

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

June 12, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On June 12, 2017, 22nd Century Group, Inc. (the “Company”) made available a copy of a letter sent to stockholders. A copy of the letter to stockholders is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in this item (including the exhibit) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liabilities of Section 18, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent, if any, expressly set forth by specific reference in such filing.

Item 9.01(d). Financial Statements and Exhibits.

(d) Exhibits.

99.1 Letter to stockholders.

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: June 12, 2017

/s/ Thomas L. James

Thomas L. James

Vice President, General Counsel and Secretary

22nd Century Creates Non-GMO Very Low Nicotine Tobacco!

Dear Fellow Shareholder:

I am writing to share with you exciting developments from our research teams: Working with our research partners at North Carolina State University, we have succeeded in creating non-GMO Very Low Nicotine (VLN) tobacco! This new breakthrough eliminates the barriers to exporting our VLN tobacco to many countries around the world. Enclosed is a June 6, 2017 press release detailing our exciting development of non-GMO VLN tobacco varieties. **During the current growing season, we will begin producing commercial quantities of seed for our new non-GMO VLN tobacco.**

Furthermore, independent of any revenue resulting from our recent research developments, our revenue for 2017 is projected to grow substantially and to far exceed the record sales numbers we posted in 2016. In fact, we have raised our 2017 revenue projections from \$12 million to over \$16 million.

But, more important than rapid revenue growth, is the kind of *exponential* growth we anticipate when we achieve regulatory approval for our X-22 prescription smoking cessation aid in development, or for our BRAND A Very Low Nicotine Modified Risk Tobacco Product (MRTP) candidate. As you know, our technology gives 22nd Century the ability to grow *the world's lowest nicotine tobacco* as well as very high nicotine tobacco. Our expansive IP portfolio and our unique experience in altering nicotine levels in the tobacco plant give 22nd Century a strong competitive advantage in the multi-billion dollar smoking cessation and reduced exposure tobacco markets.

22nd Century is in the enviable position of having THREE products in front of the FDA this year.

This June, we have a Pre-Phase III meeting with the U.S. Food and Drug Administration (FDA) for our X-22 prescription smoking cessation candidate. Also in June, we have a scheduled guidance meeting with the FDA to discuss our Very Low Nicotine BRAND A MRTP candidate. And, most recently, we secured FDA authorization for a BRAND B clinical trial. Each of these events represents a very important milestone for our Company:

- 1) **FDA MEETING FOR X-22:** The FDA's Center for Drug Evaluation and Research (CDER) granted 22nd Century a guidance meeting to discuss "X-22," which the Company is developing as its signature prescription smoking cessation aid. At this meeting, we will seek agreement from CDER/FDA on an appropriate path for X-22 to become a prescription-based cessation aid for smokers in the United States. In coordination with FDA guidance, we anticipate beginning a pivotal Phase III clinical trial for X-22, the world's only smoking cessation aid in the form of a combustible cigarette. In a recent independent, double-blind, parallel, randomized clinical trial involving 840 smokers at ten locations, researchers found, as compared with cigarettes of conventional nicotine content, 22nd Century's proprietary low nicotine SPECTRUM cigarettes were "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events." The approval of X-22 will mean that many millions of smokers will finally have access to a new and powerful tool to help them quit smoking. The value to our Company and our shareholders of achieving FDA approval for X-22 as a smoking cessation aid is hard to overestimate.
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- 2) **FDA MEETING FOR BRAND A:** Also in June, we are meeting with the FDA's Center for Tobacco Products (CTP) to discuss our MRTP application for BRAND A Very Low Nicotine cigarettes. At the meeting, we expect to receive feedback on the structure of our soon to be resubmitted MRTP application and our separate Pre-Market Tobacco Product (PMT) application. After numerous positive discussions with tobacco regulators at the March national tobacco control conference in Austin Texas, we remain convinced that **22nd Century will likely be the first – and only – company in the world to win FDA approval to sell a Modified Risk Tobacco Product (MRTP) in the United States.** Of course, having the only tobacco product with a reduced exposure claim will serve as a lightning rod for commercial sales. Achieving even a quarter of one percent market share could result in a 22nd Century market cap that is a multiple of today's valuation.
- 3) **FDA AUTHORIZED TRIAL FOR BRAND B:** The FDA has granted 22nd Century authorization to conduct a clinical trial investigating the Company's BRAND B low tar-to-nicotine ratio cigarettes. This trial is designed to confirm that as smokers make the adjustment to a higher nicotine cigarette, they take in less smoke because the nicotine is more readily available. This seminal trial will take place this summer, with results due soon after the trial is complete.

Our Company's development of important hemp/cannabis varieties is also heating up. **In March, 22nd Century announced the creation of industrial hemp plants that contain zero THC!** Zero THC hemp plants have applications in the production of industrial fibers, food products, and important new medicines. It is a break-through that is already opening the doors to massive new markets for our Company.

In summary, we are well positioned to capitalize on the multi-billion dollar smoking cessation and broader tobacco market opportunities... and we are very excited about the future ahead! We have made tremendous advances with our cannabis technology and we are now in sight of launching a brand new industrial hemp crop. 2017 promises to be an exciting time for 22nd Century Group!

Best wishes to you and your family. 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

Cautionary Note Regarding Forward-Looking Statements: This communication 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 communication, 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, 2016, filed on March 8, 2017, 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.
