22nd Century Group, Inc.
Form 10-K
March 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual Report under Section 13 or 15(d) of the Securities**

Exchange Act of 1934

For the fiscal year ended December 31, 2017

or

¨ **Transitional Report under Section 13 or 15(d) of the**

Securities Exchange Act of 1934

Commission File Number: 001-36338

22nd Century Group, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**98-0468420**
(State or other jurisdiction	(IRS Employer

of incorporation) Identification No.)

8560 Main Street, Williamsville, New York 14221

(Address of principal executive offices)

(716) 270-1523

(Registrant's telephone number, including area code)

9530 Main Street, Clarence, New York 14031

(Former name, former address
and former fiscal year, if
changed since last report)

Securities registered under Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered
Common Stock, $0.00001 par value	NYSE American

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act

Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Yes ¨ No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files)

Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ¨	Accelerated Filer x	Non-Accelerated Filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company ¨
			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. ¨

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Act). Yes ¨ No x

As of June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate value of the registrant's common stock (excluding approximately 6.5 million shares held by affiliates), based upon the $1.75 price at which such common stock was last sold on June 30, 2017, was approximately $158.4 million.

As of March 6, 2018, there were 124,136,087 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2018 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of December 31, 2017.

22nd Century Group, Inc.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition as well as our plans, objectives and expectations for our business operations and financial performance and condition that are subject to risks and uncertainties. All statements other than statements of historical fact included in this Annual Report on Form 10-K are forward-looking statements. You can identify these statements by words such as “aim,” “anticipate,” “assume,” “believe,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “objective,” “plan,” “potential,” “positioned,” “predict,” “should,” “target,” “will,” “would” and other similar expressions that predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions. These statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected, including:

- Our ability to achieve profitability and positive cash flows;
- The timing of the implementation by the U.S. Food and Drug Administration (“FDA”) with respect to regulations that will require all cigarettes sold in the United States to contain only minimally or non-addictive levels of nicotine;
- Our ability to obtain FDA clearance to market our *BRAND A* Very Low Nicotine cigarettes as a Modified Risk Tobacco Product;
- Our ability to obtain significant revenue from the licensing of our technology and/or our sale or licensing of our Very Low Nicotine tobacco and/or product;
- Our ability to manage our growth effectively;
- Our ability to retain key personnel;
- Our ability to enter into additional licensing transactions;
- Our ability to gain market acceptance for our products;
- Any potential negative impact from doing business in the legal hemp and medical cannabinoid space;

· The strict enforcement of federal laws regarding state-legal cannabis/marijuana;

· Our ability to comply with government regulations;

· Our ability to compete with competitors that may have greater resources than we have;

· The potential for our competitors to develop products that are less expensive, safer or more effective than ours;

· The potential exposure to product liability claims, product recalls and other claims; and

· Our ability to adequately protect our intellectual property and to avoid infringement on rights of third parties.

For the discussion of these risks and uncertainties and others that could cause actual results to differ materially from those contained in our forward-looking statements, please refer to “Risk Factors” in this Annual Report on Form 10-K. The forward-looking statements included in this Annual Report on Form 10-K are made only as of the date hereof. We undertake no obligation to publicly update or revise any forward-looking statement as a result of new information, future events or otherwise, except as otherwise required by law.

Unless the context otherwise requires, references to the “Company” “we” “us” and “our” refer to 22nd Century Group, Inc., a Nevada corporation, and its direct and indirect subsidiaries.

PART I

Item 1. Business.

Background

22nd Century Group, Inc. was incorporated under the laws of the State of Nevada on September 12, 2005 under the name Touchstone Mining Limited. On January 25, 2011, we entered into a reverse merger transaction with 22nd Century Limited, LLC, which we refer to herein as the "merger." Upon the closing of the merger, 22nd Century Limited, LLC became our wholly-owned subsidiary. After the merger, we succeeded to the business of 22nd Century Limited, LLC as our sole line of business.

22nd Century Limited, LLC was originally formed as a New York limited liability company on February 20, 1998 as 21st Century Limited, LLC and subsequently merged with a newly-formed Delaware limited liability company, 22nd Century Limited, LLC, on November 29, 1999. Since inception, 22nd Century Limited, LLC has sponsored research and subsequently used biotechnology to regulate the nicotine content in tobacco plants.

Overview

We are a plant biotechnology company focused on technology that allows us to increase or decrease the level of nicotine and other nicotinic alkaloids in tobacco plants and the levels of cannabinoids in hemp/cannabis plants through genetic engineering and plant breeding. Our primary mission in tobacco is to reduce the harm caused by smoking. Our primary mission in hemp/cannabis is to develop proprietary hemp strains for potential important new medicines and agricultural crops. We have an extensive intellectual property portfolio of issued patents and patent applications relating to the tobacco and hemp/cannabis plants.

In tobacco, we have developed unique and proprietary Very Low Nicotine ("VLN") tobacco that grows with 95% less nicotine than tobacco used in conventional cigarettes. Since 2011, we have provided more than 24 million research cigarettes containing our proprietary tobaccos for use in numerous independent clinical studies at many well-known study locations, with agencies of the United States federal government investing more than $100 million in such independent clinical studies. The results of these independent clinical studies have been published in peer-reviewed publications and demonstrate that our VLN tobacco has been associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events. The results of numerous completed and on-going clinical studies provide independent scientific

support for the public announcement on July 28, 2017 by the United States Food and Drug Administration ("FDA") that the FDA plans to mandate that all combustible cigarettes sold in the United States will be required to contain only minimally or non-addictive levels of nicotine. Since our proprietary VLN tobacco has been the subject of numerous completed and on-going, independent clinical studies paid for by agencies of the federal government, we are investigating the potential use of our VLN tobacco in our own products that will be intended to comply with the new FDA regulations, as well as we are investigating the potential license of the use of our VLN tobacco by third-parties. We are also investigating potential opportunities relating to our VLN tobacco outside of the United States.

In hemp, we are developing proprietary hemp strains for potential important new medicines and agricultural crops. Our current activities involve only work with legal hemp in full compliance with federal and state laws. The hemp plant and the cannabis/marijuana plant are both part of the same *cannabis sativa* genus/species of plant, except that hemp has less than 0.3% dry weight content of delta-9-tetrahydrocannabinol ("THC") and is legal under federal and state laws. The same plant, with a higher THC content, is cannabis/marijuana, which is legal under certain state laws, but which is not legal under federal law. The similarities between these plants can cause confusion. Our activities with fully legal hemp have sometimes been incorrectly perceived as us being involved in federally illegal cannabis/marijuana. This is not the case. We work only with legal hemp in full compliance with federal and state laws. We have developed hemp plants with zero (-0-) amounts of THC ("ZERO-THC"). We believe that our ZERO-THC hemp plants are a potential solution to one of the biggest challenges facing the legal hemp industry because, currently, hemp crops that grow with THC levels above the legal limit of 0.3% THC are required to be destroyed and hemp farmers cannot obtain crop insurance to protect against this risk. However, our ZERO-THC plants can be a potential solution to this risk since our ZERO-THC hemp plants will not develop THC above the legal limits for hemp. In the United States, we are working with the University of Virginia ("UVA") to (i) create unique industrial hemp plants with guaranteed levels of THC below the legal limits that define hemp for optimal growth in Virginia (thus eliminating the risk to growers of having to destroy non-conforming hemp crops), (ii) optimize other desirable hemp plant characteristics to improve the plant's suitability for growing in Virginia and in similar legacy tobacco regions of the United States, (iii) utilize high-value medical cannabinoid hemp varieties and specialized cannabinoid extraction processes for use in human theraputics, and (iv) use our unique hemp plants for phytoremediation to clean up and reclaim polluted soils. We have also obtained a license in the State of New York to research and grow hemp in response to the numerous public announcements by New York Governor Andrew Cuomo that New York State intends to become a leading grower and producer of hemp and hemp-derived products. In Canada, we conduct sponsored research on the hemp plant with Anandia Laboratories in Vancouver, British Columbia, in full compliance with Canadian regulations.

We currently are primarily involved in the following activities:

- Facilitating the timely implementation of the plan by the FDA to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine;

- Continuing to work on a Modified Risk Tobacco Product application to be resubmitted to the FDA to obtain a reduced exposure marketing authorization for our *BRAND A* Very Low Nicotine cigarettes to be marketed in the United States as "less addictive" and/or containing 95% less nicotine than conventional tobacco cigarettes;

- Seeking multiple, substantial licensing agreements for our tobacco technology and/or our proprietary tobaccos;

- Continuing to produce *SPECTRUM*® research cigarettes for the National Institute on Drug Abuse ("NIDA"), which is part of the National Institutes of Health ("NIH"), for use in independent clinical studies;

- Continuing to research and develop other novel tobacco plant varieties;

- Continuing to explore opportunities outside of the United States for the use of our Very Low Nicotine tobacco in potential over-the-counter cigarettes, such as *BRAND A*, or in a potential prescription-based, smoking cessation aid, such as *X-22*, in foreign countries that may desire such products;

- Continuing to expand our legal hemp activities and development of unique plant varieties of hemp, including (i) hemp plants with other desirable agronomic traits in addition to low to no amounts of THC for the legal hemp industry, and (ii) hemp plants with high levels of cannabidiol ("CBD") and other non-THC cannabinoids for the legal medical cannabinoid markets;

- Continuing to explore opportunities outside of the United States for the sale of our branded proprietary tobacco products, including *BRAND B, RED SUN,* and *MAGIC* cigarettes; and

- Continuing to grow our contract manufacturing business for third-party branded tobacco products.

Our future prospects depend on our ability to generate and sustain revenues from (i) licensing and/or sale of our proprietary tobacco, technology and/or products; (ii) regulatory approval by the FDA of our Modified Risk Tobacco Product application for our *BRAND A* Very Low Nicotine cigarettes, (iii) the manufacture of filtered cigar and cigarette brands of third-parties at our manufacturing facility in North Carolina; and (iv) our expanding activities in the legal hemp industry. Our ability to generate meaningful revenue from our proprietary tobacco, technology, and

products in the United States depends on: (i) the implementation by the FDA of regulations that require all combustible cigarettes sold in the United States to contain only minimally or non-addictive levels of nicotine, (ii) obtaining FDA authorization to market our potential Modified Risk Tobacco Product, *BRAND A*, in the United States as modified risk or reduced exposure, and (iii) our ability to license our technology and/or to sell our proprietary tobacco and products in international markets. Even after we receive regulatory approvals necessary to market our products in the United States or internationally, we must still meet the challenges of successful marketing, distribution and consumer acceptance.

Tobacco

Our primary mission in tobacco is to reduce the harm caused by smoking. The FDA publicly announced on July 28, 2017, that tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths per year and with direct health care and lost productivity costs totaling nearly $300 billion each year in the United States. The website of the U.S. Centers for Disease Control and Prevention (“CDC”) states that the World Health Organization (“WHO”) has reported that tobacco use causes more than 6 million deaths per year globally and direct health care and lost productivity costs of more than $1.4 trillion per year around the world. The CDC website also states that in 2015, nearly 7 in 10 (68%) adult cigarette smokers wanted to stop smoking and more than 5 in 10 (55.4%) adult cigarette smokers had made a quit attempt in the prior year.

Our proprietary VLN tobacco, which grows with 95% less nicotine than tobacco used in conventional cigarettes, has been shown in published, independent clinical studies as being associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events. These clinical studies, which were conducted by independent researchers and paid for by United States federal government agencies, provide a foundation of independent scientific support for recently proposed changes in the regulatory approach in the United States to address the harm caused by smoking combustible tobacco cigarettes. We believe these changes will significantly benefit us in the future as discussed in greater detail below.

Our Very Low Nicotine Tobacco and the FDA Mandate to Require Minimally or Non-Addictive Levels of Nicotine in all Cigarettes in the United States

The Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act") granted the FDA authority over the regulation of all tobacco products in the United States. While the Tobacco Control Act prohibits the FDA from banning cigarettes outright, it allows the FDA to require the reduction of nicotine or any other compound in tobacco and cigarette smoke.

In a June 16, 2010 press release, Dr. David Kessler, the former FDA Commissioner, recommended that "the FDA should quickly move to reduce nicotine levels in cigarettes to non-addictive levels. If we reduce the level of the stimulus, we reduce the craving. It is the ultimate harm reduction strategy." Shortly thereafter in a *Washington Post* newspaper article, Dr. Kessler said that the amount of nicotine in a cigarette should drop from about 10 milligrams to less than 1 milligram.

Since 2011, the FDA, NIDA and other federal government agencies in the United States have invested more than $100 million in independent clinical studies utilizing our proprietary tobaccos, with such studies being conducted by scientists at many well-known locations, including the Mayo Clinic, the MD Anderson Cancer Center at the University of Texas, the Johns Hopkins University, Duke University, the University of Pittsburgh, the University of Minnesota, the University of Vermont, the University of California, and others. Since 2011, we have provided more than 24 million *SPECTRUM* research cigarettes for use in these independent scientific clinical studies.

The results of these independent clinical studies utilizing our proprietary tobaccos have been published in peer-reviewed articles in well-respected publications, including the October 2015 issue of *The New England Journal of Medicine* (N Engl J Med 2015; 373:1340-1349), which published the results of a clinical trial funded by NIDA and the FDA's Center for Tobacco Products ("CTP") that was a double-blinded, parallel, randomized clinical trial involving 840 smokers at ten locations that was led by the Center for the Evaluation of Nicotine in Cigarettes. The authors of the article in *The New England Journal of Medicine* concluded that the proprietary VLN cigarettes created and supplied by us for such study were "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events." A list of the completed,

independent clinical studies that used our proprietary VLN tobacco can be found on our website at http://www.xxiicentury.com/published-clinical-studies/. A list of the on-going, independent clinical studies on our *SPECTRUM* research cigarettes can be found on our website at http://www.xxiicentury.com/on-going-clinical-studies/. Information on our website is not incorporated into this Annual Report on Form 10-K.

In 2015, the World Health Organization ("WHO") Study Group on Tobacco Product Regulation published an advisory note on a global nicotine reduction strategy 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. The WHO report referred to such cigarettes as "reduced-nicotine" cigarettes. The WHO report stated that conventional cigarettes – even those brands that deliver low nicotine *yields* as measured by machine smoking under the conditions of the International Organization for Standardization (ISO) – contain addicting levels of nicotine, but the nicotine *yields* are reduced as a result of many cigarette design features, including ventilated filters, with the result being that users puff ISO low-nicotine-yield cigarettes more intensely (i.e. they draw larger puffs more frequently than the conditions prescribed by machines) to obtain addicting levels of nicotine. However, the WHO report found that, unlike conventional cigarettes, *reduced-nicotine **content** cigarettes can limit the addictiveness of the product, as the very low nicotine **content** in the tobacco cannot deliver addicting levels of nicotine.* The WHO study stated that published research shows that switching from conventional cigarettes to cigarettes with a reduced-nicotine content of 0.4 mg/g of cigarette tobacco filler does not significantly increase craving or withdrawal symptoms and does not result in compensatory smoking (such as more intense smoking or smoking more cigarettes per day). The WHO study further stated that no specific amount of nicotine has yet been identified by the WHO as the absolute threshold for addiction; however, the WHO reported stated that it is likely to be equal to or possibly less than 0.4 mg/g of dry cigarette tobacco filler.

The WHO report cites 22nd Century's proprietary *SPECTRUM*® research cigarettes as meeting such a low level of nicotine of 0.4 mg/g of cigarette tobacco filler. The WHO report concluded that the evidence indicates that setting a maximum allowable nicotine content for all cigarettes could (i) reduce the acquisition of smoking and progression to addiction, (ii) reduce the prevalence of smoking in a proportion of addicted smokers as a result of behavioral extinction, (iii) increase the rate of quitting and reduce the number of smokers who relapse, and (iv) increase the development, availability, and use of alternative forms of nicotine, e.g. smokeless tobacco products, nicotine aerosol products, and medicinal nicotine, which have potential adverse health effects, including maintenance of addiction, but less than those of combusted products or conventional cigarettes. The WHO report stated that population benefits will result from decreased use of combusted tobacco by current cigarette smokers and from the prevention of addiction of non-smokers to cigarettes, especially among young people.

On July 28, 2017, FDA Commissioner Scott Gottlieb, M.D., announced the FDA's plan to exercise its authority under the Tobacco Control Act to require that all combustible cigarettes sold in the United States must contain only minimally or non-addictive levels of nicotine. In that public announcement, FDA Commissioner Gottlieb stated that (i) the overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes – the only legal consumer product that, when used as intended, will kill half of all long-term users, (ii) unless this course is changed, 5.6 million young people alive today will die prematurely later in life from tobacco use, (iii) envisioning a world where cigarettes would no longer create or sustain addiction, and where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of the FDA's efforts, and (iv) tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths per year and direct health care and lost productivity costs totaling nearly $300 billion each year.

On August 16, 2017, *The New England Journal of Medicine* published an article by FDA Commissioner Scott Gottlieb, M.D. and Mitchell Zeller, J.D., the Director of the FDA/CTP, entitled "A Nicotine-Focused Framework of

Public Health." In this article, FDA Commissioner Gottlieb and FDA/CTP Director Zeller stated that the Tobacco Control Act gives the FDA a regulatory tool called a tobacco "product standard" that can be used to alter the addictiveness of combustible cigarettes, and that such standards may set requirements related to an ingredient or constituent in a tobacco product, or related to any other aspect of product composition, construction, or other property, and that the establishment of the right product standard could alter the addictiveness of combustible cigarettes by setting maximum nicotine levels in such products. The article further stated that Section 907 of the Food, Drug, and Cosmetic Act authorizes the FDA to establish tobacco product standards that the FDA has determined to be appropriate for the protection of the public health, with the statute specifically noting that such a standard may address nicotine yields, among other characteristics. Although the statute prohibits the FDA from requiring the reduction of nicotine yields of a tobacco product to zero, the FDA stated in this article that the FDA has clear authority to otherwise reduce nicotine levels. The FDA concluded in this article that a nicotine-limiting standard could make cigarettes minimally addictive or non-addictive, helping current users of combustible cigarettes to quit and allowing most future users to avoid becoming addicted and proceeding to regular use, and that disrupting that progression – from experimentation to regular use to tobacco-related disease and even death – could save millions of American lives. In this article, the FDA also stated that the FDA will consider peer-reviewed, scientific studies in proposing a maximum nicotine level, but that rigorous studies of Very Low Nicotine cigarettes have evaluated the potential effects of various nicotine levels on smoking behaviors and biomarkers, and findings from such studies could inform decision-making on a possible maximum nicotine level in tobacco filler. The FDA stated that, as in all matters of public health policy, the FDA will be led by the science in this important area.

On October 5, 2017, Dr. Dorothy Hatsukami, the Co-Director of the Center for the Evaluation of Nicotine in Cigarettes and a Professor of Psychiatry and Director of the Tobacco Research Programs at the University of Minnesota, publicly announced at the 5th Annual Conference on Tobacco Regulatory Science at the Vermont Center on Behavior and Health, partial results of a newly completed Phase III clinical study of 1,250-patients from all demographics over a 20-week study period in 10 study locations across the United States that compared smokers who were assigned to (i) an immediate reduction to Very Low Nicotine content cigarettes, (ii) a gradual reduction in reduced nicotine content cigarettes, or (iii) normal nicotine content cigarettes. Dr. Hatsukami publicly stated that the full results of this Phase III study are in peer review prior to publication, but that the results reflect that an immediate approach to nicotine reduction is most likely to lead to less harm. Dr. Hatsukami also publicly stated that the study data indicates compensatory smoking is less likely to occur with an immediate reduction in nicotine, and that there was a greater likelihood of more rapid smoking cessation with the immediate approach to nicotine reduction. Our Company provided all the research cigarettes used in this Phase III study.

Since 2011, the FDA, NIDA and other federal government agencies have invested more than $100 million in independent clinical studies utilizing our proprietary tobaccos, with such studies being conducted by scientists at many different and well-known clinical study centers. During that same time, we have provided more than 24 million proprietary *SPECTRUM* research cigarettes for use in such independent clinical studies. The results of these studies have been published in peer-reviewed articles and reflect the independent scientific support for the planned mandate by the FDA that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. We believe that our VLN tobacco technology and our production and delivery of more than 24 million proprietary research cigarettes since 2011 reflects that the FDA's plan to dramatically reduce nicotine in cigarettes is technologically feasible. Since our proprietary VLN tobacco has been the subject of numerous completed and on-going clinical studies, we are investigating the potential use of our VLN tobacco in our own products that will be intended to comply with the new FDA regulations, as well as we are investigating the potential license of the use of our VLN tobacco by third-parties. In the United States, we will focus on working with the FDA on its nicotine reduction mandate and on submitting a Modified Risk Tobacco Product application for our *BRAND A* Very Low Nicotine cigarettes. Outside the United States, we will focus on working with WHO-member countries that desire to utilize our proprietary VLN tobacco to implement the WHO recommendation of limiting the sale of cigarettes to brands with a nicotine content that is not sufficient to lead to development and/or maintenance of addiction.

Products

BRAND A Very Low Nicotine Cigarettes

The tobacco in our *BRAND A* Very Low Nicotine cigarettes contains approximately 95% less nicotine than conventional cigarette brands. The strategy behind *BRAND A* is to reduce smokers' exposure to nicotine, which is the primary addictive component of cigarettes.

We are working to resubmit a Modified Risk Tobacco Product application to the FDA to obtain a reduced exposure marketing authorization for our *BRAND A* Very Low Nicotine cigarettes to be marketed as “less addictive” and/or containing 95% less nicotine than conventional tobacco cigarettes.

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of Modified Risk Tobacco Products, which includes cigarettes that (i) reduce exposure to tobacco toxins and (ii) are reasonably likely to pose lower health risks, as compared to conventional cigarettes (“Modified Risk Cigarettes”). The Tobacco Control Act required the FDA to issue specific regulations and guidance regarding applications submitted to the FDA for the authorization to label and market Modified Risk Cigarettes. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance.* We believe that our *BRAND A* Very Low Nicotine cigarettes will qualify as Modified Risk Cigarettes.

On December 31, 2015, we submitted to the FDA a Modified Risk Tobacco Product application requesting a reduced exposure marketing authorization from the FDA to market *BRAND A* as a Modified Risk Cigarette with product labeling and advertising that states that *BRAND A* has 95% less nicotine than conventional cigarettes. In December 2016, the FDA provided us with feedback on our combined Modified Risk Tobacco Product Application ("MRTPA") and Premarket Tobacco Product Application ("PMTA") for our *BRAND A* Very Low Nicotine tobacco cigarettes. In response to the FDA's requests, and in conjunction with additional clarifying guidance, we withdrew our existing application with the FDA in order to file a new MRTPA and PMTA with the FDA for *BRAND A* that will include additional scientific data and other information requested by the FDA.

In support of our expanded work on our revised MRTPA and PMTA for our *BRAND A* Very Low Nicotine cigarettes, we have increased the depth and experience of our scientific and regulatory team. On October 31, 2017, we hired Dr. James E. Swauger to be our new Senior Vice President of Science and Regulatory Affairs. Dr. Swauger was previously the leader of the scientific and regulatory functions at Reynolds American Inc., one of the largest tobacco companies in the United States. Dr. Swauger's primary responsibilities with us will be to lead and oversee our scientific and regulatory affairs, plant biotechnology, research and development, and external scientific activities, including the resubmission to the FDA of our MRTPA and PMTA for our *BRAND A* Very Low Nicotine cigarettes. On December 4, 2017, we hired Dr. Juan Tamburrino to be our new Vice President of Research and Development. Dr. Tamburrino was previously the head of the Plant Biotechnology Division of British American Tobacco, one of the largest tobacco companies in the world. Dr. Tamburrino will be an integral part of our scientific and regulatory team working on our resubmission to the FDA of our MRTPA and PMTA for our *BRAND A* Very Low Nicotine cigarettes, and our continuing research and development of improved Very Low Nicotine tobacco plants.

SPECTRUM® Government Research Cigarettes

NIDA, which is a part of NIH, provides the scientific community with controlled and uncontrolled research chemicals and drug compounds through its Drug Supply Program. In 2010, NIDA included an option to develop and produce research cigarettes with various levels of nicotine (from very low to high) in its request for proposals for a five-year contract for Preparation and Distribution of Research and Drug Products. We agreed, as a subcontractor to RTI International ("RTI"), to supply cigarettes with different nicotine contents (from very low to high) to NIDA. In August 2010, we met with officials from NIDA, FDA, RTI, CDC and the National Cancer Institute ("NCI") to finalize certain aspects of the design of these research cigarettes. These government research cigarettes produced by us under the mark *SPECTRUM®* have been, and continue to be, distributed by RTI for NIDA to independent researchers for scientific clinical studies. The *SPECTRUM®* research cigarette contract was renewed in 2015 for an additional five years.

Since 2011, the FDA, NIDA and other federal government agencies have invested more than $100 million in independent clinical studies utilizing our proprietary tobaccos, with such studies being conducted at many well-known locations, including the Mayo Clinic, the MD Anderson Cancer Center at the University of Texas, the Johns Hopkins University, Duke University, the University of Pittsburgh, the University of Minnesota, the University of Vermont,

the University of California, and others. Since 2011, we have provided more than 24 million *SPECTRUM*® research cigarettes for use in these independent clinical studies, with the most recent shipment of 2.4 million *SPECTRUM*® research cigarettes occurring in November 2017. The *SPECTRUM*® product line consists of a series of 24 cigarette styles (11 regular and 13 menthol versions) that have 8 different levels of nicotine – from very low to high. A list of the completed, independent clinical studies on our proprietary tobaccos can be found on our website at http://www.xxiicentury.com/published-clinical-studies/. A list of the on-going, independent clinical studies on our proprietary VLN tobacco can be found on our website at http://www.xxiicentury.com/on-going-clinical-studies/. Information on our website is not incorporated into this Annual Report on Form 10-K.

X-22 Prescription Smoking Cessation Aid

X-22 is a tobacco-based botanical medical product for use as an aid to smoking cessation. Our *X-22* therapy protocol calls for patients to smoke exclusively our *X-22* cigarettes over a six-week treatment period to facilitate the goal of the patient quitting smoking by the end of the treatment period. We believe that *X-22* cigarettes made from our proprietary VLN tobacco satisfy smokers' cravings for cigarettes while (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine. *X-22* involves the same smoking behavior as conventional cigarettes and, because patients are simply switching to cigarettes with a low nicotine content for 6 weeks, *X-22* does not expose the smoker to any new drugs or new side effects.

Independent clinical studies have demonstrated that smokers who smoke cigarettes containing our proprietary VLN tobacco smoke fewer cigarettes per day resulting in significant reductions in smoke exposure, including "tar," nicotine, and carbon monoxide. Due to the very low nicotine levels, compensatory smoking does not occur with cigarettes containing our proprietary VLN tobacco. A list of the completed, independent clinical studies that used our proprietary VLN tobacco can be found on our webiste at http://www.xxiicentury.com/published-clinical-studies/. We do not incorporate the information on our website into this Annual Report on Form 10-K.

As a result of the FDA's announcement on July 28, 2017 to require the reduction of nicotine to minimally or non-addictive levels in all cigarettes sold in the United States, we do not believe that there will be a market in the United States for a prescription-based product consisting of our VLN tobacco because tobacco with minimally or non-addictive levels of nicotine will be mandated by the FDA in all combustible tobacco cigarettes in the United States. Accordingly, we will continue to explore opportunities outside of the United States for *X-22* in markets where a prescription-based, smoking cessation product may be appropriate.

BRAND B Low-Tar-to-Nicotine Ratio Cigarettes

Using a proprietary high nicotine tobacco blend in conjunction with specialty cigarette components, *BRAND B* allows the smoker to achieve a satisfactory amount of nicotine per cigarette while inhaling less "tar" and carbon monoxide. At the same time, we do not expect exposure to nicotine from *BRAND B* to be significantly higher than commercially available full flavor cigarette brands. We believe smokers who desire to reduce smoke exposure, but are less concerned about nicotine, may find *BRAND B* beneficial.

In a 2001 report, entitled *Clearing the Smoke, Assessing the Science Base for Tobacco Harm Reduction*, the Institute of Medicine (the health arm of the National Academy of Sciences) notes that a low "tar"/moderate nicotine cigarette is a

viable strategy for reducing the harm caused by smoking. The report states: “Retaining nicotine at pleasurable or addictive levels while reducing the more toxic components of tobacco is another general strategy for harm reduction.”

We had previously intended to submit a Modified Risk Tobacco Product application to the FDA for *BRAND B*. However, as a result of the FDA’s announcement on July 28, 2017 to require the *reduction of nicotine* to minimally or non-addictive levels in all cigarettes sold in the United States, we no longer believe that there will be a market in the United States for *BRAND B*. As such, we will continue to explore opportunities outside of the United States for *BRAND B* in markets where that product may be appropriate.

RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco Company, LLC (“Goodrich Tobacco”), introduced in a limited capacity two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. From the year 2011 through the year 2014, there were *de minimis* sales of these brands since we intentionally did not expand the marketing and distribution of these brands until after we became a subsequent participating manufacturer under the Master Settlement Agreement (“MSA”) which occurred on August 29, 2014, when the 46 Settling States under the MSA approved our acquisition of NASCO Products, LLC (“NASCO”) and NASCO became a subsequent participating manufacturer under the MSA. During the remainder of 2014, we worked to obtain approvals from regulatory agencies in all 50 States to have our *RED SUN* brand listed on the state directories of tobacco products approved for sale in each such state. During 2014, we also worked with *Orion*, a cigarette manufacturer in Poland, to contract manufacture our proprietary tobacco products for distribution in the European Union, starting with our *MAGIC* brand. In 2015, we focused our marketing efforts for *RED SUN* on national and regional distributors, tobacconists, smoke shops and other tobacco outlets in the United States. In 2015, we also introduced our *MAGIC* cigarettes to distributors and retailers in Spain. We ceased marketing the *MAGIC* brand in Spain when the European Union changed its packaging laws to no longer allow companies to print the nicotine yield on cigarette packs. In response to the planned mandate by the FDA that all cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine, we discontinued sales in the United States of our *RED SUN* brand as of December 31, 2017. We will continue to explore opportunities outside of the United States for our *RED SUN* and *MAGIC* brands in markets where such products may be appropriate.

Hemp

Our primary mission in hemp/cannabis is to develop proprietary hemp strains for potential important new medicines and agricultural crops. Our current activities involve work with only legal hemp in full compliance with federal and state laws. The hemp plant and the cannabis/marijuana plant are both part of the same *cannabis sativa* genus/species of plant, except that hemp has less than 0.3% dry weight content of THC and is legal under federal and state laws. The same plant with a higher THC content is cannabis/marijuana, which is legal under certain state laws, but which is not legal under federal law. The similarities between these plants can cause confusion. Our activities with fully legal hemp have sometimes been incorrectly perceived as us being involved in federally illegal cannabis/marijuana. This is not the case. We work only with legal hemp in full compliance with federal and state laws.

We currently sponsor hemp research in Canada and in the United States. In Canada, we conduct sponsored research on hemp through Botanical Genetics, which is our wholly-owned subsidiary and which was incorporated to facilitate an equity investment in Anandia Laboratories, Inc. ("Anandia"), a plant biotechnology company based in Vancouver, British Columbia, Canada. On September 15, 2014, Botanical Genetics was granted a sublicense by Anandia to 2 patents and 23 patent applications relating to genes in the hemp/cannabis plant that are required for the production of cannabinoids, the "active ingredients" in the hemp/cannabis plant, with such sublicense being exclusive in the United States and co-exclusive with Anandia everywhere else in the world, except Canada where Anandia has retained exclusive rights. The Anandia sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035. Under licenses granted by the Canadian government to Anandia, we conduct research and development on unique plant varieties of hemp at Anandia, such as (i) hemp plants with low to no amounts of THC for the legal hemp industry, and (ii) hemp plants with high levels of CBD and other non-THC cannabinoids for the legal medical cannabinoid markets. Anandia and 22nd Century conduct all activities in this scientific collaboration within the parameters of all applicable licenses and permits held by Anandia for such work. The agreements with Anandia grant us exclusive rights to commercialize in the United States (and co-exclusive with Anandia everywhere else in the world outside of Canada and the United States) all results of this collaboration in consideration of royalty payments by us to Anandia.

On March 23, 2017, we publicly announced that our strategic collaboration with Anandia had resulted in new industrial hemp plants that have zero (-0-) amounts of THC ("ZERO-THC"). We believe that our ZERO-THC hemp plants are a potential solution to one of the biggest challenges facing the legal hemp industry because, currently, hemp crops that grow with THC levels above the legal limit of 0.3% THC are required to be destroyed and hemp farmers cannot obtain crop insurance to protect against this risk. However, our ZERO-THC plants offer a potential solution to this risk because our ZERO-THC hemp plants will not develop THC above the legal limits for hemp.

In the United States, we conduct sponsored research on hemp at the University of Virginia ("UVA"). In December 2016, we entered into a sponsored research agreement with UVA and an exclusive license agreement with the University of Virginia Patent Foundation d/b/a University of Virginia Licensing & Ventures Group ("UVA LVG"). Over the ensuing three years, we will invest approximately $1,000,000 in this scientific collaboration. The goals of the research

agreement include: (i) creating unique industrial hemp plants with guaranteed levels of THC below the legal limits that define hemp for optimal growth in Virginia (thus eliminating the risk to growers of having to destroy non-conforming hemp crops), (ii) optimizing other desirable hemp plant characteristics to improve the plant's suitability for growing in Virginia and in similar legacy tobacco regions of the United States, (iii) utilizing high-value medical cannabinoid hemp varieties and specialized cannabinoid extraction processes for use in human theraputics, and (iv) using our unique hemp plants for phytoremediation to clean up and reclaim polluted soils.

On October 19, 2017, we announced that we had successfully completed our hemp field trials with UVA. The 22nd Century - UVA hemp field trials used multiple oil and fiber varieties of hemp. The Company's hemp harvest with UVA identified proprietary varieties of hemp that have excellent agronomic properties for growth in Virginia. We are working with UVA on expanded plantings in 2018 of the most promising varieties of our proprietary hemp plants to optimize plant growth in the legacy tobacco region of the United States. UVA and 22nd Century conduct all activities in this scientific collaboration within the parameters of state and federal licenses and permits held by UVA for such work. The agreements with UVA and UVA LVG grant us the exclusive rights to commercialize all results of the collaboration in consideration of royalty payments by us to UVA LVG.

We are also expanding our hemp activities in our home State of New York after the many public announcements by New York Governor Andrew Cuomo that New York State ("NYS") intends to become a leading grower and producer of hemp and hemp-derived products. On October 30, 2017, we obtained a NYS hemp research and grower license to support our expanding hemp activities in New York.

As of December 31, 2017, there were (i) 34 states in the United States and the District of Columbia that have legalized hemp, (ii) 29 states in the United States and the District of Columbia that have laws and/or regulations that recognize, in one form or another, legitimate medical uses for cannabis/marijuana and consumer use of cannabis/marijuana in connection with medical treatment, and (iii) 9 states in the United States and the District of Columbia that have legalized cannabis/marijuana for adult recreational use. Many other states are considering similar legislation. Conversely, under the federal Controlled Substance Act (the "CSA"), the policies and regulations of the federal government and its agencies are that cannabis/marijuana has no medical benefit and a range of activities are prohibited, including cultivation, possession, personal use and interstate distribution of cannabis/marijuana. In the event the U.S. Department of Justice (the "DOJ") begins strict enforcement of the CSA in states that have laws legalizing medical and/or adult recreational cannabis/marijuana, there may be a direct and adverse impact to any future potential business or prospects that we may have in the cannabis/marijuana business. However, our current activities involve only work with legal hemp, which would continue since our hemp activities are permitted under applicable federal and state laws, rules, and regulations.

Intellectual Property

Our intellectual property enables us to decrease or increase the level of nicotine and other nicotinic alkaloids in tobacco plants and the levels of cannabinoids in hemp/cannabis plants through genetic engineering and plant breeding. The basic techniques include, but are not limited to, those that are used in the production of genetically modified ("GM") varieties of other crops, which are also known as "biotech crops."

We have extensive patent protection and exclusive rights covering tobacco plants with altered nicotine content produced from modifying expression of certain genes in the tobacco plant, including NBB, QTP, A622, MPO and

several transcription factor genes, and tobacco products produced from these plants. With the exception of the QTP patent family that will expire in 2018, the majority of our patent families related to nicotine biosynthesis will expire between 2021 and 2034, with certain extensions of terms in the U.S. applications resulting from patent term adjustments at the U.S. Patent and Trademark Office. (A "patent family" is a set of patents granted in various countries to protect a single invention.).

The creation and production of unique tobacco plants with agronomic traits of Very Low Nicotine levels, with sufficiently high germination rates, and sufficiently large plant yields at harvest, among many other desirable qualities, are necessary for the plants to be sufficiently reliable to be planted at commercial scale. The expiration of the QPT patent family in 2018 will provide third-parties with the freedom to target the QPT gene in the tobacco plant, but the targeting of the QPT gene alone does not mean that a third-party will be successful in creating a tobacco plant with altered levels of nicotine. The freedom to target the QPT gene means that a third-party may conduct scientific experiments to try to discover how to alter or affect the QPT gene in ways that may or may not result in a change in nicotine levels in the tobacco plant. If a third-party is subsequently able to learn, over time, how to utilize the QPT gene to alter nicotine levels in the tobacco plant, then such third-party would still need to develop and create a unique tobacco plant with *very low* levels of nicotine (not just a "reduced nicotine" plant), which would involve, among many other things, multiple plantings over multiple generations of the plants to try to create stable and reliable Very Low Nicotine plants, with no assurance that any third-party could be successful in such efforts. However, if a third-party is able, over time, to develop a tobacco plant with very low levels of nicotine, then such third party would still need to develop a Very Low Nicotine plant with sufficiently high germination rates and sufficiently large plant yields at harvest for the plant to be sufficiently reliable to be planted in large quantities to support its use at commercial scale, which would again involve, among many other things, multiple plantings over multiple generations of the plants to determine the reliability and stability of the germination rates and plant yields at harvest of such plants.

While third-parties may desire to engage in experiments with the QPT gene, we already have proprietary VLN tobacco with germination rates, plant yields at harvest, and other desirable qualities that are acceptable to us for the plant to be sufficiently reliable to be planted by us at commercial scale. We have provided more than 24 million research cigarettes containing our proprietary VLN tobacco that was grown under strict contracts with our growers and then processed and finished into cigarettes at our factory. Thus, we believe that our VLN tobacco has the agronomic qualities that are sufficient to support its use in a commercial scale product. We are also developing our next-generation VLN tobacco to continue to maintain our competitive advantage in being a unique provider of VLN tobacco to third-parties that may desire to utilize it in their finished tobacco products.

In September 2014, we entered into a Sublicense Agreement with Anandia Laboratories, Inc. (the "Anandia Sublicense"). Under the terms of the Anandia Sublicense, we were granted an exclusive sublicense in the United States and a co-exclusive sublicense in the remainder of the world, excluding Canada, to 2 U.S. patents and 23 patent applications relating to genes in the hemp/cannabis plant that are required for the production of cannabinoids, the "active ingredients" in the hemp/cannabis plant. The Anandia Sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035. As a plant biotechnology company, our entry into the legal hemp markets is a natural evolution of our activities in a plant that has important research and commercial value and applications. Under licenses granted by the Canadian government to Anandia, we conduct research and development on unique plant varieties of hemp at Anandia, such as (i) plants with low to no amounts of THC for the legal hemp industry, and (ii) plants with high levels of CBD and other non-THC cannabinoids for the legal medical cannabinoid markets.

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In December 2014, we entered into a Purchase Agreement with the National Research Council of Canada ("NRC") to acquire certain patent rights that we had previously licensed from NRC. Under the terms of the NRC Purchase Agreement, we agreed to pay NRC a total amount of $1,213,000, of which a portion was paid in cash at the closing on December 23, 2014 and with the remaining balance of such amount being paid by us to NRC in installment payments over a three-year period. We made the final installment payment to NRC in a timely manner on December 22, 2017. We do not owe any further amounts to NRC.

We own various registered trademarks in the United States and around the world. We also have exclusive plant variety rights in the United States (plant variety protection certificates are issued by the U.S. Department of Agriculture ("PVP")) and Canada. A PVP certificate prevents anyone other than the owner/licensee from planting, propagating, selling, importing or exporting a plant variety for twenty (20) years in the U.S. and, generally, for twenty (20) years in other member countries of the International Union for the Protection of New Varieties of Plants, known as UPOV, an international treaty concerning plant breeders' rights. There are currently more than 70 countries that are members of UPOV. Our current VLN tobacco is protected by PVP and our patent portfolio.

Licensing

We have been in negotiations with various parties in the tobacco, pharmaceutical, and hemp/cannabis industries for licensing our technology and proprietary plants and products. We believe that the FDA's planned action to reduce nicotine in combustible cigarettes in the United States will increase opportunities for us to potentially license our VLN tobacco technology and plants to third-parties in the United States. Further, if the tobacco laws in foreign countries change in ways that are consistent with the WHO recommendation and that are similar to the FDA's planned actions on reducing nicotine in cigarettes in the United States, we believe that international licensing opportunities relating to our VLN tobacco technology and plants will increase substantially.

On September 25, 2017, we announced that the Research License and Commercial Option Agreement, dated October 1, 2013 (the "BAT Research Agreement"), between us and British American Tobacco (Investments) Limited ("BAT"), a subsidiary of British American Tobacco plc, had ended, with BAT thereafter no longer having any rights with respect to any intellectual property or any other assets of our Company. We believe that the ending of the BAT Research Agreement was beneficial for us because we regained sole control over all rights to our intellectual property and we are no longer subject to the low monetary payments that would have resulted under the BAT Research Agreement. We believe that we have greater opportunities to negotiate significantly more favorable transactions relating to our VLN tobacco technology and plants in today's market, especially after the FDA announcement in July 2017 of its intent to mandate nicotine reductions in combustible cigarettes, as compared to 2013 when we entered into the BAT Research Agreement. We are also now in a much stronger financial position as compared to 2013, which we believe will enable us to negotiate licensing transactions from a position of strength as compared to our much weaker financial position in 2013.

We also believe that our unique hemp plants, including our ZERO-THC hemp plants, will be highly desirable in the United States. Our ZERO-THC hemp plants can be a potential solution to one of the biggest challenges facing the legal hemp industry because, currently, hemp crops that grow with THC levels above the legal limit of 0.3% THC are required to be destroyed and hemp farmers cannot obtain crop insurance to protect against this risk. However, our ZERO-THC hemp plants can be a potential solution to this risk since our ZERO-THC hemp plants will not develop THC above legal limits for hemp. We are also developing high-value medicinal cannabinoid varieties of hemp and specialized cannabinoid extraction processes for use in human therapeutics, as well as the use of our unique hemp plants for phytoremediation to clean up and reclaim polluted soils. We believe that the many uses of legal hemp in the United States and the continued growth of the hemp industry in the United States will result in hemp business opportunities and hemp licensing opportunities for us for our unique hemp plants and the cannabinoid extracts therefrom.

Research and Development

Since our inception, the majority of our research and development ("R&D") efforts have been outsourced to highly qualified groups in their respective fields. Since 1998, we have had multiple R&D agreements with North Carolina State University ("NCSU") and others resulting in exclusive worldwide licenses to various patented technologies. We have utilized the same model employed by many public-sector research organizations, which entails obtaining an exclusive option or license agreement to any invention arising out of funded research. In all cases, we fund and control all patent filings as the exclusive licensee. This model of contracting with public-sector researchers has enabled us to control R&D costs while achieving our desired results, including obtaining exclusive intellectual property rights relating to our outsourced R&D.

In August 2016, we opened our own laboratory on the Buffalo Niagara Medical Campus in Buffalo, New York where we are conducting our own proprietary research and development activities in tobacco and hemp. On October 30, 2017, we obtained a New York State hemp research and grower license to support our expanding hemp activities in New York.

In December 2016, we entered into a sponsored research agreement with the University of Virginia ("UVA") and an exclusive license agreement with the University of Virginia Patent Foundation d/b/a University of Virginia Licensing & Ventures Group ("UVA LVG") pursuant to which we will invest approximately $1,000,000 over a three-year period with UVA to create unique industrial hemp plants with guaranteed levels of THC below the legal limits and to optimize other desirable hemp plant characteristics to improve the plant's suitability for growing in Virginia and other legacy tobacco regions in the United States. This work with UVA will also involve the development and study of medically important cannabinoids to be extracted by UVA from our unique hemp plants and the use of our unique hemp plants for phytoremediation to clean up and reclaim polluted soils.

On October 19, 2017, we announced that UVA had completed its first successful harvest of our hemp plants and identified several promising hemp varieties that could form the foundation for commercial hemp production throughout the legacy tobacco regions of the United States. The 22nd Century-UVA hemp field trials used multiple oil and fiber varieties of hemp. Our hemp harvest with UVA identified proprietary varieties of hemp that have excellent agronomic properties for growth in Virginia. We intend to use the most promising hemp varieties for expanded hemp plantings with UVA in Virginia in 2018. We are also working with UVA on the development of high-value medicinal cannabinoid varieties of hemp and specialized cannabinoid extraction processes for use in human therapeutics. We incurred $297,710 of expenses for the R&D agreement at UVA for the year ended December 31, 2017. UVA and 22nd Century are conducting all activities in this scientific collaboration within the parameters of state and federal licenses and permits held by UVA for such work. The agreements with UVA and UVA LVG grant 22nd Century exclusive rights to commercialize all results of the collaboration in consideration of royalty payments by our Company to UVA LVG.

We committed to an R&D agreement with NCSU relating to nicotine biosynthesis in tobacco plants and incurred $162,408 in R&D expenses for the period from February 2014 through January 2016. We extended the agreement through January 31, 2017 at an additional cost of $85,681. During the years ended December 31, 2017 and 2016, we expensed $7,140 and $78,541, respectively, relating to this extended R&D agreement. We extended and amended our R&D agreement with NCSU as of February 13, 2018 to continue our research and development activities with NCSU relating to very low nicotine tobacco plants for a cost of approximately $88,000.

During the years ended December 31, 2017, 2016, and 2015, we incurred total R&D expenses of $3,366,468, $2,340,958, and $1,571,365 respectively.

MSA Membership

In September 2013, we entered into a Membership Interest Purchase Agreement to purchase all of the issued and outstanding membership interests of NASCO, a federally licensed tobacco product manufacturer and subsequent participating manufacturer under the Master Settlement Agreement ("MSA") (the "NASCO Acquisition"). The MSA is an accord reached in November 1998 between the State Attorneys General of 46 states, five U.S. territories, the District of Columbia and the five largest tobacco companies in the United States concerning the advertising, marketing and promotion of tobacco products. The MSA also set standards for, and imposes restrictions on, the sale and marketing of cigarettes by participating cigarette manufacturers. On August 29, 2014, we entered into an Amended Adherence Agreement with the 46 Settling States under the MSA pursuant to which the Company was approved to acquire NASCO and become a subsequent participating manufacturer under the MSA. On that same date, we closed the NASCO Acquisition and became a subsequent participating manufacturer under the MSA. NASCO has since been a wholly-owned subsidiary of our Company.

Manufacturing

We lease a cigarette manufacturing facility and warehouse located in Mocksville, North Carolina. In 2013 we purchased certain (i) cigarette manufacturing equipment, and (ii) equipment parts, factory items, office furniture and fixtures, vehicles and computers from the bankruptcy estate of PTM Technologies, Inc. ("PTM") for approximately $3.22 million.

The facility was primarily in a pre-manufacturing stage during 2014 as we sought approval during that time for us to become a subsequent participating manufacturer under the MSA. Since August 29, 2014, the Company has been a subsequent participating manufacture under the MSA. Since 2015, we have manufactured and sold our *SPECTRUM*® government research cigarettes, together with a third-party MSA cigarette brand, and several third-party filtered cigar brands, at our factory in North Carolina.

Our strategic acquisiti