



**22nd Century Group, Inc.**

March 6, 2019

## **22nd Century Files 2018 Annual Report and Announces Conference Call to Provide Business Update**

***The FDA has accepted for review the Company's MRTPA for VLN™ cigarettes***

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 2018 Annual Report on Form 10-K with the U.S. Securities and Exchange Commission. The Company will provide a business update for investors on a conference call to be held Thursday, March 7, 2019, at 4:00 PM (EST).

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: (877) 260-1479 and using Conference ID 8821519. The conference call will consist of an overview of recent business highlights and a summary of the financial information presented in the Company's 2018 Annual Report. Immediately thereafter, there will be a question and answer segment open to callers.

### **For the fourth quarter of 2018, 22nd Century's accomplishments and notable events include:**

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

On November 7, 2018, 22nd Century publicly noted that it had received preliminary results from two of its three Company-sponsored studies that are part of the Company's Modified Risk Tobacco Product application ("MRTPA") to be submitted to the FDA in December 2018. The two "Abuse Liability" studies (one for regular VLNC cigarettes and one for menthol VLNC cigarettes) were designed to measure the potential for the Company's VLNC cigarettes to create and sustain addiction. As expected, the Company's VLNC cigarettes preliminarily showed a substantially lower potential for abuse. The third Company-sponsored clinical trial, measuring the number of cigarettes consumed per day for participants switching to VLNC cigarettes over the course of 6 weeks, is on schedule and nearing completion. The Company anticipates that this third study will show that users who switch to VLNC cigarettes smoke fewer cigarettes per day and show reduced biomarkers of exposure to nicotine and other smoke components.

On December 4, 2018, 22nd Century submitted a Premarket Tobacco product application ("PMTA") with the FDA seeking authorization to commercialize the Company's "BRAND A" cigarette products under the proposed brand name "VLN™" (the product name is subject to FDA approval). 22nd Century's proposed VLN™ cigarettes are made with 22nd Century's proprietary VLNC tobacco and, as a result, contain very low levels of nicotine. A PMTA

marketing order is a prerequisite to commercializing any new tobacco product in the United States. 22nd Century's proposed VLN™ cigarettes are modeled after the Company's VLNC SPECTRUM® research cigarettes. 22nd Century's PMTA references more than 50 independent studies conducted with the Company's proprietary VLNC SPECTRUM® research cigarettes.

On December 20, 2018, 22nd Century publicly noted that the Agricultural Improvement Act of 2018, which is also known as the "2018 Farm Bill," was enacted and, among other things, further legalized hemp under U.S. federal law, but with compliance still being required with all applicable state hemp laws. Hemp plants are *Cannabis Sativa L.* plants with not more than 0.3% THC (the compound in cannabis responsible for psychotropic effects). The new federal 2018 Farm Bill will allow 22nd Century to expand its hemp research activities, to add to its hemp/cannabis intellectual property portfolio, and to increase its hemp germplasm library through the legal interstate commerce of proprietary hemp seeds/plants, all in compliance with applicable state laws. Cannabis plants with higher levels of THC (i.e. marijuana) remain illegal under U.S. federal law.

On December 27, 2018, 22nd Century submitted to the FDA the Company's MRTPA for its *BRAND A* product under the proposed brand name of VLN™ cigarettes. The Company's MRTPA requests FDA authorization for 22nd Century to state on packaging and advertising that, among other things, the proposed VLN™ cigarettes contain just 0.5mg of nicotine per gram of tobacco, which is at least 95% less nicotine than each of the 100 leading cigarette brands in the United States. In contrast, a survey of the top 100 leading cigarette brands in the United States showed that conventional and highly addictive cigarettes currently sold in the United States contain an average of 19.4mg of nicotine per gram of tobacco (with an actual nicotine range of 14.7mg to 33.2mg per gram of tobacco). The MRTPA states that 22nd Century's proposed VLN™ cigarettes are the same as the lowest nicotine content style of the Company's SPECTRUM® research cigarettes. 22nd Century's SPECTRUM® research cigarettes were developed in collaboration with the FDA and other U.S. federal government agencies to provide independent scientists with the products necessary to investigate the public health benefits of reduced-nicotine content cigarettes. 22nd Century's MRTPA references more than 50 independent studies that utilized SPECTRUM® research cigarettes. Of particular note, the six-week 840-participant study by Dr. Eric Donny, *et al.* published in the *New England Journal of Medicine* in October 2015 found that VLNC cigarettes were "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events." A more recent twenty-week study with 1,250 participants by Dr. Dorothy Hatsukami, *et al.* published in the *Journal of the American Medical Association* in September 2018 concluded that an immediate reduction in nicotine to very low levels was associated with (i) lower toxicant exposure across time; (ii) fewer cigarettes smoked per day; (iii) greater reduction in nicotine dependence; and (iv) more days in which participants smoked no cigarettes (cigarette-free days).

#### **Subsequent to the close of the fourth quarter of 2018, 22nd Century's notable events include:**

In January 2019, the FDA accepted for filing 22nd Century's PMTA for VLN™ cigarettes. In communicating to 22nd Century the status of the Company's PMTA for VLN™ cigarettes, the FDA explained: "We determined that these applications meet the filing requirements for a PMTA seeking a marketing order under section 910(c)(1)(A) (i) of the FD&C Act." The Company's PMTA is now in the Phase 3 "review" step at the FDA as part of the FDA's 4-phase review process.

More recently, 22nd Century learned that the FDA has accepted for review the Company's MRTPA for VLN™ cigarettes. The Company's MRTPA is now in Phase 2 of the FDA's review process in which the FDA is determining the suitability of the MRTPA for acceptance of filing. After the Company's MRTPA is subsequently accepted for filing and thereafter moves into Phase 3 of the FDA's review process, then the MRTPA will be posted by the FDA for public comment. 22nd Century is in continuous, two-way communication with the FDA in support of the Company's PMTA and MRTPA.

#### **2018 Financial Summary**

The Company's financial position remains strong as of December 31, 2018; cash, cash equivalents, and short-term investment securities totaled approximately \$56.4 million. The Company incurred expenses of approximately \$9.8 million relating to its MRTPA to the FDA for its "*BRAND A*" VLN™ cigarettes and received cash from the sale of its Aurora Cannabis common stock in the amount of approximately \$13.1 million during the year ended December 31, 2018.

Net sales revenue for the year ended December 31, 2018 was the highest in the Company's history at \$26,426,000, an increase of \$9,826,000, or 59.2%, over net sales revenue of \$16,600,000 for the year ended December 31, 2017.

For the year ended December 31, 2018, the Company reported a net operating loss of \$24,019,000 as compared to a net operating loss of \$13,300,000 for the year ended December 31, 2017, an increase in the net operating loss of \$10,719,000, or 80.6%. The increase in the net operating loss was primarily due to an increase in operating expenses of \$12,326,000, partially offset by \$1,607,000, representing the change in the gross loss on product sales for the year ended December 31, 2017 to a gross profit on product sales for the year ended December 31, 2018. The increase in the Company's operating expenses for the year ended December 31, 2018 were primarily the result of expenses incurred in connection with the Company's MRTPA in the amount of approximately \$9,800,000. In addition, the increase in operating expenses for the year ended December 31, 2018 included approximately \$1,230,000 in equity-based compensation recognized during the second quarter of 2018 as a result of the vesting of certain stock options previously issued to James E. Swauger, the Company's former Senior Vice President of Science and Regulatory Affairs, due to his unexpected death in April of 2018.

The Company experienced a net loss for the year ended December 31, 2018 of \$7,967,000, or (\$0.06) per share, as compared to a net loss of \$13,029,000, or (\$0.13) per share, for the year ended December 31, 2017, a decrease in the net loss of \$5,062,000. The decrease in the net loss was due primarily to the realized gain on investments in the amount of \$14,493,000, and an increase in net interest and dividend income of \$1,176,000, partially offset by an increase in the Company's net operating loss of \$10,719,000 as discussed above. The realized gain on investments relates to the transactions involving the purchase of the Company's investment in Anandia by Aurora Cannabis and the subsequent sale of the common stock of Aurora Cannabis received when Aurora Cannabis acquired Anandia. The net loss for the year ended December 31, 2018 also included non-cash expenses consisting of equity-based compensation in the amount of \$3,187,000 and depreciation and amortization in the amount of \$1,342,000.

Adjusted EBITDA (as described in the table and paragraph below) was a negative \$19,489,000, or (\$0.16) per share, for the year ended December 31, 2018, as compared to a negative Adjusted EBITDA of \$11,411,000, or (\$0.11) per share, for the year ended December 31, 2017, an increase in the negative Adjusted EBITDA of \$8,078,000, 70.8%. The increase in the negative Adjusted EBITDA of \$8,078,000 for the year ended December 31, 2018 was primarily the result of costs related to the Company's MRTPA of approximately \$9,800,000, as discussed above.

Below is a table containing information relating to the Company's Adjusted EBITDA for the years ended December 31, 2018 and 2017, including a reconciliation of net loss to Adjusted EBITDA for such periods.

	For the Years Ended December 31,		
	2018	2017	% Change
Net loss	\$ (7,966,911)	\$ (13,029,117)	-39%
Adjustments:			
Warrant liability (gain) loss - net	(48,711)	157,809	-131%
Depreciation and amortization	1,342,335	946,997	42%
Realized gain on investments	(14,492,968)	-	-100%
Unrealized gain on investments	(284,400)	(342,562)	-17%
Realized loss on short-term investment securities	54,451	-	100%
Interest expense	10,939	29,104	-62%
Interest and dividend income, net	(1,291,027)	(115,098)	1,022%
Equity-based compensation	3,187,331	941,650	238%
<b>Adjusted EBITDA</b>	<b>\$ (19,488,961)</b>	<b>\$ (11,411,217)</b>	<b>71%</b>

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 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](http://www.xxiicentury.com) and [www.botanicalgenetics.com](http://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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