



May 3, 2018

## 22nd Century Files 2018 First Quarter Report

***Company significantly increases spending on MRTP application and posts profitable quarter***

***Conference call will provide business update***

CLARENCE, 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 tobacco, and hemp/cannabis research, announced today the Company's first quarter 2018 financial results. 22nd Century will provide a business update for investors on a conference call to be held Friday, May 4, 2018, 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) 289-0438 and using Conference ID 1312887. 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 2018 Form 10-Q. Immediately thereafter, there will be a question and answer segment open to all callers.

With net sales revenue exceeding \$6 million, 22nd Century posted another record quarter. At the same time, 22nd Century significantly increased spending on the Company's Modified Risk Tobacco Product ("MRTP") application for "BRAND A" Very Low Nicotine cigarettes. However, due to the extraordinary event of the recognition of an unrealized gain on the Company's investment in Anandia Laboratories in the approximate amount of \$6 million, 22nd Century posted a profit for the first quarter. As of March 31, 2018, the Company had more than \$59 million in cash and short-term investments, which are sufficient reserves to meet regular operating expenses for a number of years.

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

On February 22, 2018, 22nd Century presented at the 2018 Annual Meeting of the Society for Research on Nicotine and Tobacco ("SRNT") the results from a survey conducted by The Harris Poll on behalf of the Company. The Harris Poll administered an international survey of more than 6,000 adults ages 18 and older in the United States, Australia, Canada, Japan, and the United Kingdom. Conducted two months before the U.S. Food and Drug Administration ("FDA") announced its plan to mandate the drastic reduction of nicotine in all cigarettes sold in the United States, the survey found that nearly 3 of every 4 adults in the United States, Japan, Australia, Canada, and the United Kingdom agree that the government should mandate that all cigarettes have very low, non-addictive levels of nicotine.

On March 19, 2018, 22nd Century announced that the FDA published in the Federal Register an Advance Notice of Proposed Rulemaking ("ANPRM") as a first step in the process of establishing a tobacco product standard that sets a maximum nicotine level for all cigarettes sold in the United States. As an important step in the FDA's official rule-making process to mandate dramatically lower nicotine in cigarettes, this ANPRM describes, in detail, the independent science that supports the FDA's proposed nicotine reduction mandate. The ANPRM references previously completed research that found: "*an absolute limit of 0.4 to 0.5 mg of nicotine per cigarette should be adequate to prevent or limit the development of addiction in most young people.*" The ANPRM also cites the results of the clinical trial by Dr. Eric Donny, *et al.*, that was published in the October 2015 issue of *The New England Journal of Medicine* that found: "*Those participants using cigarettes with the lowest nicotine content (0.4 mg per gram nicotine/gram of tobacco filler), demonstrated reduced dependence... with minimal evidence of withdrawal-related discomfort or safety concerns.*" 22nd Century provided all of the proprietary Very Low Nicotine cigarettes that made possible this clinical trial and numerous other independent clinical studies.

The FDA's ANPRM specifically mentions 22nd Century, by name, in reference to the Company's proprietary Very Low Nicotine tobacco and 22nd Century's continued provision of Very Low Nicotine cigarettes for use in independent research: "*To provide consumers with reduced risk tobacco products, companies like 22nd Century are using genetic engineering and plant breeding to produce very low nicotine tobacco for incorporation into*

cigarettes. In 2014, the company was granted patents for its process to virtually eliminate the nicotine in tobacco plants. Further, low nicotine cigarettes are produced and distributed for research purposes by Research Triangle Institute (RTI), under a contract for NIDA's Drug Supply Program. 22nd Century is acting as a vendor for RTI for this contract manufacturing SPECTRUM® cigarettes that contain 0.4 mg nicotine/gram (g) of tobacco filler."

#### **Subsequent to the close of the first quarter of 2018, 22nd Century also announced:**

On April 23, 2018, 22nd Century announced that the Food and Drug Law Institute ("FDLI") published an [article](#) by the late Dr. James Swauger, Senior Vice President of Science and Regulatory Affairs at 22nd Century. In this matter-of-fact public policy analysis, Dr. Swauger pointed out that since it is universally accepted that nicotine is the primary addictive component of cigarettes, the tobacco industry and public health officials should logically support the nicotine reduction plan proposed by the FDA.

Citing the FDA's focus on nicotine as the "common ground that both sides can stand upon to begin civil, truly productive conversations," Dr. Swauger described Very Low Nicotine content cigarettes as "well-studied by a diverse group of scientists" whose important independent research supports the FDA's planned mandate to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine.

In conclusion, the article quoted an editorial in the October 2015 edition of *The New England Journal of Medicine* by Drs. Michael Fiore and Timothy Baker that established the magnitude of the importance of FDA's plan to dramatically reduce nicotine in cigarettes: "Reducing the nicotine content of combustible tobacco to levels that will not sustain dependence seems to us to be the most promising regulatory policy option for preventing [at least] 20 million premature deaths."

#### **First Quarter 2018 Financial Summary**

Net sales revenue for the first quarter of 2018 was \$6,116,000, an increase of \$3,885,000, or 174.1%, over net sales revenue of \$2,231,000 for the three months ended March 31, 2017. The increase in net sales revenue for the first quarter of 2018 was primarily the result of continued additional sales generated from a filtered cigar manufacturing agreement that commenced in mid-May of 2017. The first quarter of 2018 net sales revenue of \$6,116,000 was the highest quarterly product revenue in the Company's history.

For the three months ended March 31, 2018, the Company reported an operating loss of \$4,969,000 as compared to an operating loss of \$2,970,000 for the three months ended March 31, 2017, an increase in the operating loss of \$1,999,000, or 67.3%. The increase in the operating loss was primarily due to an increase in operating expenses of approximately \$2,344,000, partially offset by approximately \$345,000 representing the change in the gross loss on product sales in the first quarter of 2017 to a gross profit on product sales in the first quarter of 2018. The increase in the Company's operating expenses was primarily the result of expenses incurred in connection with the Company's increased investment in its Modified Risk Tobacco Product ("MRTP") application with the FDA for "BRAND A" Very Low Nicotine cigarettes.

The Company had net income for the three months ended March 31, 2018 of \$1,387,000, or \$0.01 per share, as compared to a net loss of \$2,621,000, or (\$0.03) per share, for the three months ended March 31, 2017. The change in the net loss for the first quarter of 2017 to net income for the first quarter of 2018 amounts to \$4,008,000, or 152.9%, and was due primarily to an increase in net other income of approximately \$6,007,000, partially offset by an increase in the operating loss of approximately \$1,999,000. The increase in net other income was primarily the result of an unrealized gain on the Company's investment in Anandia Laboratories in the approximate amount of \$6,147,000, resulting from the adoption of a new accounting standard requiring that investment to be stated at fair value, based on observable price changes in orderly transactions for the identical or similar investments in Anandia. The net income for the three months ended March 31, 2018 included non-cash expenses consisting of equity-based compensation totaling approximately \$564,000 and depreciation and amortization in the approximate amount of \$292,000.

Adjusted EBITDA (as described in the paragraph and table below) was approximately a negative \$4,113,000, or (\$0.03) per share, for the three months ended March 31, 2018, as compared to approximately a negative \$2,572,000, or (\$0.03) per share, for the three months ended March 31, 2017.

Below is a table containing information relating to the Company's Adjusted EBITDA for the three months ended March 31, 2018 and 2017, including a reconciliation of net income (loss) to Adjusted EBITDA for such periods.

<b>Three Months Ended March 31,</b>		
<b>2018</b>	<b>2017</b>	<b>% Change</b>

Net income (loss)	\$ 1,386,488	\$(2,621,277)	-153%
Adjustments:			
Warrant liability (gain) loss - net	(48,711)	5,344	-1,012%
Depreciation and amortization	292,080	229,009	28%
Unrealized gain on investment	(6,147,088)	(346,180)	1,676%
Unrealized loss on investment securities	92,574	-	100%
Interest expense	-	7,919	-100%
Interest income, net	(251,840)	(15,755)	1,498%
Equity based compensation -			
Officers, directors and employees	563,876	168,979	234%
<b>Adjusted EBITDA</b>	<b><u>\$(4,112,621)</u></b>	<b><u>\$(2,571,961)</u></b>	<b><u>60%</u></b>

Adjusted EBITDA 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 income (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) income, net income (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 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, 2017, filed on March 7, 2018, 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.*

View source version on businesswire.com: <https://www.businesswire.com/news/home/20180503006590/en/>

22nd Century Group  
James Vail, 716-270-1523  
Director of Communications  
[jvail@xxiicentury.com](mailto:jvail@xxiicentury.com)

Source: 22nd Century Group, Inc.