May 7, 2019

22nd Century Files 2019 First Quarter Report and Announces Conference Call to Provide Business Update

22nd Century's proposed VLN™ cigarettes continue to fall squarely within the nicotine range that public health officials anticipate will be mandated by the FDA.

Company's financial position remains strong; cash, cash equivalents, and short-term investment securities totaled approximately $51.9 million.

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 2019 First Quarter Report on Form 10-Q with the U.S. Securities and Exchange Commission. The Company will provide a business update for investors on a conference call to be held Wednesday, May 8, 2019, at 4:00 PM (Eastern Time).

Henry Sicignano III, 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 participate by dialing: (800) 667-5617 and using Conference ID 5265600. The conference call will consist of an overview of recent business highlights and a summary of the financial information presented in the Company's first quarter 2019 Form 10-Q. Immediately thereafter, there will be a question and answer segment open to callers.

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

On March 27, 2019, the Company announced the results of a recently completed, Company-sponsored study involving its Very Low Nicotine Content ("VLNC") cigarettes, with the results of such study indicating that subjects using 22nd Century's 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 the Company's 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. The Company included this study and its results in its Modified Risk Tobacco Product ("MRTP") application submitted to the U.S. Food and Drug Administration ("FDA") for the Company's VLNC cigarettes under the proposed brand name VLN™. The Company's 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, 22nd Century's notable events include:

On April 9, 2019, the Company announced that it 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 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. 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 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 the Company's 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 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. In addition, FDA inspectors 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.

Officials from the FDA have previously indicated a "minimally-addictive or non-addictive" level of nicotine in cigarettes could be achieved at approximately 0.3 to 0.7 mg nicotine per gram of tobacco. The World Health Organization ("WHO") has similarly recommended that all WHO-member nations adopt "a [tobacco] policy of limiting the sale of cigarettes to brands with a nicotine content that is not sufficient to lead to the development and/or maintenance of addiction." 22nd Century's proposed VLN™ cigarettes – with a target concentration of 0.5 mg nicotine per gram tobacco – fall squarely within the nicotine range that public health officials anticipate will be mandated by the FDA, and that will simultaneously enable the WHO to advance its global nicotine reduction agenda. For these reasons, when 22nd Century's proprietary VLNC cigarettes achieve MRTP status, they could serve as a powerful tool and precedent in support of the FDA's broader national nicotine reduction mandate.

First Quarter 2019 Financial Summary

The Company's financial position remains strong as of March 31, 2019; cash, cash equivalents, and short-term investment securities totaled approximately $51.9 million. The Company incurred expenses of approximately $1.21 million relating to its MRTP application to the FDA for its "*BRAND A"* VLN™ cigarettes during the first quarter of 2019.

Net sales revenue for the three months ended March 31, 2019 was $6,294,000, an increase of $178,000, or 2.9%, over net sales revenue of $6,116,000 for the three months ended March 31, 2018.

For the three months ended March 31, 2019, the Company reported a net operating loss of $5,379,000 as compared to a net operating loss of $4,969,000 for the three months ended March 31, 2018, an increase in the net operating loss of $410,000, or 8.3%. The increase in the net operating loss was primarily due to an increase in operating expenses of $236,000, and a negative change in gross profit on the Company's product sales from a gross profit for the three months ended March 31, 2018 to a gross loss for the three months ended March 31, 2019 in the amount of $174,000. 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 as part of 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.

The Company experienced a net loss for the three months ended March 31, 2019 of $2,073,000, or ($0.02) per share, as compared to net income of $1,386,000, or $0.01 per share, for the three months ended March 31, 2018, a negative change from net income to a net loss in the amount of $3,459,000. The negative change from net income to a net loss was due primarily to the decrease in the unrealized gain on investment of $3,174,000, a negative change in the gross profit (loss) on product sales of $174,000, an increase in operating expenses of $236,000, partially offset by a net increase in various other income (expense) of $125,000. The net loss for the three months ended March 31, 2019 also included non-cash expenses consisting of equity-based compensation in the amount of $449,000 and depreciation and amortization in the amount of $351,000.

Adjusted EBITDA (as described in the table and paragraph below) was approximately a negative $4,580,000, or ($0.04) per share, for the three months ended March 31, 2019, as compared to a negative Adjusted EBITDA of approximately $4,113,000, or ($0.03) per share, for the three months ended March 31, 2018, an increase in the negative Adjusted EBITDA of $467,000, 11.4%. The increase in the negative Adjusted EBITDA for the three months ended March 31, 2019 was primarily the result of an increase in the operating loss of $410,000, as discussed above.

Below is a table containing information relating to the Company's Adjusted EBITDA for the quarters ended March 31, 2019 and 2018, including a reconciliation of net (loss) income to Adjusted EBITDA for such periods.

	For the Quarters Ended March 31,		
	2019	**2018**	**% Change**
Net (loss) income	$(2,072,713)	$1,386,488	-249%
Adjustments:			
Warrant liability gain, net	-	(48,711)	-100%
Depreciation and amortization	350,606	292,080	20%
Unrealized gain on investment	(2,973,533)	(6,147,088)	-52%
Unrealized loss on investment securities	-	92,574	-100%
Realized loss (gain) on investment securities	16,021	(195)	-8,316%
Interest expense	10,660	-	100%
Interest income, net	(272,243)	(251,840)	8%
Equity-based compensation	448,905	563,876	-20%
Gain on disposal of machinery and equipment	(87,351)	-	100%
Adjusted EBITDA	**$(4,579,648)**	**$(4,112,816)**	**11%**

Adjusted EBITDA, which the Company defines as earnings before interest, taxes, depreciation and amortization, as adjusted by 22nd Century 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) 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 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 increase or decrease the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering and 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 and www.botanicalgenetics.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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Source: 22nd Century Group, Inc.