



August 7, 2019

22nd Century Group Files 2019 Second Quarter Report

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a plant biotechnology company that is focused on tobacco harm reduction, Very Low Nicotine Content tobacco and hemp/cannabis research, announced today that the Company filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 with the U.S. Securities and Exchange Commission. The Company will provide a business update for investors on a conference call to be held on Thursday, August 8, 2019, at 4:00 PM (Eastern Time).

Clifford B. Fleet, President and Chief Executive Officer of 22nd Century Group, together with John T. Brodfuehrer, Chief Financial Officer, will conduct the call. Interested parties are invited to listen to the call by dialing: (800) 353-6461 and using Conference ID 7607997. The conference call will consist of an overview of recent business highlights, a discussion of the Company's strategies and a summary of the financial information presented in the Company's second quarter 2019 Form 10-Q.

For the second quarter of 2019, 22nd Century's accomplishments and notable events include:

On April 9, 2019, the Company announced that it 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 and other improved traits for agricultural applications. The KeyGene collaboration provides the Company with access to a unique suite of crop innovation platforms, including genomics, molecular genetics, trait discovery and breeding technologies. Under the agreement, 22nd Century will hold exclusive worldwide rights to all hemp/cannabis plant lines, intellectual property on metabolic traits, and research results that are developed through the KeyGene partnership.

On April 17, 2019, the Company announced the hiring of John Pritchard as the Company's 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. 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 will lead and oversee the Company's global regulatory and compliance activities, and he will engage with the U.S. Food and Drug Administration ("FDA") in support of the Company's Modified Risk Tobacco Product ("MRTP") application for 22nd Century's proprietary Very Low Nicotine Content ("VLNC") tobacco cigarettes under the proposed brand name of VLN®. 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 the Company's initiatives with foreign governments that are interested in 22nd Century's proprietary VLNC tobacco for use in their countries.

On April 30, 2019, the Company announced that the FDA conducted a comprehensive inspection of the Company's manufacturing facility in North Carolina as a part of the FDA's review of 22nd Century's Pre-Market Tobacco ("PMT") application for the Company's VLN® cigarettes. 22nd Century's proposed VLN® cigarettes are made with the Company's proprietary VLNC tobacco and contain at least 95% less nicotine as compared to the 100 leading cigarette brands in the United States. The FDA's inspection was a highly anticipated component 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 22nd Century's proprietary VLN® cigarettes and reviewed 22nd Century's raw material receiving and storage procedures, quality control processes, manufacturing equipment and systems, tobacco processing methods, and finished-products analyses procedures.

On June 14, 2019, the Company announced the appointment of Michael Zercher as its new Chief Operating Officer. Mr. Zercher joined the Company in October 2016 as Vice President of Business Development. From 2003 until 2009, Mr. Zercher served as Vice President and Managing Director of Santa Fe Natural Tobacco Company's

international business, a subsidiary of Reynolds American, Inc. and the corporate home of the Natural American Spirit tobacco brand.

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

On July 12, 2019, the Company announced the publication of a report by the Centers for Disease Control and Prevention ("CDC") that found 8 out of 10 adults in the United States are in favor of lowering nicotine levels in cigarettes. The CDC survey was conducted in 2018 and assessed adults' attitudes toward regulating nicotine levels in cigarettes in the U.S., with the survey reflecting that an overwhelming majority of adults, including 80% of cigarette smokers and 84% of former smokers, favored requiring cigarette makers to lower the nicotine levels in cigarettes to make them less addictive. In the report, the Director of CDC's Office on Smoking and Health, Corinne Graffunder, Dr.PH., M.P.H., stated, "Cigarettes and other combustible tobacco products are responsible for the overwhelming burden of death and disease from tobacco use in the United States. Lowering nicotine levels in cigarettes could help current smokers quit and make it less likely for future generations to become addicted to these products." The Company's proprietary VLNC cigarettes underpin the FDA's plans to require all cigarettes in the U.S. to be made minimally or non-addictive.

On July 19, 2019, the Company announced that the FDA accepted and filed for substantive scientific review the Company's MRTP application for its VLNC cigarettes under the proposed brand name of VLN®. The MRTP application is now moving forward in the next phase of the FDA review process.

On July 26, 2019, the Company announced that President and Chief Executive Officer Henry Sicignano III resigned for personal reasons and that Mr. Sicignano will continue to serve the Company, on a consultancy basis, for the next several years.

On August 5, 2019, the Company announced the appointment, effective August 3, 2019, of Clifford Fleet to serve as the Company's new President and Chief Executive Officer and as a member of the Company's Board of Directors. Mr. Fleet has served as a strategic advisor to 22nd Century Group since December 2018. Mr. Fleet was previously the President and Chief Executive Officer of Philip Morris USA, Inc.. Prior to that, Mr. Fleet held a variety of management and leadership positions at the Altria family of companies in Marketing, Strategy and Business Development, Investor Relations, Sales, Market Research and Operations. Mr. Fleet is a native of Virginia, and he earned four academic degrees from the College of William & Mary, including a BA, MA, JD and MBA.

Second Quarter 2019 Financial Summary

The Company used cash during the second quarter of 2019 of approximately \$4.9 million. The Company remains in a strong financial position as of June 30, 2019 with cash, cash equivalents, and short-term investment securities totaling approximately \$47.0 million.

Net sales revenue for the second quarter 2019 was \$5,815,000, a decrease of \$1,100,000, or 15.9%, from net sales revenue of \$6,915,000 for the second quarter 2018. Net sales revenue for the first half 2019 was \$12,109,000, a decrease of \$922,000, or 7.1%, from net sales revenue of \$13,031,000 for the first half 2018. The decreases in net sales revenue were primarily the result of a decrease in production volumes under various filtered cigar manufacturing contracts where revenue is recognized over time.

For the second quarter 2019, the Company reported a net operating loss of \$5,029,000 as compared to a net operating loss of \$7,041,000 for the second quarter 2018, a decrease in the net operating loss of \$2,012,000, or 28.6%. The decrease in the net operating loss was primarily due to a decrease in operating expenses of \$2,260,000, partially reduced by a negative change in gross (loss) profit on the Company's product sales from a gross profit for the second quarter 2018 to a gross loss for the second quarter 2019 in the amount of \$248,000. The decrease in operating expenses is primarily the result of a decrease in expenses relating to our MRTP application in the amount of \$2,456,000, and a decrease in equity-based compensation of \$1,166,000, partially offset by a net increase in other operating expenses in the amount of \$1,362,000. The net increase in other operating expenses includes increases in sponsored research costs, payroll and related benefits, legal fees, depreciation and amortization totaling approximately \$1.1 million. The negative change in gross (loss) profit was primarily due to additional expenses recorded to the cost of goods sold during the second quarter of 2019, consisting of an increase in FDA fees on filtered cigars and an increase in manufacturing expenses, primarily labor-related, in excess of standard costs.

For the first half 2019, the Company reported a net operating loss of \$10,408,000 as compared to a net operating loss of \$12,009,000 for the first half 2018, a decrease in the net operating loss of \$1,601,000 or 13.3%. The decrease in the net operating loss was primarily due to a decrease in operating expenses of \$2,023,000, partially

reduced by a negative change in gross (loss) profit on the Company's product sales from a gross profit for the first half 2018 to a gross loss for the first half 2019 in the amount of \$422,000. The decrease in operating expenses is primarily the result of a decrease in expenses relating to our MRTP application in the amount of \$2,482,000, and a decrease in equity-based compensation of \$1,280,000, partially offset by net increase in other operating expenses in the amount of \$1,502,000. The net increase in other operating expenses includes increases in sponsored research costs, payroll and related benefits, legal fees, depreciation and amortization totaling approximately \$1.3 million. This negative change in gross (loss) profit was primarily due to additional expenses recorded to the cost of goods sold during the second quarter 2019, consisting of an increase in FDA fees on filtered cigars and an increase in manufacturing expenses, primarily related to labor and equipment maintenance, in excess of standard costs.

The Company experienced a net loss for the second quarter 2019 of \$8,042,000, or (\$0.06) per share, as compared to a net loss of \$6,739,000, or (\$0.05) per share, for the second quarter 2018, an increase in the net loss in the amount of \$1,303,000. The increase in the net loss was due primarily to the decrease in the unrealized gain on investment of \$1,517,000 resulting from a change in the fair value of the warrant to purchase shares of Aurora Cannabis received by the Company in the Anandia sale transaction, and the expense related to the settlement of the Crede lawsuit in the amount of \$1,891,000, partially offset by a decrease in the operating loss of \$2,012,000, as discussed above, and a net increase in various other income (expense) of \$93,000. The net loss for the second quarter 2019 also included non-cash expenses consisting of equity-based compensation in the amount of \$517,000 and depreciation and amortization in the amount of \$370,000.

The Company experienced a net loss for the first half 2019 of \$10,114,000, or (\$0.08) per share, as compared to a net loss of \$5,352,000, or (\$0.04) per share, for the first half 2018, an increase in the net loss in the amount of \$4,762,000. The increase in the net loss was due primarily to the decrease in the unrealized gain on the Aurora Cannabis warrant investment of \$4,597,000, and the expense related to the settlement of the Crede lawsuit in the amount of \$1,891,000, partially offset by a decrease in the operating loss of \$1,601,000, as discussed above, and a net increase in various other income (expense) of \$125,000. The net loss for the first half 2019 also included non-cash expenses consisting of equity-based compensation in the amount of \$966,000 and depreciation and amortization in the amount of \$721,000.

Adjusted EBITDA (as described in the table and paragraph below) was a negative \$4,142,000, or (\$0.03) per share, for the second quarter 2019, as compared to a negative Adjusted EBITDA of \$5,056,000, or (\$0.04) per share, for the second quarter 2018, a decrease in the negative Adjusted EBITDA of \$914,000, or 18.1%.

Adjusted EBITDA was a negative \$8,722,000, or (\$0.07) per share, for the first half 2019, as compared to a negative Adjusted EBITDA of \$9,169,000, or (\$0.07) per share, for the first half 2018, a decrease in the negative Adjusted EBITDA of \$447,000, or 4.9%.

Below is a table containing information relating to the Company's Adjusted EBITDA for the three and six months ended June 30, 2019 and 2018, including a reconciliation of net loss to Adjusted EBITDA for such periods.

	Three Months Ended June 30,		
	2019	2018	% Change
Net loss	\$(8,041,682)	(\$6,738,652)	19%
Adjustments:			
Litigation expense	1,890,900	-	100%
Depreciation and amortization	370,048	302,219	22%
Unrealized loss on investment	1,423,945	-	100%
Realized (gain) loss on investment securities	(71,914)	42,384	-270%
Unrealized gain on investment securities	-	(92,574)	-100%
Interest expense	13,095	-	100%
Interest income, net	(243,183)	(251,670)	-3%
Equity-based compensation	516,752	1,682,228	-69%
Adjusted EBITDA	\$(4,142,039)	\$(5,056,065)	-18%
	Six Months Ended June 30,		
	2019	2018	% Change
Net loss	\$(10,114,395)	(\$5,352,164)	89%

Adjustments:			
Litigation expense	1,890,900	-	100%
Depreciation and amortization	720,653	594,299	21%
Unrealized gain on investment	(1,549,588)	(6,147,088)	-75%
Realized (gain) loss on investment securities	(55,893)	42,189	-232%
Interest expense	23,755	-	100%
Interest income, net	(515,426)	(503,510)	2%
Equity-based compensation	965,656	2,246,104	-57%
Warrant liability gain - net	-	(48,711)	-100%
Gain on disposal of machinery and equipment	(87,351)	-	100%
Adjusted EBITDA	\$(8,721,689)	\$(9,168,881)	-5%

Adjusted EBITDA, which the Company defines as earnings before interest, taxes, depreciation and amortization, as adjusted by the Company for certain non-cash and non-operating expenses, is a financial measure not prepared in accordance with generally accepted accounting principles (“GAAP”). In order to calculate Adjusted EBITDA, the Company adjusts the net loss for certain non-cash and non-operating income and expense items listed in the table above in order to measure the Company’s operating performance. The Company believes that Adjusted EBITDA is an important measure that supplements discussions and analysis of its operations and enhances an understanding of its operating performance. While management considers Adjusted EBITDA to be important, it should be considered in addition to, but not as a substitute for or superior to, other measures of financial performance prepared in accordance with GAAP, such as operating loss, net loss and cash flows from operations. Adjusted EBITDA is susceptible to varying calculations and the Company’s measurement of Adjusted EBITDA may not be comparable to those of other companies.

About 22nd Century Group, Inc.

22nd Century is a plant biotechnology company focused on technology which allows it to decrease the level of nicotine in tobacco plants and to modify the level of cannabinoids in hemp/cannabis plants through genetic engineering and modern plant breeding. The Company’s primary mission in tobacco is to reduce the harm caused by smoking. The Company’s primary mission in hemp/cannabis is to develop proprietary hemp/cannabis strains for important new medicines and agricultural crops. Visit www.xxiicentury.com for more information.

Cautionary Note Regarding Forward-Looking Statements: This press release contains forward-looking information, including all statements that are not statements of historical fact regarding the intent, belief or current expectations of 22nd Century Group, Inc., its directors or its officers with respect to the contents of this press release, including but not limited to our future revenue expectations. The words “may,” “would,” “will,” “expect,” “estimate,” “anticipate,” “believe,” “intend” and similar expressions and variations thereof are intended to identify forward-looking statements. We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances, or to reflect the occurrence of unanticipated events. You should carefully review and consider the various disclosures made by us in our annual report on Form 10-K for the fiscal year ended December 31, 2018, filed on March 6, 2019, including the section entitled “Risk Factors,” and our other reports filed with the U.S. Securities and Exchange Commission which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operation and cash flows. If one or more of these risks or uncertainties materialize, or if the underlying assumptions prove incorrect, our actual results may vary materially from those expected or projected.

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