22nd Century Group, Inc.
Form 10-K
March 06, 2019

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, 2018

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 of incorporation) (IRS Employer Identification No.)

8560 Main Street, Suite 4, Williamsville, New York 14221

(Address of principal executive offices)

(716) 270-1523

(Registrant's telephone number, including area code)

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 every Interactive Date File required to be submitted 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 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, a smaller reporting company, or an emerging growth 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 ¨ 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 29, 2018, 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 5.8 million shares held by affiliates), based upon the $2.46 price at which such common stock was last sold on June 29, 2018, was approximately $292 million.

As of March 6, 2019, there were 124,642,593 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2019 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, 2018.

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 Content cigarettes as a Modified Risk Tobacco Product with product labeling that includes the proposed brand name of VLN™ and states that the VLN™ product has 95% less nicotine than conventional cigarettes;
- Our ability to obtain revenue from the licensing of our technology and/or our sale or licensing of our Very Low Nicotine Content 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;
- Our ability to develop new or proprietary hemp strains for new medicines and agricultural crops;
- 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;
- The expected outcome or impact of any on-going or new litigation matters; 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 Content ("VLNC") tobacco that grows with at least 95% less nicotine than tobacco used in conventional cigarettes. Since 2011, we have provided more than 28 million research cigarettes containing our VLNC 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 $125 million in such independent clinical studies. The results of these independent clinical studies have been published in peer-reviewed publications and demonstrate that our VLNC 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 such 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 enact a new rule to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. On March 19, 2018, the FDA publicly announced its Advance Notice of Proposed Rulemaking ("ANPRM") to solicit public comments on the FDA's plan to enact a new nicotine reduction rule. On July 16, 2018, we publicly submitted to the FDA our formal written response to the ANPRM in which we described how (i) the FDA's proposed new rule is supported by rigorous independent, published science, (ii) the FDA's stated goal to render cigarettes minimally or non-addictive is immediately feasible as evidenced by our production and delivery of more than 28 million VLNC research cigarettes since the year 2011, and (iii) the FDA's proposed new rule is exceedingly practical and urgently needed in the interests of public health.

Since our proprietary VLNC tobacco has been the subject of numerous completed and on-going, independent clinical studies paid for by agencies of the U.S. federal government, we are investigating the use of our VLNC tobacco in our own products that will be intended to comply with the new FDA regulations. On December 5, 2018, we submitted to the FDA a new Pre-Market Tobacco product application ("PMTA") and on December 27, 2018, we submitted to the FDA a new Modified Risk Tobacco Product application ("MRTPA"), in each case for our *BRAND A* VLNC cigarettes for which we are requesting a reduced exposure marketing authorization from the FDA to market *BRAND A* as a Modified Risk Tobacco Product with product labeling that includes the proposed brand name of VLN™ and states that the VLN™ product has 95% less nicotine than conventional cigarettes. We are also investigating the license of the use of our VLNC tobacco by third-parties. We are further investigating potential opportunities relating to our VLNC 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 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 not more than 0.3% dry weight content of delta-9-tetrahydrocannabinol ("THC") and is legal under the federal 2018 Farm Bill and certain 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 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 compliance with federal and state laws.

In 2017, we announced that we had developed hemp plants with zero (-0-) amount of THC as a potential solution to one of the biggest challenges that was then facing the legal hemp industry, which was that hemp farmers were not able to obtain crop insurance to protect against the risk of their entire hemp crop being destroyed if a portion of their hemp crop grew with THC levels above the legal limit of 0.3% THC. We developed our zero-THC hemp plants in 2017 as a potential solution to that risk because our zero-THC hemp plants will not develop THC above the legal limits for hemp. However, under the new U.S. federal law known as the "2018 Farm Bill," which was enacted on December 20, 2018 and is described in more detail herein, the hemp plant has been legalized under U.S. federal law, but with compliance still being required with all applicable state hemp laws. The 2018 Farm Bill specifically authorizes federal crop insurance programs to cover hemp, so hemp farmers no longer face the loss of their hemp crops without insurance protection. Thus, any hemp plant with zero amount of THC is still a scientifically interesting plant, but the commercial viability of any zero THC hemp plant will depend on its other agronomic qualities, such as whether it has a superior fiber content, high yields, and other agronomically desirable traits for commercial uses and/or unique cannabinoid levels for possible extraction purposes. We believe that we have many such types of superior and unique hemp plant varieties, 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.

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, (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, and (iii) utilize high-value medical cannabinoid hemp varieties and specialized cannabinoid extraction processes for use in human therapeutics. 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 have conducted sponsored research on the hemp plant with Anandia Laboratories in Vancouver, British Columbia, in 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 with the FDA on our Modified Risk Tobacco Product application that we have submitted to the FDA to obtain a reduced exposure marketing authorization for our *BRAND A* Very Low Nicotine Content cigarettes to be marketed in the United States under the proposed brand name of VLN™ as containing 95% less nicotine than conventional tobacco cigarettes;

- Seeking 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 VLNC 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 Content cigarettes with product labeling that includes the proposed brand name of VLN™ and states that the VLN™ product has 95% less nicotine than conventional 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, VLN™, in the United States as a modified risk or reduced exposure product; 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. The website of the U.S. Centers for Disease Control and Prevention ("CDC") states that tobacco use causes 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 CDC website also states that in 2015, nearly 7 in 10 (68.0%) 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 VLNC tobacco, which grows with at least 95% less nicotine than tobacco used in conventional cigarettes, has been shown in numerous 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 by the FDA 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 Content 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 $125 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 28 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. For example, the October 2015 issue of *The New England Journal of Medicine* (N Engl J Med 2015; 373:1340-1349) 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 this article in *The New England Journal of Medicine* concluded that the proprietary VLNC 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."

As a further example, 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 were then 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.

On September 5, 2018, the *Journal of the American Medical Association* (JAMA) published the results of such Phase III study by Dr. Hatsukami, *et al*., in which this independent clinical study investigated the effects of an immediate reduction in nicotine content of cigarettes versus a gradual reduction in nicotine content of cigarettes. Dr. Hatsukami, *et al.*, used exclusively 22nd Century's SPECTRUM® research cigarettes to conduct this study. In this randomized, parallel, double-blind clinical study, which is the largest clinical study using VLNC cigarettes conducted to date, independent scientists assigned 1,250 participants to one of three groups: (1) smokers who were provided only with cigarettes containing VLNC tobacco with 0.4 mg of nicotine per gram of tobacco, (2) smokers who were provided with cigarettes with a gradual reduction of nicotine from 15.5 mg to 0.4 mg of nicotine per gram of tobacco, and (3) smokers who were provided with cigarettes of a conventional nicotine level with 15.5 mg of nicotine per gram of tobacco. Following two weeks of baseline study and 20 weeks of intervention, an immediate reduction in nicotine emerged as the clear winner. Compared to a gradual nicotine reduction, an immediate nicotine reduction was associated with (i) lower toxicant exposure across time; (ii) fewer cigarettes smoked per day; (iii) greater reduction in nicotine dependence; and (iv) more days in which participants smoked no cigarettes (cigarette-free days). In contrast, results from the study participants assigned to a gradual reduction in nicotine were nearly indistinguishable from the results of the study participants assigned to cigarettes with a conventional level of nicotine in the areas of dependence, number of cigarette-free days, cigarettes smoked per day, and most of the biomarkers of nicotine and tobacco smoke exposure.

In a companion article published by the University of Minnesota on September 4, 2018, Dr. Hatsukami stated that "the results of this 1,250-patient study support the benefits of rapidly reducing nicotine in all cigarettes, primarily because this approach helped smokers, who initially had no immediate intentions to quit, experience smoke-free days. This is good news because the majority of smokers want to quit smoking, but only a small percentage of smokers are successful."

A list of the completed, independent clinical studies that used our proprietary VLNC 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 (including links to third party websites) is not incorporated into this Annual Report on Form 10-K.

As further background in this matter, 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, and with the result being that users puff ISO low-nicotine-yield cigarettes more intensely (i.e. they draw larger puffs and more frequent puffs 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 report 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 Content 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.

In summary, since 2011, the FDA, NIDA and other federal government agencies have invested more than $125 million in independent clinical studies utilizing 22nd Century's 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 28 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 VLNC tobacco technology and our production and delivery of more than 28 million proprietary research cigarettes since 2011 reflects that the FDA's plan to dramatically reduce nicotine in cigarettes is technologically feasible. Since our proprietary VLNC tobacco has been the subject of numerous completed and on-going independent clinical studies, we are investigating the potential use of our VLNC 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 VLNC tobacco by third-parties. In the United States, we will focus on working with the FDA on its nicotine reduction mandate and on our Premarket Tobacco product application ("PMTA") and our Modified Risk Tobacco Product application ("MRTPA") that we submitted to the FDA in December 2018 for our *BRAND A* Very Low Nicotine Content cigarettes with product labeling that includes the proposed brand name of VLN™ and states that the VLN™ product has 95% less nicotine than conventional cigarettes. Outside the United States, we will focus on working with WHO-member countries that desire to utilize our proprietary VLNC 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 Content Cigarettes

The tobacco in our *BRAND A* Very Low Nicotine Content cigarettes contains at least 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.

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of Modified Risk Tobacco Products, which includes cigarettes marketed to (i) reduce harm or the risk of tobacco-related disease or (ii) reduce or eliminate exposure to a substance ("Modified Risk Cigarettes"). The Tobacco Control Act required the FDA to issue specific regulations and/or guidance regarding applications submitted to the FDA for the authorization to label and market Modified Risk Tobacco Products. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance*. We believe that our *BRAND A* Very Low Nicotine Content cigarettes will qualify as Modified Risk Cigarettes.

On December 31, 2015, we submitted to the FDA a combined Premarket Tobacco product application ("PMTA") and a Modified Risk Tobacco Product Application ("MRTPA") 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 PMTA/MRTPA for our *BRAND A* Very Low Nicotine Content tobacco cigarettes. In response to the FDA's requests at that time, and in conjunction with additional clarifying guidance, we withdrew our then existing applications with the FDA in order to file a new bifurcated PMTA and MRTPA with the FDA for *BRAND A* that would include additional scientific data and other information requested by the FDA.

In support of our expanded work on our revised PMTA and MRTPA for our *BRAND A* Very Low Nicotine Content cigarettes, we 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 were 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 PMTA and MRTPA for our *BRAND A* Very Low Nicotine Content cigarettes. On December 4, 2017, we also hired Dr. Juan Sanchez 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 is an integral part of our scientific and regulatory team working on our PMTA and MRTPA for our *BRAND A* Very Low Nicotine Content cigarettes, and our continuing research and development of improved Very Low Nicotine Content tobacco plants. On April 19, 2018, Dr. Swauger passed away suddenly. After the passing of Dr. Swauger, we continued to perform the additional work and tests to be included in our new PMTA and MRTPA.

On December 5, 2018, we submitted a new PMTA to the FDA and on December 27, 2018, we submitted a new MRTPA to the FDA, in each case for our *BRAND A* Very Low Nicotine Content cigarettes for which we are requesting a reduced exposure marketing authorization from the FDA to market *BRAND A* as a Modified Risk Cigarette with product labeling that includes the proposed brand name of VLN™ and states that *BRAND A* has 95% less nicotine than conventional cigarettes.

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 $125 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 28 million *SPECTRUM*® research cigarettes for use in these independent clinical studies, with the most recent shipment of 3.6 million *SPECTRUM*® research cigarettes occurring in November 2018. 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 VLNC tobacco can be found on our website at http://www.xxiicentury.com/on-going-clinical-studies/. We do not incorporate the information on our website 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 VLNC 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 VLNC 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 VLNC tobacco. A list of the completed, independent clinical studies that used our proprietary VLNC tobacco can be found on our website 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 VLNC 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 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 not more than 0.3% dry weight content of THC and is legal under the federal 2018 Farm Bill and certain 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 compliance with federal and state laws.

We currently sponsor hemp research in the United States 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 three year term, we will invest approximately $1,000,000 in this scientific collaboration. The current 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, and (iii) utilizing high-value medical cannabinoid hemp varieties and specialized cannabinoid extraction processes for use in human therapeutics.

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 we believe have excellent agronomic properties for growth in Virginia. We continued to work with UVA on our hemp plants in Virginia in 2018 and we are working with UVA on plantings in 2019 of the most promising proprietary hemp varieties 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 have also sponsored hemp research in Canada with Anandia Laboratories, Inc. ("Anandia"), a plant biotechnology company based in Vancouver, British Columbia, Canada. Previously, on September 15, 2014, we were granted a sublicense by Anandia to two 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 conducted 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 conducted 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. We developed our zero THC hemp plants as a potential solution to one of the biggest challenges that was then facing the legal hemp industry, which was that hemp farmers were not able to obtain crop insurance to protect against the risk of their entire hemp crop being destroyed if a portion of their hemp crop grew with THC levels above the legal limit of 0.3% THC. We developed our zero THC hemp plants in 2017 as a potential solution to that risk because our zero THC hemp plants will not develop THC above the legal limits for hemp. However, under the new U.S. federal law known as the "2018 Farm Bill," which was enacted on December 20, 2018 and is described in more detail below, the hemp plant has been legalized under U.S. federal law, but with compliance still being required with all applicable state hemp laws. The 2018 Farm Bill specifically authorizes federal crop insurance programs to cover hemp, so hemp farmers no longer face the loss of their hemp crops without insurance protection. Thus, any hemp plant with zero amount of THC is still a scientifically interesting plant, but the commercial viability of any zero THC hemp plant will depend on its other agronomic qualities, such as whether it has a superior fiber content, high yields, and other agronomically desirable traits for commercial uses and/or unique cannabinoid levels for possible extraction purposes. We have many such types of superior and 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.

We also expanded 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.

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," and the production of non-GM varieties of VLNC tobaccos.

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, QPT, A622, MPO and several transcription factor genes, and tobacco products produced from these plants. A portion of the QPT patent family expired in 2018, and the remainder of the QPT patent family is expected to expire in 2020, although a Brazilian application of the family, now under appeal, could expire later if granted. The majority of our other patent families related to nicotine biosynthesis are expected to expire between 2021 and 2036, 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 patent applications and patents, filed in various countries, that relate back to at least one common earlier

application.). Our Vector 21-41 VLNC tobacco plants with the QPT modification are also protected by plant variety protection (“PVP”) through 2023, which further restricts third-parties from using such plants.

The creation and production of unique tobacco plants with agronomic traits of VLNC 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 a portion of the QPT patent family in 2018 provides third parties with the freedom to target the QPT gene in the tobacco plant, but such 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 able subsequently 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 VLNC plants, with no assurance that any third party could be successful in such efforts. We believe that targeting of the QPT gene alone will not result in a VLNC tobacco plant and, hence, that other genes will have to be targeted in the tobacco plant, possibly (and we believe likely) including genes and other intellectual property for which we have continuing patent protection that would need to be used, in combination with QPT to result in VLNC tobacco. However, if a third party is able, over time, to develop a tobacco plant with very low levels of nicotine, then the third party still would need to develop a VLNC 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 again would 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.

While third parties may desire to engage in experiments with the QPT gene, we already have proprietary VLNC 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 at commercial scale. We have provided more than 28 million research cigarettes containing our proprietary VLNC tobacco that was grown under strict contracts with our exclusive growers and then processed and finished into cigarettes at our factory. Thus, we believe that our VLNC tobacco has the agronomic qualities that are sufficient to support its use in a commercial scale product. We are also developing our next-generation VLNC tobacco of non-GM bright, burley and Oriental VLNC tobaccos to continue to maintain our competitive advantage in being a unique provider of VLNC tobacco to third-parties that may desire to utilize our proprietary VLNC tobaccos in their finished tobacco products.

We also have exclusive plant variety rights in the United States (plant variety protection certificates are issued in the United States 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 VLNC tobaccos are protected by our patent portfolio and our Vector 21-41 VLNC tobacco is additionally protected by PVP.

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 two 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 conducted 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.

In addition to our patents, patent applications, and PVP certificates, we own various registered trademarks in the United States and around the world.

Licensing

We have had 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 license our VLNC 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 VLNC tobacco technology and plants will increase substantially.

We also believe that our unique hemp plants will be highly desirable in the United States. We believe that we have many types of superior and 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. We are also developing other high-value medicinal cannabinoid varieties of hemp and specialized cannabinoid extraction processes for use in human therapeutics. 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 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 also involves the development and study of medically important cannabinoids to be extracted by UVA from our unique hemp plants.

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. In 2018, we continued to use our proprietary hemp plants for plantings with UVA in Virginia. We are currently discussing 2019 planting activities with UVA. 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 $360,046 of expenses for the R&D agreement at UVA for the year ended December 31, 2018. 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. In February of 2018, we finalized an additional extension to the agreement through April 30, 2018 at a cost of $88,344. In May 2018, we finalized an additional extension to the agreement through April 30, 2019 at a total cost of $121,357. During the years ended December 31, 2018, 2017, and 2016, we expensed $169,249, $7,140, and $78,541, respectively, relating to this extended R&D agreement.

On June 22, 2018, the Company entered into an amendment to its existing license agreement with NCSU under which the Company exclusively licensed several bright and burley tobacco plant lines with Very Low Nicotine Content that are not genetically modified (non-GM) plants. The amendment provides for the Company to pay NCSU a total exclusive license fee of $1,200,000, of which $500,000 was paid by the Company to NCSU within five business days after the execution of the amendment, $400,000 will be paid on the one-year anniversary of the execution of the amendment, and $300,000 will be paid on the two-year anniversary of the execution of the amendment. The Company will also pay running royalties to NCSU based on a portion of the net sales revenue received by the Company from sales of products that contain any portions of the plant materials that have been received by the Company from NCSU.

On October 22, 2018, the Company entered into a license with the University of Kentucky (“UK”) to license on a non-exclusive basis a next-generation very low nicotine burley tobacco plant line. The UK license agreement provides for the Company to pay UK a total exclusive license fee of $1,200,000, of which $300,000 was paid by the Company to UK after the delivery by UK to the Company of certain very low nicotine burley tobacco seeds, $300,000 will be paid on the later of the one-year anniversary of the license agreement or the delivery by UK to the Company of chemical analysis of the field grown plants from such very low nicotine burley tobacco seeds, $300,000 will be paid on the later of the two-year anniversary of the license or the delivery by UK to the Company of certain other very low nicotine burley tobacco seeds, and the final installment payment of $300,000 will be paid on the later of the three-year anniversary of the license agreement or the delivery by UK to the Company of seeds of male sterile versions of each of the very low nicotine plants grown by UK for the Company from the seeds provided by UK to the Company. The Company will also pay running royalties to UK based on a portion of the net sales revenue received by the Company from sales of products that contain any portions of the plant materials that have been received by the Company from UK.

During the years ended December 31, 2018, 2017, and 2016, we incurred total R&D expenses of $14,989,746, $3,366,468, and $2,340,958, respectively. The R&D expenses for the year ended December 31, 2018 include approximately $9,800,000 in expenses relating to our PMTA and MRTPA, submitted to the FDA in December 2018, and approximately $1,230,000 in equity-based compensation expense recognized due the death in April 2018 of James Swauger, our Vice President of Science and Regulatory Affairs.

MSA Membership

In September 2013, we entered into a Membership Interest Purchase Agreement (the “NASCO Acquisition”) 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 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. 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 acquisition of our factory has allowed us to become vertically integrated so that we can control production priorities/timing and maintain the required high quality of our products, including our *SPECTRUM*® research cigarettes. In the future, our factory will also allow us to produce our own VLNC cigarette brands in the event they comply with the FDA mandate for reduced nicotine in cigarettes, as well as our *BRAND A* VLNC cigarettes if/when the FDA approves our PMTA and MRTPA submissions for *BRAND A* under our proposed product name of VLN™.

Sources of Raw Materials

We obtain a large portion of our tobacco leaf from farmers in multiple states in the United States who are under direct contracts with us. These contracts prohibit the transfer of our proprietary tobaccos, seeds and plant materials to other parties. We purchase the balance of our tobacco through third parties. As we prepare for the anticipated increased need for our proprietary VLNC tobacco in the United States in the event the FDA mandates that all combustible cigarettes contain only minimally or non-addictive levels of nicotine and/or in the event the FDA approves our PMTA and MRTPA for our *BRAND A* VLNC cigarettes under the proposed product name of VLN™, we intend to increase the amount of tobacco leaf we obtain directly from farmers under contract, both in the United States and in foreign countries.

We likewise grow hemp ourselves and under contracts with farmers that prohibit the transfer of our proprietary seeds and plant materials to other parties.

Government Regulation

FDA Mandate to Require Minimally or Non-Addictive Levels of Nicotine in all Cigarettes in the United States

The Tobacco Control Act, which became law in June 2009, 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, or mandating that nicotine levels be reduced to zero, it does allow the FDA to require the reduction of nicotine or other compounds in tobacco and cigarette smoke. In 2009, the Tobacco Control Act also banned all sales in the United States of cigarettes with flavored tobacco (other than menthol). As of June 2010, all cigarette companies were required to cease use of the terms “low tar,” “light” and “ultra light” in describing cigarettes sold in the United States.

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 contain only minimally or non-addictive levels of nicotine. On March 16, 2018, the FDA issued an Advance Notice of Proposed Rulemaking (“ANPRM”) to obtain information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes. The FDA is engaging in a required rule-making process to enact such new nicotine reduction regulations. It is uncertain how long the FDA rule-making process will take to complete.

We believe this regulatory environment represents a paradigm shift for the tobacco industry and will create opportunities for us in marketing *BRAND A* under our proposed product name of VLN™ and in licensing our proprietary technology and/or tobaccos to larger competitors. On July 16, 2018, we publicly submitted to the FDA our formal written response to the ANPRM in which we described how (i) the FDA’s proposed new rule is supported by rigorous independent, published science, (ii) the FDA’s stated goal to render cigarettes minimally or non-addictive is immediately feasible as evidenced by our production and delivery of more than 28 million VLNC research cigarettes since the year 2011, and (iii) the FDA’s proposed new rule is exceedingly practical and urgently needed in the interests of public health.

Modified Risk Cigarettes

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of Modified Risk Tobacco Products, which includes cigarettes marketed to (i) reduce harm or the risk of tobacco-related disease or (ii) reduce or eliminate exposure to a substance (“Modified Risk Cigarettes”). The Tobacco Control Act required the FDA to issue specific regulations and/or guidance regarding applications submitted to the FDA for the authorization to label and market Modified Risk Tobacco Products. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance*. On December 5, 2018, we submitted a new PMTA to the FDA and on December 27, 2018, we submitted a new MRTPA to the FDA, in each case for our *BRAND A* Very Low Nicotine Content cigarettes for which we are requesting a reduced exposure marketing authorization from the FDA to market *BRAND A* as a Modified Risk Cigarette with product labeling that includes the proposed brand name of VLN™ and states that the VLN™ product has 95% less nicotine than conventional cigarettes. We believe that our VLN™ cigarettes will qualify

as Modified Risk Cigarettes. We believe that obtaining FDA authorization to promote our VLN™ cigarettes as Modified Risk Cigarettes will create opportunities for us to market our own unique product and license our proprietary technology and/or our tobaccos to larger competitors.

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We supply our proprietary cigarettes for use by independent researchers so studies can be conducted to obtain additional information on our products. We expect this information will assist us, along with our own funded studies, in obtaining the necessary FDA authorizations to market *BRAND A* under our proposed product name of VLN™ as a Modified Risk Cigarette.

Hemp

On December 20, 2018, the Agricultural Improvement Act of 2018, which is also known as the "2018 Farm Bill," was enacted and, among other things, further legalized hemp under U.S. federal law, but with compliance still being required with all applicable state hemp laws. The 2018 Farm Bill includes certain benefits for the hemp industry in the United States, including: (i) the extension of the protections for hemp research and researchers and the conditions in which hemp research can be done, (ii) the protection of hemp farmers and hemp production under federal crop insurance programs, (iii) the permitting of the cultivation, interstate transportation and sale of hemp and hemp products in the U.S. in compliance with all other applicable federal and state laws, and (iv) the removal of hemp and hemp derived products from Schedule 1 of the Controlled Substances Act ("CSA"). However, the FDA has publicly stated that certain products derived from hemp, including cannabidiol ("CBD"), which is a cannabinoid that can be extracted from hemp, will be regulated by the FDA. Thus, participants in the hemp industry will need to comply with all applicable federal and state laws, rules and regulations in the cultivation, transportation and sale of hemp and hemp derived products.

As of December 31, 2018, (i) federal law and the laws of 40 states in the United States and the District of Columbia have legalized hemp, (ii) 33 states in the United States and the District of Columbia 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) 10 states in the United States and the District of Columbia have legalized cannabis/marijuana for adult recreational use. Many other states are considering similar legislation. Conversely, under the federal 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 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.

Competition

We are not currently aware of any competition to our VLNC tobacco inside or outside of the United States.

We are not aware of any competition to our Company in the creation and provision of VLNC tobacco research cigarettes for use in independent clinical studies. Since 2011, we have provided more than 28 million research cigarettes containing our proprietary tobaccos, including our VLNC tobacco, for use in numerous independent clinical studies at many well-known study locations, with agencies of the United States federal government investing more than $125 million in such independent clinical studies. The results of those independent clinical studies have been published in peer-reviewed publications. We are not aware of any other independent clinical studies that have been published regarding any other VLNC tobacco research cigarettes.

The results of such numerous completed and on-going clinical studies provide independent scientific support for the public announcement on July 28, 2017 by the 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 VLNC tobacco has been the subject of numerous completed and on-going, independent clinical studies paid for by agencies of the U.S. federal government, we are investigating the use of our VLNC tobacco in our own products that will be intended to comply with the new FDA regulations, as well as we are investigating the license of the use of our VLNC tobacco by third-parties. It is possible that other companies may develop products that also comply with the new FDA regulations in ways that we do not know of at this time since the FDA is still in the rule-making process. There is also no assurance that the FDA will actually implement such regulations on a timely basis or at all. We are also investigating potential opportunities relating to our VLNC tobacco outside of the United States.

As of December 31, 2017, we no longer sold any Company-owned commercial cigarette brands in the United States. During the year of 2017, we ceased the selling of our *RED SUN* brand and, during the year 2018, we continued manufacturing a third-party MSA cigarette brand for the third-party owner of that brand. Cigarette companies compete primarily on the basis of product quality, brand recognition, brand loyalty, taste, innovation, packaging, service, marketing, advertising, retail shelf space, and price. Cigarette sales can be significantly influenced by weak economic conditions, erosion of consumer confidence, competitors' introduction of low-price products or innovative products, higher taxes, higher absolute prices and larger gaps between price categories, and product regulation that diminishes the ability to differentiate tobacco products. Domestic cigarette competitors included Philip Morris USA Inc., Reynolds American Inc., Lorillard Inc., Commonwealth Brands, Inc., Liggett Group LLC, and Vector Tobacco Inc. International competitors included Philip Morris International Inc., British American Tobacco, JT International SA, Imperial Tobacco Group PLC and regional and local tobacco companies; and in some instances, government-owned tobacco enterprises such as the China National Tobacco Corporation.

In the event the FDA approves our PMTA/MRTPA for *BRAND A* under our proposed product name of VLN™, then it is possible that *BRAND* A may compete with FDA-approved smoking cessation aids. In the market for FDA-approved smoking cessation aids, our principal competitors would include Pfizer Inc., GlaxoSmithKline plc, Perrigo Company plc, Novartis International AG, and Niconovum AB, a subsidiary of Reynolds American Inc. The industry consists of major domestic and international companies, most of which have existing relationships in the markets into which we plan to sell, as well as financial, technical, marketing, sales, manufacturing, scaling capacity, distribution and other resources, and name recognition substantially greater than ours.

Employees

As of February 22, 2019, we employed eighty-two (82) people and we consider our employee relations to be good.

Corporate Information

We are a Nevada corporation and our corporate headquarters is located at 8560 Main Street, Suite 4, Williamsville, New York 14221. Our telephone number is (716) 270-1523. Our internet address is www.xxiicentury.com. All of our filings with the Securities and Exchange Commission can be accessed free of charge through our website promptly after filing; however, in the event that the website is inaccessible, we will provide paper copies of our most recent Annual Report on Form 10-K, the most recent Quarterly Report on Form 10-Q, Current Reports filed or furnished on Form 8-K, and all related amendments, excluding exhibits, free of charge upon request. These filings are also accessible on the SEC's website at www.sec.gov. We do not incorporate the information on our website into this Annual Report on Form 10-K.

Item 1A. Risk Factors.

You should carefully consider the risk factors set forth below and in other reports that we file from time to time with the Securities and Exchange Commission and the other information in this Annual Report on Form 10-K. The matters discussed in the risk factors, and additional risks and uncertainties not currently known to us or that we currently deem immaterial, could have a material adverse effect on our business, financial condition, results of operation and future growth prospects and could cause the trading price of our common stock to decline.

Risks Related to Our Business and Operations

We have had a history of losses, and we may be unable to achieve and sustain profitability.

We have experienced net losses of approximately $8.0 million, $13.0 million, and $11.6 million during the years ended December 31, 2018, 2017, and 2016, respectively. While our current balance of cash and cash equivalents and short-term investment securities is adequate to sustain operations for a number of years, generating net income in the future will depend on our ability to successfully operate our cigarette manufacturing facility, sell and market our proprietary tobacco products, and generate royalty revenue from the licensing of our intellectual property. There is no guarantee that we will be able to achieve or sustain profitability in the future. An inability to successfully achieve profitability may decrease our long-term viability.

We have had a history of negative cash flow, and our ability to sustain positive cash flow is uncertain.

We have had a history of negative cash flow from operating activities, before cash used in investing activities and cash provided by financing activities, including approximately $17.8 million of negative cash flow from operations during the year ended December 31, 2018. We believe our current position of cash and cash equivalents and short-term investment securities is adequate to sustain operations and to meet all current obligations as they come due for a number of years. Generation of positive cash flow from operations will depend on our ability to successfully implement the net income generating activities discussed in the previous risk factor discussion. An inability to successfully implement our net income producing initiatives may decrease our long-term viability.

If regulations by the FDA requiring the reduction of nicotine to minimally or non-addictive levels in all cigarettes sold in the U.S. are delayed or do not become implemented, then the demand for our proprietary Very Low Nicotine Content tobacco may not substantially increase in the U.S.

On July 28, 2017, the FDA publicly announced that it intends to implement new regulations that will mandate minimally or non-addictive levels of nicotine in all cigarettes sold in the U.S. On March 16, 2018, the FDA publicly announced its Advance Notice of Proposed Rulemaking ("ANPRM") to solicit public comments on the FDA's plan to enact a new nicotine reduction rule. On July 16, 2018, we publicly submitted to the FDA our written response to the ANPRM. Since our proprietary VLNC tobacco has been the subject of numerous completed and on-going, independent clinical studies paid for by agencies of the U.S. federal government, we are investigating the potential use of our VLNC 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 VLNC tobacco by third-parties. In this regard, on December 5, 2018, we submitted a new PMTA to the FDA and on December 27, 2018, we submitted a new MRTPA to the FDA, in each case for our *BRAND A* Very Low Nicotine Content cigarettes. We are also investigating potential opportunities relating to our VLNC tobacco outside of the United States.

However, there can be no assurance that the FDA will implement such new regulations or, if implemented, when such regulations would take effect. In the event the FDA does not implement such new regulations or implementation is delayed, then the demand for our proprietary Very Low Nicotine Content tobacco may not substantially increase in the U.S. and such action would have a material adverse effect on our business and operations.

If we fail to obtain FDA and foreign regulatory approvals for authorization to market BRAND A as a Modified Risk Cigarette, we will be unable to commercialize this potential product in and outside the U.S.

There can be no assurance that *BRAND A* will be approved by the FDA and/or by foreign regulators to be marketed as a Modified Risk Cigarette. In addition, there can be no assurance that all necessary approvals will be granted for our potential products or that review or actions will not involve delays caused by requests for additional information or testing that could adversely affect the time and cost to market and sell our potential products.

The development, testing, manufacturing, and marketing of our potential products are subject to extensive regulation by governmental authorities in the United States and throughout the world. In particular, the process of obtaining approvals by the FDA, the European Medicines Agency ("EMA") and other international FDA equivalent agencies in targeted countries is costly and time consuming, and the time required for such approvals is uncertain. Our *BRAND A* must undergo an extensive regulatory approval process mandated by the FDA in the U.S. and any other approval processes required by FDA-equivalent agencies in foreign countries where we want to introduce our potential products.

The scope of review, including product testing and exposure studies, to be required by the FDA under the Tobacco Control Act in order for cigarettes such as *BRAND A* to be marketed as Modified Risk Cigarettes has not yet been fully established, even though the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance* on March 30, 2012. Our first application for *BRAND A* as a Modified Risk Cigarette experienced delays and took a year to obtain substantial feedback from the FDA. We may be unsuccessful in establishing to the satisfaction of the FDA that *BRAND A* is a Modified Risk Cigarette. Even upon demonstrating significant reduced exposure to nicotine, the FDA may decide that allowing a modified risk claim is not in the best interest of the public health, and the FDA may not allow us to market our *BRAND A* cigarettes as Modified Risk Cigarettes. In addition, the time and cost involved in obtaining such approvals may be longer and costlier than anticipated.

The FDA could force the removal of our products from the U.S. market.

The FDA has broad authority over the regulation of tobacco products. The FDA could, among other things, force us to remove from the U.S. market our *BRAND A* even after FDA authorization to market *BRAND A* as a Modified Risk Cigarette, levy fines or change their regulations on advertising. Any adverse action by the FDA could have a material adverse impact on our business.

We intend to distribute and sell our potential products outside of the U.S., which will subject us to other regulatory risks.

In addition to seeking approval from the FDA to market our *BRAND A* as a Modified Risk Cigarette in the U.S., we intend to seek governmental approvals required to market *BRAND A* and our other products in other countries. Marketing of our products is not permitted in certain countries until we have obtained required approvals or exemptions in these individual countries. The regulatory review process varies from country to country, and approval by foreign governmental authorities is unpredictable, uncertain, and generally expensive. Our ability to market our potential products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances. We anticipate commencing the applications required in some or all of these countries following approval by the FDA; however, we may decide to file applications in advance of the FDA approval if we determine such filings to be both time and cost effective. If we export any of our potential products, or products that have not yet been cleared for commercial distribution in the U.S., then such products may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals could impair our ability to generate revenue from international sources.

Our studies and testing of any of our potential products may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional studies and/or testing for these potential products or cease our studies and testing.

We do not know whether further studies and testing of our potential products will demonstrate safety and efficacy sufficient to result in marketable products. We may not be able to obtain approval or marketing authorization for these potential products or our anticipated time of bringing these potential products to the market may be substantially delayed. We may also experience significant additional development costs and be required to undertake additional studies and/or testing if we change our potential products. Any such delays or costs could have a material adverse effect on our business.

Our working capital requirements involve estimates based on demand expectations and may increase beyond those currently anticipated, which could harm our operating results and financial condition.

We have no experience in selling Modified Risk Cigarettes or smoking cessation products on a commercial basis. As a result, we intend to base our funding and inventory decisions on estimates of future demand. If demand for our products does not increase as quickly as we have estimated, our inventory and expenses could rise, and our business and operating results could suffer. Alternatively, if we experience sales in excess of our estimates, our working capital needs may be higher than those currently anticipated. Our ability to meet any demand for our products may depend on our ability to arrange for additional financing for any ongoing working capital shortages, since it is likely that cash flow from sales will lag behind our investment requirements.

We may require additional capital before we can complete the FDA authorization process for our Modified Risk Cigarettes.

We may require additional capital in the future before we can complete the FDA authorization process for our Modified Risk Cigarettes. The cost of completing the FDA authorization process for potential Modified Risk Cigarettes is difficult to estimate since it is currently unknown exactly what the FDA will require. If we raise additional funds through the issuance of equity securities to complete the FDA authorization process for our Modified Risk Cigarettes, our stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. We could also wait for our own revenues and profits to be sufficient for us to provide such funding, which could delay our completion of the FDA authorization process for our Modified Risk Cigarettes. We also could elect to seek funds through arrangements with collaborators or licensees. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to

us.

If we cannot raise additional capital on acceptable terms, we may not be able to, among other things:

- undertake the steps necessary to seek FDA authorization of our Modified Risk Cigarettes;
- develop or enhance our potential products or introduce new products;
- expand our development, sales and marketing, and general and administrative activities;
- attract tobacco growers, customers, or manufacturing and distribution partners;
- acquire complementary technologies, products, or businesses;
- expand our operations in the United States or internationally;
- hire, train, and retain employees; or
- respond to competitive pressures or unanticipated working capital requirements.

We have no experience in managing growth. If we fail to manage our growth effectively, we may be unable to execute our business plan or to address competitive challenges adequately.

From 2013 to 2018, we grew from nine (9) employees to eighty-one (81) employees. Any growth in our business will place a significant strain on our managerial, administrative, operational, financial, information technology and other resources. We intend to further expand our overall business, customer base, employees and operations, which will require substantial management effort and significant additional investment in our infrastructure. We will be required to continue to improve our operational, financial and management controls and our reporting procedures and we may not be able to do so effectively. As such, we may be unable to manage our growth effectively.

We have limited experience in operating and managing a manufacturing facility.

We have limited experience operating and managing a manufacturing facility. The manufacture of products is subject to strict quality control, testing, and record keeping requirements, and continuing obligations regarding the submission of safety reports and other post-market information. In addition, the manufacturing of our own products will be expensive to operate without sufficient production volume. If we are unable to successfully manufacture or sell our products, we will still be liable for the costs associated with operating a manufacturing facility. Accordingly, the operation of such manufacturing facility could have a material adverse effect on our results of operations.

Our manufacturing facility is subject to FDA regulations.

Manufacturers of tobacco products must comply with FDA regulations which require, among other things, compliance with the FDA's evolving regulations on Current Good Manufacturing Practices ("cGMP(s)"), which are enforced by the FDA through its facilities inspection program. The manufacture of products is subject to strict quality control, testing and record keeping requirements, and continuing obligations regarding the submission of safety reports and other post-market information. We cannot guarantee that our current manufacturing facility will pass FDA inspections and/or similar inspections in foreign countries to produce our tobacco products, or that future changes to cGMP manufacturing standards will not also negatively affect the cost or sustainability of our manufacturing facility.

Our principal competitors in the smoking cessation market have, and any future competitors may have, greater financial and marketing resources than we do, and they may therefore develop products or other technologies similar or superior to ours, or otherwise compete more successfully than we do.

We have no experience in selling smoking cessation products. Competition in the smoking cessation aid products industry is intense, and we may not be able to successfully compete in the market. In the market for FDA-approved smoking cessation aids, our principal competitors include Pfizer Inc., GlaxoSmithKline plc, Perrigo Company plc, Novartis International AG and Niconovum AB, a subsidiary of Reynolds American Inc. The industry consists of major domestic and international companies, most of which have existing relationships in the markets in which we plan to sell, as well as financial, technical, marketing, sales, manufacturing, scaling capacity, distribution and other resources and name recognition substantially greater than ours. In addition, we expect new competitors will enter the markets for our products in the future. Potential customers may choose to do business with our more established competitors because of their perception that our competitors are more stable, are more likely to complete various projects, can scale operations more quickly, have greater manufacturing capacity, are more likely to continue as a going concern, and lend greater credibility to any joint venture. If we are unable to compete successfully against manufacturers of other smoking cessation products, our business could suffer, and we could lose or be unable to obtain market share.

Our competitors may develop products that are less expensive, safer or otherwise more appealing, which may diminish or eliminate the commercial success of any potential product that we may commercialize.

If our competitors market products that are less expensive, safer or otherwise more appealing than our potential products, or that reach the market before our potential products, we may not achieve commercial success. The market may choose to continue utilizing existing products for any number of reasons, including familiarity with or pricing of these existing products. The failure of our Modified Risk Tobacco Product to compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition, results of operations, and cash flows. Our competitors may:

- develop and market products that are less expensive, safer, or otherwise more appealing than our products;
- commercialize competing products before we or our partners can launch our products; and
- initiate or withstand substantial price competition more successfully than we can.

If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages that we believe we derive from our research approach and proprietary technologies. Our competitors may:

·operate larger research and development programs or have substantially greater financial resources than we do;

·have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;

·more effectively negotiate third-party licenses and strategic relationships; and

·take advantage of acquisition or other opportunities more readily than we can.

Government mandated prices or taxes, production control programs, shifts in crops driven by economic conditions, and adverse weather patterns may increase the cost or reduce the quality of the tobacco and other agricultural products used to manufacture our products.

We depend on independent tobacco farmers to grow our specialty proprietary tobaccos with specific nicotine contents for our potential products. As with other agricultural commodities, the price of tobacco leaf can be influenced by imbalances in supply and demand, and crop quality can be influenced by variations in weather patterns, diseases, and pests. We must also compete with other tobacco companies for contract production with independent tobacco farmers. Tobacco production in certain countries is subject to a variety of controls, including government mandated prices and production control programs. Changes in the patterns of demand for agricultural products could cause farmers to plant less tobacco. Any significant change in tobacco leaf prices or taxes, quality and quantity could affect our profitability and our business.

Our future success depends on our ability to retain key personnel.

Our success will depend to a significant extent on the continued services of our senior management team, and in particular Henry Sicignano III, our President and Chief Executive Officer, John T. Brodfuehrer, our Chief Financial Officer, and Thomas L. James, our Vice President, General Counsel and Secretary, and the continued services of Juan Sanchez Tamburrino, Ph.D., a key member of our scientific team. The loss or unavailability of any of these individuals may significantly delay or prevent the development of our potential products and other business objectives by diverting management's attention to transition matters. While each of these individuals is party to employment agreements with us, they could terminate their relationships with us at any time, and we may be unable to enforce any applicable employment or non-compete agreements.

We also rely on consultants and advisors to assist us in formulating our research and development, manufacturing, distribution, marketing, and sales strategies. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory

contracts with other organizations, that may affect their ability to contribute to us.

Product liability claims, product recalls, or other claims could cause us to incur losses or damage our reputation.

The risk of product liability claims or product recalls, and associated adverse publicity, is inherent in the development, manufacturing, marketing, and sale of tobacco and smoking cessation products. We do not currently have product liability insurance for our products or our potential products and do not expect to be able to obtain product liability insurance at reasonable commercial rates for these products. Any product recall or lawsuit seeking significant monetary damages may have a material adverse effect on our business and financial condition. A successful product liability claim against us could require us to pay a substantial monetary award. Though we currently have no pending product liability claims against us, we cannot assure you that such claims will not be made in the future.

Negative press from being in the hemp/cannabis space could have a material adverse effect on our business, financial condition, and results of operations.

The hemp plant and the cannabis/marijuana plant are both part of the same *cannabis sativa* genus/species of plant, except that hemp, by definition, has not more than 0.3% THC content and is legal under the federal 2018 Farm Bill and certain state laws, but 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, and our activities with legal hemp may be incorrectly perceived as us being involved in federally illegal cannabis/marijuana. Also, despite growing support for the cannabis/marijuana industry and legalization of cannabis/marijuana in certain U.S. states, many individuals and businesses remain opposed to the cannabis/marijuana industry. Any negative press resulting from the incorrect perception that we have entered into the cannabis/marijuana space could result in a loss of current or future business. It could also adversely affect the public’s perception of us and lead to reluctance by new parties to do business with us or to own our common stock. We cannot assure you that additional business partners, including but not limited to financial institutions and customers, will not attempt to end or curtail their relationships with us. Any such negative press or cessation of business could have a material adverse effect on our business, financial condition, and results of operations.

Any business-related cannabinoid production is dependent on laws pertaining to the hemp/cannabis industry.

On December 20, 2018, the Agricultural Improvement Act of 2018, which is also known as the "2018 Farm Bill," was enacted and legalized hemp and hemp products under U.S. federal law, but with compliance still being required with all applicable state hemp laws. However, the FDA has publicly stated that certain products derived from hemp, including cannabidiol ("CBD"), which is a cannabinoid that can be extracted from hemp, will be regulated by the FDA. Thus, participants in the hemp industry will need to comply with all applicable federal and state laws, rules and regulations in the cultivation, transportation, and sale of hemp and hemp derived products.

As of December 31, 2018, (i) federal law and the laws of 40 states in the United States and the District of Columbia have legalized hemp, (ii) 33 states and the District of Columbia allow their citizens to use medical cannabis/marijuana and, (iii) 10 states and the District of Columbia 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 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 business or prospects that we may have in the cannabis/marijuana business. Even in those jurisdictions in which the manufacture and use of medical cannabis/marijuana has been legalized at the state level, the possession, use, and cultivation of cannabis/marijuana all remain violations of federal law that are punishable by imprisonment and substantial fines. Moreover, individuals and entities may violate federal law if they intentionally aid and abet another in violating these federal controlled substance laws or conspire with another to violate them.

We currently conduct sponsored research on hemp in Virginia through the University of Virginia ("UVA"), with UVA possessing all necessary permits and licenses to engage legally in such activities. We have conducted sponsored research on hemp with Anandia Laboratories in Canada, with Anandia possessing all necessary permits and licenses to engage legally in such activities. In order to carry out research in other countries, similar licenses are required to be issued by the relevant authority in each country. We also conduct hemp research in our laboratories in New York under a license granted to us by the State of New York.

Local, state, federal, and international hemp and cannabis/marijuana laws and regulations are broad in scope and subject to evolving interpretations, which could require us to incur substantial costs associated with compliance requirements. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our operations. In addition, it is possible that regulations may be enacted in the future that will be directly applicable to our proposed business regarding cannabinoid production. It is also possible that the federal government will begin strictly enforcing existing laws, which may limit the legal uses of the hemp plant and its derivatives and extracts, such as cannabinoids. However, our work in hemp would continue since hemp research, development, and commercialization activities are permitted under applicable federal and state laws, rules, and regulations. We cannot predict the nature of any future laws, regulations, interpretations, or applications, nor can

we determine what effect additional governmental regulations or administrative policies and procedures, when and if promulgated, could have on our activities in the legal hemp industry.

The failure of our information systems to function as intended or their penetration by outside parties with the intent to corrupt them or our failure to comply with privacy laws and regulations could result in business disruption, litigation and regulatory action, and loss of revenue, assets, or personal or confidential data (Cybersecurity).

We use information systems to help manage business processes, collect and interpret business data and communicate internally and externally with employees, suppliers, customers and others. Some of these information systems are managed by third-party service providers. We have backup systems and business continuity plans in place, and we take care to protect our systems and data from unauthorized access. Nevertheless, failure of our systems to function as intended, or penetration of our systems by outside parties intent on extracting or corrupting information or otherwise disrupting business processes, could place us at a competitive disadvantage, result in a loss of revenue, assets or personal or other sensitive data, litigation and regulatory action, cause damage to our reputation and that of our brands and result in significant remediation and other costs.

Risks Related to the Tobacco Industry

The third-party tobacco products made in our manufacturing business face significant governmental action aimed at increasing regulatory requirements with the goal of significantly restricting the use of tobacco products.

We publicly announced that we discontinued U.S. sales of our *RED SUN* brand cigarettes as of December 31, 2017, in preparation for the planned mandate by the FDA that all cigarettes sold in the United States will be required to contain only minimally or non-addictive levels of nicotine. However, most of the remaining revenues of our manufacturing business are from the production of tobacco cigarettes and filtered cigars made for third-party brand owners of such products. Cigarette and filtered cigar companies face significant governmental action, especially in the United States pursuant to the Tobacco Control Act, including efforts aimed at reducing the incidence of tobacco use, restricting marketing and advertising, imposing regulations on packaging, mandating warnings and disclosure of flavors or other ingredients, prohibiting the sale of tobacco products with certain flavors or other characteristics, limiting or prohibiting the sale of tobacco products by certain retail establishments and the sale of tobacco products in certain packaging sizes, and seeking to hold retailers and distributors responsible for the adverse health effects associated with both smoking and exposure to environmental tobacco smoke. Governmental actions, combined with the diminishing social acceptance of smoking and private actions to restrict smoking, have resulted in reduced industry volume in the United States and in certain other countries, and we expect that these factors will continue to reduce consumption levels in these markets.

Significant regulatory developments will take place over the next few years in many markets, driven principally by the World Health Organization’s Framework Convention on Tobacco Control (“FCTC”). The FCTC is the first international

public health treaty on tobacco, and its objective is to establish a global agenda for tobacco regulation with the purpose of reducing initiation of tobacco use and encouraging cessation. In addition, the FCTC has led to increased efforts by tobacco control advocates and public health organizations to reduce the appeal of tobacco products. Partly because of some or a combination of these efforts, unit sales of tobacco products in certain markets, principally Western Europe and Japan, have been in general decline and we expect this trend to continue. Our operating results could be significantly affected by any significant increase in the cost of complying with new regulatory requirements.

If implemented in the future, the FDA requirement regarding graphic health warnings on cigarette packaging and in cigarette advertising is likely to have a negative impact on sales of our third-party customers' products and potential Company products.

In November 2010, as required by the Tobacco Control Act, the FDA issued a proposed rule to modify the required warnings that appear on cigarette packages and in cigarette advertisements. These warnings were finalized on June 21, 2011 and consisted of nine new textual warning statements accompanied by color graphics depicting the negative health consequences of smoking. The FDA selected nine images from the originally proposed 36 images after reviewing the relevant scientific literature, analyzing the results from an 18,000-person study, and considering more than 1,700 comments from a variety of groups. The graphic health warnings were to be located beneath the cellophane wrapping on cigarette packages and were to comprise the top 50 percent of the front and rear panels of cigarette packages. Although these graphic health warnings were scheduled to be implemented in September 2012, a federal district court and a federal appellate court ruled that the FDA's regulations were unconstitutional. Another federal district court has ordered the FDA to promulgate new graphic warning regulations in compliance with the Tobacco Control Act's mandate. The subject court has not yet ruled on the precise timeframes for the FDA's completion of this new rulemaking process; the FDA has proposed issuance of a new final rule by May of 2021, and the plaintiffs seeking to compel earlier publication have urged the court to require issuance of the final rule by January 31, 2020. If the FDA successfully implements these revised regulations in the future, and any reviewing federal court does not strike them down on constitutional or other grounds, then all cigarettes manufactured for sale or distribution in the United States will need to include these new graphic health warnings on their packages consistent with the effective date(s) included in such regulations. Any resulting reduction in the number of smokers will probably reduce the demand for the products manufactured by our factory for our potential Company products and for third-party brand owners of such products.

We may become subject to litigation related to cigarette smoking and exposure to environmental tobacco smoke, or ETS, which could severely impair our results of operations and liquidity.

Although we are not currently subject to legal proceedings related to cigarette smoking or ETS, we may become subject to litigation related to the sale, upon FDA authorization, of our *BRAND A* Modified Risk Cigarettes. Legal proceedings covering a wide range of matters related to tobacco use are pending or threatened in various U.S. and foreign jurisdictions. Various types of claims are raised in these proceedings, including product liability, consumer protection, antitrust, tax, contraband shipments, patent infringement, employment matters, claims for contribution, and claims of competitors and distributors.

Litigation is subject to uncertainty and it is possible that there could be adverse developments in pending cases. An unfavorable outcome or settlement of pending tobacco related litigation could encourage the commencement of additional litigation. The variability in pleadings, together with the actual experience of management in litigating claims, demonstrates that the monetary relief that may be specified in a lawsuit bears little relevance to the ultimate outcome.

Damages claimed in some tobacco-related litigation are significant and, in certain cases, range into the billions of dollars. We anticipate that new cases will continue to be filed. The FCTC encourages litigation against tobacco product manufacturers. It is possible that our results of operations, cash flows, or financial position could be materially affected by an unfavorable outcome or settlement of litigation.

Cigarettes are subject to substantial taxes. Significant increases in cigarette-related taxes have been proposed or enacted and are likely to continue to be proposed or enacted in numerous jurisdictions. These tax increases may affect the sales of our potential Company products and our third-parties customers' tobacco products manufactured at our factory, which could result in decreased sales and profitability of our manufacturing business.

Tax regimes, including excise taxes, sales taxes, and import duties, can disproportionately affect the retail price of manufactured cigarettes versus other tobacco products, or disproportionately affect the relative retail price, upon FDA authorization, of our *BRAND A* Modified Risk Cigarettes versus lower-priced cigarette brands manufactured by our competitors. Increases in cigarette taxes are expected to continue to have an adverse impact on sales of cigarettes resulting in (i) lower consumption levels, (ii) a shift in sales from manufactured cigarettes to other tobacco products or to lower-price cigarette categories, (iii) a shift from local sales to legal cross-border purchases of lower price products, and (iv) illicit products such as contraband and counterfeit.

We may become subject to governmental investigations on a range of matters.

Tobacco companies are often subject to investigations, including allegations of contraband shipments of cigarettes, allegations of unlawful pricing activities within certain markets, allegations of underpayment of custom duties and/or excise taxes, and allegations of false and misleading usage of descriptors such as "lights" and "ultra-lights." We cannot predict the outcome of any investigations to which we may become subject, but we may be materially affected by an unfavorable outcome of potential future investigations.

Risks Related to Intellectual Property

Our proprietary rights may expire or may not otherwise adequately protect our intellectual property, products and potential products, and if we cannot obtain adequate protection of our intellectual property, products and potential products, we may not be able to successfully market our products and potential products.

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our technologies, products, and potential products. We will only be able to protect our technologies, products, and potential products from unauthorized use by third parties to the extent that valid and enforceable patents cover them, or to the extent that other market exclusionary rights apply.

The patent positions of life sciences companies, like ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. The general patent environment outside the United States also involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may be allowed or that the scope of these patent rights could provide a sufficient degree of future protection that could permit us to gain or keep our competitive advantage with respect to these products and technology. Additionally, life science companies like ours are often dependent on creating a pipeline of products. We may not be able to develop additional potential products or proprietary technologies that produce commercially viable products or that are themselves patentable.

Although there are currently no challenges to any portion of our intellectual property, our issued patents may be subject to challenge and potential invalidation by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States, or in other countries, may diminish the value of our intellectual property. In addition, others may independently develop similar or alternative products and technologies that may be outside the scope of our intellectual property. Should third parties obtain patent rights to similar products or technology, this may have an adverse effect on our business.

The expiration of a portion of the QPT patent family in 2018 may provide third parties with the freedom to target the QPT gene in the tobacco plant, which may give third-parties the freedom to target the QPT gene in experiments to try to reduce nicotine levels in tobacco plants to levels that may satisfy the planned new nicotine reduction regulations coming from the FDA. There can be no assurance about whether any third-parties will or will not be successful in such efforts, how long or short in time such efforts will entail and/or if such efforts will or will not infringe other genes and other intellectual property on which we have continuing patent protection that would need to be used, in combination with QPT, to result in VLNC tobacco. If our competitors are able to successfully reduce nicotine levels in tobacco plants without violating our patent protections, our ability to license our technology would be negatively impacted and we would likely face increased competition.

We also rely on trade secrets to protect our technology, products, and potential products, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets, however, are difficult to protect. While we believe that we use reasonable efforts to protect our trade secrets, our own, our licensees' or our strategic partners' employees, consultants, contractors or advisors may unintentionally or willfully disclose our information to competitors. We seek to protect this information, in part, through the use of non-disclosure and confidentiality agreements with employees, consultants, advisors, and others. These agreements may be breached, and we may not have adequate remedies for a breach. In addition, we cannot ensure that those agreements will provide adequate protection for our trade secrets, know-how, or other proprietary information, or prevent their unauthorized use or disclosure.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our products and potential products, disputes may arise as to the proprietary rights of the information, which may not be resolved in our favor. Key employees are required to assign all intellectual property rights in their discoveries to us. However, these key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods, or technologies. If we were to prosecute a claim that a third party had illegally obtained and was using our trade secrets, it could be expensive and time consuming and the outcome could be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any contractual claim to this information, and our business could be harmed.

The ability to commercialize our potential products will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business.

The ability to commercialize our potential products will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third-party intellectual property rights in our field are complicated, and third-party intellectual property rights in these fields are continuously evolving. While we have conducted searches for such third-party intellectual property rights, we have not performed specific searches for third-party intellectual property rights that may raise freedom-to-operate issues, and we have not obtained legal opinions regarding commercialization of our potential products. As such, there may be existing patents that may affect our ability to commercialize our potential products.

In addition, because patent applications are published up to 18 months after their filing, and because patent applications can take several years to issue, there may be currently pending third-party patent applications and freedom-to-operate issues that are unknown to us, which may later result in issued patents.

If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process, and can divert management's attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- a court order prohibiting us from commercializing our potential products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our potential products to market.

Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

Our patent applications may not result in issued patents, which may have a material adverse effect on our ability to prevent others from commercially exploiting products similar to ours.

We own or exclusively control many issued patents and pending patent applications. We cannot be certain that these patent applications will issue, in whole or in part, as patents. Patent applications in the United States are maintained in secrecy until the patents are published or are issued. Since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we are the first creator of inventions covered by pending patent applications or the first to file patent applications on these inventions. We also cannot be certain that our pending patent applications will result in issued patents or that any of our issued patents will

afford protection against a competitor. In addition, patent applications filed in foreign countries are subject to laws, rules and procedures that differ from those of the United States, and thus we cannot be certain that foreign patent applications related to U.S. patents will be issued. Furthermore, if these patent applications issue, some foreign countries provide significantly less effective patent enforcement than in the United States.

The status of patents involves complex legal and factual questions and the breadth of claims allowed is uncertain. Accordingly, we cannot be certain that the patent applications that we or our licensors file will result in patents being issued, or that our patents and any patents that may be issued to us in the near future will afford protection against competitors with similar technology. In addition, patents issued to us may be infringed upon or designed around by others and others may obtain patents that we need to license or design around, either of which would increase costs and may adversely affect our operations.

We license certain patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects could be harmed.

We license rights to third-party intellectual property that is necessary or useful for our business, and we may enter into additional licensing agreements in the future. Our success could depend in part on the ability of some of our licensors to obtain, maintain, and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued with respect to these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we could. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Our worldwide exclusive licenses relating to tobacco from NCSU involves multiple patent families. The exclusive rights under the NCSU agreements expire on the date on which the last patent or registered plant variety covered by the subject license expires in the country or countries where such patents or registered plant varieties are in effect. The NCSU licenses relate predominately to issued patents, and our exclusive rights in the NCSU licenses are expected to expire in 2036.

Our worldwide sublicense from Anandia, a plant biotechnology company based in Vancouver, Canada, grants us exclusive rights in the United States and co-exclusive rights with Anandia everywhere else in the world (except not in Canada where Anandia retains exclusive rights) to certain patents and patent applications relating to certain genes in the hemp/cannabis plant that are required for the production of cannabinoids, the "active ingredients" in the cannabis plant. The Anandia sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustained, and you may not be able to resell your shares at or above the price at which you purchased them.

An active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, shares of common stock may not be able to be resold at or above the purchase price of such shares. Although there can be no assurances, we expect that our common stock will continue to be quoted on the New York Stock Exchange American market ("NYSE American"). However, even if our common stock continues to be quoted on the NYSE American, there is no assurance that an active market for our common stock will continue in the foreseeable future. There also can be no assurance that we can maintain such listing on the NYSE American. If we are ever no longer listed on the NYSE American or other national stock exchange in the future, then it would be more difficult to dispose of shares or to obtain accurate quotations as to the market value of our common stock compared to securities of companies whose shares are traded on national stock exchanges.

Our stock price may be highly volatile and could decline in value.

Our common stock is currently traded on the NYSE American and the market price for our common stock has been volatile. Further, the market prices for securities in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- failure or discontinuation of any of our research programs;

- delays in establishing new strategic relationships;

- delays in the development of our potential products and commercialization of our potential products;

- market conditions in our sector and issuance of new or changed securities analysts' reports or recommendations;

- general economic conditions, including recent adverse changes in the global financial markets;

- actual and anticipated fluctuations in our quarterly financial and operating results;

- developments or disputes concerning our intellectual property or other proprietary rights;

- introduction of technological innovations or new commercial products by us or our competitors;

- issues in manufacturing or distributing our products or potential products;

- market acceptance of our products or potential products;

·third-party healthcare reimbursement policies;

·FDA or other United States or foreign regulatory actions affecting us or our industry;

·litigation or public concern about the safety of our products or potential products;

·negative press or publicity regarding us or our common stock;

·the announcement of litigation against us or the results of on-going litigation;

·additions or departures of key personnel;

·third-party sales of large blocks of our common stock or third party short-selling activity;

·sales of our common stock by our executive officers, directors, or significant stockholders; and

·equity sales by us of our common stock or securities convertible into common stock to fund our operations.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock, such as the recently instituted class action and derivative lawsuits. Such lawsuits and any future related lawsuits could cause us to incur substantial costs defending the lawsuit and can also divert the time and attention of our management, which would have a negative adverse impact on our business. See the risk factor below entitled: “We are named defendant in certain litigation matters, including federal securities class action lawsuits and derivative complaints; if we are unable to resolve these matters favorably, then our business, operating results and financial condition may be adversely affected.”

We are named defendant in certain litigation matters, including federal securities class action lawsuits and derivative complaints; if we are unable to resolve these matters favorably, then our business, operating results and financial condition may be adversely affected.

We are currently involved in certain litigation matters, including securities class action and derivative litigation. See "Item 3 - Litigation" included in this Annual Report on Form 10-K. We cannot at this time predict the outcome of these matters or any future litigations matters (whether related or unrelated) or reasonably determine the probability of a material adverse result or reasonably estimate range of potential exposure, if any, that these matters or any future matters might have on us, our business, our financial condition or our results of operations, although such effects, including the cost to defend, any judgements or indemnification obligations, among others, could be materially adverse to us. In addition, in the future, we may need to record litigation reserves with respect to these matters. Further, regardless of how these matters proceed, it could divert our management's attention and other resources away from our business.

Future sales of our common stock will result in dilution to our common stockholders.

Sales of a substantial number of shares of our common stock in the public market may depress the prevailing market price for our common stock and could impair our ability to raise capital through the future sale of our equity securities. Additionally, if the holders of outstanding options or warrants exercise or convert those shares, as applicable, our common stockholders will incur dilution in their relative percentage ownership. The prospect of this possible dilution may also impact the price of our common stock.

We do not expect to declare any dividends on our common stock in the foreseeable future.

We have not paid cash dividends to date on our common stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our business, and we do not anticipate paying any cash dividends on our common stock for the foreseeable future. Additionally, the terms of any future debt facilities may preclude us from paying dividends on the common stock. As a result, capital appreciation, if any, of our common stock could be the sole source of gain for the foreseeable future.

Anti-takeover provisions contained in our articles of incorporation and bylaws, as well as provisions of Nevada law, could impair a takeover attempt.

Our amended and restated articles of incorporation and bylaws currently contain provisions that, together with Nevada law, could have the effect of rendering more difficult or discouraging an acquisition deemed undesirable by our board of directors. Our corporate governance documents presently include the following provisions:

- providing for a "staggered" board of directors in which only one-third (1/3) of the directors can be elected in any year;
- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend, and other rights superior to our common stock; and
- limiting the liability of, and providing indemnifications to, our directors and officers.

These provisions, alone or together, could delay hostile takeovers and changes in control of our Company or changes in our management.

As a Nevada corporation, we also may become subject to the provisions of Nevada Revised Statutes Sections 78.378 through 78.3793, which prohibit an acquirer, under certain circumstances, from voting shares of a corporation's stock after crossing specific threshold ownership percentages, unless the acquirer obtains the approval of the stockholders of the issuer corporation. The first such threshold is the acquisition of at least one-fifth, but less than one-third of the outstanding voting power of the issuer. We may become subject to the above referenced Statutes if we have 200 or more stockholders of record, at least 100 of whom are residents of the State of Nevada and do business in the State of Nevada directly or through an affiliated corporation.

As a Nevada corporation, we are subject to the provisions of Nevada Revised Statutes Sections 78.411 through 78.444, which prohibit an "interested stockholder" from entering into a combination with the corporation, unless certain conditions are met. An "interested stockholder" is a person who, together with affiliates and associates, beneficially owns (or within the prior two years did own) 10 percent or more of the corporation's voting stock.

Any provision of our amended and restated articles of incorporation, our bylaws or Nevada law that has the effect of delaying or deterring a change in control of our Company could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

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Item 1B Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal administrative offices are located at 8560 Main Street, Suite 4, Williamsville, New York 14221. On October 4, 2017, we entered a lease for such office space in Williamsville, New York with an initial three-year term and with a monthly lease payment of $6,375. The office space lease contains three (3) additional extensions; with each lease extension being for an additional one (1) year in duration, exercisable at our option. Future minimum annual lease payments under the lease will be approximately $76,000, $76,000, and $80,000 for each of the years ended December 31, 2019, 2020, and 2021, respectively.

On May 1, 2016, we entered into a sublease for laboratory space in Buffalo, New York. The sublease called for a monthly payment of $1,471 through April 30, 2018. Additionally, on February 1, 2017, we entered into an amendment to the initial sublease calling for the sublease of additional lab space at a cost of $1,219 per month, bringing the total monthly lease obligation to $2,690. On April 26, 2017, we entered into a further amendment to the sublease to extend the term of the sublease for an additional twelve (12) months, commencing on May 1, 2017 at a total cost of $2,770 per month for the total lease obligation. On February 21, 2018, we entered into a new sublease amendment that extended the sublease term through June 30, 2019 and calls for a monthly sublease payment of $5,706 beginning on March 1, 2018. Future minimum sublease payments for the year ended December 31, 2019 will be approximately $34,000.

We lease a manufacturing facility and warehouse located in North Carolina on a triple net lease basis. The manufacturing facility lease commenced on January 14, 2014 and had an initial term of twelve (12) months. The manufacturing facility lease contains four (4) additional extensions; with one lease extension being for an additional one (1) year and with the other three (3) lease extensions each being for an additional two (2) years in duration, exercisable at our option. We are currently in the second two-year lease extension term that will expire on October 31, 2019. The lease expense for our manufacturing facility for the years ended December 31, 2018, 2017 and 2016 amounted to approximately $169,000, $156,000 and $146,000, respectively. The future minimum annual lease payments if we exercise each of the additional extensions are approximately as follows:

Year ended December 31, 2019 - $169,000
Year ended December 31, 2020 - $169,000
Year ended December 31, 2021 - $141,000

On August 14, 2017, we entered into a lease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment, to store our proprietary tobacco leaf and to store inventory used in our contract manufacturing business. The lease calls for a monthly payment of $4,665, expired on August 14, 2018 and contains twelve-month renewal options as long as we continue to lease the warehouse. Future minimum annual lease payments will be approximately $56,000 per year for each subsequent year the warehouse space is leased by us.

Item 3. Legal Proceedings.

From time to time we may be involved in claims arising in the ordinary course of business. To our knowledge other than the case described below, no material legal proceedings, governmental actions, investigations or claims are currently pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

Crede Case

On April 26, 2016, Crede CG III, LTD. ("Crede") filed a complaint against the Company in the United States District Court for the Southern District of New York (the "SDNY Court") entitled Crede CG III, LTD. v. 22nd Century Group, Inc. On May 19, 2016, Crede filed an Amended Complaint that included seven counts, alleging among other things, that the Company allegedly breached and/or interfered with certain agreements entered into with Crede, including the joint venture agreement relating to efforts to sell the Company's proprietary tobacco into China, the Tranche 1A warrant and the prior securities purchase agreement with Crede. The Amended Complaint sought money damages, to rescind the securities purchase agreement, to obtain declaratory and injunctive relief to require the Company to issue to Crede 2,077,555 shares of the Company's common stock under the exchange provision of the Tranche 1A warrant, and entry of an injunction prohibiting the Company from selling tobacco into China without the joint venture's involvement. The Amended Complaint also sought attorney's fees and such other relief as the Court may deem just and proper. We believe that the claims are frivolous, meritless and that the Company has substantial legal and factual defenses to the claims.

On May 19, 2016, Crede filed a motion for preliminary injunction, asking the SDNY Court to require the Company to issue 2,077,555 shares of its common stock to Crede under the exchange provision of the Tranche 1A warrant. After conducting an evidentiary hearing on this motion on June 14, 2016, the SDNY Court denied Crede's motion and held, among other things, that Crede did not prove the potential for irreparable harm or a likelihood of success on its claim for such 2,077,555 shares under the Tranche 1A warrant, and that there was a likelihood that Crede had violated the Activity Restrictions as defined and contained in the Tranche 1A warrant, which would bar Crede's claim for such shares from the Company.

Following such ruling, on July 11, 2016, the Company filed a motion to sever the Crede lawsuit into two separate cases, requesting all claims relating to the Tranche 1A warrant and the securities purchase agreement to stay in the SDNY Court and all claims relating to the China joint venture agreement to be transferred to the United States District Court for the Western District of New York (the "WDNY Court"), where the Company's headquarters are located. On January 20, 2017, the SDNY Court granted the Company's motion.

On February 14, 2017, Crede voluntarily dismissed its lawsuit against the Company in the WDNY Court.

On February 21, 2017, the SDNY Court granted the Company's request to file a motion for summary judgment for the claims remaining in the SDNY Court, with all discovery in the case being deferred until after the SDNY Court conducts a hearing and issues its decision on the summary judgment motion of the Company. On March 20, 2017, the Company filed its motion for summary judgment for the claims remaining in the SDNY Court. The response by Crede to the Company's summary judgment motion was filed by Crede on May 1, 2017. On May 15, 2017, the Company filed its response to Crede's filing.

On December 28, 2017, the SDNY Court issued its decision in response to the Company's motion for summary judgement, with such decision (i) granting the Company's motion for summary judgement relating to Count II of the Amended Compliant, which eliminates Crede's claim to rescind the prior securities purchase agreement, dated September 17, 2014, and denies Crede's claim for the return of any money from the Company under that securities purchase agreement, and (ii) denying the Company's motion for summary judgement on the remaining Counts of the Amended Compliant. In this decision, the SDNY Court also found that Crede breached the Activity Restrictions as defined and contained in the Tranche 1A warrant. As a result of this decision by the SDNY Court, the parties will now proceed with discovery in the case in preparation for a trial on the remaining Counts III, IV and V of the Amended Complaint, which relate to Crede's claim (i) to exchange the Tranche 1A warrant for 2,077,555 shares of our common stock even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant, (ii) for an unquantified additional amount of shares of our common stock that allegedly still remains under the Tranche 1A warrant even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant; and (iii) for alleged damages for the alleged breach of the Tranche 1A warrant in an amount in excess of $18 million, plus costs and interest, even though Crede breached the Activity Restrictions contained in the Tranche 1A warrant.

On July 13, 2018, the SDNY Court denied Crede's request to extend the discovery deadline. As a result of such ruling, the discovery in the Crede case has been concluded. On July 20, 2018, the SDNY Court granted the request by the Company to file a motion for partial summary judgment to substantially limit the various damage claims by Crede, with the remaining schedule in the case being deferred until after the SDNY Court rules on such motion.

The Company filed its partial summary judgment motion on August 20, 2018, after which Crede filed its response on September 27, 2018, after which the Company filed its reply to Crede's response on October 11, 2018. On February 15, 2019, the SDNY Court issued its decision in response to the Company's motion for partial summary judgment, with such decision (i) granting the Company's motion to limit Crede's claims for damages of not more than $10 million and (ii) denying the Company's other motions seeking to further limit the damages claims by Crede because the SDNY Court desires for the parties to present evidence on their respective positions in a bench trial (a trial in front of the judge without a jury). The SDNY Court further ordered the parties to submit a joint letter on or before March 1, 2019, setting forth their availability for a bench trial in the second half of 2019. On March 1, 2019, the parties submitted such joint letter to the SDNY Court setting forth their availability for a bench trial in the second half of 2019.

The Company believes that the claims are frivolous, meritless and that the Company has substantial legal and factual defenses to the claims. The Company has defended and intends to continue to defend against these claims vigorously.

Class Action Cases

On January 21, 2019, Matthew Jackson Bull, a resident of Denver, Colorado, filed a Complaint against the Company, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Matthew Bull, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, *Case No. 1:19-cv-00409*. The Complaint filing discloses that Plaintiff Mr. Bull purchased 3,000 shares of the Company's common stock from September 14, 2016 to October 15, 2018 at share prices between $.91 and $2.57 per share, and that on September 24, 2018, he sold 419 shares for a profit at $2.88 per share. Mr. Bull sues individually and seeks to bring a class action for persons or entities who acquired the Company's common stock between February 18, 2016 and October 25, 2018, and alleges in Count I that the Company's Annual Reports on Form 10-K for the years 2015, 2016 and 2017 allegedly contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, and alleges in Count II that Messrs. Sicignano and Brodfuehrer are supposedly liable for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Complaint seeks declaratory relief, unspecified money damages, and attorney's fees and costs. The Complaint has not yet been served on the Company, Mr. Sicignano or Mr. Brodfuehrer and, therefore, the Company and Messrs. Sicignano and Brodfuehrer have not yet filed responses. We believe that the claims are frivolous, meritless and that the Company and Messrs. Sicignano and Brodfuehrer have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and Messrs. Sicignano and Brodfuehrer against such claims.

On January 29, 2019, Ian M. Fitch, a resident of Essex County Massachusetts, filed a Complaint against the Company, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Ian Finch, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, *Case No. 2:19-cv-00553*. The Complaint filing discloses that the Plaintiff Mr. Fitch purchased 3,300 shares of the Company's common stock on October 11, 2017 at $3.04 per share. Mr. Fitch sues individually and seeks to bring a class action for persons or entities who acquired the Company's common stock between February 18, 2016 and October 25, 2018, and alleges in Count I that the Company's Annual Reports on Form 10-K for the years 2015, 2016 and 2017 allegedly contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, and alleges in Count II that Messrs. Sicignano and Brodfuehrer are supposedly liable for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Complaint seeks declaratory relief, unspecified money damages, and attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and Messrs. Sicignano and Brodfuehrer have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and Messrs. Sicignano and Brodfuehrer against such claims.

Shareholder Derivative Cases

On February 6, 2019, Melvyn Klein, a resident of Nassau County New York, filed a shareholder derivative claim against the Company, the Company's Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the United States District Court for the Eastern District of New York entitled: Melvyn Klein, derivatively on behalf of 22nd Century Group v. Henry Sicignano, III, Richard M. Sanders, Joseph Alexander Dunn, Nora B. Sullivan, James W. Cornell, John T. Brodfuehrer and 22nd Century Group, Inc., *Case No. 1:19-cv-00748.* Mr. Klein brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties for allegedly allowing the Company to make false statements; (ii) the director defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iii) the defendants allegedly violated Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made; and (iv) the director defendants allegedly violated Section 14(a) of the Securities Exchange Act and Rule 14a-9 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made in the Company's proxy statement. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims.

On February 11, 2019, Stephen Mathew filed a shareholder derivative claim against the Company, the Company's Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the Supreme Court of the State of New York, County of Erie, entitled: Stephen Mathew, derivatively on behalf of 22nd Century Group, Inc. v. Henry Sicignano, III, John T. Brodfuehrer, Richard M. Sanders, Joseph Alexander Dunn, James W. Cornell, Nora B. Sullivan and 22nd Century Group, Inc., *Index No. 801786/2019.* Mr. Mathew brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties for allegedly allowing the Company to make false statements; (ii) the director defendants were allegedly unjustly enriched by allegedly benefitting from allegedly allowing the Company to make false statements; (iii) the defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iv) the individual defendants allegedly abused their ability to control and influence the Company; and (v) the individual defendants allegedly engaged in gross mismanagement. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims.

On February 19, 2019, the Company received a demand letter from attorneys representing Van McClendon, a shareholder of the Company, in which Mr. McClendon demanded that the Company's Board of Directors take action to pursue certain purported causes of action on behalf of the Company to remedy alleged breaches of fiduciary duties by each of the members of the Company's Board of Directors, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer.

Item 4. Mine Safety Disclosures.

Not applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is quoted on the NYSE American under the symbol "XXII." As of December 31, 2018, there were 95 holders of record of shares of our common stock.

Dividend Policy

We have not previously and do not plan to declare or pay any dividends on our common stock. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including current financial condition, operating results and current and anticipated cash needs.

Recent Issuances of Unregistered Securities

None.

Shares authorized for issuance under equity compensation plans

On April 12, 2014, our shareholders approved the 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (the "OIP") and the authorization of 5,000,000 shares of our common stock available for issuance thereunder. On April 29, 2017, our shareholders approved an amendment to the OIP to increase the number of shares available for issuance by an additional 5,000,000 shares. The OIP allows for the granting of equity and cash incentive awards to eligible individuals over the life of the OIP, including the issuance of up to an aggregate of 10,000,000 shares of the Company's common stock pursuant to awards under the OIP. The OIP has a term of ten years and is administered by the Compensation Committee of the Company's Board of Directors to determine the various types of incentive awards that may be granted to recipients under this plan and the number of shares of common stock to underlie each such award under the OIP.

The following table summarizes the number of stock options granted, net of forfeitures and sales, the weighted-average exercise price of such stock options and the number of securities available to be issued under the OIP as of December 31, 2018:

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders	8,172,082	$ 1.59	1,602,115	
Equity compensation plans not approved by security holders	-	N/A	-	
Total	8,172,082		1,602,115	(1)

(1) Consists of shares available for award under the OIP.

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Stock Performance Graph

The following information in this Item of the Annual Report on Form 10-K is not deemed to be "soliciting material" or to be "filed" with the Securities and Exchange Commission or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or to the liabilities of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference to any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that we specifically incorporate such information into such filing.

The performance graph shown below compares the cumulative total shareholder return on the Company's common stock, based on the market price of the common stock, with the total return of the NYSE American Composite Index and the NASDAQ US Small Cap Biotechnology Index for the period covering December 31, 2013 through December 31, 2018. The comparison of total return assumes that a fixed investment of $100 was invested on December 31, 2013 in the Company's common stock and in each of the foregoing indicies and further assumes the reinvestment of dividends. The stock price performance shown on the graph is not necessarily indicative of future price performance.

Item 6. Selected Financial Data.

The selected consolidated financial data for each of the five years in the period ending December 31, 2018 are derived from our audited financial statements. The selected consolidated financial data should be read in conjunction with our audited consolidated financial statements and the notes thereto contained in Item 15, and Management's Discussion and Analysis of Financial Condition and Results of Operations and Comprehensive Loss, as set forth in Item 7 of this Annual Report on Form 10-K.

	Years Ended December 31,				
	2018	**2017**	**2016**	**2015**	**2014**
Consolidated Statements of Operations and Comprehensive Loss data:					
Revenue	$26,426,347	$16,600,244	$12,279,979	$8,521,998	$528,991
Gross profit (loss)	$898,987	$(707,912)	$(429,699)	$(580,562)	$30,555
Operating expenses (1)	$23,575,279	$11,644,955	$10,115,968	$10,689,010	$11,302,623
Equity based compensation included in operating expenses	$3,187,331	$941,650	$911,382	$3,585,540	$4,524,468
Operating loss	$(24,018,627)	$(13,299,864)	$(11,387,847)	$(12,043,883)	$(11,767,364)
Warrant liability gain (loss) - net (2)	$48,711	$(157,809)	$29,615	$144,550	$(3,827,794)
Net loss	$(7,966,911)	$(13,029,117)	$(11,581,430)	$(11,031,931)	$(15,595,358)
Loss per common share - basic and diluted	$(0.06)	$(0.13)	$(0.15)	$(0.16)	$(0.26)
Common shares used in basic earnings per share calculation	124,298,981	101,161,380	79,842,773	68,143,284	59,993,413
Consolidated Balance Sheet data:					
Working capital	$56,023,982	$63,308,249	$13,548,118	$3,991,828	$8,033,399
Total assets	$77,302,136	$79,739,406	$27,642,357	$18,370,512	$21,953,515
Total debt	$1,537,365	$-	$307,938	$616,520	$1,100,655
Total shareholders' equity	$71,280,735	$75,426,200	$24,334,359	$11,728,500	$15,219,737
Other data:					
Net cash used in operating activities	$(17,844,266)	$(12,068,383)	$(9,887,580)	$(7,321,811)	$(6,582,730)
Net cash provided by (used in) investing activities (3)	$15,145,044	$(60,586,245)	$(553,770)	$(450,661)	$(2,707,992)
Net cash (used in) provided by financing activities	$(355,387)	$62,845,974	$20,149,241	$5,130,082	$9,862,810
Acquisition of patents and trademarks (4)	$656,985	$450,208	$356,541	$413,180	$726,989
Depreciation	$522,695	$353,435	$326,124	$319,699	$230,012
Amortization (5)	$819,640	$593,562	$516,056	$454,612	$265,284

(1) Operating expenses include costs for research and development, general and administrative, and sales and marketing, and exclude depreciation and amortization expense. Operating expenses for the year ended December 31, 2018 include approximately $9,800,000 of expenses relating to our MRTPA.

(2) Warrant liability gain (loss) - net also includes the warrant amendment inducement expense of $144,548 for the year ended December 31, 2014.

(3) Includes $58,979,131 used to purchase short-term investment securities during the year ended December 31, 2017.

(4) Includes cash paid for patent and trademark costs during the applicable year.

(5) Includes the amortization of patent costs and license fees.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This discussion should be read in conjunction with the other sections of this Form 10-K, including "Risk Factors," and the Financial Statements and notes thereto. The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this Annual Report on Form 10-K. See "Forward-Looking Statements." Our actual results may differ materially. For purposes of this Management's Discussion and Analysis of Financial Condition and Results of Operations, references to the "Company," "we," us" or "our" refer to the operations of 22nd Century Group, Inc. and its direct and indirect subsidiaries for the periods described herein.

Business 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 important potential 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.

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 revised 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 Content cigarettes to be marketed in the United States under the proposed brand name of VLN™ and containing 95% less nicotine than conventional tobacco cigarettes;

- Seeking 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 VLNC 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 desire such potential products;

- Continuing to expand our legal hemp activities and development of unique plant varieties of hemp, including (i) hemp plants with 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.

Recent Developments

For the fourth quarter of 2018, our accomplishments and notable events include:

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

On December 5, 2018, we submitted a Premarket Tobacco Application ("PMTA") with the FDA seeking authorization to commercialize the Company's "*BRAND A*" cigarette products under the proposed brand name VLN™ (the product name is subject to FDA approval). 22nd Century's proposed VLN™ cigarettes – the subject of the PMTA – are made with 22nd Century's proprietary VLN™ tobacco and, as a result, contain very low levels of nicotine. A PMTA marketing order is a prerequisite to commercializing any new tobacco product in the United States. 22nd Century's proposed VLN™ cigarettes are modeled after the Company's VLNC SPECTRUM® research cigarettes. 22nd Century's PMTA for the proposed VLN™ brand cigarettes references more than 50 independent studies conducted using the Company's proprietary SPECTRUM® research cigarettes. The World Health Organization ("WHO") Study Group on Tobacco Product Regulation has recommended that all member countries limit the nicotine content of cigarettes to the level found in our VLNC SPECTRUM® cigarettes.

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

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

Results of Operations

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017 and Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

Revenue - Sale of products, net

2018 vs. 2017

We realized net revenue from the sale of products in the amount of $26,426,347 during the year ended December 31, 2018, as compared to net revenues of $16,600,244 during the year ended December 31, 2017, an increase of $9,826,103, or 59.2%. Included in net revenue were sales of *SPECTRUM*® research cigarettes in the amount of $607,000 and $325,320 for the years ended December 31, 2018 and 2017, respectively. The increase in net revenue from the sale of products for 2018 was primarily the result of additional net sales revenue generated from our contract manufacturing business as compared to net sales revenue for the year ended December 31, 2017.

2017 vs. 2016

We realized net revenue from the sale of products in the amount of $16,600,244 during the year ended December 31, 2017, as compared to net revenues of $12,279,979 during the year ended December 31, 2016, an increase of $4,320,265, or 35.2%. Included in net revenue were sales of *SPECTRUM*® research cigarettes in the amount of $325,320 and $328,912 for the years ended December 31, 2017 and 2016, respectively. The increase in net revenue from the sale of products for 2017 was primarily the result of additional net sales revenue generated from a new contract to manufacture existing brands of filtered cigars that began in mid-May of 2017.

Costs of goods sold - Products

2018 vs. 2017

During the year ended December 31, 2018, cost of goods sold were $25,527,360, or 96.6% of net sales revenue. During the year ended December 31, 2017, cost of goods sold were $17,308,156, or 104.3%, of net sales revenue, resulting in a gross loss on sales of products in the amount of $707,912. The $1,606,899 improvement from a gross loss for the year ended December 31, 2017 to a gross profit for the year ended December 31, 2018 was primarily the result of increased factory utilization. Additionally, included in the cost of goods sold during 2018 was a net write off of obsolete finished goods and raw materials inventory in the approximate amount of $154,000, resulting in an increase in the cost of goods sold by such amount.

During the year ended December 31, 2017, cost of goods sold were $17,308,156, or 104.3% of net revenue. We were not operating the factory at full production capacity during 2017, but we began utilizing a portion of the excess capacity as a result of the new filtered cigar contract manufacturing agreement that commenced in mid-May of 2017. As a result, the cost of goods sold, which included the cost of raw material components, direct manufacturing costs and an overhead allocation, was in excess of net sales revenue. Additionally, included in the cost of goods sold during 2017 was a net write off of obsolete finished goods and raw materials inventory in the approximate amount of $257,000, resulting in an increase in the cost of goods sold by such amount.

2017 vs. 2016

During the year ended December 31, 2017, cost of goods sold were $17,308,156, or 104.3% of net revenue. We were not operating the factory at full production capacity during 2017, but we began utilizing a portion of the excess capacity as a result of the new filtered cigar contract manufacturing agreement that commenced in mid-May of 2017. As a result, the cost of goods sold, which included the cost of raw material components, direct manufacturing costs and an overhead allocation, was in excess of net sales revenue. Additionally, included in the cost of goods sold during 2017 was a net write off of obsolete finished goods and raw materials inventory in the approximate amount of $257,000, resulting in an increase in the cost of goods sold by such amount.

During the year ended December 31, 2016, cost of goods sold were $12,709,678, or 103.5% of net revenue. We were not operating the factory at full production capacity during 2016. As a result, the cost of goods sold, which included the cost of raw material components, direct manufacturing costs and an overhead allocation, was in excess of net sales revenue. Additionally, included in the cost of goods sold for the year ended December 31, 2016 is an increase in inventory reserves in the amount of $145,000.

Research and development expense

2018 vs. 2017

Research and development expenses were $14,989,746 for the year ended December 31, 2018, an increase of $11,623,278, or 345.3%, from $3,366,468 for the year ended December 31, 2017. This increase was primarily the result of an increase in expenses relating to our MRTPA with the FDA for our VLNC cigarettes of approximately $9,542,000, an increase in equity-based compensation of approximately $1,663,000 (includes approximately $1,230,000 in equity-based compensation recognized due to the death of our Senior Vice President of Science and Regulatory Affairs in the second quarter of 2018), an increase in expenses relating to out laboratory operations of approximately $455,000, an increase in payroll and related benefits of approximately $443,000, an increase in consulting fees of approximately $114,000, and a net increase in various other R&D expenses of approximately $13,000, partially offset by a decrease in license and royalty fees in the approximate amount of $195,000, a decrease in sponsored research of approximately $241,000, and a decrease in the net write off of our proprietary leaf inventory of approximately $171,000, during the year ended December 31, 2018, as compared to the year ended December 31, 2017.

2017 vs. 2016

Research and development expenses were $3,366,468 for the year ended December 31, 2017, an increase of $1,025,510, or 43.8%, from $2,340,958 for the year ended December 31, 2016. This increase was primarily the result of an increase in sponsored research costs and testing costs in the approximate amount of $441,000, a net write off of approximately $335,000 of our proprietary leaf inventory, an increase in laboratory expenses in the approximate amount of $102,000, an increase in payroll and payroll related costs of approximately $118,000, an increase in costs related to our modified risk tobacco products of approximately $59,000 and an increase in equity based compensation of approximately $46,000, partially offset by a decrease in license and royalty fees in the approximate amount of $63,000 and a decrease in legal expenses of approximately $26,000, during the year ended December 31, 2017, as compared to the year ended December 31, 2016.

General and administrative expense

2018 vs. 2017

General and administrative expense was $7,658,119 for the year ended December 31, 2018, an increase of $541,584, or 7.6%, from $7,116,535 for the year ended December 31, 2017. The increase was primarily due to an increase in payroll and payroll related benefits of approximately $371,000, an increase in equity-based compensation of approximately $543,000, an increase in legal and accounting expenses of approximately $229,000, an increase in annual SEC and NYSE American compliance costs of approximately $60,000, an increase in Board of Director related expenses of approximately $73,000, an increase in business insurance of approximately $56,000, and a net increase in various other general and administrative expenses of approximately $102,000, partially offset by a decrease in expenses relating to investor relations of approximately $722,000, and a decrease in consulting fees of approximately $170,000, during the year ended December 31, 2018 as compared to the year ended December 31, 2017.

2017 vs. 2016

General and administrative expense was $7,116,535 for the year ended December 31, 2017, an increase of $923,266, or 14.9%, from $6,193,269 for the year ended December 31, 2016. The increase was primarily due to an increase in payroll and payroll related benefits of approximately $858,000, an increase in travel expenses of approximately $79,000, an increase in annual meeting costs and seminars and conference fees of approximately $84,000 and a net increase in various other general and administrative expenses of approximately $15,000, partially offset by a decrease in equity based compensation of approximately $69,000 and a decrease in legal and accounting fees of approximately $44,000, during the year ended December 31, 2017 as compared to the year ended December 31, 2016.

Sales and marketing expense

2018 vs. 2017

Sales and marketing costs were $927,414 for the year ended December 31, 2018, a decrease of $234,538, or 20.2%, from $1,161,952 for the year ended December 31, 2017. The decrease in the sales and marketing expenses were primarily the result of a decrease in payroll and payroll related benefits of approximately $209,000, a decrease in advertising and promotion costs of approximately $40,000, and a decrease in travel related costs of approximately $24,000, partially offset by an increase in and an increase in equity-based compensation of approximately $40,000, during the year ended December 31, 2018 as compared to the year ended December 31, 2017.

2017 vs. 2016

Sales and marketing costs were $1,161,952 for the year ended December 31, 2017, a decrease of $419,789, or 26.5%, from $1,581,741 for the year ended December 31, 2016. The decrease in the sales and marketing expenses were primarily the result of a decrease in advertising and promotion costs of approximately $529,000 and a decrease in travel related costs of approximately $48,000, partially offset by an increase in payroll and expenses related to payroll of approximately $89,000 and an increase in equity-based compensation of approximately $78,000, during the year ended December 31, 2017 as compared to the year ended December 31, 2016.

Depreciation expense

2018 vs. 2017

Depreciation expense for the year ended December 31, 2017 amounted to $522,695, an increase of $169,260, or 47.9%, from $353,435 for the year ended December 31, 2017. The increase was primarily due to depreciable acquisitions of machinery and equipment during the years ended December 31, 2018 and 2017 in the approximate amount of $467,000 and $1,235,000, respectively, primarily consisting of equipment additions in our NASCO factory operations in North Carolina, equipment additions in our laboratory facility in Buffalo, New York, and leasehold improvements to our new corporate office in Williamsville, New York.

2017 vs. 2016

Depreciation expense for the year ended December 31, 2017 amounted to $353,435, an increase of $27,311, or 8.4%, from $326,124 for the year ended December 31, 2016. This increase is primarily due to additional depreciation expenses on some assets acquired and placed in service during 2017 and a full year of depreciation expense taken on assets acquired during 2016. Machinery and equipment acquired during 2017 of approximately $1,235,000 related primarily to packing equipment at our factory in North Carolina that was not placed in service during 2017. The equipment was placed in service in 2018.

Amortization expense

2018 vs. 2017

Amortization expense, relating to amortization taken on capitalized patent costs and license fees, for the year ended December 31, 2018 amounted to $819,640, an increase of $226,078, or 38.10%, from $593,562 for the year ended December 31, 2017. The increase is primarily due to amortization on additional patent costs incurred during the years ended December 31, 2018 and 2017 in the amounts of $751,492 and $582,040, respectively, and amortization taken in 2018 on the fees relating to new licenses agreements in the amount of approximately $2,326,000.

2017 vs. 2016

Amortization expense, relating to amortization taken on capitalized patent costs and license fees, for the year ended December 31, 2017 amounted to $593,562, an increase of $77,506, or 15.0%, from $516,056 for the year ended December 31, 2016. The increase is primarily due to amortization on additional patent costs incurred during the years ended December 31, 2017 and 2016 in the amounts of $582,040 and $541,882, respectively.

Warrant liability gain (loss), net

2018 vs. 2017

The warrant liability gain of $48,711 for the year ended December 31, 2018 was due to a decrease in the estimated fair value of the warrants that was primarily attributable to a decrease in our underlying stock price during the period prior to the cashless exercise of the remaining 94,721 stock warrants containing the anti-dilutive features that created the warrant liability in July 2018. Accordingly, there was no warrant liability gain (loss) recorded for the remainder of 2018 and there will be no warrant liability gain (loss) in future periods unless we issue securities with anti-dilution features.

The warrant liability loss of $157,809 for the year ended December 31, 2017 was due to the increase in the estimated fair value of the warrants during the year. The increase in the estimated fair value of the warrants was primarily attributable to an increase in our underlying stock price from $1.09 per share at December 31, 2016, as compared to

$2.80 per share at December 31, 2017, and with the expiration of certain warrants during 2017.

2017 vs. 2016

The warrant liability loss of $157,809 for the year ended December 31, 2017 was due to the increase in the estimated fair value of the warrants during the year. The increase in the estimated fair value of the warrants was primarily attributable to an increase in our underlying stock price from $1.09 per share at December 31, 2016, as compared to $2.80 per share at December 31, 2017, and with the expiration of certain warrants during 2017.

The warrant liability gain of $29,615 for the year ended December 31, 2016 was due to the decrease in the estimated fair value of certain outstanding warrants during the year. The decrease in the estimated fair value of the warrants was primarily attributable to a decrease in our underlying stock price from $1.40 per share at December 31, 2015, as compared to $1.09 per share at December 31, 2016, and with certain warrants aging closer to their expiration dates with the passage of time.

Realized loss on short-term investment securities

2018 vs. 2017

In December of 2017, we funded a short-term investment account with excess capital raised from a registered direct offering in October of 2017. Investments in the short-term investment account are managed in accordance with our investment policy. The realized loss on short-term investment securities of $54,451 for the year ended December 31, 2018, was a loss resulting from the maturity of various debt instruments held in the short-term investment account.

2017 vs. 2016

There were no realized gains or losses on short-term investment securities for the years ended December 31, 2017 and 2016.

Realized gain on investments

2018 vs. 2017

In January of 2018, Anandia closed a private placement of common stock reducing our equity investment in Anandia to 14.8%. On August 8, 2018, all of Anandia's outstanding common stock was acquired by Aurora Cannabis, Inc. ("Aurora") (TSX: ACB.TO), in exchange for (i) free trading shares of Aurora common stock, and (ii) warrants with a five-year term to purchase one-half of a share of Aurora common stock for each whole share of Aurora common stock received as part of the transaction (the "Anandia transaction"). As a result of the transaction, we received 1,947,943 shares of Aurora common stock and warrants to purchase 973,971 shares of Aurora common stock that had a fair value of $9,221,594 and $2,807,958, respectively. We recorded a realized gain on the transaction in the amount of $4,515,971 during the third quarter of 2018. Additionally, the unrealized gain on our investment in Anandia in the amount of $6,147,088 under ASU 2016-01 from the first quarter of 2018 became a realized gain at time of the Anandia transaction. Subsequent to the transaction, we sold all our Aurora common stock resulting in net sales proceeds $13,051,503 and realized a gain on the sale of $3,829,909. The realized gain from the Anandia transaction, the gain from ASU 2016-01, and the sale of the Aurora common shares resulted in an aggregate realized gain of $14,492,968 for the year ended December 31, 2018.

2017 vs. 2016

There were no realized gains or losses from investments for the years ended December 31, 2017 and 2016.

Unrealized gain (loss) on investments

2018 vs. 2017

The warrants to purchase 973,971 shares of Aurora common stock, described above and in Note 9 to our consolidated financial statements, are considered an equity security, and are recorded at fair value. The Company recorded the fair value of the stock warrants of $3,092,358 at December 31, 2018, using the Black-Scholes pricing model, and recorded an unrealized gain on the warrants in the amount of $284,400 for the year ended December 31, 2018.

On February 17, 2017, a dilutive event reduced our ownership in Anandia to 19.4%, an ownership percentage below the 20% ownership threshold for the use of the equity method of accounting. Accordingly, we discontinued applying the equity method of accounting for our equity investment in Anandia, effective on the date of the dilutive event. We recorded a gain on investment of $16,872 for year ended December 31, 2017 (the gain for the year ended December 31, 2017, reflects our proportionate gain through February 16, 2017). In addition, and as a result of the February 17, 2017 dilutive event, we recorded a gain in accordance with the derecognition provisions of Accounting Standards Codification 323 (“ASC 323”) in the amount of $336,834. We recorded a total gain on the investment in the amount of $346,180 for the year ended December 31, 2017 (pertains to the period up to February 17, 2017) by aggregating the Company’s share of Anandia’s gain, the gain recorded under ASC 323 and the amortization of the intangible asset represented by the difference between our equity investment in Anandia and our portion of the net assets of Anandia in the amount of $7,526. On July 25, 2017 another dilutive event occurred resulting in an additional reduction in our ownership in Anandia to 19%.

2017 vs. 2016

On February 17, 2017, a dilutive event reduced our ownership in Anandia to 19.4%, an ownership percentage below the 20% ownership threshold for the use of the equity method of accounting. Accordingly, we discontinued applying the equity method of accounting for our equity investment in Anandia, effective on the date of the dilutive event. We recorded a gain on investment of $16,872 for year ended December 31, 2017 (the gain for the year ended December 31, 2017, reflects our proportionate gain through February 16, 2017). In addition, and as a result of the February 17, 2017 dilutive event, we recorded a gain in accordance with the derecognition provisions of Accounting Standards Codification 323 (“ASC 323”) in the amount of $336,834. We recorded a total gain on the investment in the amount of $346,180 for the year ended December 31, 2017 (pertains to the period up to February 17, 2017) by aggregating the Company’s share of Anandia’s gain, the gain recorded under ASC 323 and the amortization of the intangible asset represented by the difference between our equity investment in Anandia and our portion of the net assets of Anandia in the amount of $7,526. On July 25, 2017 another dilutive event occurred resulting in an additional reduction in our ownership in Anandia to 19%.

The loss on equity investment of $202,338 for the year ended December 31, 2016 consisted of (i) our 24.4% (25.0% ownership prior to a dilutive event on September 8, 2016) share of Anandia’s net loss for the year ended December 31, 2016 in the amount of $144,690, and (ii) amortization of the intangible asset represented by the difference between our equity investment in Anandia and our portion of the net assets of Anandia in the amount of $57,648.

Dividend income

2018 vs. 2017

During the period of 2018 that we owned common stock in Aurora, Aurora spun off a subsidiary into a separate publicly traded Canadian company. Non-Canadian shareholders received a one-time cash dividend and as a result of this transaction we received a cash dividend in the amount of $221,991.

2017 vs. 2016

There was no dividend income received by us during the years ended December 31, 2017 and 2016.

Interest income, net

2018 vs. 2017

Interest income, net for the ended December 31, 2018 was $1,069,036, an increase of $953,938 from interest income of $115,098 for the year ended December 31, 2017. The increase in net interest income (interest income less investment fees) was the result of net interest earned for the full year of 2018 in our short-term investment account that was originally established in December of 2017.

2017 vs. 2016

Interest income, net for the year ended December 31, 2017 was $115,098, an increase of $98,213, from interest income of $16,885 for the year ended December 31, 2016. As a result of capital raised from a registered direct offering in October of 2017, we invested excess cash in various interest-bearing short-term securities. Due to such additional investments, interest income was substantially greater during 2017 as compared to 2016.

Interest expense

2018 vs. 2017

Interest expense was $10,939 and $29,104 for the years ended December 31, 2018 and 2017, respectively. The interest expense for the year ended December 31, 2018 was derived from interest accreted on notes payable to NCSU and the University of Kentucky. Interest expense for the year ended December 31, 2017 was derived from the interest component of severance payments made on accrued severance and the accretion of interest on a note payable.

2017 vs. 2016

Interest expense decreased for the year ended December 31, 2017 to $29,104 from $37,745 for the year ended December 31, 2016. This decrease of $8,641 was due to a decrease in the interest component of severance payments, where the severance accrual had previously been recorded on a discounted basis using our incremental borrowing rate and a decrease in interest accreted on a note payable.

Net loss

2018 vs. 2017

We had a net loss for the year ended December 31, 2018 of $7,966,911 as compared to a net loss of $13,029,117 for the year ended December 31, 2017. The decrease in the net loss of $5,062,206, or 38.9%, was primarily the result of an increase in gross profit on product sales of approximately $1,607,000, an increase in realized gain on investments of approximately $14,493,000 in connection with the Anandia transaction and the sale of Aurora common shares, an increase in dividend income of approximately $222,000, an increase in warrant liability gain of approximately $206,000, and an increase in interest income, net of approximately $954,000, partially offset by an increase in operating expenses of $12,326,000, a net increase in other expense items of approximately $36,000, and a decrease in the unrealized gain on investments of approximately $58,000. The increase in operating expenses of approximately $12,326,000 was primarily the result of an increase in expenses relating to our MRTPA with the FDA for our VLNC cigarettes of approximately $9,542,000, and an increase in R&D equity-based compensation of approximately $1,663,000 (includes approximately $1,230,000 in equity-based compensation recognized due to the death of our Senior Vice President of Science and Regulatory Affairs in the second quarter of 2018).

2017 vs. 2016

We had a net loss for the year ended December 31, 2017 of $13,029,117 as compared to a net loss of $11,581,430 for the year ended December 31, 2016. The increase in the net loss of $1,447,687, or 12.5%, was primarily the result of the increase in gross loss on product sales of approximately $278,000, and an increase in operating expenses of approximately $1,634,000, partially offset by a net decrease in other expenses of approximately $464,000.

Other comprehensive income

2018 vs. 2017

We maintain an account for short-term investment securities that are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as Other comprehensive income or loss. We recorded an unrealized loss on short-term investment securities, net of tax in the amount of $21,653 and recorded

a reclassification of losses to net loss, net of tax in the amount of $43,016 resulting in other comprehensive income, net of tax in the amount of $21,363 for the year ended December 31, 2018.

2017 vs. 2016

There was no other comprehensive income or loss for the years ended December 31, 2017 or 2016.

Liquidity and Capital Resources

Working Capital

As of December 31, 2018, we had positive working capital of approximately $56.0 million compared to positive working capital of approximately $63.3 million at December 31, 2017, a decrease of approximately $7.3 million. This decrease in working capital is due a decrease in current assets of approximately $6.4 million, which is primarily due to a decrease in cash and cash equivalents and short-term investment securities of approximately $6.3 million, and an increase in current liabilities of approximately $0.9 million. We used approximately $17.8 million in operating activities during the year ended December 31, 2018, however, we were able to maintain a cash and cash equivalents, and short-term investment balance of approximately $56.4 million as a result of approximately $13.1 million in net cash proceeds from our sale of the common stock of Aurora.

We must successfully execute our business plan to increase revenue in order to achieve positive cash flows from operations to sustain adequate liquidity without requiring additional funds from capital raises and other external sources to meet minimum operating requirements. On December 30, 2016, we filed a Form S-3, universal shelf registration statement with the U.S. Securities and Exchange Commission (“SEC”) that was declared effective by the SEC on January 17, 2017. The universal shelf registration statement will allow, but not compel, the Company to raise up to $100 million of capital over a three-year period ending January 17, 2020 through a wide array of securities at times and in amounts to be determined by the Company. Following the October 2017 registered direct offering, the universal shelf registration has approximately $46 million of remaining capacity. If required, there can be no assurance that additional capital will be available on acceptable terms or at all.

Cash demands on operations

We had cash and cash equivalents and short-term investment securities at December 31, 2018 of $56,353,864. We believe this amount of cash and cash equivalents and short-term investment securities will be adequate to sustain normal operations and meet all current obligations as they come due for a number of years. During the year ended December 31, 2018, we experienced an operating loss of approximately $24,019,000 (including approximately $9,800,000 in expenses relating to our MRTPA) and used cash in operations of approximately $17,844,000. Excluding discretionary expenses relating to R&D, patent and trademark costs, contract growing of our proprietary tobacco, modified risk tobacco products and certain nonrecurring expenses relating to factory capital expenses, and investor relations and marketing costs, our monthly cash expenditures are approximately $850,000. In addition, we expect to incur an estimated additional amount of approximately $1,500,000 in expenses relating to our MRTPA by the end of the second quarter of 2019. There may be additional future costs relating to our MRTPA should the FDA require additional studies.

Net cash used in operating activities

2018 vs. 2017

In the year ended December 31, 2018, $17,844,266 of cash was used in operating activities as compared to $12,068,383 of cash used in operating activities in the year ended December 31, 2017; an increase of $5,775,883. The increase in use of cash in operations was primarily due to the increase in the cash portion of the net loss in the amount of $6,926,191, offset by a decrease in cash used from working capital components related to operations in the amount of $1,150,308, for the year ended December 31, 2018 as compared to the year ended December 31, 2017.

2017 vs. 2016

In the year ended December 31, 2017, $12,068,383 of cash was used in operating activities as compared to $9,887,580 of cash used in operating activities in the year ended December 31, 2016; an increase of $2,180,803. The increase in use of cash in operations was primarily due to the increase in the cash portion of the net loss in the amount of $1,894,341 and an increase in cash used from working capital components related to operations in the amount of $286,462, for the year ended December 31, 2017 as compared to the year ended December 31, 2016.

Net cash provided by (used in) investing activities

2018 vs. 2017

In the year ended December 31, 2018, net cash provided by investing activities was $15,145,044 as compared to $60,586,245 of cash used in investing activities during the year ended December 31, 2017. During the year ended December 31, 2018 the cash provided by investing activities consisted of net cash provided from our sale of the common stock of Aurora in the amount of $13,051,503 and net cash provided by transactions relating to our short-term investment account in the amount of $3,199,165, partially offset by cash used in the acquisition of patents and trademarks and machinery and equipment in the amount of $1,105,624. During the year ended December 31, 2017 the cash used in investing activities consisted of cash used to purchase short-term investments in the amount of $58,979,131 and cash used in the acquisition of patents and trademarks and machinery and equipment in the amount of $1,607,114.

2017 vs. 2016

In the year ended December 31, 2017, net cash used in investing activities was $60,586,245 as compared to $553,770 of cash used in investing activities during the year ended December 31, 2016. The increase in cash used in investing activities of $60,032,474 was due to the purchase of short-term investment securities of $58,979,131, an increase in the cash used for the acquisition of machinery and equipment in the amount of $959,677 and an increase in cash used in the acquisition of patents and trademarks in the amount of $93,667, for the year ended December 31, 2017 as compared to the year ended December 31, 2016.

Net cash (used in) provided by financing activities

2018 vs. 2017

During the year ended December 31, 2018, we used $355,387 in our financing activities as a result of payments on notes payable in the amount of $800,000, offset by net cash proceeds received from the exercise of stock options in the amount of $444,613.

During the year ended December 31, 2017, we generated $62,845,974 from our financing activities as a result of net cash proceeds from the exercise of warrants in the amount of $12,447,108 and net cash proceeds from the October 2017 registered direct offering in the amount of $50,732,200, partially offset by a payment on a note payable in the amount $333,334.

2017 vs. 2016

During the year ended December 31, 2017, we generated $62,845,974 from our financing activities as a result of net cash proceeds from the exercise of warrants in the amount of $12,447,108 and net cash proceeds from the October 2017 registered direct offering in the amount of $50,732,200, partially offset by a payment on a note payable in the amount $333,334.

During the year ended December 31, 2016, we generated $20,149,241 from our financing activities primarily as a result of net cash proceeds from the sale of units in three registered direct offerings in February, July and October of 2016 in the aggregate amount of $20,482,378, offset by a payment on a note payable in the amounts of $333,333.

Contractual Obligations

The following table summarizes by category our expected future cash outflows associated with contractual obligations in effect at December 31, 2018:

	Payments Due by Period				
	Total	**Year Ended December 31, 2019**	**Years Ended December 31, 2020 & 2021**	**Years Ended December 31, 2022 & 2023**	**More Than Five Years**
Notes payable	$1,600,000	$ 700,000	$ 600,000	$ 300,000	$ -
Operating lease obligations (1)	830,968	317,181	340,888	172,900	-
Consulting agreements	450,000	435,000	15,000	-	-
License fees	2,615,000	280,000	620,000	445,000	1,270,000
Tobacco growing	1,200,000	1,200,000	-	-	-
Sponsored research	806,354	806,354	-	-	-
Total	$7,502,322	$ 3,738,535	$ 1,575,888	$ 917,900	$1,270,000

(1) Include potential lease obligations due upon exercise of various lease option renewals.

Critical Accounting Policies and Estimates

Accounting principles generally accepted in the United States of America, or U.S. GAAP, require estimates and assumptions to be made that affect the reported amounts in our consolidated financial statements and accompanying notes. Some of these estimates require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations.

Short-term Investment Securities

Our short-term investment securities are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. Our short-term investment securities are carried at fair value within current assets on the Company's Consolidated Balance Sheets, with fair value based on either quoted market prices or pricing models maximizing the use of observable inputs for similar securities. We view our available-for-sale securities as available for use in current operations regardless of the stated maturity date of the security. Our investment policy states that all investment securities must have a maximum maturity of twenty-four (24) months or less and the maximum weighted maturity of the investment securities must not exceed twelve (12) months. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as other comprehensive income or loss on our Consolidated Statements of Operations and Comprehensive Loss. Realized gains and losses on short-term investment securities are recorded in the other income (expense) portion of our Consolidated Statements of Operations and Comprehensive Loss. Interest earned, net of investment fees, on the short-term investment securities are included in interest income.

Inventory

Inventories are valued at the lower of cost or net realizable value. Cost is determined using an average cost method for tobacco leaf inventory and raw materials inventory and standard cost is primarily used for finished goods inventory. Inventories are evaluated to determine whether any amounts are not recoverable based on slow moving or obsolete condition and are written off or reserved as appropriate.

Revenue Recognition

On January 1, 2018, we adopted ASC 606, Revenue from Contracts with Customers and all related amendments (the "new revenue standard") for all contracts using the modified retrospective method. Under the modified retrospective method, we were required to record a cumulative-effect adjustment to the opening balance of retained earnings on January 1, 2018. We determined that the adoption of the new revenue standard did not require a cumulative-effect adjustment. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

We recognize revenue when it satisfies a performance obligation by transferring control of the product to a customer. Our customer contracts consist of obligations to manufacture the customer's branded filtered cigars and cigarettes. For certain contracts, the performance obligation is satisfied over time as we determine, due to contract restrictions, it does not have an alternative use of the product, and it has an enforceable right to payment as the product is manufactured. We recognize revenue under those contracts at the unit price stated in the contract based on the units manufactured. The manufacturing process is completed on a daily basis and, therefore, there were no performance obligations partially satisfied at December 31, 2018. For contracts where the performance obligation is satisfied at a point in time, we recognize revenue when the product is transferred to the customer. Revenue from the sale of our products is recognized net of cash discounts, sales returns and allowances. There was no allowance for discounts or returns and allowances at December 31, 2018 and 2017.

We generally require a down payment from its customers prior to commencement of manufacturing the product. Amounts received in advance of satisfying the performance obligations are recorded as deferred revenue. Customer payment terms vary depending on the terms of each customer contract, but payment is generally due prior to product shipment or within extended credit terms up to twenty-one (21) days after shipment.

Impairment of Long-Lived Assets

We review the carrying value of our amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable. We also assess recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. Non-amortizing intangibles (e.g. trademarks) are reviewed annually for impairment. We have not recognized any impairment losses during the three-year period ended December 31, 2018.

Amortization Estimates of Intangible Assets

We generally determine amortization based on the estimated useful lives of the assets and record amortization expense on a straight-line method over such lives. The remaining life of the primary patent in each patent family is generally used to determine the estimated useful life of the related patent costs.

Valuation of our Equity Securities

We use a fair-value based method to determine compensation for all arrangements under which Company employees and others receive shares, options or warrants to purchase shares of our common stock. Equity based compensation expense is recorded over the requisite service period based on estimates of probability and time of achieving milestones and vesting. For accounting purposes, the shares will be considered issued and outstanding upon vesting.

Income taxes

We recognize deferred tax assets and liabilities for any basis differences in our assets and liabilities between tax and U.S. GAAP reporting, and for operating loss and credit carry-forwards. In light of our history of cumulative net operating losses and the uncertainty of their future utilization, we have established a valuation allowance to fully offset our net deferred tax assets as of December 31, 2018 and 2017.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. Derivative financial instruments are initially recorded at fair market value and then are revalued at each reporting date, with changes in fair value reported in the Consolidated Statements of Operations and Comprehensive Loss.

The classification of derivative instruments are evaluated at the end of each reporting period. Derivative instruments are classified in the consolidated balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the consolidated balance sheet date.

Inflation

Inflation did not have a material effect on our operating results for the years ended December 31, 2018, 2017 and 2016.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by Item 303(a)(4) of Regulation S-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to various market risks in the ordinary course of our business, which consist primarily of interest rate risk associated with our cash and cash equivalents and short-term investments and foreign exchange rate risk. Additionally, the value of our stock warrants in Aurora is primarily based on the underlying price of Aurora's common stock and fluctuations in its value could impact the fair value of the stock warrants.

Interest Rate Risk

We do not believe we are exposed to material direct interest rate risk associated with changes in interest rates other than with respect to our cash equivalents and short-term investments securities. We invest excess cash in cash equivalents and short-term investment securities primarily consisting of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, commercial paper, and certificates of deposit that earn interest based on fluctuating interest rates. We believe changes in these interest rate will not have a material impact on our financial statements. Additionally, we have no interest rate sensitive debt, and as such, are not exposed to interest rate changes relating to debt instruments.

Foreign Exchange Risk

The majority of our revenues and expenses are transacted in in U.S. dollars. A small portion of our vendors are paid in foreign currencies. The exercise price on the Aurora stock warrants is stated in Canadian dollars. Accordingly, we have some foreign currency risk with respect to such exercise price. We do not believe that fluctuations in foreign currency rates associated with these non-U.S. dollars transaction will have a material impact on our financial statements.

Equity Risk

As a result of the exercise of stock warrants in 2018 that were previously issued by us, we no longer have outstanding stock warrants that contain anti-dilution clauses. As such, we no longer carry a warrant liability on our Consolidated Balance Sheets as of December 31, 2018 and we have no corresponding equity risk pertaining to stock warrants issued by us.

The stock warrants we received from Aurora are considered equity securities and are carried at fair value using the Black-Scholes pricing model. These stock warrants are exposed to market volatilities, changes in the underlying stock price of Aurora, and interest rates. A 20% increase or decrease in the volatility factor used in the Black-Scholes model at December 31, 2018 would have the impact of increasing or decreasing the fair value of the stock warrants by approximately $505,000.

Item 8. Financial Statements and Supplementary Data.

The required financial statements and the notes thereto are contained in a separate section of this Form 10-K beginning with the page following Item 15 (Exhibits and Financial Statement Schedules, including Selected Quarterly Financial Data).

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K to ensure information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms. These disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit is accumulated and communicated to management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control - Integrated Framework (2013)*, our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

Freed Maxick CPAs, P.C., an independent registered public accounting firm, has audited the consolidated financial statements included in this Annual Report on Form 10-K and, as part of their audit, has issued a report, included herein, on the effectiveness of our internal control over financial reporting.

Our system of internal control over financial reporting was designed to provide reasonable assurance regarding the preparation and fair presentation of published financial statements in accordance with accounting principles generally accepted in the United States. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Controls over Financial Reporting

There was no change in the Company’s internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors

22nd Century Group, Inc.

Opinion on the Internal Control Over Financial Reporting

We have audited 22nd Century Group Inc. and Subsidiaries (the Company) internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets as of December 31, 2018 and 2017 and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows of the Company for each of the three years in the period ended December 31, 2018 of the Company and our report dated March 6, 2019 expressed an unqualified opinion.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting in the accompanying "Management's Annual Report on Internal Controls Over Financial Reporting".

Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities

and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Freed Maxick CPAs, P.C.
Buffalo, New York
March 6, 2019

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information concerning our executive officers, directors and corporate governance is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2019 Annual Meeting of Stockholders.

Set forth below is information regarding our directors, executive officers and key personnel as of March 6, 2019:

Name	Age	Position
Henry Sicignano, III	51	President, Chief Executive Officer and Director
John T. Brodfuehrer	61	Chief Financial Officer & Treasurer
Thomas L. James, Esq.	60	Vice President, General Counsel and Secretary
Joseph Alexander Dunn, Ph.D.	65	Director*
James W. Cornell	62	Director**
Richard M. Sanders	66	Director***
Nora B. Sullivan	61	Director****

* Dr. Dunn is currently Associate Dean for Research and Professor of Pharmaceutical Sciences at D'Youville College of Pharmacy in Buffalo, New York and has served in this capacity since April 1, 2010.

** Mr. Cornell is currently the President and Chief Executive Officer of Praxiis, LLC, an enterprise that provides support for clients in organizational change, leadership development and transactional advisory services. Mr. Cornell is also the current Manager of Larkin Center Management, LLC, a real estate development company, and has served in this capacity since October 2010.

*** Since August 2009, Mr. Sanders has served as a General Partner of Phase One Ventures, LLC, a venture capital firm which focuses on nanotechnology and biotechnology start-up opportunities in New Mexico and surrounding states.

**** Since May 18, 2015, Ms. Sullivan is currently President of Sullivan Capital Partners, LLC, a financial services company providing investment banking and consulting services to privately held businesses and publicly traded entities. Ms. Sullivan focuses on activities and related strategic planning, due diligence and integration issues.

Code of Ethics

In 2006, we adopted a Code of Ethics that applies to all our employees. A copy of our Code of Ethics is available on our website at xxiicentury.com and will be provided to any person requesting same without charge. To request a copy of our Code of Ethics, please make a written request to our General Counsel, c/o 22nd Century Group, Inc., 8560 Main Street, Suite 4, Williamsville, New York 14221. Future material amendments or waivers relating to the Code of Ethics will be disclosed on our website within four business days following the date of such amendment or waiver.

Item 11. Executive Compensation.

Information is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2019 Annual Meeting of Stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2019 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2019 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services.

Information is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2019 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements

(b) Financial Statement Schedules

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors

22nd Century Group, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 22nd Century Group, Inc. and Subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the schedule in item 15 (b) (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal controls over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework* issued by Committee of Sponsoring Organizations of the Treadway Committee in 2013, and our report dated March 6, 2019 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Freed Maxick, CPAs, P.C.

We have served as the Company's auditor since 2011.

Buffalo, New York

March 6, 2019

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31,

	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$604,925	$3,659,534
Short-term investment securities	55,748,939	58,975,513
Accounts receivable	871,293	957,066
Inventory, net	3,043,949	3,282,537
Prepaid expenses and other assets	928,420	746,805
Total current assets	61,197,526	67,621,455
Machinery and equipment, net	3,260,748	3,316,047
Other assets:		
Intangible assets, net	9,751,504	7,435,411
Investment	3,092,358	1,366,493
Total other assets	12,843,862	8,801,904
Total assets	$77,302,136	$79,739,406
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable	$689,148	$-
Accounts payable	2,574,840	2,080,691
Accrued expenses	1,826,481	1,987,675
Deferred revenue	83,075	28,350
Warrant liability	-	216,490
Total current liabilities	5,173,544	4,313,206
Long-term portion of notes payable	848,217	-
Total liabilities	6,021,761	4,313,206
Commitments and contingencies (Note 14)	-	-
Shareholders' equity		
10,000,000 preferred shares, $.00001 par value		
300,000,000 common shares, $.00001 par value		
Capital stock issued and outstanding:		
124,642,593 common shares (123,569,367 at December 31, 2017)	1,246	1,236
Capital in excess of par value	170,392,249	166,592,536
Accumulated other comprehensive income	21,363	-

Accumulated deficit	(99,134,483)	(91,167,572)
Total shareholders' equity	71,280,375	75,426,200
Total liabilities and shareholders' equity	$77,302,136	$79,739,406

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
Years Ended December 31,

	2018	2017	2016
Revenue:			
Sale of products, net	$26,426,347	$16,600,244	$12,279,979
Cost of goods sold (exclusive of depreciation shown separately below):			
Products	25,527,360	17,308,156	12,709,678
Gross profit (loss)	898,987	(707,912)	(429,699)
Operating expenses:			
Research and development (including equity-based compensation of $1,846,116, $182,854 and $136,946, respectively)	14,989,746	3,366,468	2,340,958
General and administrative (including equity-based compensation of $1,167,859, $625,202 and $718,610, respectively)	7,658,119	7,116,535	6,193,269
Sales and marketing (including equity-based compensation of $173,356 $133,594 and $55,826, respectively)	927,414	1,161,952	1,581,741
Depreciation	522,695	353,435	326,124
Amortization	819,640	593,562	516,056
	24,917,614	12,591,952	10,958,148
Operating loss	(24,018,627)	(13,299,864)	(11,387,847)
Other income (expense):			
Warrant liability gain (loss), net	48,711	(157,809)	29,615
Realized loss on short-term investment securities	(54,451)	-	-
Realized gain on investments	14,492,968	-	-
Unrealized gain (loss) on investments	284,400	342,562	(202,338)
Dividend income	221,991	-	-
Interest income, net	1,069,036	115,098	16,885
Interest expense	(10,939)	(29,104)	(37,745)
	16,051,716	270,747	(193,583)
Loss before income taxes	(7,966,911)	(13,029,117)	(11,581,430)
Income taxes	-	-	-
Net loss	$(7,966,911)	$(13,029,117)	$(11,581,430)
Other comprehensive income:			
	(21,653)	-	-

Unrealized loss on short-term investment securities, net of tax of ($5,756) in 2018	43,016	-	-
Reclassification of losses to net loss, net of tax of $11,435 in 2018	21,363	-	-
Comprehensive loss	$(7,945,548)	$(13,029,117)	$(11,581,430)
Net loss per common share - basic and diluted	$(0.06)	$(0.13)	$(0.15)
Common shares used in basic and diluted earnings per share calculation	124,298,981	101,161,380	79,842,773

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
Years Ended December 31, 2018, 2017, and 2016

	Common Shares Outstanding	Par Value of Common Shares	Capital in Excess of Par Value	Accumulated Other Comprehensive Income	Accumulated Deficit	Shareholders' Equity
Balance at December 31, 2015	71,006,844	710	78,284,815	-	$(66,557,025)	$11,728,500
Stock issued in February 2016 registered direct offering, net	5,000,000	50	5,091,741	-	-	5,091,791
Stock issued in July 2016 registered direct offering, net	6,172,840	62	4,682,702	-	-	4,682,764
Stock issued in October 2016 registered direct offering, net	8,500,000	85	10,707,738	-	-	10,707,823
Reclassification of warrant liability to capital in excess of par	-	-	2,810,000	-	-	2,810,000
Equity-based compensation	15,811	-	894,715	-	-	894,715
Stock issued in connection with warrant exercise	2,618	-	196	-	-	196
Net loss	-	-	-	-	(11,581,430)	(11,581,430)
Balance at December 31, 2016	90,698,113	907	102,471,907	-	(78,138,455)	24,334,359
Equity-based compensation	-	-	941,650	-	-	941,650
Stock issued in connection with warrant exercises	12,249,327	122	12,446,986	-	-	12,447,108
Stock issued in connection with stock option exercises	51,927	1	(1)	-	-	-

Stock issued in October 2017 registered direct offering, net	20,570,000	206	50,731,994	-	-	50,732,200
Net loss	-	-	-	-	(13,029,117)	(13,029,117)
Balance at December 31, 2017	123,569,367	1,236	166,592,536	-	(91,167,572)	75,426,200
Stock issued in connection with warrant exercises	490,012	5	(5)	-	-	-
Stock issued in connection with option exercises	583,214	5	444,608	-	-	444,613
Equity-based compensation	-	-	3,187,331	-	-	3,187,331
Reclassification of warrant liability to capital in excess of par	-	-	167,779	-	-	167,779
Unrealized loss on short-term investment securities, net of tax	-	-	-	(21,653)	-	(21,653)
Reclassification of losses to net loss, net of tax				43,016		43,016
Net loss	-	-	-	-	(7,966,911)	$(7,966,911)
Balance at December 31, 2018	124,642,593	$ 1,246	$170,392,249	$ 21,363	$(99,134,483)	$71,280,375

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31,

	2018	2017	2016
Cash flows from operating activities:			
Net loss	$(7,966,911)	$(13,029,117)	$(11,581,430)
Adjustments to reconcile net loss to cash used in operating activities:			
Amortization and depreciation	1,199,794	848,974	744,157
Amortization of license fees	142,541	98,022	98,022
Unrealized (gain) loss on investments	(284,400)	(342,562)	202,338
Realized gain on the sale of investments	(14,492,968)	-	-
Realized loss on short-term investment securities	54,451	-	-
Warrant liability (gain) loss	(48,711)	157,809	(29,615)
Accretion of interest on note payable and accrued severance	10,939	29,104	37,745
Equity-based employee compensation expense	3,187,331	941,650	880,509
Equity-based payments for outside services	-	-	30,873
Decrease in allowance for doubtful accounts	-	(10,000)	-
(Decrease) increase in inventory reserve	(95,000)	(60,623)	145,000
(Increase) decrease in assets:			
Accounts receivable	85,773	(906,074)	10,238
Inventory	333,588	(129,228)	(531,356)
Prepaid expenses and other assets	(181,615)	(551,236)	497,856
Increase (decrease) in liabilities:			
Accounts payable	323,070	473,804	(136,297)
Accrued expenses	(166,873)	586,109	(21,965)
Accrued severance	-	(203,365)	(233,655)
Deferred revenue	54,725	28,350	
Net cash used in operating activities	(17,844,266)	(12,068,383)	(9,887,580)
Cash flows from investing activities:			
Acquisition of patents and trademarks	(656,985)	(450,208)	(356,541)
Acquisition of machinery and equipment	(448,639)	(1,156,906)	(197,229)
Proceeds from the sale of investments	13,051,503	-	-
Sales and maturities of short-term investment securities	37,415,159	-	-
Purchase of short-term investment securities	(34,215,994)	(58,979,131)	-
Net cash provided by (used in) investing activities	15,145,044	(60,586,245)	(553,770)
Cash flows from financing activities:			
Payment on notes payable	(800,000)	(333,334)	(333,333)
Proceeds from exercise of stock options	444,613	-	-
Net proceeds from exercise of stock warrants	-	12,447,108	196
Net proceeds from October 2017 registered direct offering	-	50,732,200	-
Net proceeds from October 2016 registered direct offering	-	-	10,707,823
Net proceeds from July 2016 registered direct offering	-	-	4,682,764
Net proceeds from February 2016 registered direct offering	-	-	5,091,791
Net cash (used in) provided by financing activities	(355,387)	62,845,974	20,149,241

Net (decrease) increase in cash and cash equivalents	(3,054,609)	(9,808,654)	9,707,891
Cash and cash equivalents - January 1,	3,659,534	13,468,188	3,760,297
Cash and cash equivalents - December 31,	$604,925	$3,659,534	$13,468,188
Supplemental disclosures of cash flow information:			
Net cash paid for:			
Cash paid during the period for interest	$-	$29,104	$37,745
Cash paid during the period for income taxes	$-	$-	$-
Non-cash investing and financing activities:			
Patent and trademark additions included in accounts payable	$152,322	$188,818	$185,341
Machinery and equipment additions included in accounts payable	$18,757	$77,913	$7,765
Unrealized gain on short-term investment securities	$27,042	$-	$-
Licenses acquired with notes payable	$2,326,427	$-	$-
Reclassification of warrant liability to capital in excess of par	$167,779	$-	$2,810,000

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2018

NOTE 1. - NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation - The accompanying consolidated financial statements include the accounts of 22nd Century Group, Inc. ("22nd Century Group"), its three wholly-owned subsidiaries, 22nd Century Limited, LLC ("22nd Century Ltd"), NASCO Products, LLC ("NASCO"), and Botanical Genetics, LLC ("Botanical Genetics"), and two wholly-owned subsidiaries of 22nd Century Ltd, Goodrich Tobacco Company, LLC ("Goodrich Tobacco") and Heracles Pharmaceuticals, LLC ("Heracles Pharma", formerly known as Hercules Pharmaceuticals, LLC) (collectively, the "Company"). All intercompany accounts and transactions have been eliminated.

Nature of Business - 22nd Century Ltd is a plant biotechnology company specializing in technology that allows (i) for the level of nicotine and other nicotinic alkaloids in tobacco plants to be decreased or increased through genetic engineering and plant breeding and (ii) the levels of cannabinoids in hemp plants to be decreased or increased through genetic engineering and plant breeding. Goodrich Tobacco and Heracles Pharma are business units for the Company's (i) potential modified risk tobacco products and (ii) smoking cessation product, respectively. NASCO is a federally licensed tobacco products manufacturer, a subsequent participating member under the tobacco Master Settlement Agreement ("MSA") between the tobacco industry and the settling states under the MSA and operates the Company's tobacco products manufacturing business in North Carolina. Botanical Genetics is a wholly-owned subsidiary of 22nd Century Group and was incorporated to facilitate the original investment in Anandia Laboratories, Inc., more fully described in Note 9, and performs research and development related to the Company's hemp business.

Reclassifications - Certain items in the 2017 and 2016 financial statements have been reclassified to conform to the 2018 classification.

Preferred stock authorized - The Company is authorized to issue "blank check" preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock.

Concentration of Credit Risk **-** The Company maintains its cash in bank deposits which, at times, may exceed federally insured limits. The Company has not experienced any losses on such accounts. The Company believes it is not exposed to any significant risk with respect to its cash accounts.

Cash and cash equivalents – The Company considers all highly liquid investments with maturities of three months or less at the date of acquisition to be cash equivalents. Cash equivalents included in this category consist of a bank certificate of deposit in the amount of $0 and $3,000,000 at December 31, 2018 and 2017, respectively. Cash and cash equivalents are stated at cost, which approximates fair value.

Short-term investment securities – The Company's short-term investment securities are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. The Company's short-term investment securities are carried at fair value within current assets on the Company's Consolidated Balance Sheets. The Company views its available-for-sale securities as available for use in current operations regardless of the stated maturity date of the security. The Company's investment policy states that all investment securities must have a maximum maturity of twenty-four (24) months or less and the maximum weighted maturity of the investment securities must not exceed twelve (12) months. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as other comprehensive income or loss on the Company's Consolidated Statements of Operations and Comprehensive Loss. Realized gains and losses on short-term investment securities are recorded in the other income (expense) portion of the Company's Consolidated Statements of Operations and Comprehensive Loss. Interest earned, net of investment fees, on the short-term investment securities are included in interest income.

Accounts receivable - The Company periodically reviews aged account balances for collectability. The Company established an allowance for doubtful accounts of $0 at both December 31, 2018 and December 31, 2017.

Inventory - Inventories are valued at the lower of cost or net realizable value. Cost is determined using an average cost method for tobacco leaf inventory and raw materials inventory and standard cost is primarily used for finished goods inventory. Inventories are evaluated to determine whether any amounts are not recoverable based on slow moving or obsolete condition and are written off or reserved as appropriate. Inventories at December 31, 2018 and December 31, 2017 consisted of the following:

	December 31, 2018	December 31, 2017
Inventory - tobacco leaf	$ 1,556,581	$ 1,552,474
Inventory - finished goods		
Cigarettes and filtered cigars	156,702	289,004
Inventory - raw materials		
Cigarette and filtered cigar components	1,430,666	1,636,059
	3,143,949	3,477,537
Less: inventory reserve	100,000	195,000
	$ 3,043,949	$ 3,282,537

Machinery and equipment – Machinery and equipment are recorded at their acquisition cost and depreciated on a straight-line basis over their estimated useful lives ranging from 3 to 10 years. Depreciation commences when the asset is placed in service.

Intangible Assets **-** Intangible assets are recorded at cost and consist primarily of (1) expenditures incurred with third-parties related to the processing of patent claims and trademarks with government authorities, as well as costs to acquire patent rights from third-parties, (2) license fees paid for third-party intellectual property, (3) costs to become a signatory under the tobacco MSA, and (4) license fees paid to acquire a predicate cigarette brand. The amounts capitalized relate to intellectual property that the Company owns or to which it has exclusive rights. The Company's intellectual property capitalized costs are amortized using the straight-line method over the remaining statutory life of the granted patent assets in each of the Company's patent families, which have estimated expiration dates ranging from 2019 to 2036. Periodic maintenance or renewal fees are expensed as incurred. Annual minimum license fees are charged to expense. License fees paid for third-party intellectual property are amortized on a straight-line basis over the last to expire patents, which patent expiration dates are expected to range from 2019 through 2036. The Company believes costs associated with becoming a signatory to the MSA and acquiring a predicate cigarette brand have an indefinite life and as such, no amortization is taken. Total intangible assets at December 31, 2018 and 2017 consisted of the following:

	December 31, 2018	December 31, 2017
Intangible assets, net		
Patent and trademark costs	$ 7,136,774	$ 6,327,467
Less: accumulated amortization	3,194,565	2,517,465
Patent and trademark costs, net	3,942,209	3,810,002
License fees, net (see Note 14)	3,776,426	1,450,000
Less: accumulated amortization	469,131	326,591
License fees, net	3,307,295	1,123,409
MSA signatory costs	2,202,000	2,202,000
License fee for predicate cigarette brand	300,000	300,000
	$ 9,751,504	$ 7,435,411

Amortization expense relating to the above intangible assets for the years ended December 31, 2018, 2017, and 2016 amounted to $819,640, $593,562 and $516,056, respectively.

The estimated annual average amortization expense for the next five years is approximately $445,000 for patent costs and $238,000 for license fees.

Impairment of Long-Lived Assets - The Company reviews the carrying value of its amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable. The Company assesses recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. There was no impairment loss recorded during the years ended December 31, 2018, 2017, or 2016.

Income Taxes - The Company recognizes deferred tax assets and liabilities for any basis differences in its assets and liabilities between tax and U.S. GAAP reporting, and for operating loss and credit carry-forwards.

Considering the Company's history of cumulative net operating losses and the uncertainty of their future utilization, the Company has established a valuation allowance to fully offset its net deferred tax assets as of December 31, 2018 and 2017.

The Company's federal and state tax returns for the years ended December 31, 2015 through December 31, 2017 are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2018.

The Tax Cuts and Jobs Act of 2017 (the "TCJA") was signed into law on December 22, 2017. The TCJA includes significant changes to the U.S. corporate income tax system, including a Federal corporate rate reduction from 35% to 21%. In accordance with a question and answer document issued by the Financial Accounting Standards Board ("FASB") staff on January 18, 2018, the Company is applying the guidance in Securities and Exchange Commission Staff Accounting Bulletin ("SAB") 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, which provides guidance on applying FASB Accounting Standards Codification ("ASC") 740, Income Taxes, if the accounting for certain income tax effects of the TCJA are incomplete by the time the financial statements are issued for a reporting period. Specifically, SAB 118 permits companies to use reasonable estimates and provisional amoun