22nd Century Group, Inc.

November 7, 2019

22nd Century Group Files 2019 Third Quarter Report

22nd Century Builds Strong Momentum for its Very Low Nicotine Content Tobacco and Makes Significant Progress in the Development of Valuable New Hemp/Cannabis Plants

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE American: XXII), a plant biotechnology company that is a leader in tobacco harm reduction, Very Low Nicotine Content (VLNC) tobacco and hemp/cannabis research, announced today that the Company filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 with the U.S. Securities and Exchange Commission. As previously announced, the Company will provide a business update for investors on an audio only webcast to be held on Friday, November 8, 2019, at 9:00 AM Eastern time.

Clifford B. Fleet, President and Chief Executive Officer of 22nd Century Group, together with John Brodfuehrer, Chief Financial Officer, will conduct the webcast. Interested parties are invited to listen to the audio only webcast at: www.xxiicentury.com/media/2019Q3BusinessUpdate. The webcast 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 third quarter 2019 Form 10-Q.

Third Quarter Highlights

"We have made meaningful progress against the two strategic focus areas outlined three months ago in our previous conference call," said Cliff Fleet, CEO of 22nd Century Group. "We are leveraging the Company's leading position and core strengths in plant biotechnology to create shareholder value in the two spaces of tobacco and legal hemp/cannabis.

"We have had active and very constructive dialogue with the U.S. Food and Drug Administration (FDA) on our tobacco product applications. Our Modified Risk Tobacco Product (MRTP) application is moving quickly through the review process – on what appears to be a much faster timeframe than previous MRTP applications filed by others. Our regulatory affairs team is already preparing for the presentation of our application to FDA's Tobacco Product Scientific Advisory Committee, which is an important milestone for 22nd Century. We are also actively working to support FDA's efforts to implement a reduced-nicotine product standard for cigarettes with a variety of initiatives. We look forward to the FDA's issuance of a Notice of Proposed Rule Making (NPRM), which will begin the next phase in the establishment of this new tobacco product standard.

"In the legal hemp/cannabis space we are making meaningful progress to build a strong business in this fast growing and dynamic industry. We have a strong position centered around our leadership in hemp/cannabis plant research, comprehensive expertise in FDA-regulated spaces, a leadership team with deep experience in consumer-packaged goods, as well as a strong and flexible balance sheet. We have been rapidly expanding our leading position in hemp/cannabis plant genetics through our relationship with KeyGene as well as our own internal work, which we believe will make 22nd Century a sought-after partner and source for plant material and genetics in the legal hemp/cannabis industry. We are looking closely at every aspect of the value chain and are highly encouraged by the relationships we are already building in pursuit of the unique growth opportunities this nascent industry presents for 22nd Century.

"Also, over the past few months we have found opportunities to significantly reduce our spending in certain areas that are no longer considered critical, which allows us to prudently manage our cash utilization while also thoughtfully funding growth investments. These cost-reduction efforts already have started to show a positive impact on our corporate performance, as our underlying cash utilization rate significantly improved from the second quarter of this year into the third quarter. We expect that our underlying cash utilization, excluding any investments in outside companies, will also improve as we move into next year, while still supporting investments in our core areas of focus such as our FDA applications, support of a reduced-nicotine product standard, hemp/cannabis plant R&D and our overall hemp/cannabis growth plans."

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

On July 12, 2019, a report by the Centers for Disease Control and Prevention (CDC) found 8 out of 10 adults in the United States, including 80% of cigarette smokers and 84% of former smokers, are in favor of reducing nicotine levels in cigarettes to minimally or non-addictive levels as proposed by FDA. These survey results show broad-based support across the U.S., even among people who smoke, for the implementation of a reduced-nicotine product standard to dramatically improve public health.

On July 17, 2019, the FDA accepted and filed for substantive scientific review the Company's MRTP application for its proprietary VLNC cigarettes under the proposed brand name of VLN®. The MRTP application seeks a reduced exposure marketing authorization from the FDA to allow VLN® cigarettes to be marketed with the claim that they contain 95% less nicotine than conventional tobacco cigarettes, as well as other related claims. Since 2011, the Company has supplied more than 28 million SPECTRUM® research cigarettes made with 22nd Century's VLNC tobacco for use in numerous independent scientific studies funded by the National Institutes of Health (NIH) and other U.S. federal government agencies. Collectively, these studies show that smokers who use 22nd Century's VLNC cigarettes (i) reduce their nicotine exposure and dependence, (ii) smoke fewer cigarettes per day, (iii) experience reduced withdrawal symptoms, (iv) increase their number of smoke-free days, and (v) double their quit attempts. 22nd Century's shareholders and the general public are invited to provide comments in support of 22nd Century's MRTP application on the FDA's official website at the following link:
https://www.regulations.gov/comment?D=FDA-2019-N-0994-0001

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 brings with him a significant expertise in consumer-packaged goods and public-company leadership, having previously been the President and Chief Executive Officer of Philip Morris USA, Inc.

Subsequent to the end of the third quarter of 2019, our accomplishments and notable events include:

On October 21, 2019, following an industry-wide cigarette price increase, the Company announced an increase in the pricing of third-party cigarette products sold by the Company to its contract manufacturing customers. As a result of this price increase, the Company expects to improve its gross margin performance for cigarettes.

On October 24, 2019, John Pritchard, the Company's Vice President of Regulatory Science, presented at the Food and Drug Law Institute's Tobacco and Nicotine Products Regulation and Policy Conference in Washington, D.C. The presentation, which was part of a panel session entitled "Reading the Tobacco Leaves: Paths and Challenges for a Nicotine Reduction Rule," addressed the potential scope, technical feasibility, nicotine level and timing of the FDA's proposed reduced-nicotine product standard for combustible cigarettes.

The Company concluded several field trials of its non-GMO, flue-cured bright and burley VLNC tobacco lines. In independent testing, these plant lines have shown nicotine reductions of up to 98% compared to conventional cigarette tobaccos. The Company plans to continue field trials in support of the anticipated commercialization of its proprietary VLNC cigarettes and in support of the implementation of the FDA's proposed reduced nicotine product standard.

The Company's worldwide, exclusive partnership with KeyGene in hemp/cannabis research and development continues to deliver important results. "The current analysis of multiple hemp and cannabis plant lines and the development of our proprietary cannabis genomic database support our efforts to discover and isolate lines with differential cannabinoid content," explained Juan Sanchez Tamburrino, Ph.D., Vice President of R&D at 22nd Century Group. "These are critical steps toward creating hemp/cannabis plant lines with high commercial value."

The Company's on-going activities with KeyGene should facilitate and accelerate the Company's hemp/cannabis R&D activities to produce hemp/cannabis plants with exceptional cannabinoid profiles and other superior agronomic traits for medical, therapeutic and agricultural uses, among many other applications.

Third Quarter 2019 Financial Summary

The Company used cash during the third quarter of 2019 of approximately $3.3 million, compared to approximately $4.9 million for the second quarter of 2019. The Company remains in a strong financial position as of September 30, 2019 with cash, cash equivalents, and short-term investment securities totaling approximately $43.7 million.

Net sales revenue for the third quarter of 2019 was $6,462,000, an increase of $202,000, or 3.2%, from net sales revenue of $6,260,000 for the third quarter of 2018. Net sales revenue for the first nine months of 2019 was $18,571,000, a decrease of $720,000, or 3.7%, from net sales revenue of $19,291,000 for the first nine months of 2018. The increase in net sales revenue for the third quarter of 2019 was primarily the result of an increase in sales relating to contract manufactured cigarettes, and the decrease in net sales revenue for the nine months ended September 30, 2019 was primarily the result of a decrease in revenue from the production of contract manufactured filtered cigars.

For the third quarter of 2019, the Company reported a net operating loss of $7,606,000 as compared to a net operating loss of $6,209,000 for the third quarter of 2018, an increase in the net operating loss of $1,397,000, or 22.5%. The increase in the net operating loss was primarily due to an increase in operating expenses of $1,225,000 and the negative change in gross (loss) profit on the Company’s product sales from a gross profit for the third quarter 2018 to a gross loss for the third quarter 2019 in the amount of $172,000. The increase in operating expenses was primarily the result of an impairment charge taken during the third quarter of 2019 in the amount of $1,142,000, a severance expense relating to the resignation of the Company’s former CEO in the amount of $721,000, a write off of tobacco inventory in the amount of $882,000, an increase in equity-based compensation in the amount of $967,000, an increase in payroll related expenses in the amount of $379,000, and an increase in sponsored research expenses of $275,000, partially offset by a decrease in expenses relating to our MRTP application in the amount of $3,080,000, and a net increase in other operating expenses in the amount of $61,000. The impairment charge was the result of the Company’s review of its patent and trademark costs performed in connection with the Company’s review of its strategic priorities during the third quarter of 2019. The negative change in gross (loss) profit was primarily due to additional expenses recorded to the cost of goods sold during the third quarter of 2019, consisting of an increase in FDA fees on filtered cigars and an increase in manufacturing expenses, primarily related to labor.

For the first nine months of 2019, the Company reported a net operating loss of $18,014,000 as compared to a net operating loss of $18,218,000 for the first nine months of 2018, a decrease in the net operating loss of $204,000, or 1.1%. The decrease in the net operating loss was primarily due to a decrease in operating expenses of $799,000, as offset by the negative change in gross (loss) profit on the Company’s product sales from a gross profit for the nine months ended September 30, 2018 to a gross loss for the nine months ended September 30, 2019 in the amount of $595,000. The decrease in operating expenses was primarily the result of a decrease in expenses relating to our MRTP application in the amount of $5,562,000, a decrease in equity-based compensation in the amount of $313,000, and a decrease in investor relations expenses of $357,000, partially offset by an impairment charge taken during the third quarter of 2019 in the amount of $1,142,000, a severance expense relating to the resignation of the Company’s former CEO in the amount of $721,000, a write off of tobacco inventory in the amount of $882,000, an increase in payroll related expenses in the amount of $703,000, an increase in sponsored research expenses of $1,103,000, an increase in legal expenses of $197,000, an increase in depreciation and amortization expense of $164,000, and a net increase in other operating expenses in the amount of $521,000. The negative change in gross (loss) profit was primarily due to additional expenses recorded to the cost of goods sold during the nine months ended September 30, 2019, consisting of an increase in FDA fees on filtered cigars and an increase in manufacturing expenses, primarily related to labor.

The Company experienced a net loss for the third quarter 2019 of $10,246,000, or ($0.08) per share, as compared to net income of $6,305,000, or $0.05 per share, for the third quarter 2018, an increase in the net loss in the amount of $16,551,000. The increase in the net loss was due primarily to a decrease in the one-time realized gain on investments relating to the Anandia/Aurora transactions during the third quarter of 2018 of $8,346,000, a negative change in the unrealized (loss) gain on investment with respect to the Aurora stock warrants of $6,883,000, an increase in operating expenses of $1,225,000, as discussed above, and the negative change in the gross (loss) profit on sales of product of $172,000, as discussed above, partially offset by an increase in net other income (expense) items of $75,000. The net loss for the third quarter of 2019 also included non-cash expenses consisting of equity-based compensation in the amount of $1,440,000 and depreciation and amortization in the amount of $390,000.

The Company experienced a net loss for the first nine months of 2019 of $20,360,000, or ($0.16) per share, as compared to net income of $952,000, or $0.01 per share, for the first nine months of 2018, a negative change in the amount of $21,312,000. The increase in the net loss was due primarily to a decrease in the one-time realized gain on investments relating to the Anandia/Aurora transactions during the third quarter of 2018 of $8,346,000, a negative change in the unrealized (loss) gain on investment with respect to the Aurora stock warrants of $11,481,000, a non-cash, one-time litigation expense of $1,891,000, and the negative change in the gross (loss) profit on sales of product of $595,000, as discussed above, partially offset by a decrease in operating expenses of $799,000, as discussed above, and an increase in net other income (expense) items of $202,000. The net loss for the first nine months of 2019 also included non-cash expenses consisting of equity-based compensation in the amount of $2,406,000 and depreciation and amortization in the amount of $1,111,000.

Adjusted EBITDA (as described in the table and paragraph below) was a negative $3,030,000, or ($0.02) per share, for the third quarter of 2019, as compared to a negative Adjusted EBITDA of $5,384,000, or ($0.04) per share, for the third quarter 2018, a decrease in the negative Adjusted EBITDA of $2,354,000, or 43.7%.

Adjusted EBITDA was a negative $11,665,000, or ($0.09) per share, for the first nine months of 2019, as compared to a negative Adjusted EBITDA of $14,553,000, or ($0.12) per share, for the first nine months of 2018, a decrease in the negative Adjusted EBITDA of $2,888,000, or 19.8%.

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

	Three Months Ended September 30,		
	2019	**2018**	**% Change**
Net (loss) income	$(10,245,717)	$6,304,654	-263%
Adjustments:			
Unrealized loss (gain) on investment	2,959,898	(3,923,156)	-175%
Realized gain on investment	-	(8,345,880)	-100%
Realized (gain) loss on investment securities	(90,489)	6,272	-1543%
Impairment charge	1,142,349	-	100%
Inventory write off	881,588	-	100%
Severance expense	720,838	-	100%
Depreciation and amortization	390,407	352,017	11%
Interest expense	12,795	4,431	189%
Interest income, net	(242,003)	(255,155)	-5%
Equity-based compensation	1,440,225	472,833	205%
Adjusted EBITDA	**$(3,030,109)**	**$(5,383,984)**	**-44%**

	Nine Months Ended September 30,		
	2019	**2018**	**% Change**
Net (loss) income	$(20,360,113)	$952,490	-2238%
Adjustments:			
Unrealized loss (gain) on investment	1,410,310	(10,070,244)	-114%
Realized gain on investment	-	(8,345,880)	-100%
Realized (gain) loss on investment securities	(146,832)	48,461	-403%
Litigation expense	1,890,900	-	100%
Impairment charge	1,142,349	-	100%
Inventory write off	881,588	-	100%
Severance expense	720,838	-	100%
Warrant liability gain - net	-	(48,711)	-100%
Depreciation and amortization	1,111,060	946,316	17%
Interest expense	36,550	4,431	725%
Interest income, net	(757,429)	(758,665)	0%
Equity-based compensation	2,405,881	2,718,937	-12%
Adjusted EBITDA	**$(11,664,898)**	**$(14,552,865)**	**-20%**

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, as well as certain one-time 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) income 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) income 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 plants for important new medicines and agricultural crops. Visit www.xxiicentury.com for more information.

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