	-	1,982,187
U.S. government agency bonds	4,099,321	34,565	-	4,133,886
	<u>\$ 37,240,628</u>	<u>\$ 199,554</u>	<u>\$ (15,271)</u>	<u>\$ 37,424,911</u>

Available-for-Sale Securities – December 31, 2018				
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$ 38,579,541	\$ 48,796	\$ (49,282)	\$ 38,579,055
U.S. treasury securities	2,959,063	11,837	-	2,970,900
U.S. government agency bonds	4,099,321	15,691	-	4,115,012
	<u>\$ 45,637,925</u>	<u>\$ 76,324</u>	<u>\$ (49,282)</u>	<u>\$ 45,664,967</u>

The following table sets forth a summary of the Company's available-for-sale securities in its short-term investment account for amortized cost basis and fair value by contractual maturity at March 31, 2019 and December 31, 2018:

	Available-for-Sale Securities March 31, 2019		Available-for-Sale Securities December 31, 2018	
	Amortized Cost Basis	Fair Value	Amortized Cost Basis	Fair Value
	Due in one year or less	\$ 32,512,234	\$ 32,664,641	\$ 43,050,306
Due after one year through two years	4,728,394	4,760,270	2,587,619	2,582,290
	<u>\$ 37,240,628</u>	<u>\$ 37,424,911</u>	<u>\$ 45,637,925</u>	<u>\$ 45,664,967</u>

NOTE 6. – NOTES 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. 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.

On October 22, 2018, the Company entered into a License Agreement with the University of Kentucky. Under the terms of the License Agreement, the Company is obligated to pay the University of Kentucky milestone payments totaling \$1,200,000, of which amount \$300,000 was payable upon execution, and \$300,000 will be payable annually over the next three years on the anniversary of the execution of the License Agreement. The Company has recorded the present value of the obligations under the License Agreement as a note payable that originally amounted to \$1,151,201. The cost of the of acquired licenses amounted to \$1,151,201 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 2033.

After the accretion of interest during the three months ended March 31, 2019 in the amount of \$10,660, the balance remaining on these two notes payable as of March 31, 2019 amounted to \$1,548,025, with \$698,048 and \$849,977 reported as current and long-term, respectively, on the Company's Consolidated Balance Sheets (notes payable balance of \$1,537,365 as of December 31, 2018, with \$689,148 and \$848,217 reported as current and long-term, respectively).

NOTE 7. - WARRANTS FOR COMMON STOCK

At March 31, 2019, 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.

The Company's outstanding warrants at March 31, 2019 do not include anti-dilution features and therefore are not considered derivative instruments and do not have an associated warrant liability.

The following table summarizes the Company's warrant activity since December 31, 2017:

	Number of Warrants
Warrants outstanding at December 31, 2017	12,088,080
Warrants exercised during 2018	(794,869)
Warrants outstanding at March 31, 2019 and December 31, 2018	11,293,211

There were no warrants issued or exercised in the first quarter of 2019.

NOTE 8. - 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 months ended March 31, 2019 and 2018 were \$86,589 and \$137,232, 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 months ended March 31, 2019 and 2018, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$4,557 and \$29,262, 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. The License calls for the Company to pay NCSU a non-refundable, non-creditable minimum annual royalty in the amount of \$15,000 in 2019, \$25,000 in 2020 and 2021, and \$50,000 per year thereafter for the remaining term of the License. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the three months ended March 31, 2019 and 2018, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$4,256 and \$0, respectively. This License continues through the life of the last-to-expire patent, expected to be in 2036.

On February 10, 2014, the Company entered into a sponsored research and development agreement (the “Agreement”) with NCSU. 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 months ended March 31, 2019 and 2018 were \$30,339 and \$80,982, respectively.

Other license agreements - Additionally, the Company has entered into the following five 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 \$59,547 and \$24,506 for the three months ended March 31, 2019 and 2018, respectively, and was included in Amortization expense on the Company’s Consolidated Statements of Operations and Comprehensive Income (Loss).

On October 22, 2018, the Company entered into a License Agreement (the “License”) with the University of Kentucky. Under the terms of the License, the Company is obligated to pay the University of Kentucky 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 6 – Notes Payable for License Fee. The present value of the payments in the amount of \$1,151,201 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 2033.

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 6 – Notes Payable for License Fee. The present value of the payments in the amount of \$1,175,226 are included in Intangible assets, net on the Company’s Consolidated Balance Sheets, and will be amortized on a straight-line basis over the last-to-expire patent, which is expected to be in 2036.

On August 22, 2014, the Company entered into a Commercial License Agreement with Precision PlantSciences, Inc. (the "Precision License"). The Precision License grants the Company a non-exclusive, but fully paid up right and license to use technology and materials owned by Precision PlantSciences for a license fee of \$1,250,000. The Precision License continues through the life of the last-to-expire patent, which is expected to be in 2028.

On August 27, 2014, the Company entered into an additional exclusive License Agreement (the "License Agreement") with NCSU. Under the License Agreement, the Company paid NCSU a non-refundable, non-creditable lump sum license fee of \$125,000, and the Company must pay to NCSU an additional non-refundable, non-creditable lump sum fee of \$75,000 upon issuance of a U.S. utility patent included in the patent rights. The Company is obligated to pay to NCSU an annual minimum royalty fee of \$30,000 in 2019 and \$50,000 per year thereafter for the remaining term of the License Agreement. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the three months ended March 31, 2019 and 2018, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$7,676 and \$4,470, 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. As discussed in Note 4, Anandia was purchased by Aurora on August 8, 2018 and has become a wholly-owned subsidiary of Aurora. The Anandia Sublicense is still in effect.

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 months ended March 31, 2019 and 2018, expenses related to the Agreement amounted to \$0 and \$130,850, 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 4, 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.

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 months ended March 31, 2019 and 2018, expenses related to the agreements amounted to \$74,534 and \$103,967, 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 months ended March 31, 2019 and 2018, expenses related to the Agreement amounted to \$25,000 and \$0, respectively.

On February 1, 2019, the Company entered into a Master Collaboration and Research Agreement (the “Agreement”) with a Natural Good Medicines, LLC (“NGM”), the owners of certain hemp and cannabis plant lines (the “NGM Material”). The Agreement calls for NGM to cultivate, grow and process a certain amount of the NGM Material with the financial support of the Company. NGM has granted the Company certain exclusive rights to the hemp and cannabis plant lines of NGM. Additionally, three (3) years from the effective date of the Agreement, NGM and the Company will mutually share in the proceeds from the sale of non-propagating parts of the NGM Material. The Company’s total financial commitment under the Agreement is \$403,000 which has been included in Research and development expenses on the Company’s Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2019.

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 months ended March 31, 2019 and 2018, the Company incurred expenses relating to these contracts in the approximate amount of \$1,211,000 and \$1,296,000, respectively. Future financial commitments under these contracts are estimated to amount to approximately an additional \$400,000 and are expected to be completed over the next three 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.

Crede Case

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

On July 13, 2018, the SDNY Court denied Crede's request to extend the discovery deadline. As a result of such ruling, the discovery in the Crede case has 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. On February 15, 2019, the SDNY Court issued its decision in response to the Company's motion for partial summary judgment, with such decision (i) granting the Company's motion to limit Crede's claims for damages of not more than \$10 million and (ii) denying the Company's other motions seeking to further limit the damages claims by Crede because the SDNY Court desires for the parties to present evidence on their respective positions in a bench trial (a trial in front of the judge without a jury). The SDNY Court further ordered the parties to submit a joint letter on or before March 1, 2019, setting forth their availability for a bench trial in the second half of 2019. On March 1, 2019, the parties submitted such joint letter to the SDNY Court setting forth their availability for a bench trial in the second half of 2019.

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.

Class Action Cases

On January 21, 2019, Matthew Jackson Bull, a resident of Denver, Colorado, filed a Complaint against the Company, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Matthew Bull, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, Case No. 1:19-cv-00409. The Complaint filing alleges that Plaintiff Mr. Bull purchased 3,000 shares of the Company's common stock from September 14, 2016 to October 15, 2018, at share prices between \$0.91 and \$2.57 per share, and that on September 24, 2018, he sold 419 shares for a profit at \$2.88 per share. Mr. Bull sues individually and seeks to bring a class action for persons or entities who acquired the Company's common stock between February 18, 2016 and October 25, 2018, and alleges in Count I that the Company's Annual Reports on Form 10-K for the years 2015, 2016 and 2017 allegedly contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, and alleges in Count II that Messrs. Sicignano and Brodfuehrer are liable for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Complaint seeks declaratory relief, unspecified money damages, and attorney's fees and costs. The Complaint has not yet been served on the Company, Mr. Sicignano or Mr. Brodfuehrer and, therefore, the Company and Messrs. Sicignano and Brodfuehrer have not yet filed responses. We believe that the claims are frivolous, meritless and that the Company and Messrs. Sicignano and Brodfuehrer have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and Messrs. Sicignano and Brodfuehrer against such claims.

On January 29, 2019, Ian M. Fitch, a resident of Essex County Massachusetts, filed a Complaint against the Company, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Ian Fitch, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, Case No. 2:19-cv-00553. The Complaint filing alleges that the Plaintiff Mr. Fitch purchased 3,300 shares of the Company's common stock on October 11, 2017 at \$3.04 per share. Mr. Fitch sues individually and seeks to bring a class action for persons or entities who acquired the Company's common stock between February 18, 2016 and October 25, 2018, and alleges in Count I that the Company's Annual Reports on Form 10-K for the years 2015, 2016 and 2017 allegedly contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, and alleges in Count II that Messrs. Sicignano and Brodfuehrer are liable for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Complaint seeks declaratory relief, unspecified money damages, and attorney's fees and costs.

On March 25, 2019, Plaintiffs' counsel in the *Fitch* litigation filed a motion: (1) substituting Joseph Noto, Garden State Tire Corp, and Stephens Johnson for Mr. Fitch as purportedly representative plaintiffs, (2) moving to consolidate the litigation with the *Bull* litigation, and (3) seeking to be appointed as lead counsel in the consolidated action. Plaintiffs' counsel in the *Bull* litigation filed and then withdrew a comparable motion seeking to consolidate the cases and be appointed as lead counsel. The motion in the *Fitch* litigation remains pending.

Neither the Company nor Messrs. Sicignano or Brodfuehrer have been served with the Complaint or proposed Amended Complaint in this case. We believe that the claims are frivolous, meritless and that the Company and Messrs. Sicignano and Brodfuehrer have substantial legal and factual defenses to the claims. Once served with the Amended Complaint, we intend to vigorously defend the Company and Messrs. Sicignano and Brodfuehrer against such claims.

Shareholder Derivative Cases

On February 6, 2019, Melvyn Klein, a resident of Nassau County New York, filed a shareholder derivative claim against the Company, the Company's Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the United States District Court for the Eastern District of New York entitled: Melvyn Klein, derivatively on behalf of 22nd Century Group v. Henry Sicignano, III, Richard M. Sanders, Joseph Alexander Dunn, Nora B. Sullivan, James W. Cornell, John T. Brodfuehrer and 22nd Century Group, Inc., Case No. 1:19-cv-00748. Mr. Klein brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties for allegedly allowing the Company to make false statements; (ii) the director defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iii) the defendants allegedly violated Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made; and (iv) the director defendants allegedly violated Section 14(a) of the Securities Exchange Act and Rule 14a-9 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made in the Company's proxy statement. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims. On April 11, 2019, pursuant to a stipulation from the parties, the Court ordered this litigation stayed and transferred the stayed action to the Western District of New York.

On February 11, 2019, Stephen Mathew filed a shareholder derivative claim against the Company, the Company's Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the Supreme Court of the State of New York, County of Erie, entitled: Stephen Mathew, derivatively on behalf of 22nd Century Group, Inc. v. Henry Sicignano, III, John T. Brodfuehrer, Richard M. Sanders, Joseph Alexander Dunn, James W. Cornell, Nora B. Sullivan and 22nd Century Group, Inc., Index No. 801786/2019. Mr. Mathew brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties for allegedly allowing the Company to make false statements; (ii) the director defendants were allegedly unjustly enriched by allegedly benefitting from allegedly allowing the Company to make false statements; (iii) the defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iv) the individual defendants allegedly abused their ability to control and influence the Company; and (v) the individual defendants allegedly engaged in gross mismanagement. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims. On April 12, 2019, the parties jointly filed a Stipulated Notice of Removal in United States District Court for the Western District of New York. On the same date, the parties also filed a joint stipulation staying the litigation. On April 23, 2019, the parties jointly filed an Amended Stipulated Notice of Removal in the Western District of New York.

On February 19, 2019, the Company received a demand letter from attorneys representing Van McClendon, a shareholder of the Company, in which Mr. McClendon demanded that the Company's Board of Directors take action to pursue certain purported causes of action on behalf of the Company to remedy alleged breaches of fiduciary duties by each of the members of the Company's Board of Directors, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer. On February 28, 2019, the Board appointed a Special Committee of independent directors and instructed the Committee to assess whether pursuing the claims detailed in the demand letter would be in the best interests of the Company.

NOTE 9. - (LOSS) INCOME PER COMMON SHARE

The following table sets forth the computation of basic and diluted (loss) income per common share for the three-month periods ended March 31, 2019 and 2018, respectively:

	<u>March 31,</u> <u>2019</u>	<u>March 31,</u> <u>2018</u>
Net (loss) income attributed to common shareholders	\$ <u>(2,072,713)</u>	\$ <u>1,386,488</u>
Denominator for basic (loss) income per share-weighted average shares outstanding	124,644,721	124,019,946
Effect of dilutive securities:		
Warrants and options outstanding	<u>-</u>	<u>20,144,492</u>
Denominator for diluted (loss) income per common share-weighted average shares adjusted for dilutive securities	<u>124,644,721</u>	<u>144,164,438</u>
Net (loss) income per common share - basic	\$ <u>(0.02)</u>	\$ <u>0.01</u>
Net (loss) income per common share - diluted	\$ <u>(0.02)</u>	\$ <u>0.01</u>

Dilutive securities outstanding at March 31, 2019 and 2018, respectively, are presented below. Securities outstanding at March 31, 2019 were excluded from the computation of income (loss) per share because they would have been anti-dilutive.

	March 31, 2019	March 31, 2018
Warrants	11,293,211	11,387,932
Options	8,627,582	8,756,560
	<u>19,920,793</u>	<u>20,144,492</u>

NOTE 10. – 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 March 31, 2019, the Company had available 975,115 shares remaining for future awards under the OIP.

During the three months ended March 31, 2019, the Company issued awards for restricted stock units from the OIP for 633,000 shares to eligible individuals, with such restricted stock unit awards having vesting periods ranging from one to three years. During the three months ended March 31, 2018, the Company issued stock option awards from the OIP for 1,131,841 shares to eligible individuals, with such stock option awards having vesting periods ranging from one to three years. All restricted stock units are valued based on the stock price of the Company’s common stock on the date of the award and all stock option awards were valued using the Black-Scholes option-pricing model on the date of the award.

For the three months ended March 31, 2019 and 2018, the Company recorded compensation expense related to stock option awards granted under the OIP of \$448,905 and \$563,876, respectively.

As of March 31, 2019, unrecognized compensation expense related to non-vested stock options amounted to approximately \$4,134,000, which is expected to be recognized as follows: approximately \$1,312,000, \$1,125,000, \$470,000 and \$62,000 during 2019, 2020, 2021 and 2022, respectively. Approximately \$1,165,000 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 three months ended March 31, 2019 and 2018:

	2019	2018
Risk-free interest rate (weighted average)	n/a	2.67%
Expected dividend yield	n/a	0%
Expected stock price volatility	n/a	90%
Expected life of options (weighted average)	n/a	5.45 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, 2017 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	8,156,691	\$ 1.28		
Granted in 2018	1,631,841	\$ 2.64		
Exercised in 2018	(612,259)	\$ 0.87		
Expired / cancelled in 2018	(504,191)	\$ 1.71		
Outstanding at December 31, 2018	8,672,082	\$ 1.54		
Exercised in Q1 2019	(35,000)	\$ 0.95		
Forfeited in Q1 2019	(9,500)	\$ 2.76		
Outstanding at March 31, 2019	<u>8,627,582</u>	<u>\$ 1.54</u>	5.5 years	<u>\$ 3,703,254</u>
Exercisable at March 31, 2019	<u>6,050,841</u>	<u>\$ 1.48</u>	4.5 years	<u>\$ 2,724,825</u>

The weighted average grant date fair value of stock options issued during the three months ended March 31, 2018 was \$1.82. There were no stock options issued during the three months ended March 31, 2019. The total fair value of options that vested during the three months ended March 31, 2019 and 2018 amounted to \$1,188,374 and \$235,715, respectively. There were 35,000 options exercised on a cashless basis during the three months ended March 31, 2019 resulting in the issuance of 17,407 shares of the Company's common stock. There were 327,781 options exercised on a cash and cashless basis during the three months ended March 31, 2018 resulting in the issuance of 315,540 shares of the Company's common stock and provided proceeds to the Company of \$217,500 from such stock option exercises.

NOTE 11. – SUBSEQUENT EVENTS

On April 3, 2019, the Company entered into a Framework Collaborative Research Agreement (the "Agreement") with KeyGene N.V. ("KeyGene") under which KeyGene has agreed to work exclusively with the Company with respect to the *Cannabis Sativa L.* plant and all uses thereof (the "Field") for an initial term of five (5) years and an option for an additional two (2) years in consideration of the Company paying KeyGene an aggregate of Six Million United States Dollars (\$6,000,000) over the initial term of the Agreement, with a portion of such amount being contingent on KeyGene achieving certain milestone deliverables for the Company. The Company will exclusively own all results and all intellectual property relating to the results from this collaboration with KeyGene ("Results"). The Company will pay royalties in varying amounts to KeyGene relating to the Company's commercialization in the Field of certain Results. The Company has granted KeyGene a license to commercialize the Results outside of the Field and KeyGene will pay royalties in varying amounts to the Company relating to KeyGene's commercialization outside of the Field of the Results. The Agreement also includes customary termination provisions for both KeyGene and the Company as well as representations, warranties, and covenants by the parties that are customary for a transaction of this nature.

On May 3, 2019, the Company's stockholders approved an amendment to the OIP to increase the number of shares available for issuance by an additional 5,000,000 shares.

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

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that reflect, when made, the Company's expectations or beliefs concerning future events that involve risks and uncertainties. Forward-looking statements frequently are identified by the words "believe," "anticipate," "expect," "estimate," "intend," "project," "will be," "will continue," "will 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 obtain FDA clearance for our Modified Risk Tobacco Product; our ability to gain market acceptance for our products; our ability to prevail in litigation; and our ability to maintain our rights to our intellectual property licenses. For a discussion of these and all other known risks and uncertainties that could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, 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 to improve other agronomic traits for improved agricultural applications. 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; working to obtain a reduced exposure marketing authorization from the FDA for our Modified Risk Tobacco Product ("MRTP") application to the FDA for our *BRAND A* Very Low Nicotine Content ("VLNC") cigarettes to be marketed in the United States under the proposed brand name of "VLNTM" cigarettes 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 VLNC tobacco that grows with at least 95% less nicotine than conventional cigarette tobacco. We collectively refer to all of our various types of VLNC tobacco under the Company's trademark name: VLNTM tobacco, which is also the proposed brand name of the product that is the subject of our MRTP application with the FDA. 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 28 million SPECTRUM[®] research cigarettes containing our proprietary VLNTM 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 \$125 million in independent clinical studies using our SPECTRUM[®] research cigarettes. The results of these studies, as published in peer-reviewed publications (including but not limited to the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and many others), show that our proprietary VLNC cigarettes containing our unique VLNTM tobacco are associated with: (1) reduced smoking, (2) lower nicotine exposure, (3) increased quit attempts, and (4) 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 VLNTM tobacco is shown on the Company's website at <http://www.xxicentury.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.xxicentury.com/on-going-clinical-studies/>. The numerous independent clinical studies on VLNC cigarettes provides the scientific foundation 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. On March 19, 2018, the FDA publicly announced its Advance Notice of Proposed Rulemaking ("ANPRM") to solicit public comments on the FDA's plan to enact a new nicotine reduction rule. On July 16, 2018, we publicly submitted to the FDA our formal written response to the ANPRM in which we described how (i) the FDA's proposed new rule is supported by rigorous independent, published science, (ii) the FDA's stated goal to render cigarettes minimally or non-addictive is immediately feasible as evidenced by our production and delivery of more than 28 million VLNC research cigarettes since the year 2011, and (iii) the FDA's proposed new rule is exceedingly practical and urgently needed in the interests of public health. 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/cannabis, 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 not more than 0.3% dry weight content of delta-9-tetrahydrocannabinol ("THC"). The 2018 federal Farm Bill legalized hemp and cannabinoids extracted from hemp in the U.S., but such extracts remain subject to state laws and the regulation by other U.S. federal agencies, such as the FDA and the U.S. Department of Agriculture ("USDA"). 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 agronomically desirable traits for commercial uses and/or unique cannabinoid levels for possible extraction purposes. We believe that we have many types of superior and unique hemp plant varieties, including (i) hemp plants with low to no amounts of THC and other desirable agronomic traits 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. 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%, which is the legal limit that defines hemp for optimal growth in Virginia, (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, and (iii) utilize high-value medical cannabinoid hemp varieties and specialized cannabinoid extraction processes for use in human therapeutics. We have also obtained a license in the State of New York to research and grow hemp in that state. In Canada, we previously conducted sponsored research on the hemp plant with Anandia Laboratories in Vancouver, British Columbia, in full compliance with Canadian regulations. In Europe, we will be working with KeyGene NV, global leader in plant research involving high-value genetic traits and increased crop yields, in an exclusive, worldwide collaboration that will focus on developing hemp/cannabis plants with exceptional cannabinoid profiles and other superior agronomic traits for medical, therapeutic and agricultural uses, among many other applications.

Additional information about our business and operations is contained in our Annual Report on Form 10-K for the year ended December 31, 2018. Information on our website is not incorporated by reference into this Form 10-Q.

Strategic Objectives

Our strategic objectives include the following:

- Facilitating the 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;
- Continuing to work with the FDA on our Modified Risk Tobacco Product application that we have submitted 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 under the proposed brand name of “VLNTM” 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 VLNC tobacco technology and/or our VLNC 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;

- Continuing to research and develop other novel tobacco plant varieties;
- Continuing to explore opportunities outside of the United States for the use of our VLNC tobacco in potential over-the-counter cigarettes, such as *BRAND A*, or in a potential prescription-based, smoking cessation aid, such as *X-22*, in foreign countries that may desire such products;
- Continuing to expand our legal hemp/cannabis 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;
- Continuing to explore opportunities outside of the United States for the sale of our branded proprietary tobacco products; and
- Continuing to grow our contract manufacturing business for third-party branded tobacco products.

For the first quarter of 2019, our accomplishments and notable events include:

On March 27, 2019, we announced the results of a recently completed, Company-sponsored study involving our Very Low Nicotine Content (“VLNC”) cigarettes, with the results of such study indicating that subjects using our VLNC product had 97% less nicotine in their blood as compared to their blood-nicotine levels after use of their usual brand of highly addictive commercial cigarettes. In contrast, when the study subjects used nicotine gum, which is a common nicotine replacement therapy, the users’ nicotine level in their blood was only 69% less than when they used their usual brand of cigarettes. The study results also showed that the users’ cravings for cigarettes and urge to smoke were significantly reduced when using our VLNC product. Overall, the results of this study suggest that (i) VLNC cigarettes have a lower potential for abuse than conventional cigarettes, and (ii) VLNC cigarettes have a potential for abuse that may be comparable to using nicotine gum. We included this study and its results in our Modified Risk Tobacco Product (“MRTP”) application submitted to the U.S. Food and Drug Administration (“FDA”) for our VLNC cigarettes under the proposed brand name VLN™. Our MRTP application seeks the FDA’s authorization to advertise that VLN™ cigarettes contain 95% less nicotine as compared to the 100 top-selling cigarette brands in the United States.

Subsequent to the close of the first quarter of 2019, we also announced:

On April 9, 2019, we announced that we had entered into a worldwide strategic research and development agreement with KeyGene NV, a global leader in plant research involving high-value genetic traits and increased crop yields. This exclusive, worldwide collaboration will focus on the development of hemp/cannabis plants with exceptional cannabinoid profiles for medical and therapeutic use, among other applications and other improved agronomic traits for commercial crop applications for agricultural uses. The KeyGene collaboration provides us with access to a unique suite of crop innovation platforms, including genomics, molecular genetics, trait discovery and breeding technologies. Under the agreement, we will hold exclusive worldwide rights to all hemp/cannabis plant lines, intellectual property on metabolic traits, and research results that are developed through the partnership. We announced that the focus of the collaboration will specifically include the following:

- (i) Creating a genetic database which utilizes the results of genomic analyses of several hundred existing, exceptional hemp/cannabis plant lines for use in the acceleration of our development and licensing of uniquely characterized and improved hemp/cannabis plants;
- (ii) Enhancing genetic variation to empower our development of new and significantly improved varieties of hemp/cannabis plant lines and varieties with highly desirable cannabinoid profiles optimized for medicinal or therapeutic applications;

- (iii) Creating a proprietary and industry-leading high-resolution “molecular genetic map” of the entire cannabis plant genome to facilitate rapid, cost-effective breeding of innovative varieties of hemp/cannabis plants with distinctive agronomic traits;
- (iv) Analyzing the genomic sequences of multiple species of the hemp/cannabis plant and identifying shared genetic markers, allowing us to develop improved commercial hemp/cannabis plant lines more rapidly than through conventional plant breeding approaches; and
- (v) Initiating the rapid-cycle generation of hemp/cannabis plant lines with distinctive cannabinoid and terpene profiles to create elite lines.

On April 17, 2019, we announced the hiring of John Pritchard as our new Vice President of Regulatory Science. Mr. Pritchard was formerly the Head of Regulatory Science for Imperial Brands, U.K., one of the largest tobacco companies in the world. Over the course of his 12 years with Imperial Brands, Mr. Pritchard served in key management roles in product stewardship, compliance, research, and regulatory departments. As the head of Imperial Brand’s scientific regulatory engagement team, Mr. Pritchard led Imperial Brand’s technical regulatory strategy and external scientific engagement on global product regulation. Mr. Pritchard has also held other scientific and regulatory posts in the private and public sector, including roles with Charles River, a leading global contract research organization, and with the U.K. Health Protection Agency (now, Public Health England). Mr. Pritchard received a Master of Science Degree in Toxicology from the University of Birmingham, England and his Bachelor of Science Degree in Pharmacology from the University of Aberdeen, Scotland. With work cited by the U.S. Surgeon General, the World Health Organization, and Public Health England, Mr. Pritchard has considerable experience in the fields of tobacco harm reduction and next generation tobacco products. Mr. Pritchard will lead and oversee our global regulatory and compliance activities and he will engage with the FDA in support of our MRTP application for VLN™ cigarettes. In addition, Mr. Pritchard will work in support of the planned rule by the FDA to require the reduction of the nicotine content of all cigarettes sold in the U.S. to “minimally or non-addictive levels.” Mr. Pritchard will also lead our initiatives with foreign governments that are interested in 22nd Century’s proprietary VLNC tobacco for use in their countries.

On April 30, 2019, we announced that the FDA conducted a comprehensive inspection of our manufacturing facility in North Carolina as a part of the FDA’s review of our Pre-Market Tobacco (PMT) application for our VLNC cigarettes under the proposed brand name VLN™, in which application we seek the FDA’s authorization to commercialize VLN™ brand cigarettes and to communicate to consumers that VLN™ cigarettes contain at least 95% less nicotine as compared to the 100 leading cigarette brands in the United States. The FDA’s inspection was part of the third phase of the FDA’s four phase review process for the PMT application. The FDA’s stated goal for the inspection was “to verify the information and data contained in the [PMT] application.” As such, the FDA inspectors witnessed production of our proprietary VLN™ cigarettes and the FDA inspectors reviewed our raw material receiving and storage procedures, quality control processes, manufacturing equipment and systems, tobacco processing methods, and finished-products analyses procedures.

Three Months Ended March 31, 2019 Compared to Three Months Ended March 31, 2018

Revenue - Sale of products, net

In the three months ended March 31, 2019, we realized net sales revenue from the sale of products in the amount of \$6,293,648, an increase of \$177,609, or 2.9%, from net sales revenue of \$6,116,039 for the three months ended March 31, 2018. The increase in net sales revenue for the first quarter of 2019 was primarily the result of an increase in the sale of contract manufactured filtered cigars of approximately \$294,000, and a net increase in other miscellaneous sales activities of approximately \$16,000, partially offset by a decrease in the sales of contract manufactured cigarettes of \$132,000, as compared to the first quarter of 2018.

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

During the three months ended March 31, 2019, cost of goods sold were \$6,396,558, or 101.6%, of net sales revenue, resulting in a gross loss on sales of products in the amount of \$102,910. During the three months ended March 31, 2018, cost of goods sold were \$6,044,461, or 98.8%, of net sales revenue, resulting in a gross profit on sales of products in the amount of \$71,578. The negative change from a gross profit for the three months ended March 31, 2018 to a gross loss for the three months ended March 31, 2019 was primarily the result of additional expenses recorded to the cost of goods sold during the first quarter of 2019, as compared to the first quarter of 2018. The additional expenses consisted primarily of (1) an increase in fees due to the FDA on filtered cigars of approximately \$100,000, and (2) a net increase in other manufacturing expenses charged to the cost of goods sold of approximately \$60,000, relating mainly to labor and equipment maintenance costs.

Research and development expense

Research and development ("R&D") expense was \$2,451,442 in the three months ended March 31, 2019, a decrease of \$65,327, or 2.6%, from \$2,516,769 in the three months ended March 31, 2018. This decrease was primarily the result of a decrease in equity-based compensation expense of approximately \$121,000, a decrease in payroll and related benefits of approximately \$95,000, a decrease in product testing costs of approximately \$48,000, a decrease in costs relating to our MRTP application with the FDA for our VLNC cigarettes of approximately \$36,000, and a net decrease in various other R&D expenses of approximately \$3,000, partially offset by an increase in sponsored research costs of approximately \$154,000, an increase in costs related to our laboratory operations of approximately \$63,000, and an increase in consulting fees of approximately \$21,000.

General and administrative expense

General and administrative expense was \$2,242,502 in the three months ended March 31, 2019, an increase of \$210,110, or 10.3%, from \$2,032,392 in the three months ended March 31, 2018. The increase was mainly due to an increase in payroll and related benefits of approximately \$23,000, an increase in legal and accounting fees of approximately \$135,000, an increase in business insurance costs of approximately \$21,000, an increase in Board of Director related expenses of approximately \$36,000, an increase in consulting and other professional services of approximately \$75,000, an increase in travel related expenses of approximately \$33,000, and a net increase in various other general and administrative expenses of approximately \$57,000, partially offset by a decrease in expenses relating to investor relations of approximately \$170,000.

Sales and marketing

During the three months ended March 31, 2019, we incurred sales and marketing expenses of \$231,699, an increase of \$32,590, or 16.4%, from \$199,109 in the three months ended March 31, 2018. The increase in sales and marketing expenses was primarily the result of an increase in payroll and related benefit costs of approximately \$20,000, an increase in equity-based compensation of approximately \$14,000, and an increase in travel related expenses of approximately \$9,000, partially offset by a decrease in expenses relating to advertising of approximately \$10,000.

Depreciation expense

Depreciation expense for the three months ended March 31, 2019 amounted to \$135,047, an increase of \$10,519, or 8.5%, from \$124,528 for the three months ended March 31, 2018. The increase was primarily due to depreciable acquisitions of machinery and equipment during the year ended December 31, 2018 and the three months ended March 31, 2019 in the aggregate amount of approximately \$753,000, primarily consisting of equipment additions in our NASCO factory operations in North Carolina.

Amortization expense

Amortization expense for the three months ended March 31, 2019 amounted to \$215,559, an increase of \$48,007, or 28.7%, from \$167,552 for the three months ended March 31, 2018. The amortization expense relates to amortization taken on capitalized patent costs and license fees. The increase was primarily due to amortization taken on additional patent costs incurred during the three months ended March 31, 2019 and the year ended December 31, 2018 of approximately \$187,000 and \$751,000, respectively, and additional amortization of approximately \$35,000 taken during the first quarter of 2019 on the cost of a new licenses with NCSU and the University of Kentucky that began in the third and fourth quarters of 2018.

Unrealized gain on investment

The warrants to purchase 973,971 shares of Aurora common stock, described in Note 4 to our consolidated financial statements, are considered an equity security, and are recorded at fair value. We recorded the fair value of the stock warrants of \$6,065,891 at March 31, 2019, using the Black-Scholes pricing model, and recorded an unrealized gain on the warrants in the amount of \$2,973,533 for the three months ended March 31, 2019.

During the first quarter of 2018, we began accounting for our equity investment in Anandia in accordance with Financial Accounting Standards Board ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. This guidance changes how entities account for equity investments that do not result in consolidation and are not accounted for under the equity method of accounting. Under ASU 2016-01, we are required to measure our investment in Anandia at fair value at the end of each reporting period and recognize changes in fair value in net income. A practicability exception 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 January of 2018 (an orderly transaction), 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.

Realized (loss) gain on short-term investment securities

We maintain a short-term investment account to invest our excess cash. Investments in the short-term investment account are managed in accordance with our investment policy. We realized a (loss) gain on short-term investment securities of (\$16,021) and \$195 for the three months ended March 31, 2019 and 2018, respectively, resulting from the maturity of various debt instruments held in the short-term investment account.

Unrealized loss on short-term investment securities

During the three months ended March 31, 2018, the unrealized loss on short-term investment securities of \$92,574 was recorded in the Other income (expense) section of our Consolidated Statements of Operations and Comprehensive Income (Loss) and was reclassified to Other comprehensive income (loss) in the second quarter of 2018.

Gain on the sale of machinery and equipment

During the three months ended March 31, 2019, we sold a piece of machinery and equipment no longer required in our factory operations in North Carolina and recorded a gain on the sale in the amount of \$87,351.

Warrant liability gain, net

During July of 2018, the remaining 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 first quarter of 2019 and there will be no warrant liability gain (loss) in future periods unless we issue securities containing anti-dilution features.

The warrant liability gain of \$48,711 for the first quarter of 2018 was due to a decrease in the estimated fair value of the warrants during the period.

Interest income, net

Interest income, net for the three months ended March 31, 2019, was \$272,243, an increase of \$20,403, or 8.1%, from interest income of \$251,840 for the three months ended March 31, 2018. The increase in net interest income (interest income less investment fees) was the result of additional net interest earned in our short-term investment account primarily due to higher interest rates on outstanding investments during the three months ended March 31, 2019, as compared to interest rates on outstanding investments during the three months ended March 31, 2018.

Interest expense

Interest expense was \$10,660 for the three months ended March 31, 2019 and was derived from the accretion of interest on notes payable to NCSU and the University of Kentucky. We had no interest expense for the three months ended March 31, 2018.

Net (loss) income

We had a net loss for the three months ended March 31, 2019 of \$2,072,713 as compared to net income of \$1,386,488 in the three months ended March 31, 2018. The change from net income for the three months ended March 31, 2018 to a net loss for the three months ended March 31, 2019 amounted to a decrease of \$3,459,201, or 249.5%, and was primarily the result of a decrease in the unrealized gain on investment of approximately \$3,174,000, a negative change in the gross profit (loss) on product sales of approximately \$174,000, and an increase in operating expenses of approximately \$236,000, partially offset by a net increase in various other income (expenses) of approximately \$125,000.

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, and U.S. treasury securities 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 in the amount of \$146,899 and recorded a reclassification of losses to net loss in the amount of \$16,021, resulting in other comprehensive income in the amount of \$162,920 for the three months ended March 31, 2019.

Liquidity and Capital Resources

Working Capital

As of March 31, 2019, we had working capital of approximately \$51.3 million compared to working capital of approximately \$56.0 million at December 31, 2018, a decrease of approximately \$4.7 million. This decrease in working capital was primarily due to a decrease in net current assets of approximately \$3.7 million and an increase in net current liabilities of approximately \$1.0 million. Cash, cash equivalents and short-term investment securities decreased by approximately \$4.5 million and the remaining net current assets increased by approximately \$0.8 million. We used approximately \$4.7 million of cash in operating activities during the three months ended March 31, 2019.

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 March 31, 2019 of \$51,852,855. 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 three months ended March 31, 2019, we experienced an operating loss of approximately \$5,379,000 (including approximately \$1,211,000 in expenses relating to our MRTP application) and used cash in operations of approximately \$4,682,000. 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 \$950,000. In addition, we expect to incur an estimated amount of approximately an additional \$400,000 in expenses relating to our MRTP application over approximately the next three months.

Net cash used in operating activities

In the three months ended March 31, 2019, \$4,681,789 of cash was used in operating activities as compared to \$3,143,878 of cash used in operating activities in the three months ended March 31, 2018, an increase of \$1,537,911. 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 \$391,750 and an increase in cash used for working capital components related to operations in the amount of \$1,146,161 for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018.

Net cash provided by investing activities

In the three months ended March 31, 2019, net cash provided by investing activities was \$4,665,825, as compared to \$4,812,088 of cash provided by investing activities during the three months ended March 31, 2018, a decrease in net cash provided by investing activities of \$146,263. The decrease was primarily the result of a decrease in net cash provided from transactions relating to our short-term investment account in the amount of \$386,281, partially offset by 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 \$73,868, and an increase in cash provided by the sale of machinery and equipment in the amount of \$166,150.

Net cash provided by financing activities

During the three months ended March 31, 2019, there was no cash provided by or used in financing activities. During the three months ended March 31, 2018, we had \$217,500 of cash provided by financing activities from the exercise of various stock options.

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, 2018, except for the adoption of ASU 2016-02, Leases, on January 1, 2019 as more fully described in Note 3 to our Consolidated Financial Statements.

Inflation

Inflation did not have a material effect on our operating results for the three months ended March 31, 2019 and 2018, 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, 2018.

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 first quarter of 2019 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.

Crede Case

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

On July 13, 2018, the SDNY Court denied Crede's request to extend the discovery deadline. As a result of such ruling, the discovery in the Crede case has 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. On February 15, 2019, the SDNY Court issued its decision in response to the Company's motion for partial summary judgment, with such decision (i) granting the Company's motion to limit Crede's claims for damages of not more than \$10 million and (ii) denying the Company's other motions seeking to further limit the damages claims by Crede because the SDNY Court desires for the parties to present evidence on their respective positions in a bench trial (a trial in front of the judge without a jury). The SDNY Court further ordered the parties to submit a joint letter on or before March 1, 2019, setting forth their availability for a bench trial in the second half of 2019. On March 1, 2019, the parties submitted such joint letter to the SDNY Court setting forth their availability for a bench trial in the second half of 2019.

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.

Class Action Cases

On January 21, 2019, Matthew Jackson Bull, a resident of Denver, Colorado, filed a Complaint against the Company, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Matthew Bull, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, Case No. 1:19-cv-00409. The Complaint alleges that Plaintiff Mr. Bull purchased 3,000 shares of the Company's common stock from September 14, 2016 to October 15, 2018, at share prices between \$0.91 and \$2.57 per share, and that on September 24, 2018, he sold 419 shares for a profit at \$2.88 per share. Mr. Bull sues individually and seeks to bring a class action for persons or entities who acquired the Company's common stock between February 18, 2016 and October 25, 2018, and alleges in Count I that the Company's Annual Reports on Form 10-K for the years 2015, 2016 and 2017 allegedly contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, and alleges in Count II that Messrs. Sicignano and Brodfuehrer are liable for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Complaint seeks declaratory relief, unspecified money damages, and attorney's fees and costs. The Complaint has not yet been served on the Company, Mr. Sicignano or Mr. Brodfuehrer and, therefore, the Company and Messrs. Sicignano and Brodfuehrer have not yet filed responses. We believe that the claims are frivolous, meritless and that the Company and Messrs. Sicignano and Brodfuehrer have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and Messrs. Sicignano and Brodfuehrer against such claims.

On January 29, 2019, Ian M. Fitch, a resident of Essex County Massachusetts, filed a Complaint against the Company, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Ian Fitch, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, Case No. 2:19-cv-00553. The Complaint alleges that the Plaintiff Mr. Fitch purchased 3,300 shares of the Company's common stock on October 11, 2017 at \$3.04 per share. Mr. Fitch sues individually and seeks to bring a class action for persons or entities who acquired the Company's common stock between February 18, 2016 and October 25, 2018, and alleges in Count I that the Company's Annual Reports on Form 10-K for the years 2015, 2016 and 2017 allegedly contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, and alleges in Count II that Messrs. Sicignano and Brodfuehrer are liable for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Complaint seeks declaratory relief, unspecified money damages, and attorney's fees and costs.

On March 25, 2019, Plaintiffs' counsel in the *Fitch* litigation filed a motion: (1) substituting Joseph Noto, Garden State Tire Corp, and Stephens Johnson for Mr. Fitch as purportedly representative plaintiffs, (2) moving to consolidate the litigation with the *Bull* litigation, and (3) seeking to be appointed as lead counsel in the consolidated action. Plaintiffs' counsel in the *Bull* litigation filed and then withdrew a comparable motion seeking to consolidate the cases and be appointed as lead counsel. The motion in the *Fitch* litigation remains pending.

Neither the Company nor Messrs. Sicignano or Brodfuehrer have been served with the Complaint or proposed Amended Complaint in this case. We believe that the claims are frivolous, meritless and that the Company and Messrs. Sicignano and Brodfuehrer have substantial legal and factual defenses to the claims. Once served with the Amended Complaint, we intend to vigorously defend the Company and Messrs. Sicignano and Brodfuehrer against such claims.

Shareholder Derivative Cases

On February 6, 2019, Melvyn Klein, a resident of Nassau County New York, filed a shareholder derivative claim against the Company, the Company's Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the United States District Court for the Eastern District of New York entitled: Melvyn Klein, derivatively on behalf of 22nd Century Group v. Henry Sicignano, III, Richard M. Sanders, Joseph Alexander Dunn, Nora B. Sullivan, James W. Cornell, John T. Brodfuehrer and 22nd Century Group, Inc., Case No. 1:19-cv-00748. Mr. Klein brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties for allegedly allowing the Company to make false statements; (ii) the director defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iii) the defendants allegedly violated Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made; and (iv) the director defendants allegedly violated Section 14(a) of the Securities Exchange Act and Rule 14a-9 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made in the Company's proxy statement. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims. On April 11, 2019, pursuant to a stipulation from the parties, the Court ordered this litigation stayed and transferred the stayed action to the Western District of New York.

On February 11, 2019, Stephen Mathew filed a shareholder derivative claim against the Company, the Company's Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the Supreme Court of the State of New York, County of Erie, entitled: Stephen Mathew, derivatively on behalf of 22nd Century Group, Inc. v. Henry Sicignano, III, John T. Brodfuehrer, Richard M. Sanders, Joseph Alexander Dunn, James W. Cornell, Nora B. Sullivan and 22nd Century Group, Inc., Index No. 801786/2019. Mr. Mathew brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties for allegedly allowing the Company to make false statements; (ii) the director defendants were allegedly unjustly enriched by allegedly benefitting from allegedly allowing the Company to make false statements; (iii) the defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iv) the individual defendants allegedly abused their ability to control and influence the Company; and (v) the individual defendants allegedly engaged in gross mismanagement. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims. On April 12, 2019, the parties jointly filed a Stipulated Notice of Removal in United States District Court for the Western District of New York. On the same date, the parties also filed a joint stipulation staying the litigation. On April 23, 2019, the parties jointly filed an Amended Stipulated Notice of Removal in the Western District of New York.

On February 19, 2019, the Company received a demand letter from attorneys representing Van McClendon, a shareholder of the Company, in which Mr. McClendon demanded that the Company's Board of Directors take action to pursue certain purported causes of action on behalf of the Company to remedy alleged breaches of fiduciary duties by each of the members of the Company's Board of Directors, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer. On February 28, 2019, the Board appointed a Special Committee of independent directors and instructed the Committee to assess whether pursuing the claims detailed in the demand letter would be in the best interests of the Company.

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, 2018, as filed with the SEC on March 6, 2019.

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 10.1†](#) [Framework Collaborative Research Agreement, dated as of April 3, 2019, between KeyGene N.V. and 22nd Century Group, Inc.](#)

[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

† Certain portions of the exhibit have been omitted pursuant Regulation S-K Item 601(b) because it is both (i) not material to investors and (ii) likely to cause competitive harm to the Company is publicly disclosed.

SIGNATURES

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

22nd CENTURY GROUP, INC.

Date: May 7, 2019

/s/ Henry Sicignano III
Henry Sicignano III
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 7, 2019

/s/ John T. Brodfuehrer
John T. Brodfuehrer
Chief Financial Officer
(Principal Accounting and Financial Officer)

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (1) NOT MATERIAL TO INVESTORS AND (2) LIKELY TO CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

FRAMEWORK COLLABORATIVE RESEARCH AGREEMENT

by

KEYGENE N.V.

and

22nd Century Group, Inc.

FRAMEWORK COLLABORATIVE RESEARCH AGREEMENT

This Framework Collaborative Research Agreement (the “**Agreement**”), is made this 3rd day of April 2019 (“**Effective Date**”) by and between

1. **Keygene N.V.**, a company organized and existing under the laws of The Netherlands, having its registered office at Agro Business Park 90, 6708 PW Wageningen, The Netherlands, duly represented by its Managing Director, Dr. Arjen van Tunen, (hereinafter further referred to as “**KeyGene**”),

and

2. **22nd Century Group, Inc.**, a corporation organized and existing under the laws of State of Nevada in the United States of America, having its principal offices at 8560 Main Street, Suite 4, Williamsville, New York 14221, United States of America, duly represented by its President and Chief Executive Officer, Henry Sicignano III (hereinafter further referred to as “**XXII**”),

with the parties also being hereinafter individually referred to as “**Party**” and collectively as “**Parties**”.

WHEREAS

- (a) XXII is a company active in, amongst others, the field of cannabis and hemp, and has proprietary expertise, knowledge and germplasm relating to cannabis and hemp;
- (b) KeyGene is a company active in the field of agricultural biotechnology, genomics and phenomics, and has proprietary expertise, knowledge and technologies for generating and analyzing molecular genetic and phenotypic data, molecular mutagenesis, lead discovery and lead validation, breeding tool and/or trait development;
- (c) XXII desires to retain KeyGene to perform certain research, consulting and advisory services for XXII, and KeyGene desires to perform such services; and
- (d) the Parties wish to set forth in writing the terms and conditions of their agreement with regard to rights and obligations of the Parties related to the services described herein.

NOW, THEREFORE, in consideration of the mutual premises and promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto intending to be legally bound do hereby agree as follows:

Article 1 – Definitions

In this Agreement the following terms, either in plural or in single form, have the following meanings:

- 1.1 **Affiliate:** means any entity directly or indirectly controlled by a Party, where, for the purposes of this definition “**control**” means the actual power, either directly or indirectly through one or more intermediaries, to determine the management and policy of an entity in a decisive way, whether through the direct or indirect ownership of more than fifty percent (50%) of the voting shares, or by contract or otherwise.
- 1.2 **Biological Material:** means any and all XXII proprietary germplasm and other biological material supplied by XXII to KeyGene for the execution of a Project.
- 1.3 **Change of Control:** means with regard to a Party any of the following: (i) such Party sells, leases or exchanges all or substantially all of its assets to any other person or entity; or (ii) at least fifty percent (50%) of the outstanding voting shares in such Party are sold to a third party; or (iii) any other event pursuant to which the persons or entities that Control such Party immediately prior to such event do no longer Control such Party immediately after such event. “**Control**” for this purpose means: owner or holder of fifty percent (50%) or more of the voting stock or other equity interest of the Party with the power to vote, or the power in fact to control the management decisions of such Party through the ownership of securities, or by contract, or otherwise.
- 1.4 **Consultancy Services:** means the expert assistance and general advice requested by XXII to be supplied by KeyGene to XXII in accordance with a PAS.
- 1.5 **Contract Year:** means each consecutive twelve (12) month period from the Effective Date or its applicable calendar year anniversary.
- 1.6 **Exclusivity Period:** means the period that XXII pays at least the Minimum Research Funding Amount during each Contract Year as Research Funding, not exceeding a period of seven (7) Contract Years; provided, however, that (i) the Exclusivity Period shall end immediately upon any termination of this Agreement (A) in accordance with Section 12.2 or (B) by KeyGene in accordance with Section 12.3 and (ii) upon any termination of this Agreement by XXII in accordance with Section 12.3, the Exclusivity Period shall continue through the end of the sixtieth (60) month after the Effective Date.
- 1.7 **Field:** means any and all use of, research regarding, and/or commercialization of hemp and/or cannabis (all versions and types of the genus *Cannabis Sativa L plant*), and/or any parts thereof, for any and all purposes, including but not limited to human, medical, agricultural, veterinary, therapeutic and other such purposes.

- 1.8 **KeyGene Background:** means all protocols, methods, procedures, know-how, trade secrets, information, data (e.g. sequences), biological materials, software, technologies and/or combinations thereof, whether in electronic form or not and whether or not laid down in protocols, and all intellectual property rights related thereto, owned by, licensed in or otherwise in the possession of KeyGene (i) as of the Effective Date or (ii) after the Effective Date if discovered independently by KeyGene and not in furtherance of this Agreement, in each case which are required or may otherwise be useful for the performance of a specific Project.
- 1.9 **KeyGene Identified Targets:** means Results that constitute or are based on genes, alleles and other regulatory elements that are identified by KeyGene in the course of a Project (i.e. KeySeeQ output), other than publicly known regulatory elements. **Non-KeyGene Identified Targets:** means Results that constitute or are based on genes, alleles and other regulators that are publicly known regulatory elements.
- 1.10 **Net Sales:** means (i) the gross revenue received by XXII and its Affiliates from the sale of Project Technology Results, KeyGene Identified Targets, Non-KeyGene Identified Targets and/or products or services that incorporate, are based on or use Project Technology Results, KeyGene Identified Targets or Non-KeyGene Identified Targets, less (ii) returns, allowances or credits, rebates, excise, sales, use or value-added taxes or other fees imposed by government entities, tariffs, costs of packing, transportation and insurance, delivery charges, cash and trade discounts allowed, and import or export duties. **KeyGene Net Sales:** means (i) the gross revenue received by KeyGene and its Affiliates from the sale of Results and/or products or services that incorporate, are based on or use Results, less (ii) returns, allowances or credits, rebates, excise, sales, use or value-added taxes or other fees imposed by government entities, tariffs, costs of packing, transportation and insurance, delivery charges, cash and trade discounts allowed, and import or export duties.
- 1.11 **License Income:** means any and all gross revenue actually received by XXII and its Affiliates in consideration of the grant of a license in respect of the Project Technology Results, KeyGene Identified Targets and/or Non-KeyGene Identified Targets. License Income includes running royalties, upfront fees, annual fees and milestone fees actually paid by such licensee to XXII. It does not include any consideration paid to XXII or its Affiliates for research and development work or other non-commercial work with such licensee in connection with the grant of such license. **KeyGene License Income:** means any and all gross revenue actually received by KeyGene and its Affiliates in consideration of the grant of a sublicense in respect of the Results. KeyGene License Income includes running royalties, upfront fees, annual fees and milestone fees actually paid by such licensee to KeyGene. It does not include any consideration paid to KeyGene or its Affiliates for research and development work or other non-commercial work with such licensee in connection with the grant of such license.

- 1.12 **PAS or Project Approval Sheet or Statement of Work:** means a written document a template of which is attached as **Annex 1** to this Agreement, agreed to in writing by both Parties and to be attached to and incorporated in this Agreement, containing the following elements, if applicable:
- (i) the objective of the Project;
 - (ii) the type of Project;
 - (iii) a description of XXII Background and Biological Material and KeyGene Background to be contributed by the Parties to the extent needed to conduct the Project;
 - (iv) the Project proposal or work plan, including milestones if applicable, and the intended deliverables as to expected Results;
 - (v) a description of the consultancy to be rendered by KeyGene (if applicable);
 - (vi) the R&D amounts and consultancy fee for the Project pursuant to Article 7; and
 - (vii) the duration of the Project.
- 1.13 **Project:** means the research, development and/or consultancy activities to be performed by KeyGene, as further detailed in a PAS.
- 1.14 **Project Technology Results:** means (i) any and all protocols, methods, procedures, know-how, software, inventions, technologies and/or combinations thereof, whether in electronic form or not and whether or not laid down in protocols that (A) is developed, created and/or generated by KeyGene from the execution of a Project, (B) is applicable to the Field, and (C) is expressly a deliverable of a Project as further detailed in a PAS and/or is otherwise expressly agreed by the Parties prior to the commencement of a respective Project as being a Project Technology Result, unless otherwise agreed to in writing by the Parties after the commencement of a Project and (ii) any other protocols, methods, procedures or technologies that may be separately approved by the Steering Committee as Project Technology Results.
- 1.15 **Research Funding:** means the aggregate amounts payable by XXII to KeyGene under the Projects pursuant to Sections 7.1 (R&D amounts) and 7.2 (consultancy fees).
- 1.16 **Residual Expertise:** means protocols, methods, procedures, know-how, software, inventions, technologies and/or combinations thereof, whether in electronic form or not and whether or not laid down in protocols that (i) is developed, created and/or generated by KeyGene from the execution of a Project, (ii) is not specific to the Field, and (iii) is a generic crop technology that has general applicability outside the Field. Without limiting the foregoing and for the avoidance of doubt, Residual Expertise does not include Project Technology Results, KeyGene Identified Targets or Non-KeyGene Identified Targets.
- 1.17 **Results:** means any and all data (e.g., genotype data, expression data, transcriptomics data, metabolomic data, and sequences), plant materials, information, biological materials, genes, plant varieties, maps, analysis, improvements, results, deliverables, discoveries, inventions, work product, , know-how and/or combinations thereof, whether in electronic form or not and whether or not laid down in protocols, and all intellectual property rights related thereto, (i) developed, created, resulting and/or generated from the execution of a Project, (ii) delivered by KeyGene to XXII under this Agreement (including any PAS), (iii) otherwise invented, reduced to practice, created, developed or made by KeyGene in the performance of the Consultancy Services and/or (iv) derived, generated, developed or propagated from any Biological Material, in each case excluding Residual Expertise and KeyGene Background. Results includes Project Technology Results.

1.18 **Steering Committee:** has the meaning as defined in Article 5.

1.19 **XXII Background:** means all protocols, methods, procedures, know-how, trade secrets, information, data (e.g. sequences), Biological Material, software, technologies and/or combinations thereof, whether in electronic form or not and whether or not laid down in protocols, and all intellectual property rights related thereto, owned by, licensed in or otherwise in the possession of XXII (i) as of the Effective Date or (ii) after the Effective Date if discovered independently by XXII and not in furtherance of this Agreement, in each case which are required or may otherwise be useful for the performance of a specific Project.

Article 2 – Scope of the Agreement and Exclusivity

2.1 This Agreement describes the terms and conditions under which KeyGene will conduct mutually agreed research, services and/or consultancy in the Field.

2.2 During the Exclusivity Period, KeyGene and its Affiliates will not work with, provide any services to, provide any assistance or advise to, be engaged by, or provide any scientific information or deliverable to any third party in the Field. During the Exclusivity Period, KeyGene and its Affiliates will provide consulting services solely to XXII in the Field. For sake of clarity, KeyGene is entitled to conduct internal research in the Field during the Exclusivity Period for KeyGene's internal knowledge, but not with or for any third party.

Article 3 – Initiation and execution of Projects

Initiation of the activities

3.1 Upon written request from XXII to initiate a new Project, and provided KeyGene has no obligations towards third parties preventing it from entering into such new Project, the Parties will promptly commence and diligently pursue good faith discussions with a view to executing a PAS covering such new Project. The Parties will aim to execute such PAS within three (3) months following such written request. During the Exclusivity Period, KeyGene agrees that KeyGene and its Affiliates will not enter into any agreements with or obligations towards any third party that would prevent KeyGene from entering into a new Project in the Field with XXII.

- 3.2 All terms and conditions of this Agreement will start to apply to such new Project as of the latest signature date of the PAS which incorporates such PAS into this Agreement.
- 3.3 The first Projects to be conducted by KeyGene pursuant to and governed by this Agreement are attached hereto as Annex 2. Annex 2 will be updated from time to time with additional mutually agreed upon Projects.
- 3.4 In case of a conflict between the terms of this Agreement and any more specific terms included in any PAS attached hereto and incorporated in this Agreement, the more specific terms of the PAS shall prevail; provided, however, that notwithstanding anything contain in this Agreement of any PAS to the contrary, nothing in any PAS shall adversely affect XXII's exclusive rights in the Field during the Exclusivity Period. In case of conflict between the terms of this Agreement and any PAS that is due to conflict of law, the terms of this Agreement shall prevail.

Performance of the activities

- 3.5 KeyGene shall use commercially reasonable efforts, including but not limited to the assignment of all necessary qualified personnel and all of its technology resources, and including where applicable and agreed, the KeyGene Background, to execute the activities assigned to it under each agreed Project substantially in accordance with the planning and objectives as described in the applicable PAS. KeyGene shall, furthermore, execute its activities under this Agreement in accordance with generally accepted scientific and ethical standards.
- 3.6 XXII shall supply to KeyGene the XXII Background and Biological Material required to execute each agreed Project in a timely and suitable manner as mutually agreed in writing by the Parties, all as described in the applicable PAS and as may be further expressly agreed in writing between the Parties.
- 3.7 KeyGene shall keep and maintain lab records documenting its activities and results pursuant to each agreed Project, in a manner that is appropriate for the purpose of protecting the intellectual property rights attaching to such results and for regulatory purposes and for the use of such information by XXII in XXII's use of the Results in its scientific and/or commercial activities. Without limiting the foregoing, KeyGene will (i) promptly and fully inform XXII in writing of any Results setting forth in reasonable detail the nature of the Results, (ii) promptly deliver to XXII the Results, including without limitation a stand-alone software program, operating system and all data related to Results, which will be resident and fully operable on XXII's or XXII's designees computer server(s), together with any other software, files or tools, needed to fully access, search and use any such data (including without limitation any related genome annotations), (iii) cause all of KeyGene's agents, owners, consultants, contractors, servants, representatives and employees to assign all right, title and interest in and to any and all Results to XXII, (iv) execute and deliver to XXII each document, instrument and other writing, and take any other action, reasonably requested by XXII to assist or facilitate XXII in protecting XXII's interest in any Results (including, without limitation, assisting with XXII's preparation of any patent, plant variety right, copyright or trademark application) or to vest all right, title and interest in Results in XXII, and (v) execute, acknowledge and deliver promptly to XXII such written instruments and do and cause to be done all matter of things and other acts as may be necessary, appropriate or convenient in the reasonable opinion of XXII to obtain, secure and maintain United States and/or foreign patents, United States and/or foreign plant variety rights, United States or foreign copyright registrations, or any other legal protections in any country (where reasonable out-of-pocket costs incurred by KeyGene in doing so will be reimbursed by XXII) and to vest the entire right, title and interest in the Results in XXII.

- 3.8 KeyGene shall only be allowed to subcontract any part of its activities under this Agreement to a third party if such subcontractor and such subcontracted activity has been mutually agreed to in writing by the Parties in a PAS prior to KeyGene utilizing such third-party subcontractor, all as described in the applicable PAS, and further provided that KeyGene shall ensure that KeyGene's subcontractor is obligated to and complies with all the intellectual property and confidentiality terms and conditions of this Agreement as if such subcontractor was a party to this Agreement; provided, however, that XXII acknowledges and agrees that KeyGene may freely subcontract any part of its activities under this Agreement to KeyGene's Affiliates, including, without limitation, KeyGene's U.S. subsidiary, KeyGene, Inc. KeyGene shall ensure that all subcontracts that may expose any subcontractor to Confidential Information, Biological Material and/or Results incorporate the terms and conditions of this Agreement, to the extent applicable, including, without limitation (i) each subcontractor's level of service, systems, and control which must be at least as stringent as those required of KeyGene under this Agreement, and (ii) the terms and conditions of this Agreement relating to confidentiality, security and intellectual property ownership and rights. KeyGene will be solely liable for all acts and omissions by all subcontractors and third-parties utilized by KeyGene, including all costs, expenses, charges and other obligations of and/or to any such third-party. Any act or omission of any subcontractor or third-party utilized by KeyGene shall be deemed an act or omission of KeyGene. Any breach of these terms and conditions by its subcontractor will be regarded as a default by KeyGene itself.

Reporting & Supply of Deliverables

- 3.9 The Parties shall consult each other and discuss the progress of the Project(s) as often as necessary for reaching the objectives of the Project(s). Without prejudice to the generality of the foregoing, KeyGene shall provide a written progress report to XXII no less than every six (6) months and a final report within two (2) months upon completion of each Project ("**Report**"). Such consultation and reporting are hereby delegated to the Steering Committee.

3.10 Delivery of Results which are biological material shall be done in compliance with applicable laws and regulations.

Article 4 – Consultancy

- 4.1 If Consultancy Services are expressly desired by XXII as set forth in a PAS, then the Steering Committee shall define the content and nature of such Consultancy Services. Such Consultancy Services may include but are not limited to general advice, the establishment of new project plans, the exchange of personnel at each other's premises, and advice on strategies for protection of intellectual property rights.
- 4.2 Unless expressly agreed otherwise in writing, the Consultancy Services will be started by KeyGene as soon as possible after the signature date of the corresponding PAS in which XXII has expressly requested such Consulting Services.
- 4.3 Where necessary, KeyGene is entitled to replace employees it has assigned to perform the Consultancy Services without obtaining XXII's advance permission to do so, provided however that KeyGene shall inform XXII thereof as soon as possible and that such replacement involves employees with equal or greater expertise and who are able to perform the Consultancy Services effectively.
- 4.4 KeyGene, in furnishing the Consultancy Services, will be acting as an independent contractor. Nothing in this Agreement shall create any relationship of agent and principal, partnership, or employer and employee between the Parties or between one of the Parties and the other Party's employees.

Article 5 – Steering Committee

- 5.1 The Parties hereby establish a Steering Committee to identify, coordinate and supervise the Project(s), as well as the general collaboration between the Parties.
- 5.2 The Steering Committee consists of two (2) representatives of each Party. Each Party shall be entitled to appoint and withdraw its representative at its sole discretion. In the event a member of the Steering Committee is absent for a period of more than four (4) months, the Party with such absent representative shall appoint a substitute-representative on behalf of such Party.
- 5.3 The Steering Committee shall meet at least six (6) times per year, alternating in person or by means of telephone/videoconferencing. Meetings in person shall be at the premises of either XXII's offices or KeyGene's United States offices in Maryland, except that KeyGene may elect not more than one time each Contract Year to conduct an in-person meeting at KeyGene's office in The Netherlands, in all cases as mutually agreed by the Steering Committee. If meetings take place at the premises of XXII more than twice per year, the travel costs and accommodation costs of the KeyGene members of the Steering Committee shall be reimbursed by XXII.

- 5.4 The Steering Committee shall be responsible for the coordination of the design and the follow up of the Project(s). The Steering Committee shall convene to discuss and recommend on any critical decision to be made in such Project(s).
- 5.5 During the meeting of the Steering Committee, the representatives of each Party shall describe the progress, milestones, planning and financial status of the Project(s), and any other aspects of all then ongoing issues related to the Project(s) or other interesting developments that are of relevance to both Parties, and potential new projects pursuant to Section 3.1.
- 5.6 The Steering Committee is not authorized to take binding decisions on behalf of the Parties, unless expressly agreed otherwise in writing by the Parties. The role of the Steering Committee shall be to advise the Parties.

Article 6 – Biological Material

- 6.1 XXII shall supply KeyGene with the Biological Material in the quantities mutually agreed upon by KeyGene and XXII as set out in the applicable PAS and on the delivery date as set out in the applicable PAS. XXII acknowledges that KeyGene can only start with the execution of its activities under the Project(s) once it has received the Biological Material and associated XXII Background that it requires to conduct its activities under the Project(s).
- 6.2 The Biological Material shall be supplied in a form mutually agreed upon by KeyGene and XXII as set out in the applicable PAS. XXII shall use commercially reasonable efforts to ensure that the Biological Material is of the condition for analysis and/or other agreed use as set out in the applicable PAS. In the event the Biological Material is not of the condition as set out in the applicable PAS as mutually determined by the Parties, then XXII shall as soon as possible supply proper Biological Material and KeyGene will postpone the execution of its activities under the affected Project(s) accordingly. In the event XXII is not able to supply the proper Biological Material as set out in the applicable PAS within a reasonable time frame and in accordance with the PAS, the Parties shall mutually agree in good faith whether to amend or to terminate the affected Project(s).
- 6.3 KeyGene shall use the Biological Material with caution and prudence, and with a degree of professional skill, sound practice and judgment normally exercised in any experimental work performed by recognized professionals in the field of research or testing of materials like the Biological Material. The Parties shall comply in all material respects with all laws and governmental rules, regulations and guidelines which are provided with and applicable to the import, export, inter-state transport, growing, use and disposition of the Biological Materials, and all of such Party's other activities under this Agreement, including without limitation biosafety procedures. All expenses necessary and incurred in connection with complying with the applicable laws and regulations shall be the responsibility of the applicable Party. In no event shall either Party be liable for any use by the other Party ("**Commercializing Party**") of the Biological Material or for any claim, liability, cost, expense, damage, deficiency, loss or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) that may arise from or in connection with the Commercializing Party's use, handling, storage, or disposition of the Biological Material.

- 6.4 The Biological Material shall be used solely by employees of KeyGene (or KeyGene's sub-contractors approved by XXII under this Agreement) who are involved in the Project(s). KeyGene will not give access to the Biological Material, any Results which comprise biological or tangible materials, any derivatives of Biological Material, and/or any portion thereof (collectively, the "**Restricted Material**") to any person or entity, except KeyGene's sub-contractors approved by XXII under this Agreement or those persons under KeyGene's direct supervision and control. KeyGene shall not, by action or inaction, give, cause or allow access to, make available, distribute, convey, transfer, sell or disclose by any means any Restricted Material to any third party without the prior written consent of XXII.
- 6.5 All expenses in connection with the supply of the Biological Material by XXII to KeyGene will be borne by XXII. XXII shall be responsible at XXII's cost and expense for obtaining all necessary permits/approvals/licenses for the import/export of the Biological Material from/to KeyGene's facilities/laboratories in the United States. KeyGene shall be responsible for any importation of the Biological Material to any KeyGene facilities outside of the United States, provided that XXII shall reimburse KeyGene for any pre-approved shipping costs for such Biological Materials that are transported by KeyGene outside of the United States.
- 6.6 XXII warrants that the Biological Material will meet the quality standards set forth in the applicable PAS, or XXII will inform KeyGene in advance of any deficiencies in the Biological Materials with respect to such standards. KeyGene will then decide if the Biological Material will be used in the Project(s) by KeyGene. Furthermore, XXII represents and warrants to KeyGene that XXII has all rights (including, if applicable, any necessary regulatory approvals and clearances) and title in the Biological Material necessary for the delivery to, and use by, KeyGene as contemplated by the PAS.
- 6.7 Unless expressly agreed otherwise in writing, KeyGene will return or, at XXII's option, destroy all Restricted Material after completion or termination of the Project(s). All Restricted Material shall be the sole and exclusive property of XXII.

Article 7 – R&D Funding, Milestones, Minimum Commitment and Other Payments

R&D Funding and Consultancy Fees

- 7.1. As remuneration for the activities executed by KeyGene in connection with each agreed Project pursuant to this Agreement, XXII shall pay to KeyGene the R&D amounts set out in the associated PAS, in each case which shall be due as follows unless otherwise mutually agree in the associated PAS: (i) [*] of the total amount due under the PAS will be paid by XXII to KeyGene at the commencement of the Project to which such PAS relates and (ii) the remaining [*] of the total amount due under the PAS will be paid by XXII to KeyGene within thirty (30) days after the Parties mutually agree that KeyGene has achieved the milestones set forth in **Annex 3** attached to this Agreement, which are applicable to each Project, as may be further described in greater detail in the PAS for the Project (“**Milestone Fees**”).
- 7.2. The remuneration for the Consultancy Services is on an hourly fee basis. The consultancy fee for the Consultancy Services will be negotiated as part of the relevant PAS. These rates are excluding travelling and other out-of-pocket expenses pre-approved in writing by XXII prior to being incurred and then actually incurred by KeyGene in the performance of the Consultancy Services, which shall be invoiced separately on a cost basis. All reimbursable expenses of KeyGene, including without limitation any travel expenses, must be preapproved in writing by XXII and no fees or expenses shall be paid by XXII unless agreed to in writing in advance of their incursion. Unless agreed otherwise in writing by the Parties, KeyGene may invoice the consultancy hours and expenses on a monthly basis. KeyGene reserves the right, once per calendar year, for the first time on the first anniversary of the Effective Date, to increase the hourly fee, which increase shall not be more than [*] per calendar year.
- 7.3. Within sixty (60) days after the end of each Contract Year, KeyGene shall send a written overview of the amounts actually due from and/or paid by XXII for Projects and/or the Consultancy Services rendered by KeyGene and its Affiliates in such preceding Contract Year (“**Actual Expenditure**”).

Minimum Research Funding to maintain Exclusivity

- 7.4. If and as long as XXII pays to KeyGene in Research Funding per Contract Year an aggregate amount of (i) no less than[*], less (ii) any Milestone Fees due to KeyGene upon the achievement of milestones identified for completion during such Contract Year but not yet completed through no fault of XXII under this Agreement and therefore not yet paid for such Contract Year pursuant to Section 7.1 (the “**Minimum Research Funding Amount**”), the Exclusivity Period and Section 2.2 shall apply (for a maximum of seven (7) Contract Years). If in any Contract Year the Research Funding is less than said Minimum Research Funding Amount, XXII has the right to pay the balance to KeyGene within thirty (30) days after receipt by XXII of the Actual Expenditure report from KeyGene for such Contract Year and, if such balance payment is made prior to the expiration of such thirty (30) day period, then the Exclusivity Period shall continue. In the absence of payment of such Minimum Research Funding Amount and/or payment of the balance for any Contract Year, the Exclusivity Period shall end on the day after the expiration of such thirty (30) day period.

Patent Milestones

- 7.5. XXII shall be responsible for and shall solely control all intellectual property filings regarding the Results with legal counsel selected by XXII in XXII's sole and absolute discretion. KeyGene will cooperate fully with XXII in such filing, prosecution, and maintenance.
- 7.6. XXII will pay KeyGene [*] on the filing of each first patent application in a patent family (on a patent family by patent family basis) claiming, incorporating or otherwise based in material part on a KeyGene Identified Target or a Project Technology Result.
- 7.7. XXII will pay KeyGene [*] on the granting of each first patent in a patent family (on a patent family by patent family basis) claiming, incorporating or otherwise based in material part on a KeyGene Identified Target or a Project Technology Result.

Royalties to KeyGene

- 7.8. XXII will pay to KeyGene a royalty on Net Sales as follows:
 - i. [*] of Net Sales of KeyGene Identified Targets, or products or services that incorporate, are based on, or otherwise make use of KeyGene Identified Targets;
 - ii. [*] of Net Sales of Non-KeyGene Identified Targets, or products or services that incorporate, are based on, or otherwise make use of Non-KeyGene Identified Targets;
 - iii. A royalty on Net Sales of Project Technology Results, or products or services that incorporate, are based on, or otherwise make use of Project Technology Results, in each case in the amount (if any) as may be mutually agreed by the Parties on a Project by Project basis in the applicable PAS.
- 7.9. XXII will pay to KeyGene a royalty on License Income related to KeyGene Identified Targets and Non-KeyGene Identified Targets of[*] of such License Income. A Royalty on License Income related to Project Technology Results will be agreed on a Project by Project basis in the applicable PAS.
- 7.10. If XXII would require a third party license to obtain or maintain freedom to operate to commercialize the Results, or otherwise require a license to be able to commercialize the Results without infringing third party rights, XXII may deduct such royalty from the royalty owed to KeyGene, provided that the resulting royalty payable to KeyGene by XXII shall never be less than [*] of the royalty otherwise owed to KeyGene. For the avoidance of doubt: this anti-stacking clause is only applicable when the commercialization of the Results *as such* would, in absence of a license, infringe third party intellectual property rights. If XXII would desire to commercialize the Results in a formulated form and/or in combination with a device or other product or in a special packaging, royalties payable by XXII for such formulation and/or other product and/or packaging are not deductible from royalties payable to KeyGene.

Royalties to XXII

- 7.11. KeyGene will pay to XXII a royalty on KeyGene Net Sales as follows:
- i. [*] of KeyGene Net Sales of KeyGene Identified Targets, or products or services that incorporate, are based on, or otherwise make use of KeyGene Identified Targets;
 - ii. [*] of KeyGene Net Sales of Results other than KeyGene Identified Targets and Project Technology Results, or products or services that incorporate, are based on, or otherwise make use of such Results (other than KeyGene Identified Targets and Project Technology Results);
 - iii. A royalty on KeyGene Net Sales of Project Technology Results, or products or services that incorporate, are based on, or otherwise make use of Project Technology Results, in each case in the amount (if any) as may be mutually agreed by the Parties on a Project by Project basis in the applicable PAS.
- 7.12. KeyGene will pay to XXII a royalty on KeyGene License Income of [*] of such KeyGene License Income.

General

- 7.13. Royalties shall be payable within forty-five (45) days after the end of each calendar quarter in which royalties are earned under this Agreement and such royalty payments shall be accompanied with a specification of the Net Sales received by the paying Party and its Affiliates and License Income received by the paying Party and its Affiliates from licensees in such calendar quarter and a calculation of the royalties thus due to the other Party.
- 7.14. If requested in writing by either Party, the other Party shall, and shall require that its Affiliates and licensees shall, at all reasonable times during normal business hours permit an independent certified public accountant to make an examination and audit of all records required to be kept pursuant to this Article 7, such examination and audit not to occur more than once each calendar year. Prompt adjustment shall be made for any errors disclosed by such examination. If said audit reveals underpayments to the Party performing the audit in excess of five percent (5%) of the payments made to it, then the under-paying Party will reimburse the auditing Party for all reasonable costs associated with such audit within ten (10) days of receipt of notice from the auditing Party setting forth such costs of the independent certified public accountant.
- 7.15. Each Party will bear its own costs and expenses in connection with its activities under the Project(s), including costs for employees and material related to the Project(s).
- 7.16. All amounts payable under this Agreement are non-refundable and non-creditable. All payments shall be net payments without deduction of any bank or transfer charges or withholding taxes.
- 7.17. All amounts payable under this Agreement are inclusive of value added tax and excise or sales taxes or levies, and shall be due within thirty (30) days of the date of the relevant invoice, effectively in the currency of the United States, without the right to set off or withholding payment, by remittance by electronic wire transfer of funds to a bank account as specified in the invoice or by payment by certified cheque.
- 7.17.1 Withholding taxes. If applicable laws, rules or regulations require the withholding of taxes with respect to any amounts payable under this Agreement, the applicable Party shall make such withholding payments and shall subtract the amount thereof from the payments due to the other Party. The withholding Party shall submit to the other Party appropriate proof of payment of the withheld taxes as well as the official receipts within a reasonable period of time. The withholding Party shall provide the other Party reasonable assistance in order to allow the other Party to obtain the benefit of any present or future treaty against double taxation which may apply to the payments due by the withholding Party to the other Party.
- 7.18. If a Party fails to make any payment due and payable under this Agreement by the due date for payment, then such Party shall pay monthly interest on the overdue amount at the rate of one percent (1%). Such interest shall accrue on a daily basis from the due date until actual payment of the overdue amount. Such Party shall pay the interest together with the overdue amount. After a year, interest due shall also bear interest at the rate of one percent (1%). Moreover, such Party will be charged with all any actual expenses of judicial and extra-judicial collection.

Article 8 – Ownership & IP Rights & Licenses

Background / Biological Material

- 8.1. XXII shall own and retain ownership of the XXII Background including all intellectual property rights related thereto. KeyGene shall not receive any rights and licenses to use the XXII Background other than for the performance of the activities under a PAS and/or as agreed explicitly in this Agreement.
- 8.2. KeyGene shall own and retain ownership of the KeyGene Background including all intellectual property rights related thereto. XXII shall not receive any rights and licenses to use the KeyGene Background other than for the performance of the activities under a PAS and/or as agreed explicitly in this Agreement, which includes the license by KeyGene to XXII of the KeyGene Background as provided in Section 8.6 of this Agreement.

Foreground

- 8.3. XXII shall exclusively own all the Results, including all intellectual property rights related thereto, unless otherwise mutually agreed to in writing in the PAS. For the sake of clarity, such ownership right includes the full power of disposal, derivation, propagation, sublicense and enforcement unless otherwise agreed in this Agreement or a PAS.
- 8.4. KeyGene hereby assigns, transfers and conveys to XXII all right, title and interest in and to the Results. KeyGene shall execute and deliver to XXII such documents, instrument and other writings reasonably requested by XXII to vest all right, title and interest in the Results in XXII.
- 8.5. KeyGene shall exclusively own all Residual Expertise, including all intellectual property rights related thereto. For the sake of clarity, such ownership right includes the full power of disposal, derivation, propagation, sublicense and enforcement.
- 8.6. KeyGene hereby grants to XXII and its Affiliates a worldwide, non-exclusive, perpetual, royalty-free right and license, with the right to sublicense, license in the Field to the KeyGene Background and the Residual Expertise to the extent needed by XXII to protect the Results, to protect any intellectual property rights in the Results and/or to commercialize in the Field the Results, including without limitation any Project Technology Result. It is agreed that the *Cannabis Sativa* L. protoplast regeneration protocol to be developed in the first Project will be a Project Technology Result.
- 8.7. During the Exclusivity Period, XXII hereby grants to KeyGene and its Affiliates a worldwide and exclusive right and license, with the right to sublicense, to use, commercialize and apply the Results (including intellectual property rights related thereto) outside the Field (i.e. in crops or plant species other than hemp and cannabis) as it deems fit; provided, however, that KeyGene and its Affiliates shall not sublicense, use, commercialize, or apply, and shall have not right to sublicense, use, commercialize, or apply, the Results in tobacco. After the Exclusivity Period, XXII hereby grants to KeyGene and its Affiliates a worldwide and non-exclusive right and license, with the right to sublicense, to use, commercialize and apply the Results (including intellectual property rights related thereto) outside the Field (i.e. in crops or plant species other than hemp and cannabis) as it deems fit; provided, however, that KeyGene and its Affiliates shall not sublicense, use, commercialize, or apply, and shall have not right to sublicense, use, commercialize, or apply, the Results in tobacco.

- 8.8. Nothing else in this Agreement shall be construed as granting to the other Party any right and/or license with respect to Biological Material, XXII Background, KeyGene Background and/or Results, other than as explicitly stated in this Agreement.

Article 9 – Confidentiality

- 9.1. XXII undertakes to hold all KeyGene Background, or any part thereof, and any information (including data, protocols and documents) related thereto, (hereinafter referred to as “**KeyGene’s Confidential Information**”), in strictest confidence and shall, therefore, not disclose KeyGene’s Confidential Information in whatever form, either in whole or in part, to a third party with the exception of Affiliates, which Affiliates shall be bound by the same confidentiality undertaking as XXII, nor make KeyGene’s Confidential Information publicly available, unless KeyGene has given its previous written consent thereto.
- 9.2. KeyGene undertakes to hold all XXII Background, Biological Material and Results, or any part thereof, and any information (including data, protocols and documents) related thereto, (hereinafter referred to as “**XXII’s Confidential Information**”), in strictest confidence and shall, therefore, not disclose XXII’s Confidential Information in whatever form, either in whole or in part, to a third party with the exception of Affiliates, which Affiliates shall be bound by the same confidentiality undertaking as KeyGene, nor make XXII’s Confidential Information publicly available, unless XXII has given its previous written consent thereto.
- 9.3. The confidentiality obligations set out in this Article 9 will remain in full force and effect (i) during the full term of this Agreement and for a period of ten (10) years after the date of termination or expiration. The confidentiality obligations will not be applicable to that part of the KeyGene’s Confidential Information or XXII’s Confidential Information where a Party is able to demonstrate by written records that:
- (a) it was already in the public domain at the time of supply by the disclosing Party or that it has become part of the public domain after the time of supply by the disclosing Party, otherwise than through breach or omission on the part of the receiving Party or any of its Affiliates; or
 - (b) it was already in the possession of the receiving Party or any of its Affiliates at the time of supply by the disclosing Party as evidenced by tangible contemporaneous written records; or
 - (c) it has been lawfully supplied to the receiving Party or any of its Affiliates by a third party, without such third party being under any confidentiality obligation; or
 - (d) it is required to be disclosed, (i) by operation of law, statute, rule, regulation or by order of a court of competent jurisdiction or a government authority or relevant securities exchange having competent jurisdiction, or, (ii) in connection with any notification, registration or authorization requirements related to the research, development, production and/or commercialization of products resulting from the use of the Results, or, (iii) in connection with any application for intellectual property rights covering results generated under this Agreement, provided the Party applying for such intellectual property rights owns such results and/or has the right under this Agreement to file an application to obtain intellectual property rights covering such results, provided that, to the extent it is legally permitted to do so, the disclosing Party gives the other Party as much advance notice of disclosure as possible in order to permit the other Party the opportunity to seek and obtain legal protections against such disclosure.

- 9.4. For the sake of clarity, the confidentiality obligations set out in this Article 9 shall not impede the exercise of the rights and licenses expressly granted to the Parties under this Agreement.
- 9.5. Any proposals for Projects or Consultancy Services written by KeyGene shall also be considered KeyGene's Confidential Information. Only after prior written approval by KeyGene may XXII share the information contained within such proposals with third parties.
- 9.6. The Parties shall hold the terms of this Agreement and any PAS in strictest confidence and shall not disclose or allow the disclosure of the terms of this Agreement, any PAS, or any part thereof, to any third party or make the terms of this Agreement or any PAS publicly available unless the Parties have agreed otherwise or unless disclosure is required by law, rule or regulation, including but not limited to the securities laws of the United States and the rules and regulations of the U.S. Securities and Exchange Commission and/or the New York Stock Exchange American market.

Article 10 – Publications and Disclosure

- 10.1. After signing of this Agreement, by mutual agreement of the Parties and on a mutually agreed date, the Parties may send out a mutually agreed press announcement about the existence of this Agreement between the Parties; provided, however that if XXII is required to disclose and/or file this Agreement sooner by applicable law, rule or regulation, then XXII shall be permitted to do so in a timely manner since XXII cannot be late in its required public filings as a public company. Any further press communication other than the agreed press announcement about the Agreement may only be done by either Party after prior written consent of the other Party.
- 10.2. XXII shall not publish the Results without the prior written consent of KeyGene if KeyGene's name is identified in such publication. XXII may publish or publicly disclose any of the Results without the prior written consent of KeyGene so long as KeyGene's name is not identified in or is identifiable from such publication or disclosure.

Article 11 – Disclaimers and Limitations of liability

- 11.1. The Parties cannot guarantee and extend no warranties to each other that:
- a. any Results or Project Technology Results, including the desired Results or Project Technology Results as specified in the PAS(s), will be obtained by executing the Project and/or rendering the Consultancy Services; or
 - b. the Results or Project Technology Results will not contain any immaterial errors and/or inaccuracies.
 - c. the Results or Project Technology Results are suitable for the purpose for which the respective Parties wishes to use them or that the respective Parties will be able to use and/or apply the Results or Project Technology Results;
 - d. the Results and Project Technology Results, the use and/or application thereof, and/or other acts in relation thereto, will not knowingly infringe any patent or any other intellectual property right or license of a third party.
- 11.2. XXII shall in all cases be entirely and solely responsible and liable for XXII's use and/or application of, and/or XXII's other acts in relation to the Results. XXII will use the Results and Project Technology Results only in accordance with the applicable laws including, where applicable, good clinical practices, good manufacturing practices and personal data protection laws. KeyGene represents and warrants that it will use commercially reasonable efforts to ensure that all of its work, the Results and the Project Technology Results will be free from any material errors and inaccuracies and will not knowingly (without the obligation to perform a "freedom to operate" or similar search) infringe any patent or other intellectual property right or license of a third-party.
- 11.3. Any recommendations, opinions or findings expressed by KeyGene employees during the Consultancy Services or stated in the Report are based on circumstances and facts as they existed at the time KeyGene performed such Consultancy Services or produced such Report. Any changes in such circumstances and facts upon which such Consultancy Services and/or Report are based may adversely affect any recommendations, opinions or findings contained in such Report, in which case KeyGene shall notify XXII in writing of such changes in a timely manner after KeyGene becomes aware of such changes.
- 11.4. KeyGene shall in all cases be entirely and solely responsible and liable for KeyGene's use and/or application of, and/or KeyGene's other acts in relation to the Results. KeyGene will use the Results and Project Technology Results only in accordance with the applicable laws including, where applicable, good clinical practices, good manufacturing practices and personal data protection laws.
- 11.5. Save for maliciously intentional or grossly negligent acts by the directors or officers of KeyGene, KeyGene, its shareholders, officers, directors, representatives and/or agents shall not be liable for any damage arising out of or in connection with the interpretation, use, inability to use and/or application of the Results and the Report by XXII, its Affiliates and licensees or arising out of or in connection with the infringement of third party intellectual property rights. In no circumstances shall KeyGene be liable for loss, damage, costs, or expenses of any nature whatsoever incurred or suffered by the other Party or its Affiliates, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, that is (i) of an indirect, special or consequential nature or for (ii) any loss of profits, revenue, reputation, business opportunity, or goodwill. Nothing in this Agreement shall exclude any person's liability to the extent that it may not be so excluded under applicable law, including any liability for death or personal injury caused by that person's negligence, or liability for fraud or fraudulent representation. Save for maliciously intentional or grossly negligent acts by the directors or officers of XXII, XXII, its shareholders, officers, directors, representatives and/or agents shall not be liable for any damage arising out of or in connection with the interpretation, use, inability to use and/or application of the Biological Material, XXII Background and the Results by KeyGene, its Affiliates and licensees or arising out of or in connection with the infringement of third party intellectual property rights. In no circumstances shall XXII be liable for loss, damage, costs, or expenses of any nature whatsoever incurred or suffered by the other Party or its Affiliates, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, that is (i) of an indirect, special or consequential nature or for (ii) any loss of profits, revenue, reputation, business opportunity, or goodwill. Nothing in this Agreement shall exclude any person's liability to the extent that it may not be so excluded under applicable law, including any liability for death or personal injury caused by that person's negligence, or liability for fraud or fraudulent representation.

- 11.6. XXII shall, subject to the limitations set forth in Section 11.5, indemnify, defend and hold harmless KeyGene and its Affiliates, and their respective directors, officers or representatives, if any, from and against all damages, losses, obligations, liabilities (including without limitation patent infringement and product liability), claims, actions or courses of action, encumbrances, costs and expenses, (including without limitation reasonable attorney's fees), suffered, sustained, incurred or required to be paid arising out of, based upon, in connection with or as a result of:
- (i) XXII's and/or its Affiliate's use and/or application of, and/or other acts in relation to, any of the Biological Material, KeyGene Background, Results or Project Technology Results, and/or
 - (ii) XXII's and/or its Affiliate's use of any data, products or materials developed or generated by making use of and/or applying the Biological Material, KeyGene Background, the Results or Project Technology Results or any part thereof, and/or
 - (iii) Any negligent or intentional breach of this Agreement by XXII and/or its Affiliates.
- 11.7. KeyGene shall, subject to the limitations set forth in Section 11.5, indemnify, defend and hold harmless XXII and its Affiliates, and their respective directors, officers or representatives, if any, from and against all damages, losses, obligations, liabilities (including without limitation patent infringement and product liability), claims, actions or courses of action, encumbrances, costs and expenses, (including without limitation reasonable attorney's fees), suffered, sustained, incurred or required to be paid arising out of, based upon, in connection with or as a result of:
- (i) KeyGene and/or its Affiliate's use and/or application of, and/or other acts in relation to, any of the Biological Material, XXII Background, the Results, the Project Technology Results, and/or
 - (ii) KeyGene's and/or its Affiliate's use of any data, products or materials developed or generated by making use of and/or applying the Biological Material, XXII Background, the Results, or Project Technology Results or any part thereof, and/or
 - (iii) Any negligent or intentional breach of this Agreement by KeyGene and/or its Affiliates.

Article 12 – Term and Termination

- 12.1. This Agreement will come into force and effect on the Effective Date and, other than provided below, will have a duration of five (5) Contract Years. Prior to the end of the fourth (4th) Contract Year, the Parties may by mutual agreement extend the Agreement for another two (2) Contract Years, in which event the Steering Committee shall come up with additional Projects.
- 12.2. This Agreement may be terminated at any time upon mutual written consent of the Parties hereto.
- 12.3. Each of the Parties is entitled to forthwith terminate this Agreement in writing, in the event that:
- a. the other Party has breached one or more of its material obligations under this Agreement and such breach is either not capable of being remedied (such as breach of confidentiality obligations) or, if capable of being remedied, is not remedied within thirty (30) days after the breaching Party has received written notification requesting such breach to be remedied; and/or
 - b. the other Party is declared bankrupt or a petition for the bankruptcy or suspension of debt of this Party is filed or this Party passes a resolution or a court makes an order for its winding up (otherwise by way of solvent liquidation where the emergent company assumes its obligations); and/or the other Party suspends, threatens to suspend, payment of its debts or is unable to pay its debts as they fall due or admits inability to pay its debts or is deemed unable to pay its debts within the meaning of applicable bankruptcy or insolvency laws to which such Party is subject, or a petition is filed, a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of that other Party, other than for the sole purpose of a scheme for a solvent amalgamation of that other Party with one or more other companies or the solvent reconstruction of the other Party, or a court makes an order for its winding up.

Article 13 – Consequences of termination

- 13.1. In the event a Project is terminated, the Agreement shall not be affected and shall remain in full force and effect.
- 13.2. In the event the Agreement is terminated pursuant to Section 12.2, the Projects and/or Consultancy Services that have not yet finalized before the termination date of the Agreement shall remain in full force and effect until the delivery of the Report(s) of the Projects and payment of all sums due thereunder.

- 13.3. On termination of the Agreement, unless such things are needed by such Party to perform its obligations under a Project (and then only until such time), as soon as reasonably practical:
- (a) KeyGene shall return or destroy, as directed by XXII, any Biological Material; and
 - (b) The Parties shall return all of the other Party's equipment and materials. Until these are returned that Party shall be solely responsible for the safe-keeping.
- 13.4. In the event the Agreement is terminated for cause pursuant to Section 12.3, the following consequences shall occur:
- (a) the Projects and the Consultancy Services shall immediately be terminated per the termination date of the Agreement; and
 - (b) all sums that became due from XXII to KeyGene for Projects and Consultancy Services prior to the date of termination shall remain due and outstanding from XXII to KeyGene and shall be promptly paid thereafter by XXII to KeyGene; and
 - (c) all sums that became due from KeyGene to XXII under this Agreement prior to the date of termination shall remain due and outstanding from KeyGene to XXII and shall be promptly paid thereafter by KeyGene to XXII.
 - (d) KeyGene shall return or destroy, as directed by XXII, any Results.
- 13.5. The rights and licenses granted under or pursuant to this Agreement shall continue notwithstanding any expiry or termination of this Agreement except that either Party is entitled to terminate such rights and licenses immediately in writing in the event that:
- (a) any material terms of such rights and licenses have been breached and such breach is either not capable of being remedied (such as breach of confidentiality obligations) or, if capable of being remedied, not remedied within thirty (30) days after the breaching Party has received written notification requesting such breach to be remedied; and/or
 - (b) the other Party suspends, threatens to suspend, payment of its debts or is unable to pay its debts as they fall due or admits inability to pay its debts or is deemed unable to pay its debts, or a petition is filed, a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of that other Party, other than for the sole purpose of a scheme for a solvent amalgamation of that other Party with one or more other companies or the solvent reconstruction of the other Party, or a court makes an order for its winding up.
- 13.6. The provisions of this Agreement that by their nature are intended to survive termination or expiration shall survive termination or expiration of this Agreement, which shall include in any event Sections 6.4, 6.6 and 6.7 (Biological Material), Sections 7.5 - 7.20 (Milestones and Royalties and subject to the term provided in Section 13.7), Sections 8.1 - 8.8 (Ownership, IP Rights and, subject to Section 13.5, the licenses), Articles 9 (Confidentiality), 10 (Publication), 11 (Disclaimers and Limitations of Liability), 13 (Consequences of Termination), 14 (Notices), 15 (Governing Law and Dispute Resolution), Sections 16.1 (warranty), 16.3 (force majeure), 16.4 (assignment), 16.5 (severability), 16.7 (variation), 16.9 (rights and remedies), 16.10 (equitable rights), 16.11 (rights of third parties) and 16.12 (entire agreement), as well as Article 1 (Definitions) to the extent the definitions are used in the surviving Articles, shall survive and remain in full force effect after the termination or expiration of this Agreement or of any specific Project and/or Consultancy Services hereunder.
- 13.7. Notwithstanding any termination or expiration of this Agreement, the royalty payment, reporting and audit obligations of each Party to the other Party shall continue until the later of (i) expiration of the last to expire patents or plant variety rights included in the Results or (ii) fifteen (15) years from the Effective Date if no such patents or plant variety rights issue in the United States.

Article 14 – Notices

14.1. Any notice required to be given under this Agreement shall be deemed to be sufficiently given, only if sent by overnight international delivery service, or by email, with receipt confirmed, addressed to the Party to be notified at its address shown below, or at such other address and/or contact person as may later be furnished by either Party in writing to the notifying Party.

	If to KeyGene:	If to XXII:
Address	Keygene N.V. PO Box 216 6700 AE Wageningen The Netherlands	22nd Century Group, Inc. 8560 Main Street, Suite 4 Williamsville, New York 14221 United States of America
Attn.	Managing Director	President and Chief Executive Officer
Email		

Article 15 – Governing law and dispute resolution

15.1. This Agreement shall be governed by and construed and interpreted in accordance with the laws of the State of New York, United States.

15.2. These dispute resolution procedures shall be the exclusive means for resolution of disputes arising out of or relating to this Agreement, or its breach.

- 15.3. If a dispute arises out of or relates to this Agreement, or its breach, the disputing Party may give the other Party written notice of any dispute not resolved in the normal course of business. Within thirty (30) days after delivery of the written notice, executives who have authority to settle the controversy and who are at a higher level of management than the persons with direct responsibility for administration of this Agreement shall meet at a mutually acceptable time and place and thereafter as often as they reasonably deem necessary, to attempt to resolve the dispute.
- 15.4. If the dispute has not been resolved by negotiation within forty-five (45) days after delivery of the initial notice of negotiation, or if the Parties failed to meet within thirty (30) days after delivery, the Parties agree to attempt to resolve the dispute through mediation by a sole mediator selected by the Parties or, at any time at the option of a Party, to mediation under the ICC Mediation Rules.
- 15.5. If not thus resolved, the Parties agree to submit the matter to settlement proceedings under the ICC ADR Rules. If the dispute has not been settled pursuant to the said Rules within forty-five (45) days following the filing of a Request for ADR or within such other period as the Parties may agree in writing, such dispute shall, upon the written request of either Party, be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with the said Rules of Arbitration. The place of arbitration shall be New York, USA. The proceedings shall be conducted in the English language.

Article 16 – Miscellaneous

- 16.1. Each Party represents and warrants:
- (a) that any and all of its Affiliates, to which any rights and licensed are granted hereunder, will properly and timely fulfill any and all of the obligations hereunder and any default or breach of any of the provisions of this Agreement by any Affiliate will be observed and construed as a breach or default of the concerning provision by the Party concerned; and
 - (b) that it has full power and authority to carry out the actions contemplated under this Agreement.
- 16.2. For the purposes of this Agreement, a Force Majeure Event shall mean an event, condition, or circumstances or its effect which:
- (a) is beyond the reasonable control of and occurs without fault or negligence on the part of the Party claiming it as a Force Majeure Event; and
 - (b) causes a delay or disruption in the performance of any obligation under this Agreement despite all reasonable efforts of the Party claiming it as a Force Majeure Event to prevent it or mitigate its effects.

- 16.3. Neither Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement if such delay or failure result from any of the Force Majeure Event. In such circumstances the time for performance shall be extended by a period equivalent to the period which performance shall be delayed or failed to be performed. If the period of delay or non-performance caused by any of the Force Majeure Event continues for twelve (12) weeks the Party not affected may terminate this Agreement by giving thirty (30) days' written notice to the affected Party. Upon termination thereof, neither party shall have any further claims against the other party in relation to any breach arising from a Force Majeure Event.
- 16.4. A Party shall not be entitled to assign or transfer the rights and obligations of this Agreement, either in whole or in part, without the prior written consent of the other Party.
- 16.5. Should any provision in this Agreement or any document related to it turn out to be invalid, illegal or unenforceable, it will not affect the validity or enforceability of this Agreement as far as the provisions other than the invalid provisions are concerned. In that event, the aim of the Parties shall be to replace the provision that is invalid by one that is valid and in line with the intention of the Parties upon entering into this Agreement.
- 16.6. Any amendments or additions made to this Agreement shall only be valid and binding between the Parties if made in writing and executed by authorized signatories of both Parties.
- 16.7. No variation of this Agreement shall be effective unless it is in writing and signed by the Parties (or their authorised representatives). Any variation of this Agreement agreed by the Parties in accordance with this Section shall be deemed to apply to all future Projects entered after the date of such variation, but shall not apply to Projects already in force at that date unless such variation specifically so provides.
- 16.8. Nothing in this Agreement shall give either Party any authority to act or make representations or commitments on behalf of the other Party or to create any contractual liability to a third party on behalf of the other Party, and nothing in this Agreement is intended to, or shall be deemed to, establish any partnership between any of the Parties.
- 16.9. The rights and remedies provided in this Agreement are in addition to, and not exclusive of, any rights and remedies provided by law.
- 16.10. Without prejudice to any other rights or remedies that a Party ("**First Party**") may have, the other Party ("**Other Party**") acknowledges and agrees that damages alone would not be an adequate remedy for any breach of the terms of this Agreement by the First Party. Accordingly, the First party shall be entitled to the remedies of injunction, specific performance or other equitable relief for any threatened or actual breach of the terms of this Agreement.

- 16.11. A party which is not a party to this Agreement shall not have any rights under this Agreement to enforce any term of this Agreement.
- 16.12. This Agreement comprises the entire agreement between the Parties and supersedes and extinguishes all previous drafts, agreements, arrangements and understandings between them whether written or oral, relating to its subject matter.
- 16.13. Headings are for convenience only.

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in twofold by their duly authorized representatives.

Keygene N.V.

22nd Century Group, Inc.

Name: Dr. Arjen J. van Tunen
Title: Managing Director
Date: _____

Name: Henry Sicignano III
Title: President & Chief Executive Officer
Date: _____

ANNEX 1

Template PAS

Project Approval Sheet (PAS)

ANNEX 2

First Project PAS

Project Approval Sheet (PAS)

ANNEX 3

Milestones

CERTIFICATIONS

I, **Henry Sicignano III, Chief Executive Officer of 22nd CENTURY GROUP, INC.,** certify that:

1. I have reviewed this quarterly report on Form 10-Q of 22nd CENTURY GROUP, INC.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2019

/s/ Henry Sicignano III
Henry Sicignano III
President, Chief Executive Officer and Director
(Principal Executive Officer)

CERTIFICATIONS

I, **John T. Brodfuehrer, Chief Financial Officer of 22nd CENTURY GROUP, INC.,** certify that:

1. I have reviewed this quarterly report on Form 10-Q of 22nd CENTURY GROUP, INC.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2019

/s/ John T. Brodfuehrer
John T. Brodfuehrer
Chief Financial Officer
(Principal Financial Officer)

Written Statement of the Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. §1350

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Executive Officer of 22nd CENTURY GROUP, INC. (the "Company"), and I, the undersigned Chief Financial Officer of the Company, hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Date: May 7, 2019

/s/ Henry Sicignano III

Henry Sicignano III
President and Chief Executive Officer

Date: May 7, 2019

/s/ John T. Brodfuehrer

John T. Brodfuehrer
Chief Financial Officer
