

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 16, 2015

22nd Century Group, Inc.
(Exact Name of Registrant as Specified in Charter)

Nevada
(State or Other Jurisdiction of Incorporation)

001-36338
(Commission File Number)

98-0468420
(I.R.S. Employer
Identification No.)

9530 Main Street
Clarence, New York
(Address of Principal Executive Office)

14031
(Zip Code)

Registrant's telephone number, including area code: (716) 270-1523

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure.

On December 16, 2015, 22nd Century Group, Inc. (the “Company”) issued a press release announcing that it had distributed a letter to its shareholders and attaching a copy of the letter. A copy of the press release is furnished as Exhibit 99.1 herewith and is incorporated herein by reference.

Item 9.01(d): Financial Statements and Exhibits.

Exhibit 99.1 Press Release dated December 16, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

22nd Century Group, Inc.

Date: December 16, 2015

/s/ Thomas L. James

Thomas L. James

Vice President, General Counsel & Secretary

22nd Century Group Files Form 8-K with Letter to Shareholders

December 16, 2015

Clarence, New York – 22nd Century Group, Inc. (NYSE MKT: XXII), a plant biotechnology company that is a leader in tobacco harm reduction, announced today that the Company filed a Form 8-K to make available to the public the following letter to shareholders:

Dear Fellow Shareholders:

As we approach the end of the year, I am writing to summarize for you the many exciting developments occurring here at 22nd Century Group. As you know, 2015 was the first year in which we began to actively commercialize our significant intellectual property portfolio. Our total revenues for 2014 were less than \$530,000. In contrast, we reported revenues of approximately \$5.6 million for the nine months ended September 30, 2015, and we believe that we will achieve more than \$8 million in revenue for the full year of 2015, which exceeds our prior financial projections and will be the highest revenue in our history.

22nd Century is uniquely positioned as the only tobacco company with the mission of reducing the harm caused by smoking. In support of this mission, 22nd Century Group has a dominant, global intellectual property portfolio that now includes more than 200 issued patents and more than 50 pending patents. Indeed, 22nd Century controls all the genes in the tobacco plant needed to regulate and control nicotine, the addictive drug in tobacco. Accordingly, 22nd Century has the unique ability to produce Very Low Nicotine (“VLN”) tobacco for (i) commercial cigarettes such as our MAGIC brand of “0.0 mg nicotine” cigarettes currently sold in Europe, (ii) research cigarettes such as our SPECTRUM brand of cigarettes which feature multiple levels of nicotine (as highlighted in the October 2015 edition of *The New England Journal of Medicine*), and (iii) X-22, the world’s only combustible cigarette under development as a smoking cessation product. Our expansive IP portfolio and our unique experience in altering nicotine levels in the tobacco plant have given our Company a strong competitive advantage in the billion dollar smoking cessation market and in the premium specialty tobacco products markets.

Capturing a mere fraction of a percent of the U.S. cigarette market – or a nominal percentage of the billion dollar smoking cessation market – would catapult the value of our Company. Indeed, management is confident that our proprietary technology will enable us to do exactly that.

As a result of our recent accomplishments – in the laboratory, in our MSA-authorized factory, and in the marketplace – we have assembled all the crucial elements of a Modified Risk Tobacco Product (MRTP) application that will soon be submitted to the U.S. Food and Drug Administration (FDA) for reduced exposure labeling of our BRAND A Very Low Nicotine cigarettes. We believe 22nd Century will be the first company in the world to achieve MRTP designation for a combustible cigarette. Indeed, we believe that 22nd Century is closing 2015 with a very strong foundation for continued success and growth in 2016. Below are highlights of our achievements from the past year. In 2015, we:

- Completed the BRAND A Modified Risk Tobacco Product (MRTP) application and plan to submit this application to the FDA this month.
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- Expanded our IP portfolio, enhancing its value to our shareholders with our global ownership or exclusive control of more than 200 issued patents and more than 50 pending patent applications.
- Appointed a full-time FDA expert, Gregg Gellman, as our new Director of Business Development and Regulatory Affairs.
- Hired Paul Rushton, Ph.D., as Vice President of Plant Biotechnology. Paul was a unique find as he is one of the world's foremost experts on tobacco genome sequencing and he has completed extensive work on our proprietary tobacco plants as part of a research team at the University of Virginia that conducted sponsored research studies for 22nd Century.
- Identified and met with several potential strategic partners towards funding Phase III clinical trials for our X-22 prescription smoking-cessation aid in development.
- Received an order for approximately 5 million SPECTRUM research cigarettes from the U.S. federal government for ongoing research.
- Commenced new cannabis research with Anandia Laboratories in Canada.
- Launched the RED SUN super-premium cigarette brand in the first quarter of this year and have grown our retail store count to more than 600 locations nationwide.
- Launched MAGIC cigarettes in more than 900 state-licensed retail shops in Spain.
- Expanded our third-party contract manufacturing base with the addition of six new contract partners.

Pending receipt of final third party analysis and prior to the end of December, we plan to submit a Modified Risk Tobacco Product application to the FDA for our BRAND A VLN tobacco cigarettes. There are several independent clinical trials that support our submission. Of notable importance, an independent clinical study using our SPECTRUM research cigarettes, funded in part by the FDA, and published in October 2015 in *The New England Journal of Medicine* (<http://www.nejm.org/doi/full/10.1056/NEJMsa1502403>), found that smokers of our VLN cigarettes (95% less nicotine than conventional brands) consumed far fewer cigarettes per day and doubled their quit attempts versus smokers of conventional cigarettes, all with minimal withdrawal symptoms and without compensatory smoking or any serious adverse events. Because of the compelling results of this and six other independent Phase II and Phase III independent clinical studies using our VLN tobacco, we believe the FDA will approve our claim of reduced exposure to nicotine and approve BRAND A as the first Modified Risk Tobacco product in the United States. We believe that this reduced exposure designation will likely lead to important licensing opportunities for our Company.

Our strategic new hires are experienced experts who will work to bring our unique intellectual property and scientific know-how to commercial success. Gregg Gellman is charged with shepherding FDA submissions for our modified risk cigarettes in development (BRAND A and BRAND B) and X-22, our smoking cessation product in development. Paul Rushton, our Vice President of Plant Biotechnology, is uniquely qualified to grow and commercialize our impressive patent portfolio relating to each of tobacco and cannabis.

We are also excited that a new research agreement with Anandia Laboratories in Vancouver, Canada to develop, protect and commercially produce proprietary cannabis strains will lead to exciting commercialization opportunities. The primary goals of our current research activities relating to cannabis are to develop, protect and commercially produce plant varieties that include (i) plants with low to no amounts of THC for the commercial hemp industry and (ii) plants with high levels of cannabidiol, or CBD, and other non-THC cannabinoids for the legal medical marijuana markets.

Growth Trajectory into 2016

In recent months, management has identified and met with several pharmaceutical companies, national retail chains and other significant potential strategic partners in our on-going efforts to contract with a third party to fund Phase III clinical trials for X-22. We believe X-22 is more effective than any current NRTs on the market and presents smokers with no new side effects and minimal or no withdrawal symptoms. Best of all, smokers who wish to quit overwhelmingly prefer the choice of smoking cessation using... a cigarette! In early 2016, we anticipate entering into a joint venture with a significant third-party company to bring 22nd Century's hugely important VLN tobacco-based smoking cessation product to market.

The vertical integration of our manufacturing facility in North Carolina allows us to promptly and accurately produce our own proprietary and highly specialized products. The factory gives us the independence and self-determination to produce our proprietary products in a very competitive, increasingly regulated retail marketplace. We are continuing to grow RED SUN sales, to fulfill our contracts to produce SPECTRUM research cigarettes, and to bring in new contract manufacturing business. These revenues are expected to provide a stable platform of sustainable, profitable work for our factory and our Company.

Though we have not yet signed an Asian joint venture agreement, we have entered into discussions to launch our proprietary VLN products in Asia and in the Middle East. In January 2016, a contingent of scientists and business people from Asia are scheduled to visit our NASCO manufacturing operations in North Carolina. Additionally, several other important regional distributors have already inquired about securing distribution rights for our VLN products in the Middle East. Both Asia and the Middle East represent significant markets for 22nd Century's tobacco products.

Dr. Eric Donny (the lead author of the study published in *The New England Journal of Medicine*), explained in an article posted on www.usatoday.com, "The evidence is getting stronger that reducing nicotine reduces smoking and makes people less addicted to cigarettes and, in doing so, might make them more likely to quit." As the nuances of this and other clinical studies coalesce into accepted fact, we believe that multiple commercial uses of 22nd Century's remarkable Very Low Nicotine tobacco will be recognized as critical elements of a global tobacco harm reduction strategy.

Indeed, we are well positioned to capitalize on the multi-billion dollar smoking cessation and broad tobacco market opportunities that I have described above and we are extremely excited about the future ahead.

Best wishes to you and your family for a happy holiday season. Thank you for your investment in our Company and for your continued support as a 22nd Century shareholder.

Sincerely,



Henry Sicignano, III
President and Chief Executive Officer

About 22nd Century Group, Inc.

22nd Century Group 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 cannabis plants through genetic engineering and plant breeding. The Company's primary mission is to reduce the harm caused by smoking. 22nd Century currently owns or exclusively controls more than 200 issued patents and more than 50 pending patent applications around the world. The Company's strong IP position led to a licensing agreement with British American Tobacco ("BAT"), the world's second largest tobacco company. Visit www.xxiicentury.com for more information.

Cautionary Note Regarding Forward-Looking Statements:

This letter 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, 2014, filed on February 5, 2015, 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.
