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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

Exchange Act of 1934

For the fiscal year ended December 31, 2017

or

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

Securities Exchange Act of 1934

Commission File Number: 001-36338

22nd Century Group, Inc.

(Exact name of registrant as specified in its charter)

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

of incorporation) Identification No.)

8560 Main Street, Williamsville, New York 14221

(Address of principal executive offices)

(716) 270-1523

(Registrant's telephone number, including area code)

9530 Main Street, Clarence, New York 14031

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

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

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

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

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

Yes ¨ No x

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

Yes ¨ No x

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

Yes x No ¨

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

Yes x No ¨

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

22nd Century Group, Inc.

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Cautionary Note Regarding Forward-Looking Statements

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

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

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

· Our ability to comply with government regulations;

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

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

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

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

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

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

PART I

Item 1. Business.

Background

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

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

Overview

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

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

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

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

We currently are primarily involved in the following activities:

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

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

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

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

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

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

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

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

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

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

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

Tobacco

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Products

BRAND A Very Low Nicotine Cigarettes

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

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

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

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

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

SPECTRUM® Government Research Cigarettes

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

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

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

X-22 Prescription Smoking Cessation Aid

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

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

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

BRAND B Low-Tar-to-Nicotine Ratio Cigarettes

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

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

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

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

RED SUN and MAGIC Cigarettes

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

Hemp

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

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

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

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

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

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

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

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

Intellectual Property

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

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

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

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

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

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

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

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

Licensing

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

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

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

Research and Development

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

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

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

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

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

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

MSA Membership

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

Manufacturing

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

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

Our strategic 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 VLN cigarette brands in the event they comply with the FDA mandate for reduced nicotine in cigarettes, as well as our *BRAND A* Very Low Nicotine cigarettes if the FDA approves our MRTPA and PMTA filings for *BRAND A*.

Sources of Raw Materials

We obtain a large portion of our tobacco leaf from farmers in multiple states in the United States that 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 VLN tobacco in the United States in the event the FDA mandates that all combustible cigarettes contain only minimally or non-addictive levels of nicotine, 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 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 using 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. The FDA will be 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* and in licensing our proprietary technology and/or tobaccos to larger competitors.

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 that (i) reduce exposure to tobacco toxins and (ii) are reasonably likely to pose lower health risks as compared to conventional cigarettes ("Modified Risk Cigarettes"). On March 30, 2012, the FDA issued Modified Risk Tobacco Product Applications Draft Guidance. We believe that our *BRAND A* Very Low Nicotine cigarettes will qualify as Modified Risk Cigarettes. In addition, the Tobacco Control Act allows the FDA to mandate the use of reduced risk technologies in conventional tobacco products and cigarettes which could create opportunities for us to license our proprietary technology and/or our tobaccos to larger competitors.

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* as a Modified Risk Cigarette.

Hemp

The Agricultural Act of 2014, which became law on February 7, 2014, is also known as the Farm Bill. Section 7606 of this federal statute, titled "Legitimacy of Industrial Hemp Research," gave authorization to state departments of agriculture and institutions of higher learning in states that have legalized hemp cultivation to grow the crop for research and pilot programs. Since the implementation of the Farm Bill, more than 30 states have passed laws regarding industrial hemp.

On August 12, 2016, the U.S. Department of Agriculture ("USDA") publicly issued, with the concurrence of the U.S. Drug Enforcement Administration ("DEA") and the FDA, the following *Statement of Principles on Industrial Hemp* to inform the public how federal law applies to activities associated with industrial hemp that is grown and cultivated in accordance with Section 7606 of the Agricultural Act of 2014:

Section 7606 of the Agricultural Act of 2014 legalized the growing and cultivating of industrial hemp for research purposes in States where such growth and cultivation is legal under State law, notwithstanding existing federal statutes that would otherwise criminalize such conduct. The statutorily sanctioned conduct, however, was limited to growth and cultivation by an institution of higher education or State department of agriculture for purposes of agricultural or other academic research or under the auspices of a State agricultural pilot program for the growth, cultivation, or marketing of industrial hemp.

Section 7606 authorized State departments of agriculture to promulgate regulations to carry out these pilot programs but did not provide a specific delegation to the USDA or any other agency to implement the program. As well, the statute left open many questions regarding the continuing application of federal drug control statutes to the growth, cultivation, manufacture, and distribution of industrial hemp products, as well as the extent to which growth by private parties and sale of industrial hemp products are permissible. Section 7606 did not remove industrial hemp from the controlled substances list. Therefore, federal law continues to restrict hemp-related activities, to the extent that those activities have not been legalized under section 7606.

USDA, having consulted with and received concurrence from the DEA and the FDA, therefore, is issuing this statement of principles to inform the public regarding how federal law applies to activities involving industrial hemp so that individuals, institutions, and States that wish to participate in industrial hemp agricultural pilot programs can do so in accordance with Federal law.

- The growth and cultivation of industrial hemp may only take place in accordance with an agricultural pilot program to study the growth, cultivation, or marketing of industrial hemp established by a State department of agriculture or State agency responsible for agriculture in a State where the production of industrial hemp is otherwise legal under State law.

The State agricultural pilot program must provide for State registration and certification of sites used for growing or cultivating industrial hemp. Although registration and certification is not further defined, it is recommended that such registration should include the name of the authorized manufacturer, the period of licensure or other time period during which such person is authorized by the State to manufacture industrial hemp, and the location, including Global Positioning System coordinates, where such person is authorized to manufacture industrial hemp.

Only State departments of agriculture, and persons licensed, registered, or otherwise authorized by them to conduct research under an agricultural pilot program in accordance with Section 7606, and institutions of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), or persons employed by or under a production contract or lease with them to conduct such research, may grow or cultivate industrial hemp as part of the agricultural pilot program.

The term “industrial hemp” includes the plant *Cannabis sativa* L. and any part or derivative of such plant, including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed) with a tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis. The term “tetrahydrocannabinols” includes all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols.

For purposes of marketing research by institutions of higher education or State departments of agriculture (including distribution of marketing materials), but not for the purpose of general commercial activity, industrial hemp products may be sold in a State with an agricultural pilot program or among States with agricultural pilot programs but may not be sold in States where such sale is prohibited. Industrial hemp plants and seeds may not be transported across State lines.

Section 7606 specifically authorized certain entities to “grow or cultivate” industrial hemp but did not eliminate the requirement under the Controlled Substances Import and Export Act that the importation of viable cannabis seeds must be carried out by persons registered with the DEA to do so. In addition, any USDA phytosanitary requirements that normally would apply to the importation of plant material will apply to the importation of industrial hemp seed.

Section 7606 did not amend the Federal Food, Drug, and Cosmetic Act. For example, section 7606 did not alter the approval process for new drug applications, the requirements for the conduct of clinical or nonclinical research, the oversight of marketing claims, or any other authorities of the FDA as they are set forth in that Act.

The Federal Government does not construe Section 7606 to alter the requirements of the Controlled Substances Act (CSA) that apply to the manufacture, distribution, and dispensing of drug products containing controlled substances. Manufacturers, distributors, dispensers of drug products derived from cannabis plants, as well as those conducting research with such drug products, must continue to adhere to the CSA requirements.

- Institutions of higher education and other participants authorized to carry out agricultural pilot programs under Section 7606 may be able to participate in USDA research or other programs to the extent otherwise eligible for participation in those programs.

Competition

We are not aware of any competition to our Company in the creation and provision of tobacco research cigarettes with Very Low Nicotine content for use in independent clinical studies. Since 2011, we have provided more than 24 million research cigarettes containing our proprietary tobaccos, including our Very Low Nicotine content 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 $100 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 tobacco research cigarette with Very Low Nicotine content.

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 VLN tobacco has been the subject of numerous completed and on-going, independent clinical studies paid for by agencies of the federal government, we are investigating the potential use of our VLN tobacco in our own products that will be intended to comply with the new FDA regulations, as well as we are investigating the potential license of the use of our VLN tobacco by third-parties. 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 VLN tobacco outside of the United States. We are not aware of any competition to our Company and our VLN tobacco inside or outside of the United States.

As of December 31, 2017, we no longer sell any commercial cigarettes in the United States. During the year of 2017, we had not yet ceased the selling of our *RED SUN* brand and 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 MRTP application for *BRAND A*, 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, 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 23, 2018, we employed seventy-nine (79) 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, Williamsville, New York 14221 (our former address was 9530 Main Street, Clarence, New York 14031). 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 $13.0 million, $11.6 million and $11.0 million during the years ended December 31, 2017, 2016 and 2015, 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 $12.1 million of negative cash flow from operations during the year ended December 31, 2017. 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 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. 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 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 more costly 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 2017, we grew from nine (9) employees to seventy-nine (79) 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 and Novartis International AG. 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

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· 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, 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, 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, Dr. James Swauger, our Senior Vice President of Science and Regulatory Affairs, and Thomas L. James, our Vice President, General Counsel and Secretary. 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 less than 0.3% THC content and is legal under federal and 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 any 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.

As of December 31, 2017, there were (i) 34 states in the United States and the District of Columbia that have legalized hemp, (ii) 29 states and the District of Columbia that allow their citizens to use medical cannabis/marijuana and, (iii) 9 states and the District of Columbia that have legalized cannabis/marijuana for adult recreational use. Many other states are considering similar legislation. Conversely, under the federal Controlled Substance Act (the "CSA"), the policies and regulations of the federal government and its agencies are that cannabis/marijuana has no medical benefit and a range of activities are prohibited, including cultivation, possession, personal use, and interstate distribution of cannabis/marijuana. In the event the U.S. Department of Justice (the "DOJ") begins strict enforcement of the CSA in states that have laws legalizing medical and/or adult recreational cannabis/marijuana, there may be a direct and adverse impact to any future 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 through Anandia Laboratories in Canada and through sponsored research on hemp in Virginia through the University of Virginia ("UVA"), in each case with Anandia and UVA 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.

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.

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.

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 judge ruled that these warnings are unconstitutional. If these graphic health warnings are implemented in the future, all cigarettes manufactured for sale or distribution in the United States will need to include these new graphic health warnings on their packages. Any reduction in the number of smokers will probably reduce the demand for the products manufactured by our factory 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 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 not 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.

Our patent protection relating to the QPT gene expires in 2018. The expiration of the QPT patent family will 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 and/or how long or short in time such efforts will entail. 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 will expire in 2023.

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 prices for our common stock have 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;
- additions or departures of key personnel;
- third-party sales of large blocks of our common stock;
- 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. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

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, Williamsville, New York 14221 (our former principal office was located at 9530 Main Street, Clarance, New York 14031). On October 4, 2017, we entered a new lease for new office space in Williamsville, New York with an initial three-year term and with a monthly lease payment of $6,375. Future minimum annual lease payments under the new office lease will be approximately $64,000, $76,000 and $76,000 for the years ended December 31, 2018, 2019 and 2020, respectively.

On May 1, 2016, we entered into a sublease for laboratory space in Buffalo, New York. The sublease calls 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, 2018 and 2019 will be approximately $63,000 and $34,000, respectively.

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, 2017, 2016 and 2015 amounted to approximately $156,000, $146,000 and $127,000, respectively. The future minimum annual lease payments if we exercise each of the additional extensions are approximately as follows:

Year ended December 31, 2018 - $169,000
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, expires 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.

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 January 26, 2018, the SDNY Court entered a case management order that such discovery be completed by May 18, 2018 and scheduling a pretrial conference for May 23, 2018.

We believe 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.

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, 2017, there were 98 holders of record of shares of our common stock. The following table sets forth, for the quarters indicated, the high and low sales prices per share of our common stock, as derived from quotations provided by the NYSE American.

Quarter Ended	High	Low
December 31, 2017	$3.50	$1.95
September 30, 2017	$3.34	$1.33
June 30, 2017	$2.00	$1.13
March 31, 2017	$1.35	$0.81
December 31, 2016	$1.71	$0.90
September 30, 2016	$1.48	$0.79
June 30, 2016	$0.98	$0.73
March 31, 2016	$1.44	$0.71

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

During November of 2017, we issued 5,250 shares of common stock to an investor that exercised 5,250 warrants for cash to purchase shares of our common stock.

During the first quarter of 2018, we issued 426,180 shares of common stock to various investors from the cashless exercise of 700,148 warrants to purchase shares of our common stock.

The shares were offered and sold pursuant to exemptions from the registration requirements under Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

Shares authorized for issuance under equity compensation plans

On April 12, 2014, our stockholders 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 stockholders 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, 2017:

	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	7,656,691	$ 1.31	2,933,956	
Equity compensation plans not approved by security holders	-	N/A	-	
Total	7,656,691		2,933,956	(1)

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

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, 2012 through December 31, 2017. The comparison of total return assumes that a fixed investment of $100 was invested on December 31, 2012 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, 2017 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, as set forth in Item 7 of this Annual Report on Form 10-K.

	Years Ended December 31,				
	2017	2016	2015	2014	2013
Consolidated Statements of Operations data:					
Revenue	$16,600,244	$12,279,979	$8,521,998	$528,991	$7,278,383
Gross (loss) profit	$(707,912)	$(429,699)	$(580,562)	$30,555	$6,816,712
Operating expenses (1)	$11,644,955	$10,115,968	$10,689,010	$11,302,623	$4,859,976
Equity based compensation included in operating expenses	$941,650	$911,382	$3,585,540	$4,524,468	$2,361,962
Operating (loss) profit	$(13,299,864)	$(11,584,097)	$(12,043,883)	$(11,767,364)	$1,812,447
Warrant liability (loss) gain - net (2)	$(157,809)	$29,615	$144,550	$(3,827,794)	$(27,339,024)
Net loss	$(13,029,117)	$(11,581,430)	$(11,031,931)	$(15,595,358)	$(26,153,158)
Loss per common share - basic and diluted	$(0.13)	$(0.15)	$(0.16)	$(0.26)	$(0.60)
Common shares used in basic earnings per share calculation	101,161,380	79,842,773	68,143,284	59,993,413	43,635,182
Consolidated Balance Sheet data:					
Working capital	$63,308,249	$13,548,118	$3,991,828	$8,033,399	$6,759,781
Total assets	$79,739,406	$27,642,357	$18,370,512	$21,953,515	$12,286,744
Total debt	$-	$307,938	$616,520	$1,100,655	$174,925
Total shareholders' equity (deficit)	$75,426,200	$24,334,359	$11,728,500	$15,219,737	$7,522,888
Other data:					
Net cash used in (provided by) operating activities	$(12,068,383)	$(9,887,580)	$(7,321,811)	$(6,582,730)	$3,855,834
Net cash used in investing activities (3)	$(60,586,245)	$(553,770)	$(450,661)	$(2,707,992)	$(3,742,789)
Net cash provided by financing activities	$62,845,974	$20,149,241	$5,130,082	$9,862,810	$5,717,366
Acquisition of patents and trademarks (4)	$450,208	$356,541	$413,180	$726,989	$290,336
Depreciation	$353,435	$326,124	$319,699	$230,012	$3,028
Amortization (5)	$593,562	$516,056	$454,612	$265,284	$141,261

(1) Operating expenses include costs for research and development, general and administrative, pre-manufacturing facility, and sales and marketing, and exclude depreciation and amortization expense.

(2) Warrant liability (loss) gain - net also includes the warrant amendment inducement expense of $144,548 and $3,736,313 for the years ended December 31, 2014 and 2013, respectively.

(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 for all five years presented and includes the amortization of patent costs and license fees for the years ended December 31, 2017, 2016, 2015 and 2014.

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 cigarettes to be marketed in the United States as "less addictive" and/or containing 95% less nicotine than conventional tobacco cigarettes;
- Seeking multiple, substantial licensing agreements for our tobacco technology and/or our proprietary tobaccos;
- Continuing to produce *SPECTRUM*® research cigarettes for the National Institute on Drug Abuse ("NIDA"), which is part of the National Institutes of Health ("NIH"), for use in independent clinical studies;
- Continuing to research and develop other novel tobacco plant varieties;
- Continuing to explore opportunities outside of the United States for the use of our Very Low Nicotine tobacco in potential over-the-counter cigarettes, such as *BRAND A*, or in a potential prescription-based, smoking cessation aid, such as *X-22*, in foreign countries that 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 2017, our accomplishments and notable events include:

On October 6, 2017, we announced that Dr. Dorothy Hatsukami revealed preliminary findings of a 1,250-patient, 20-week study that employed our *SPECTRUM* research cigarettes to compare smokers who were assigned to: (i) an immediate reduction to Very Low Nicotine cigarettes; (ii) gradual reduction in reduced nicotine content cigarettes; or (iii) normal nicotine content cigarettes. The details of this Phase III study are under peer review prior to publication, but on October 5, 2017, at the 5th Annual Conference on Tobacco Science at the Vermont Center on Behavior and Health, Dr. Hatsukami publicly stated 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 the there was a “greater likelihood of more rapid smoking cessation” with the immediate approach to nicotine reduction. We provided all the research cigarettes used in this Phase III study.

On October 9, 2017, we announced that we entered into an agreement with institutional investors to receive approximately $54 million in gross proceeds in a registered direct offering through the sale of 20.57 million shares of common stock at a price of $2.625 per share. This no-warrant financing was the largest capital raise in our history and increased our cash balance to more than $60 million.

On October 19, 2017, we announced that the University of Virginia ("UVA") completed its first successful harvest of the Company's hemp plants and identified several promising hemp varieties that could form the foundation for commercial hemp production throughout the legacy tobacco belt region 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. 22nd Century and UVA will use the most promising varieties for expanded hemp plantings in 2018. We are also working with UVA on the development of high-value medicinal cannabinoid varieties of hemp and specialized cannabinoid extraction processes for use in human therapeutics.

On November 2, 2017, we announced the hiring of James E. Swauger, Ph.D., as our Senior Vice President of Science and Regulatory Affairs. Dr. Swauger was previously the leader of the scientific and regulatory functions at Reynolds American Inc. ("Reynolds"). Dr. Swauger's career with Reynolds spanned 23 years and included management positions in science and regulatory affairs. From 2008 through 2016, while serving as the Vice President of Regulatory Oversight, Dr. Swauger managed the creation, submission and oversight of numerous scientific applications and regulatory filings with the FDA and other federal, state, and local regulatory agencies. Dr. Swauger received his Ph.D. Degree in Biochemical Toxicology from The Johns Hopkins University in 1990 and his Bachelor of Science Degree in Toxicology (Magna cum laude) from Northeastern University in 1985. Dr. Swauger's primary responsibilities are to lead and oversee our scientific and regulatory affairs, plant biotechnology, research and development, and external scientific activities, including re-submitting to the FDA our Modified Risk Tobacco Product application for *BRAND A* Very Low Nicotine cigarettes.

On November 30, 2017, we announced that we had shipped 2.4 million *SPECTRUM*® research cigarettes for NIDA, which is part of NIH. As a subcontractor under federal government contracts, we have supplied proprietary *SPECTRUM*® research cigarettes for NIDA since 2011. 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.

On December 4, 2017, we announced the hiring of Juan Sanchez Tamburrino, Ph.D., as our Vice President of Research and Development. Dr. Tamburrino was previously the head of the Plant Biotechnology Division of British American Tobacco (NYSE: BTI). Dr. Tamburrino earned his Ph.D. Degree in molecular biology and genetics at the Weill Cornell Graduate School of Medical Sciences at Cornell University, a partnership program with the Sloan Kettering Cancer Research Institute. After completing six years of post-doctoral research in plant biology at the Rockefeller University in New York, Dr. Tamburrino served as an Associate Professor at Universidad Tarapacá in

Chile before becoming the Research Manager at Pioneer Hi-Bred International (a DuPont company now known as DuPont Pioneer). Dr. Tamburrino will be an integral part of our scientific and regulatory team working on our resubmission to the FDA of our Modified Risk Tobacco Product application for *BRAND A* Very Low Nicotine cigarettes, and our continuing research and development of improved Very Low Nicotine tobacco plants.

Results of Operations

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016 and Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

Revenue - Sale of products, net

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.

2016 vs. 2015

We realized net revenue from the sale of products in the amount of $12,279,979 during the year ended December 31, 2016, as compared to net revenues of $8,521,998 during the year ended December 31, 2015, an increase of $3,757,981, or 44.1%. Included in net revenue were sales of *SPECTRUM*® research cigarettes in the amount of $328,912 and $242,658 for the years ended December 31, 2016 and 2015, respectively. The increase in net revenue from sales of products for 2016 was primarily due to the sale of products from the continued growth of our contract manufacturing operations in our North Carolina factory.

Costs of goods sold - Products

2017 vs. 2016

During the year ended December 31, 2017, cost of goods sold were $17,308,156, or 104.3% of net revenue. Excise taxes and certain regulatory fees in the approximate amount of $8,533,000 are included in the cost of goods sold. 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. Excise taxes and certain regulatory fees in the approximate amount of $7,452,000 are included in the cost of goods sold. 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.

2016 vs. 2015

During the year ended December 31, 2016, cost of goods sold were $12,709,678, or 103.5% of net revenue. Excise taxes and certain regulatory fees in the approximate amount of $7,452,000 are included in the cost of goods sold. 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.

During the year ended December 31, 2015, cost of goods sold were $9,102,560, or 106.8% of net revenue. Excise taxes and certain regulatory fees in the approximate amount of $5,703,000 are included in the cost of goods sold. We were not operating the factory at full production capacity during 2015. 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.

Research and development expense

2017 vs. 2016

Research and development expense was $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.

2016 vs. 2015

Research and development expense was $2,340,958 for the year ended December 31, 2016, an increase of $769,593, or 49.0%, from $1,571,365 for the year ended December 31, 2015. This increase was primarily the result of an

increase in sponsored research costs and testing costs in the approximate amount of $235,000, an increase in royalty and license fees of approximately $269,000, an increase in payroll and payroll related costs of approximately $238,000, an increase in consulting fees of approximately $74,000, an increase in R&D related travel expenses of approximately $48,000, an increase in legal fees of approximately $26,000 and an increase in expenses associated with our laboratory established in 2016 in the approximate amount of $72,000, partially offset by a decrease in equity based compensation in the approximate amount of $31,000 and a decrease in modified risk costs of approximately $174,000, during the year ended December 31, 2016, as compared to the year ended December 31, 2015.

General and administrative expense

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.

2016 vs. 2015

General and administrative expense was $6,193,269 for the year ended December 31, 2016, a decrease of $1,566,858, or 20.2%, from $7,760,127 for the year ended December 31, 2015. The decrease was primarily due to a decrease in equity based compensation to third-party service providers in the approximate amount of $2,238,000 (approximately $1,979,000 of the decrease pertained to the Crede consulting fee), a decrease in employee equity based compensation of approximately $428,000, a decrease in payroll and employee related costs of approximately $237,000, a decrease in legal and accounting fees of approximately $33,000, and a decrease in NYSE American related costs of approximately $65,000, partially offset by an increase in investor relations costs of approximately $931,000, an increase in consulting fees of approximately $150,000, an increase relating to press release costs of approximately $50,000, an increase in costs relating to information technology of approximately $40,000, an increase in general business insurance of approximately $17,000, an increase in director fees of approximately $98,000 and a net increase in various other general and administrative expenses of approximately $148,000 during the year ended December 31, 2016 as compared to the year ended December 31, 2015.

Sales and marketing costs

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 costs 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.

2016 vs. 2015

Sales and marketing costs were $1,581,741 for the year ended December 31, 2016, an increase of $224,223, or 16.5%, from $1,357,518 for the year ended December 31, 2015. The increase in the sales and marketing costs were primarily the result of an increase of payroll and expenses related to payroll of approximately $312,000, an increase in equity based compensation of approximately $15,000, partially offset by a decrease in advertising and promotion of costs of approximately $103,000 during the year ended December 31, 2016 as compared to the year ended December 31, 2015.

Depreciation

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 in the amount of $1,234,819 related primarily to packing equipment at our factory in North Carolina that was not placed in service during 2017 and is expected to be placed in service during the first quarter of 2018.

2016 vs. 2015

Depreciation expense for the year ended December 31, 2016 amounted to $326,124, an increase of $6,425, or 2.0%, from $319,699 for the year ended December 31, 2015. This increase is primarily due to additional depreciation expensed on newly acquired assets during the year ended December 31, 2016 in the amount of $204,994.

Amortization

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.

2016 vs. 2015

Amortization expense, relating to amortization taken on capitalized patent costs and license fees, for the year ended December 31, 2016 amounted to $516,056, an increase of $61,444, or 13.5%, from $454,612 for the year ended December 31, 2015. The increase is primarily due to amortization on additional patent costs incurred during the years ended December 31, 2016 and 2015 in the amounts of $541,882 and $654,069, respectively.

Warrant liability (loss) gain - net

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.

2016 vs. 2015

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 the 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 the expiration of certain warrants during 2016.

The warrant liability gain of $144,550 for the year ended December 31, 2015 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 $1.65 per share at December 31, 2014, as compared to $1.40 per share at December 31, 2015, and with certain warrants aging closer to their expiration dates with the passage of time.

Settlement proceeds

2017 vs. 2016

There were no settlement proceeds during the years ended December 31, 2017 and 2016.

2016 vs. 2015

On April 10, 2015, we entered into a settlement of legal disputes with an unrelated third-party pursuant to which the third-party became obligated to pay us a total of $1,000,000. During 2015, we received payments under the settlement in the aggregate amount of $1,000,000 in full settlement of the dispute.

Gain (loss) on investment

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.

2016 vs. 2015

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.

The loss on equity investment of $95,684 for the year ended December 31, 2015 consisted of (i) our 25% share of Anandia's net loss for the year ended December 31, 2015 in the amount of $38,036, 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.

Unrealized loss on short-term investment securities

2017 vs. 2016

Unrealized loss on short-term investment securities was $3,618 and $0 for the years ended December 31, 2017 and 2016, respectively. 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 investment securities. The unrealized loss results from the change in fair value of our investment in certain corporate and U.S. government agency bonds.

2016 vs. 2015

There was no unrealized loss on short-term investment securities during the years ended December 31, 2016 and 2015.

Interest income

2017 vs. 2016

Interest income for the year ended December 31, 2017 was $115,098, an increase of $98,213, or 581.7%, 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 investment securities. Due to such additional investments, interest income was substantially greater during 2017 as compared to 2016.

2016 vs. 2015

Interest income for the year ended December 31, 2016 was $16,885, a decrease of $14,313, or 45.9%, from interest income of $31,198 for the year ended December 31, 2015. The interest income earned in both 2016 and 2015 was generated from excess cash invested in a money market account.

Interest expense

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.

2016 vs. 2015

Interest expense decreased for the year ended December 31, 2016 to $37,745 from $52,982 for the year ended December 31, 2015. This decrease of $15,237 consisted primarily of a decrease of approximately $8,000 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 of approximately $7,000 on a demand bank loan that was paid off in December of 2015.

Net loss

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 of approximately $278,000, an increase in operating expenses of $1,634,000, partially offset by a net decrease in other expenses of approximately $464,000.

2016 vs. 2015

We had a net loss for the year ended December 31, 2016 of $11,581,430 as compared to a net loss of $11,031,931 for the year ended December 31, 2015. The increase in the net loss of $549,499, or 5.0%, was primarily the result of the decrease in settlement proceeds of $1,000,000 and a net increase in other expenses of approximately $206,000, offset by a decrease in our gross loss of approximately $151,000 and a net decrease in operating expenses in the amount of approximately $505,000.

Liquidity and Capital Resources

Working Capital

As of December 31, 2017, we had positive working capital of approximately $63.3 million compared to positive working capital of approximately $13.5 million at December 31, 2016, an increase of approximately $49.8 million. This increase in working capital is due to an increase in current assets of approximately $50.8 million, which is primarily due to a net increase in cash and cash equivalents and short-term investment securities of approximately $49.2 million, an increase in net accounts receivable of approximately $0.9 million, an increase in net inventory of approximately $0.2 million and an increase of prepaid expenses and other assets of approximately $0.5 million, partially offset by a net increase in current liabilities of approximately $1.0 million. The net increase in cash and cash equivalents and short-term investment securities is primarily the result of cash generated from a registered direct offering in October of 2017 resulting in net proceeds to us of approximately $50.7 million and net proceeds from the exercise of stock warrants during 2017 of approximately $12.4 million, reduced by cash used in operating activities of approximately $12.1 million, cash used to acquire patents, trademarks and machinery and equipment of approximately $1.6 million, and $0.3 million used for payment on the note payable.

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, 2017 of $62,635,047. 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 ending December 31, 2017, we experienced an operating loss of approximately $13,300,000 and used cash in operations of approximately $12,068,000. 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, investor relations and marketing costs, our monthly cash expenditures are approximately $925,000.

Net Cash used in operating activities

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 end December 31, 2016.

2016 vs. 2015

In the year ended December 31, 2016, $9,887,580 of cash was used in operating activities as compared to $7,321,811 of cash used in operating activities in the year ended December 31, 2015; an increase of $2,565,769. 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 $2,881,706 offset by a decrease in cash used from working capital components related to operations in the amount of $315,937 for the year ended December 31, 2016 as compared to at year end December 31, 2015.

Net cash used in investing activities

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.

2016 vs. 2015

In the year ended December 31, 2016, net cash used in investing activities was $553,770 as compared to $450,661 of cash used in investing activities during the year ended December 31, 2015. The increase in cash used in investing activities of $103,109 was due to an increase of $159,748 in cash used for the acquisition of machinery and equipment, partially offset by a decrease in cash used in the acquisition of patents and trademarks in the amount of $56,639, for the year ended December 31, 2016 as compared to the year ended December 31, 2015.

Net cash provided by financing activities

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.

2016 vs. 2015

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.

During the year ended December 31, 2015, we generated $5,130,082 from our financing activities primarily as a result of net cash proceeds from the sale of units in a June 2015 registered direct offering in the amount of $5,576,083, cash provided from the exercise of warrants in the amount of $50,688, and the collection of an amount due from a related party in the amount of $46,069, offset by payments on our demand bank loan and note payable in the amounts of $174,925 and $333,333, respectively.

Contractual Obligations

The following table summarizes by category our expected future cash outflows associated with contractual obligations in effect at December 31, 2017:

	Payments Due by Period				
	Total	Year Ended December 31, 2018	Years Ended December 31, 2019 & 2020	Years Ended December 31, 2021 & 2022	More Than Five Years
Operating lease obligations (1)	974,649	295,475	525,486	153,688	-
Consulting agreements	815,000	488,000	171,000	156,000	-
License fees	2,880,000	265,000	590,000	645,000	1,380,000
Sponsored research (2)	893,188	556,191	336,997	-	-
Total	$5,562,837	$ 1,604,666	$ 1,623,483	$ 954,688	$1,380,000

(1) Does not include potential lease obligations due upon exercise of various lease option renewals.

(2) Does not include an additional $653,200 in sponsored research fees potentially due to Anandia under the Company's option to exercise the third-year option contained in the agreement with Anandia.

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 and certificates of deposit with maturities greater than three months as the time of acquisition. Our short-term investment securities are carried at fair value within current assets on our Consolidated Balance Sheets, with fair value based on quoted market prices. We view our available-for-sale securities as available for use in current operations regardless of the stated maturity date of the security. Realized and unrealized gains and losses on short-term investment securities are reflected in other income (expense) on our Consolidated Statements of Operations. Net interest earned 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

We recognize revenue from product sales at the point the product is shipped to a customer and title has transferred. Revenue from the sale of products is recognized net of cash discounts, sales returns and allowances. Cigarette and filtered cigar federal excise taxes and other regulatory fees in the approximate amount of $8,533,000, $7,452,000 and $5,703,000 are included in net sales for the years ended December 31, 2017, 2016 and 2015, respectively, except on sales of *SPECTRUM*® research cigarettes, exported cigarettes, exported filtered cigars and in-bond sales of filtered cigars to other federally licensed tobacco product manufactures, to which such taxes do not apply.

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, 2017.

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, 2017 and 2016.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair market value and then is revalued at each reporting date, with changes in fair value reported in the Consolidated Statements of Operations. The methodology for valuing our outstanding warrants classified as derivative instruments utilizes a lattice model approach which includes probability weighted estimates of future events, including volatility of our common stock.

The classification of derivative instruments, including whether such instruments should be recorded as liabilities or equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the 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 balance sheet date.

Inflation

Inflation did not have a material effect on our operating results for the years ended December 31, 2017, 2016 and 2015.

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 warrant liability is primarily based on the underlying price of our common stock and fluctuations in its value could impact our warrant liability expense.

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 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. Our 19.0% investment in Anandia at December 31, 2017 has limited foreign currency risk. Anandia is a Canadian company using the Canadian dollar as its functional currency. We currently account for our investment in Anandia using the cost method, and as such, we have limited exposure to foreign currency risk. We do not believe that fluctuations in foreign currency rates associated with these non-U.S. dollar transaction will have a material impact on our financial statements.

Equity Risk

We have a warrant liability of $216,490 on our consolidated balance sheet at December 31, 2017. This liability consists of a warrant liability associated with warrants issued by us. The fair value calculation, as discussed in Note 14 of our consolidated financial statements, of the warrants is exposed to market volatilities, changes in the price of our common stock, and interest rates. Only a small percentage of our outstanding warrants contain an anti-dilution clause that gives rise to the warrant liability (see Note 15 of our consolidated financial statements for additional details), and as such, our exposure to this risk is significantly mitigated. Additionally, the outstanding warrants associated with the warrant liability expire in August of 2018. During the year ended December 31, 2017, we experienced a loss of

$157,809 as a result of the change in the fair value of the warrant liability. A 10% increase or decrease in the volatility factor used as of December 31, 2017 would have the impact of increasing or decreasing the warrant liability by approximately $300.

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, 2017.

Freed Maxick CPA's, 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, 2017 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

The Board of Directors and Shareholders

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, 2017, 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, 2017, 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, 2017 and 2016 and the related consolidated statements of operations, changes in shareholders' equity and cash flows of the Company for each of the three years in the period ended December 31, 2017 of the Company and our report dated March 7, 2018 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 7, 2018

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 2018 Annual Meeting of Stockholders.

Set forth below is information regarding our directors, executive officers and key personnel as of March 6, 2018:

Name	Age	Position
Henry Sicignano, III	50	President, Chief Executive Officer and Director
John T. Brodfuehrer	60	Chief Financial Officer & Treasurer
James E. Swauger, Ph. D.	56	Senior Vice President of Science and Regulatory Affairs
Thomas L. James, Esq.	59	Vice President, General Counsel and Secretary
Joseph Alexander Dunn, Ph.D.	64	Director*
James W. Cornell	61	Director**
Richard M. Sanders	65	Director***
Nora B. Sullivan	60	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. Focusing 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 of 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, 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 2018 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 2018 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 2018 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 2018 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements

(b) Financial Statement Schedules

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

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, 2017 and 2016, the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, 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, 2017, based on criteria established in *Internal Control – Integrated Framework* issued by Committee of Sponsoring Organizations of the Treadway Committee in 2013. Our report dated March 7, 2018 expressed an opinion that the Company had maintained effective internal controls over financial reporting as of December 31, 2017, based upon the criteria established in *Internal Control – Integrated Framework* issued by Committee of Sponsoring Organizations of the Treadway Committee in 2013.

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 7, 2018

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 31,

	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	$3,659,534	$13,468,188
Short-term investment securities	58,975,513	-
Accounts receivable, net	957,066	40,992
Inventory, net	3,282,537	3,092,686
Prepaid expenses and other assets	746,805	195,569
Total current assets	67,621,455	16,797,435
Machinery and equipment, net	3,316,047	2,434,663
Other assets:		
Intangible assets, net	7,435,411	7,389,946
Investment	1,366,493	1,020,313
Total other assets	8,801,904	8,410,259
Total assets	$79,739,406	$27,642,357
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of note payable	$-	$307,938
Accounts payable	2,080,691	1,340,156
Accrued expenses	1,987,675	1,401,566
Accrued severance	-	199,657
Deferred income	28,350	-
Warrant liability	216,490	-
Total current liabilities	4,313,206	3,249,317
Warrant liability	-	58,681
Total liabilities	4,313,206	3,307,998
Commitments and contingencies (Note 17)	-	-
Shareholders' equity		
10,000,000 preferred shares, $.00001 par value		
300,000,000 common shares, $.00001 par value		
Capital stock issued and outstanding:		
123,569,367 common shares (90,698,113 at December 31, 2016)	1,236	907

Capital in excess of par value	166,592,536	102,471,907
Accumulated deficit	(91,167,572)	(78,138,455)
Total shareholders' equity	75,426,200	24,334,359
Total liabilities and shareholders' equity	$79,739,406	$27,642,357

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended December 31,

	2017	2016	2015
Revenue:			
Sale of products, net	$16,600,244	$12,279,979	$8,521,998
Cost of goods sold (exclusive of depreciation shown separately below):			
Products	17,308,156	12,709,678	9,102,560
Gross loss	(707,912)	(429,699)	(580,562)
Operating expenses:			
Research and development (including equity based compensation of $182,854, $136,946 and $167,837, respectively)	3,366,468	2,340,958	1,571,365
General and administrative (including equity based compensation of $625,202, $718,610 and $3,376,664, respectively)	7,116,535	6,193,269	7,760,127
Sales and marketing (including equity based compensation of $133,594, $55,826 and $41,039, respectively)	1,161,952	1,581,741	1,357,518
Depreciation	353,435	326,124	319,699
Amortization	593,562	516,056	454,612
	12,591,952	10,958,148	11,463,321
Operating loss	(13,299,864)	(11,387,847)	(12,043,883)
Other income (expense):			
Warrant liability (loss) gain - net	(157,809)	29,615	144,550
Settlement Proceeds	-	-	1,000,000
Loss on the disposition of machinery and equipment	-	-	(15,130)
Gain (loss) on investment	346,180	(202,338)	(95,684)
Unrealized loss on short-term investment securities	(3,618)	-	-
Interest income	115,098	16,885	31,198
Interest expense	(29,104)	(37,745)	(52,982)
	270,747	(193,583)	1,011,952
Loss before income taxes	(13,029,117)	(11,581,430)	(11,031,931)
Income taxes	-	-	-
Net loss	$(13,029,117)	$(11,581,430)	$(11,031,931)

Loss per common share - basic and diluted	$(0.13)	$(0.15)	$(0.16)
Common shares used in basic and diluted earnings per share calculation	101,161,380	79,842,773	68,143,284

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

Years Ended December 31, 2017, 2016 and 2015

	Common Shares Outstanding	Par Value of Common Shares	Capital in Excess of Par Value	Accumulated Deficit	Shareholders' Equity
Balance at December 31, 2014	64,085,042	$ 641	$ 70,744,190	$ (55,525,094)	$ 15,219,737
Common stock issued in June 2015 registered direct offering, net	6,000,000	60	5,576,023	-	5,576,083
Equity based compensation	553,896	6	1,623,417	-	1,623,423
Stock issued in connection with warrant exercise	40,000	-	50,688	-	50,688
Stock issued in connection with equity investment	377,906	4	324,996	-	325,000
Stock cancellation	(50,000)	(1)	(34,499)	-	(34,500)
Net loss	-	-	-	(11,031,931)	(11,031,931)
Balance at December 31, 2015	71,006,844	710	78,284,815	(66,557,025)	11,728,500
Common stock issued in February 2016 registered direct offering, net	5,000,000	50	5,091,741	-	5,091,791
Common stock issued in July 2016 registered direct offering, net	6,172,840	62	4,682,702	-	4,682,764
Common 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)	-	-
Common 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

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years Ended December 31,

	2017	2016	2015
Cash flows from operating activities:			
Net loss	$(13,029,117)	$(11,581,430)	$(11,031,931)
Adjustments to reconcile net loss to cash used in operating activities:			
Amortization and depreciation	848,974	744,157	676,289
Amortization of license fees	98,022	98,022	98,022
(Gain) loss on investment	(346,180)	202,338	95,684
Accretion of interest on note payable and accrued severance	29,104	37,745	45,121
Loss on the disposition and sale of machinery and equipment	-	-	15,130
Unrealized loss on short-term investment securities	3,618	-	-
Warrant liability loss (gain)	157,809	(29,615)	(144,550)
Equity based employee compensation expense	941,650	880,509	1,326,393
Equity based payments for outside services	-	30,873	2,259,147
(Decrease) increase in allowance for doubtful accounts	(10,000)	-	10,000
(Decrease) increase in inventory reserve	(60,623)	145,000	60,000
(Increase) decrease in assets:			
Accounts receivable	(906,074)	10,238	(61,230)
Inventory	(129,228)	(531,356)	(701,534)
Prepaid expenses and other assets	(551,236)	497,856	(478,955)
Increase (decrease) in liabilities:			
Accounts payable	473,804	(136,297)	86,332
Accrued expenses	586,109	(21,965)	649,271
Accrued severance	(203,365)	(233,655)	(225,000)
Deferred income	28,350	-	-
Net cash used in operating activities	(12,068,383)	(9,887,580)	(7,321,811)
Cash flows from investing activities:			
Acquisition of patents and trademarks	(450,208)	(356,541)	(413,180)
Acquisition of machinery and equipment	(1,156,906)	(197,229)	(37,481)
Purchase of short-term investment securities	(58,979,131)	-	-
Net cash used in investing activities	(60,586,245)	(553,770)	(450,661)
Cash flows from financing activities:			
Net proceeds from exercise of warrants	12,447,108	196	50,688
Payments on borrowings - demand bank loan	-	-	(174,925)
Payments on borrowings - note payable	(333,334)	(333,333)	(333,333)
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 proceeds from June 2015 registered direct offering	-	-	5,576,083

Stock cancellation	-	-	(34,500)
Net payments from related party	-	-	46,069
Net cash provided by financing activities	62,845,974	20,149,241	5,130,082
Net (decrease) increase in cash and cash equivalents	(9,808,654)	9,707,891	(2,642,390)
Cash and cash equivalents - beginning of period	13,468,188	3,760,297	6,402,687
Cash and cash equivalents - end of period	$3,659,534	$13,468,188	$3,760,297
Supplemental disclosures of cash flow information:			
Net cash paid for:			
Cash paid during the period for interest	$29,104	$37,745	$7,600
Cash paid during the period for income taxes	$-	$-	$-
Non-cash transactions:			
Patent and trademark additions included in accounts payable	$188,818	$185,341	$310,078
Patent and trademark additions included in accrued expenses	$-	$-	$17,715
Machinery and equipment additions included in accounts payable	$77,913	$7,765	$2,525
Issuance of common stock in connection with equity investment	$-	$-	$325,000
Reclassification of warrant liability to capital in excess of par due to voiding			
of exchange rights clause in Crede Tranche 1A warrant	$-	$2,810,000	$-

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017

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 premium cigarettes and (ii) smoking cessation product, respectively. The Company acquired the membership interests of NASCO on August 29, 2014. 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 cigarette manufacturing business in North Carolina. Botanical Genetics is a wholly-owned subsidiary of 22nd Century Group and was incorporated to facilitate an investment more fully described in Note 11.

Reclassifications - Certain items in the 2016 and 2015 financial statements have been reclassified to conform to the 2017 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 **-** Financial instruments that potentially subject the Company to concentration of credit risk consist of cash accounts in financial institutions. Although the cash accounts exceed the federally insured deposit amount, management does not anticipate nonperformance by the financial institutions. Management reviews the

financial viability of these institutions on a periodic basis.

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. 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 and certificates of deposit 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, with fair value based on quoted market prices. 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. All short-term investment securities had a maturity of less than twelve (12) months at December 31, 2017. Realized and unrealized gains and losses on short-term investment securities are reflected in other income (expense) on the Company's Consolidated Statements of Operations. Net interest earned on the short-term investment securities are included in interest income.

Accounts receivable - The Company periodically reviews aged account balances for collectability. As of December 31, 2017, and 2016, the Company has established an allowance for doubtful accounts in the amount of $0 and $10,000, respectively.

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, 2017 and December 31, 2016 consisted of the following:

	December 31, 2017	December 31, 2016
Inventory – tobacco leaf	$ 1,552,474	$ 1,936,039
Inventory – finished goods		
Cigarettes and filtered cigars	289,004	340,523
Inventory – raw materials		
Cigarette and filtered cigar components	1,636,059	1,071,747
	3,477,537	3,348,309
Less: inventory reserve	195,000	255,623
	$ 3,282,537	$ 3,092,686

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 primary patent in each of the Company's two primary patent families, which expire in 2018 and 2028 (the assets' estimated lives), respectively. Periodic maintenance or renewal fees and any annual minimum license fees are charged to research and development expense as incurred. 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 range from 2028 through 2035. The Company believes costs associated with becoming a signatory to the MSA and acquiring the predicate cigarette brand have an indefinite life and as such, no amortization is taken. Total intangible assets at December 31, 2017 and 2016 consist of the following:

	December 31, 2017	December 31, 2016
Intangible assets, net		

Patent and trademark costs	$ 6,327,467	$ 5,688,440
Less: accumulated amortization	2,517,465	2,021,926
Patent and trademark costs, net	3,810,002	3,666,514
License fees, net (see Note 17)	1,450,000	1,450,000
Less: accumulated amortization	326,591	228,568
License fees, net	1,123,409	1,221,432
MSA signatory costs	2,202,000	2,202,000
License fee for predicate cigarette brand	300,000	300,000
	$ 7,435,411	$ 7,389,946

Amortization expense relating to the above intangible assets for the years ended December 31, 2017, 2016 and 2015 amounted to $593,562, $516,056 and $454,612, respectively.

The estimated annual average amortization expense for the next five years is approximately $403,000 for patent costs and $98,000 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, 2017, 2016 or 2015.

Income Taxes - The Company recognizes deferred tax assets and liabilities for any basis differences in its assets and liabilities between tax and 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, 2017 and 2016.

The Company's federal and state tax returns for the years ended December 31, 2014 through December 31, 2016 are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2017.

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 amounts for some line items for taxes when preparing year-end 2017 financial statements. The Company has completed the accounting under the TCJA, and accordingly, has reported the effects in these financial statements. Additional disclosures required by SAB 118 are included in Note 20 – Income Taxes.

Stock Based Compensation - The Company uses a fair-value based method to determine compensation for all arrangements under which Company employees and others receive shares or options to purchase common shares of the Company. Stock 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.

Revenue Recognition - The Company recognizes revenue from product sales at the point the product is shipped to a customer and title has transferred. Revenue from the sale of products is recognized net of cash discounts, sales returns and allowances. Cigarette and filtered cigar federal excise taxes and other regulatory fees in the approximate amount of $8,533,000, $7,452,000 and $5,703,000 are included in net sales for the years ended December 31, 2017, 2016 and 2015, respectively, except on sales of *SPECTRUM*® research cigarettes, exported cigarettes, exported filtered cigars and in-bond sales of filtered cigars to other federally licensed tobacco product manufactures, to which such taxes do not apply.

Derivatives - The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair market value and then is revalued at each reporting date, with changes in fair value reported in the Consolidated Statements of Operations. The methodology for valuing our outstanding warrants classified as derivative instruments utilizes a lattice model approach which includes probability weighted estimates of future events, including volatility of our common stock. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified on the balance sheet as current or non-current based on if the net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

Research and Development **-** Research and development costs are expensed as incurred.

Advertising - The Company expenses advertising costs as incurred. Advertising expense was approximately $75,000, $325,000 and $229,000 for the years ended December 31, 2017, 2016 and 2015, respectively.

Loss Per Common Share - Basic loss per common share is computed using the weighted-average number of common shares outstanding. Diluted loss per share is computed assuming conversion of all potentially dilutive securities. Potential common shares outstanding are excluded from the computation if their effect is anti-dilutive.

Commitment and Contingency Accounting **-** The Company evaluates each commitment and/or contingency in accordance with the accounting standards, which state that if the item is more likely than not to become a direct liability, then the Company will record the liability in the financial statements. If not, the Company will disclose any material commitments or contingencies that may arise.

Use of Estimates **-** The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

Fair Value of Financial Instruments - The Company's financial instruments include cash and cash equivalents, short-term investment securities, receivables, accounts payable, accrued expenses, accrued severance, note payable and warrant liability. Other than for cash equivalents, short-term investment securities and warrant liability, fair value is assumed to approximate carrying values for these financial instruments, since they are short term in nature, they are receivable or payable on demand, or had stated interest rates that approximate the interest rates available to the Company as of the reporting date. The determination of the fair value of cash equivalents, short-term investment securities and warrant liability are discussed in Note 14.

Equity Investments **-** The Company accounts for investments in equity securities of other entities under the equity method of accounting if the Company's investment in the voting stock is greater than or equal to 20% and less than a majority, and the Company has the ability to have significant influence over the operating and financial policies of the investee. If the Company's equity investment of other entities is less than 20%, and the Company has no significant influence over the operating or financial policies of the entity, and such equity investment does not have a readily determinable market value, the Company uses the cost method of accounting for the investment.

Accounting Pronouncements - In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, "Revenue from Contracts with Customers," which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. The revised effective date for the ASU is for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). In August 2015, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers (Topic 606) - Deferral of the Effective Date," which deferred the effective date of ASU 2014-09 to annual reporting periods beginning after December 15, 2017, with earlier application permitted as of annual reporting periods beginning after December 15, 2016. In March 2016, the FASB issued ASU No. 2016-08, "Revenue from Contracts with Customers (Topic 606) - Principal versus Agent Considerations," to clarify the implementation guidance on principal versus agent. In April 2016, the FASB issued ASU No. 2016-10, "Revenue from Contracts with Customers (Topic 606) - Identifying Performance Obligations and Licensing," which clarifies the identifying performance obligations and licensing implementation guidance. The Company has completed its review and assessment of all outstanding contracts and has applied the five-step model to the contracts to evaluate the quantitative and qualitative impacts the new standards will have on the Company's business. Based on the review and assessment, the Company will recognize revenue over time on certain contracts but believes the new guidance will not have a material impact on the Company's reported revenues, results of operations, cash flows or financial position.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. This guidance changes how entities account for equity investments that do not result in consolidation and are not accounted for under the equity method of accounting. Entities will be required to measure these investments at fair value at the end of each reporting period and recognize changes in fair value in net income. A practicability exception will be available for equity investments that do not have readily determinable fair values, however; the exception requires the Company to adjust the carrying amount for impairment and observable price changes in orderly transactions for the identical or a similar investment of the same issuer. This guidance also changes certain disclosure requirements and other aspects of current US GAAP. This guidance is effective for fiscal years beginning after December 15, 2017 and is applicable to the Company in fiscal 2018. The Company has evaluated the impact of the adoption of ASU 2016-01 on its consolidated financial statements, specifically relating to its investment in Anandia (see Note 11). The Company expects to recognize income in the first quarter of 2018 of approximately $6,000,000 as a result of adjusting the investment to fair value based on an orderly transaction in January 2018.

In February 2016, the FASB issued ASU 2016-02, “Leases,” which supersedes existing lease guidance under GAAP. Under the new guidance, lessees will be required to recognize leases as right of use assets and liabilities for leases with lease terms of more than twelve months. The guidance will apply for both finance and operating leases. The effective date for the ASU is for annual periods beginning after December 15, 2018 and interim periods therein. The Company is currently evaluating the impact of the ASU on its consolidated financial statements.

NOTE 2. – OCTOBER 2017 REGISTERED DIRECT OFFERING

On October 10, 2017, the Company closed a registered direct offering (the “Offering”) with institutional investors purchasing an aggregate of 20,570,000 shares of the Company’s common stock at a price of $2.6250 per share generating net cash proceeds for the Company of $50,732,200, after deducting expenses associated with the transaction. The securities purchase agreement entered into with the institutional investors provides that, subject to certain exceptions, for a period of one year following the closing of the Offering, the Company will be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of common stock or common stock equivalents (or a combination of units thereof) involving a variable rate transaction, which generally includes any transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of common stock either (A) at a conversion price or exchange rate that is based upon and/or varies with the trading prices of or quotations for the shares of common stock at any time after the initial issuance of such securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the common stock or (ii) enters into any agreement, whereby the Company may issue securities at a future determined price.

NOTE 3. – JUNE 2017 WARRANT EXERCISE AGREEMENTS

On June 19, 2017, the Company entered into Warrant Exercise Agreements (the “Agreements”) with all the holders (the “Holders”) of outstanding warrants to purchase up to 7,043,211 shares of common stock of the Company at $1.00 per share and warrants to purchase up to 4,250,000 shares of common stock of the Company at $1.45 per share (collectively, the “Warrants”). These Warrants to purchase shares of the Company’s common stock were acquired by the Holders in registered direct offerings in October of 2016 and in July of 2016, respectively, as more fully described in Notes 4 and 5 below. The Company and the Holders agreed that the Holders would, subject to beneficial ownership limitations on exercise contained in the Warrants, exercise all the Warrants for cash. In June 2017, the Holders exercised 3,229,711 Warrants at $1.00 per share and 2,354,948 Warrants at $1.45 per share, resulting in net proceeds to the Company in the amount of $6,169,212, after deducting expenses associated with the transaction. In July and August of 2017, the Holders exercised 3,813,500 Warrants at $1.00 per share and 1,895,052 Warrants at $1.45 per share, resulting in net proceeds to the Company in the amount of $6,167,646, after deducting expenses associated with the transaction.

In consideration for the Holders exercising their Warrants for cash, the Company issued to each Holder a new warrant (the “New Warrants”) to purchase shares of common stock of the Company equal to the number of shares of common stock received by each Holder upon the cash exercise of the Holder’s Warrants. The terms of the New Warrants are substantially similar to the terms of the Warrants exercised, except the New Warrants (i) have an exercise price equal to $2.15 per share and (ii) are exercisable six months from the date of issuance of the New Warrants for a period of five (5) years. Accordingly, the Company issued an aggregate of 11,293,211 New Warrants to the Holders, upon exercise of the Holder’s Warrants as described above. The New Warrants had a fair value of $16,049,031 at issuance and have been recorded as an adjustment to capital in excess of par.

NOTE 4. – OCTOBER 2016 REGISTERED DIRECT OFFERING

On October 19, 2016, the Company closed a registered direct offering with two institutional investors of units consisting of 8,500,000 shares of the Company's common stock and warrants to purchase 4,250,000 shares of the Company's common stock at an exercise price of $1.45 per share. The warrants were exercisable for a period of sixty-six (66) months after issuance, were not exercisable for a period of six months immediately following the issuance and had a fair value of approximately $3,380,000 at issuance. The holders of the warrants did not have the right to exercise any portion of the warrants if the holders, together with its respective affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's common stock (including securities convertible into common stock) outstanding immediately after the exercise; provided, however, that the holder could increase or decrease this limitation at any time, although any increase shall not be effective until the 61st day following the notice of increase and the holder could not increase this limitation in excess of 9.99%. The common stock and warrants were sold for $1.3425 per unit, resulting in net proceeds to the Company in the amount of $10,707,823, after deducting expenses associated with the transaction. All the warrants issued in the offering were exercised as described in Note 3 above.

NOTE 5. – JULY 2016 REGISTERED DIRECT OFFERING

On July 27, 2016, the Company closed a registered direct offering of common stock and warrants consisting of 6,172,840 shares of the Company's common stock and warrants to purchase 7,043,211 shares of the Company's common stock. The warrants provided for an exercise price of $1.00 per share and 1,543,210 of the warrants were exercisable immediately and had a fair value of approximately $858,000 at issuance and 5,500,001 of the warrants were exercisable six months from the date of issuance and had a fair value of approximately $3,058,000 at issuance. All the warrants had a term of 5.5 years. The common stock and warrants were sold for $0.81 per unit, resulting in net proceeds to the Company in the amount of $4,682,764, after deducting expenses associated with the transaction. All the warrants issued in the offering were exercised as described in Note 3 above. In addition, on July 27, 2016, the Company terminated an aggregate of 5.5 million warrants with exercise prices of $1.21 and $1.25 per share previously issued in conjunction with registered direct offerings in February of 2016 and June of 2015, as further described in Note 6 and Note 7.

NOTE 6. - FEBRUARY 2016 REGISTERED DIRECT OFFERING

On February 5, 2016, the Company closed a registered direct offering of common stock and warrants consisting of 5,000,000 shares of the Company's common stock and warrants to purchase 2,500,000 shares of the Company's common stock at an exercise price of $1.21 per share. The warrants were exercisable for a period of sixty-six (66) months after issuance, were not exercisable for a period of six months immediately following the issuance and had a fair value of approximately $1,940,000 at issuance. The common stock and warrants were sold for $1.10 per unit,

resulting in net proceeds to the Company in the amount of $5,091,791, after deducting expenses associated with the transaction. The warrants associated with this transaction were terminated on July 27, 2016.

NOTE 7. - JUNE 2015 REGISTERED DIRECT OFFERING

On June 2, 2015, the Company closed a registered direct offering of units consisting of 6,000,000 shares of the Company’s common stock and warrants to purchase 3,000,000 shares of the Company’s common stock at an exercise price of $1.25 per share. The warrants were exercisable for a period of sixty-six (66) months after issuance, were not exercisable for a period of six months immediately following the issuance and had a fair value of approximately $2,067,000 at issuance. The common stock and warrants were sold for $1.00 per unit, resulting in net proceeds to the Company in the amount of $5,576,083, after deducting expenses associated with the transaction. The warrants associated with this transaction were terminated on July 27, 2016.

NOTE 8. - JOINT VENTURE, CONSULTING AGREEMENT AND ASSOCIATED WARRANTS

On June 22, 2015, the Company terminated its joint venture arrangement with Crede CG III, Ltd. (“Crede”) and a third-party due to non-performance and other breaches of the arrangement by Crede and its principals. The Company also notified Crede that the Company reserved and did not waive any rights that the Company may have to assert any and all claims that it may have against Crede, its employees, agents, representatives or affiliates thereof, which are allowable by law or in equity, including claims for breach of the warrant agreements entered into with Crede.

The six-month Consulting Agreement (the “Consulting Agreement”), entered into with Crede on September 29, 2014, expired on March 29, 2015. The value of the warrants issued in conjunction with the Consulting Agreement in the aggregate amount of $4,070,000 and initially recorded as prepaid consulting fees have been fully amortized. The final amortization of the prepaid consulting fees amounted to $1,978,785 for the three months ended March 31, 2015 and were included in General and administrative expenses in the Company’s Consolidated Statements of Operations.

Four tranches of warrants were issued to Crede in conjunction with the Consulting Agreement as follows: Tranche 1A warrant to purchase 1,250,000 shares of Company common stock, Tranche 1B warrant to purchase 1,000,000 shares of Company common stock, Tranche 2 warrant to purchase 1,000,000 shares of Company common stock and Tranche 3 warrant to purchase 1,000,000 shares of Company common stock. The Tranche 1A warrant contained an exchange rights clause that required derivative liability treatment under FASB ASC 480 - “Distinguishing Liabilities from Equity.” The Company valued the derivative liability associated with the Tranche 1A warrant at inception at $2,810,000 and the liability was recorded on the Company’s Consolidated Balance Sheets in Warrant liability. In March 2016, the Company provided notice to Crede that Crede repeatedly breached the activity restrictions contained in the warrant agreements and because the terms of the Tranche 1A warrant provide that the availability of the exchange feature was subject to compliance with such activity restrictions, the exchange rights clause contained in the Tranche 1A warrant was no longer available and was thereafter void (although the remaining amount of shares underlying the warrant without the exchange feature remained fully exercisable at $3.36 per share through the warrant expiration date of September 29, 2016). Accordingly, the Company reclassified the warrant liability associated with the Tranche 1A warrant to Capital in excess of par on its Consolidated Balance Sheets during March 2016. The Tranche 1A and Tranche 1B warrants all expired without exercise on September 29, 2016.

The Tranche 2 and Tranche 3 warrants were not exercisable unless and until certain revenue milestones were attained, as defined in the prior joint venture agreement between Crede and the Company. As stated above, the Company terminated the joint venture agreement on June 22, 2015. Accordingly, such revenue milestones will never be satisfied, and the Tranche 2 and Tranche 3 warrants will never be exercisable.

NOTE 9. - MANUFACTURING FACILITY

The Company’s manufacturing operations at its North Carolina factory were not at full production capacity throughout the year ended December 31, 2017, and the Company significantly expanded capacity during the second and third quarters of 2017 in order to fulfill anticipated new manufacturing contracts. In mid-May of 2017, the Company began the first phase of a manufacturing contract for an existing brand of filtered cigars under a new contract manufacturing agreement (the “New Agreement”) with a third-party and continued manufacturing a third-party MSA cigarette brand and other filtered cigars on a contract basis. The New Agreement has increased revenue, has resulted in an increase in the utilization of production capacity, and has required the hiring of additional personnel. Raw material component costs, direct manufacturing costs, and an overhead allocation are included in the Cost of goods sold and Finished goods inventory. General and administrative expenses of the factory amounted to $943,185, $551,678 and $607,713 for the years ended December 31, 2017, 2016 and 2015, respectively.

NOTE 10. - MACHINERY AND EQUIPMENT

Machinery and equipment at December 31, 2017 and 2016 consists of the following:

	Useful Life	December 31, 2017	December 31, 2016
Cigarette manufacturing equipment	3 - 10 years	$4,302,299	$3,193,580
Office furniture, fixtures and equipment	5 years	110,499	103,945
Laboratory equipment	5 years	32,193	19,076
Leasehold improvements	5 years	106,429	-
		4,551,420	3,316,601
Less: accumulated depreciation		1,235,373	881,938
Machinery and equipment, net		$3,316,047	$2,434,663

Depreciation expense was $353,435, $326,124 and $319,699 for the years ended December 31, 2017, 2016 and 2015, respectively.

NOTE 11. - INVESTMENT IN ANANDIA

The Company (through its wholly-owned subsidiary, Botanical Genetics), holds an equity investment in Anandia Laboratories, Inc., a Canadian plant biotechnology company (“Anandia”). At December 31, 2017 and 2016, the Company’s investment balance in Anandia was $1,366,493 and $1,020,313, respectively, and is classified within Other assets on the accompanying Consolidated Balance Sheets. The Company’s ownership was originally 25% and through a series of dilutive events, the Company’s ownership percentage became approximately 19% at December 31, 2017. A specific dilutive event on February 17, 2017 (the “Dilutive Event”), reduced the Company’s ownership below the 20% threshold for use of the equity method of accounting. Accordingly, the Company discontinued applying the equity method of accounting for the investment in Anandia, effective on the date of the Dilutive Event. After the Dilutive Event, the Company accounts for its investment in Anandia under the cost method.

The Company’s gain (loss) on the investment was $346,180, ($202,338) and ($95,684) for the years ended December 31, 2017, 2016 and 2015, respectively. The gain (loss) consists of (i) the Company’s pro-rata share of Anandia’s income (loss) in the amount of $16,872, ($144,690) and ($38,036) for the years ended December 31, 2017, 2016 and 2015, respectively, (the gain for the year ended December 31, 2017, reflects the Company’s proportionate gain only through the Dilutive Event) and, (ii) the amortization of an intangible asset of $1,199,000 represented by the excess of the Company’s carrying value of its investment in Anandia over the Company’s share of Anandia’s books value as of

September 15, 2014 in the amount of $7,526, $57,648 and $57,648 for the years ended December 31, 2017, 2016 and 2015, respectively. After the Dilutive Event, the Company discontinued amortizing this intangible asset. In addition, and as a result of the Dilutive Event, the Company recorded a gain in accordance with the derecognition provisions of Accounting Standards Codification 323 ("ASC 323"). ASC 323 states that an investor (the Company) shall account for an issuance by an investee (Anandia) as if the investor had sold a proportionate share of its investment in the investee and the investor will record a gain or loss resulting from the investee share issuance. As such, the Company recorded a gain of $336,834 during the three months ended March 31, 2017, as a result of the Dilutive Event.

See the Accounting Pronouncements section of Note 1 – Nature of Business and Significant Accounting Policies relating to ASU 2016-01 and Note 22 – Subsequent Events for additional information relating to the Company's investment in Anandia.

NOTE 12. - NOTES PAYABLE AND PATENT ACQUISITION

On December 22, 2014, the Company entered into a Purchase Agreement (the "Purchase Agreement") with the National Research Council of Canada ("NRC") to acquire certain patent rights that the Company had previously licensed from NRC under a license agreement between the parties. The Purchase Agreement provided for payment by the Company to NRC for the NRC patent rights a total amount of $1,213,000, of which $213,000 was paid in cash at the closing on December 23, 2014, and with the remaining $1,000,000 balance to be paid in three equal installments of $333,333 in December of 2015, 2016 and 2017, respectively, with no interest on the installment payments unless the Company defaults on any such installment payments. As such, the Company computed the present value of the note payable using the Company's incremental borrowing rate. The resulting present value of the note payable amounted to $925,730 at December 31, 2014. After all scheduled installment payments made by the Company to NRC and the accretion of interest, the remaining present value of the note payable amounted to $0 and $307,938, respectively, at December 31, 2017 and 2016. The cost of the acquired patents in the amount of $1,138,730 (cash of $213,000 plus the original discounted notes payable in the amount of $925,730) are included in Intangible assets, net on the Company's Consolidated Balance Sheets. All previous license agreements between NRC and the Company were terminated as a condition of the Purchase Agreement.

NOTE 13. - SEVERANCE LIABILITY

The Company recorded an accrual for severance during the fourth quarter of 2014 in the initial amount of $624,320 in accordance with FASB ASC 712 - "Compensation - Nonretirement Postemployment Benefits." The severance accrual relates to the October 25, 2014 termination of Joseph Pandolfino, the Company's former Chairman of the Board and Chief Executive Officer. The prior Employment Agreement with Mr. Pandolfino provided that in certain circumstances Mr. Pandolfino would receive severance payments in the gross amount of $18,750 per month, subject to customary withholdings, over a term of 36 months. Amounts owed to Mr. Pandolfino have been discounted using the Company's incremental borrowing rate. As a result of the severance benefit payments made during 2017 and 2016, the discounted current balance of the severance liability amounted to $0 and $199,657, at December 31, 2017 and 2016, respectively.

NOTE 14. – FAIR VALUE MEASUREMENTS

FASB ASC 820 - "Fair Value Measurements and Disclosures" establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities;

- Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and

- Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value.

A financial asset's or a financial liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table presents information about our assets and liabilities measured at fair value at December 31, 2017 and 2016, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	Asset and Liabilities at Fair Value As of December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Certificate of deposit	$-	$3,000,000	$-	$3,000,000
Short-term investment securities:				
Certificates of deposit	-	6,000,000	-	6,000,000
Money market funds	41,526,540	-	-	41,526,540
Corporate bonds		9,450,933	-	9,450,933
U.S. government agency bonds	-	1,998,040	-	1,998,040
Total cash equivalents and short-term investment securities	$41,526,540	$20,448,973	$-	$61,975,513
Liabilities				
Warrant liability (current)	$-	$-	$216,490	$216,490

	Asset and Liabilities at Fair Value As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Certificate of deposit	$-	$ -	$-	$-
Short-term investment securities:				
Certificates of deposit	-	-	-	-
Money market funds	-	-	-	-
Corporate bonds		-	-	-
U.S. government agency bonds	-	-	-	-
Total cash equivalents and short-term investment securities	$-	$ -	$-	$-
Liabilities				
Warrant liability	$-	$ -	$58,681	$58,681

The warrant liability is measured at fair value using certain estimated factors such as volatility and probability which are classified within Level 3 of the valuation hierarchy. Significant unobservable inputs that are used in the fair value measurement of the Company’s derivative warrant liabilities include volatility. Significant increases (decreases) in the volatility input would result in a significantly higher (lower) fair value measurement.

NOTE 15. - WARRANTS FOR COMMON STOCK

At December 31, 2017, the Company had outstanding warrants to purchase 12,088,080 shares of common stock of the Company, of which warrants to purchase 94,721 shares contain an anti-dilution feature and excluding 2,000,000 Tranche 2 and 3 warrants that will never become exercisable, as discussed in Note 8.

During the year ended December 31, 2017, the Company issued 11,293,211 warrants in conjunction with June 2017 Warrant Exchange Agreements. These warrants have an exercise price equal to $2.15 per share and are exercisable for a period of six months from the date of issuance for a period of five (5) years. See Note 3 for additional details.

During the year ended December 31, 2017, warrant holders exercised 12,763,238 warrants with 1,286,277 of such warrants exercised on a cashless basis. Additionally, 223,814 warrants expired unexercised during the year ended December 31, 2017.

During the year ended December 31, 2016, the Company issued an aggregate of 13,793,211 warrants in conjunction with three registered direct offerings, of which 2,500,000 warrants had an exercise price of $1.21 per share, 7,043,211 had an exercise price of $1.00 per share and 4,250,000 had an exercise price of $1.45 per share. These warrants had a term of sixty-six (66) months. Additionally, the Company cancelled warrants totaling 5,500,000 previously issued in registered direct offerings in February of 2016 and June of 2015. See Notes 4, 5, 6 and 7 for additional details.

During the year ended December 31, 2016, warrant holders exercised 67,042 warrants, primarily on a cashless basis, and 6,831,115 warrants expired unexercised.

Outstanding warrants at December 31, 2017 consist of the following:

Warrant Description	Number of Warrants	Exercise Price	Expiration
December 2011 convertible NP warrants [3]	700,148	$1.3816	February 6, 2018
August 2012 convertible NP warrants [1]	94,721	$0.9310	August 8, 2018
June 2017 warrants pursuant to warrant exercise agreements	11,293,211	$2.1500	December 20, 2022
Total warrants outstanding [2]	12,088,080		

(1) Includes anti-dilution features.
(2) Excludes 2,000,000 Tranche 2 and Tranche 3 warrants that will never become execrable, as discussed in Note 8.
(3) Warrants were exercised on a cashless basis prior to February 6, 2018.

The Company estimates the value of warrant liability upon issuance of the warrants and at each balance sheet date using the binomial lattice model to allocate total enterprise value to the warrants and other securities in the Company's capital structure. Volatility was estimated based on historical observed equity volatilities and implied (forward) or expected volatilities for a sample group of guideline companies and consideration of recent market trends.

As a result of the previously exercisable exchange rights contained in the Tranche 1A warrants, the financial instrument was previously considered a liability in accordance with FASB Accounting Standards Codification Topic 480 - "Distinguishing Liabilities from Equity" ("ASC 480"). More specifically, ASC 480 requires a financial instrument to be classified as a liability if such financial instrument contains a conditional obligation that the issuer must or may settle by issuing a variable number of its equity securities if, at inception, the monetary value of the obligation is based on a known fixed monetary amount. As a result of the actions by Crede that caused the exchange rights feature to be voided (see Note 8 - Joint Venture, Consulting Agreement and Associated Warrants for additional information), the Company reclassified the Tranche 1A warrant liability to Capital in excess of par. The Tranche 1A warrant expired in September 2016 unexercised.

The following table is a roll-forward summary of the warrant liability:

Fair value at December 31, 2014	$3,042,846
Gain as a result of change in fair value	(144,550)
Fair value at December 31, 2015	$2,898,296
Reclassification of warrant liability to capital in excess of par	(2,810,000)
Gain as a result of change in fair value	(29,615)
Fair value at December 31, 2016	$58,681
Loss as a result of change in fair value	157,809
Fair value at December 31, 2017	$216,490

The aggregate net (loss) gain as a result of the Company's warrant liability for the years ended December 31, 2017, 2016 and 2015 amounted to ($157,809), $29,615 and $144,550, respectively, which are included in Other income (expense) under Warrant liability (loss) gain - net in the accompanying Consolidated Statements of Operations.

The following table summarizes the Company's warrant activity since December 31, 2015:

	Number of Warrants
Warrants outstanding at December 31, 2015	16,634,778
Warrants issued in conjunction with registered direct offering	2,500,000
Unexercisable warrants[1]	(2,000,000)
Warrants exercised during January 2016	(67,042)
Warrants expired during January 2016	(6,831,115)
June 2015 registered direct offering warrants cancelled	(3,000,000)
February 2016 registered direct offering warrants cancelled	(2,500,000)
Warrants issued in conjunction with July 2016 registered direct offering	7,043,211
Additional warrants due to anti-dilution provisions	2,089
Warrants expired during September 2016[2]	(2,250,000)
Warrants issued in conjunction with October 2016 registered direct offering	4,250,000
Warrants outstanding at December 31, 2016	13,781,921
Warrants expired during February 2017	(172,730)
Warrants exercised during March 2017	(202,500)
Warrants exercised during April 2017	(162,000)
Warrants exercised during May 2017	(221,366)
Warrants expired during May 2017	(45,834)
Warrants exercised during June 2017	(532,244)
Warrants issued pursuant to June 2017 warrant exercise agreements	11,293,211
Warrants exercised pursuant to June 2017 warrant exercise agreements	(11,293,211)
Warrants exercised during August 2017	(240,667)
Warrants exercised during October 2017	(85,000)
Warrants exercised during November 2017	(26,250)
Warrants expired in November 2017	(5,250)
Warrants outstanding at December 31, 2017	12,088,080
Composition of outstanding warrants:	
Warrants containing anti-dilution feature	94,721
Warrants without anti-dilution feature	11,993,359
	12,088,080

(1) Tranche 2 and Tranche 3 warrants that will never become exercisable, as discussed in Note 8.
(2) Tranche 1A and Tranche 1B warrants expired unexercised on September 29, 2016.

NOTE 16. - RETIREMENT PLAN

The Company sponsors a defined contribution plan under IRC Section 401(k). The plan covers all employees who meet the minimum eligibility requirements. Under the 401(k) plan eligible employees are allowed to make voluntary deferred salary contribution to the plan, subject to statutory limits. The Company has elected to make Safe Harbor Non-elective Contributions to the plan for eligible employees in the amount of three percent (3%) of the employee's compensation. Total employer contributions to the plan for the years ended December 31, 2017, 2016 and 2015 amounted to $98,368, $84,499 and $56,208, respectively.

NOTE 17. - COMMITMENTS AND CONTINGENCIES

License Agreements - Under its exclusive worldwide license agreement with North Carolina State University ("NCSU"), the Company is required to pay minimum annual royalty payments, which are credited against running royalties on sales of licensed products. The minimum annual royalty is $225,000. The license agreement continues through the life of the last-to-expire patent, which is expected to be 2022. The license agreement also requires a milestone payment of $150,000 upon FDA approval or clearance of a product that uses the NCSU licensed technology. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. These costs vary from year to year and the Company has certain rights to direct the activities that result in these costs. During the years ended December 31, 2017, 2016 and 2015 the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to $71,596, $84,191 and $103,641, respectively.

On December 8, 2015, the Company entered into an additional license agreement (the "License") with NCSU. Under the terms of the License, the Company paid NCSU a non-refundable, non-creditable lump sum license fee of $150,000. Additionally, the License calls for the Company to pay NCSU a non-refundable, non-creditable minimum annual royalties beginning on December 31, 2018 in the amount of $10,000. The minimum annual royalty payment increases to $15,000 in 2019, $25,000 in 2020 and 2021, and $50,000 per year thereafter for the remaining term of the License. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the years ended December 31, 2017, 2016 and 2015, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to $31,947, $6,075 and $0, respectively. This License continues through the life of the last-to-expire patent, expected to be in 2035.

On February 10, 2014, the Company entered into a sponsored research and development agreement (the "Agreement") with NCSU. Under the terms of the Agreement, the Company paid NCSU $162,408 over the two-year term of the Agreement, which grants certain licensed rights to the Company. The Company had extended the Agreement through January 31, 2017 at an additional cost of $85,681. In February 2018, the Company finalized an additional extension to this Agreement that obligates the Company to approximately $88,000 of additional sponsored research costs.

All payments made under the above referenced license agreement and the sponsored research and development agreement are initially recorded as a Prepaid expense on the Company's Consolidated Balance Sheets and subsequently expensed on a straight-line basis over the applicable period and included in Research and development costs on the Company's Consolidated Statements of Operations. The amounts expensed during the years ended December 31, 2017, 2016 and 2015 were $232,140, $447,808 and $156,204, respectively.

On August 22, 2014, the Company entered into a Commercial License Agreement with Precision PlantSciences, Inc. (the "Precision License"). The Precision License grants the Company a non-exclusive, but fully paid up right and license to use technology and materials owned by Precision PlantSciences for a license fee of $1,250,000. The Precision License continues through the life of the last-to-expire patent, which is expected to be in 2028.

On August 27, 2014, the Company entered into an additional exclusive License Agreement (the "License Agreement") with NCSU. Under the License Agreement, the Company paid NCSU a non-refundable, non-creditable lump sum license fee of $125,000, and the Company must pay to NCSU an additional non-refundable, non-creditable lump sum fee of $75,000 upon issuance of a U.S. utility patent included in the patent rights. A patent was issued during the first quarter of 2017 under this clause, and accordingly, the $75,000 was due and payable to NCSU. The $75,000 cost is included in Research and development costs on the Company's Consolidated Statements of Operations. Additionally, the License Agreement calls for the Company to pay NCSU three non-refundable, non-creditable license maintenance fees in the amount of $15,000 per annum in each of December 2015, 2016 and 2017. Beginning in calendar year 2018, the Company is obligated to pay to NCSU an annual minimum royalty fee of $20,000 in 2018, $30,000 in 2019, and $50,000 per year thereafter for the remaining term of the License Agreement. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the years ended December 31, 2017, 2016 and 2015, the aggregated costs incurred related to capitalized patent costs and patent maintenance expense amounted to $41,033, $43,740 and $75,351, respectively. The License Agreement continues through the life of the last-to-expire patent, which is expected to be in 2034.

On September 15, 2014, the Company entered into a Sublicense Agreement with Anandia Laboratories, Inc. (the "Anandia Sublicense"). Under the terms of the Anandia Sublicense, the Company was granted an exclusive sublicense in the United States and a co-exclusive sublicense in the remainder of the world, excluding Canada, to the licensed Intellectual Property (more fully discussed in Note 11). The Anandia Sublicense calls for an up-front fee of $75,000, an annual license fee of $10,000, the payment of patent filing and maintenance costs, and a running royalty on future net sales. The Anandia Sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035.

The Precision License, the License Agreement with NCSU and the Anandia Sublicense are included in Intangible assets, net in the Company's Consolidated Balance Sheets and the applicable license fees will be amortized over the term of the agreements based on their last-to-expire patent date. Amortization expense during the years ended December 31, 2017, 2016 and 2015 amounted to $98,022, $98,022 and $98,022, respectively, and was included in Research and development costs on the Company's Consolidated Statements of Operations.

On September 28, 2015, the Company's wholly-owned subsidiary, Botanical Genetics, entered into a Sponsored Research Agreement (the "Agreement") with Anandia Laboratories Inc. ("Anandia"). Pursuant to the Agreement, Anandia is conducting research on behalf of the Company relating to the cannabis/hemp plant. The Agreement had an initial term of twelve (12) months from the date of the Agreement and can be extended at the sole option of the Company for two (2) additional periods of twelve (12) months each (of which the option on the first twelve (12) month period has

been extended). The Company paid Anandia $379,800 over the initial term of the Agreement. On March 13, 2017, the Company entered into Amendment No. 1 to the Agreement (the "Amendment"). The Amendment has a term of twelve (12) months and calls for the Company to pay Anandia a total of $785,100 in equal monthly installments of $65,425. During the years ended December 31, 2017, 2016 and 2015 expenses related to the Agreement amounted to $654,250, $263,400 and $116,400, respectively, and are included in Research and development costs on the Company's Consolidated Statements of Operations. The Company is evaluating the final twelve (12) month option which calls for the Company to pay Anandia $653,200 under the Agreement. Under the terms of the Agreement, the Company will have co-exclusive worldwide rights with Anandia to all the intellectual property resulting from the sponsored research between the Company and Anandia. The party that commercializes such intellectual property in the future will pay royalties in varying amounts to the other party, with the amount of such royalties being dependent upon the type of products that are commercialized in the future. If either party sublicenses such intellectual property to a third-party, then the Company and Anandia will share equally in such sublicensing consideration.

The Company had an R&D agreement with the University of Virginia ("UVA") relating to nicotine biosynthesis in tobacco plants. The extended term of the R&D agreement with UVA expired on October 31, 2016. In December 2016, the Company entered into a new 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") pursuant to which the Company 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 optimize other desirable hemp plant characteristics to improve the plant's suitability for growing in Virginia and other legacy tobacco regions of the United States. This work with UVA will also involve the development and study of medically important cannabinoids to be extracted by UVA from the Company's hemp plants. UVA and the Company will 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 the Company exclusive rights to commercialize all results of the collaboration in consideration of royalty payments by the Company to UVA LVG. The Company incurred expenses under the agreement in the amount $296,710, $224,560 and $224,428 for the years ended December 31, 2017, 2016 and 2015, respectively. and are included in Research and development costs on the Company's Consolidated Statements of Operations.

Lease Agreements - The Company leases a manufacturing facility and warehouse located in North Carolina on a triple net lease basis. The lease commenced on January 14, 2014, and had an initial term of twelve (12) months. The 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 the option of the Company. The Company is currently in the second two-year lease extension term that will expire on October 31, 2019. The lease expense for the years ended December 31, 2017, 2016 and 2015 amounted to approximately $156,000, $146,000 and $127,000, respectively. The future minimum annual lease payments if the Company exercises each of the additional extensions are approximately as follows:

Year ended December 31, 2018 - $169,000
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, the Company entered into a lease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment, to store the Company's proprietary tobacco leaf and to store inventory used in the Company's contract manufacturing business. The lease calls for a monthly payment of $4,665, expires on August 14, 2018 and contains twelve-month renewal options as long as the Company continues to lease the warehouse. Future minimum lease payments will be approximately $56,000 per year for each subsequent year the warehouse space is leased by the Company.

During 2017 and 2016, the Company entered into three separate leases for warehouse space in North Carolina to accommodate its contract manufacturing business. As of December 31, 2017, each of these leases have been terminated with no future lease obligations.

The Company previously had a lease for its office space in Clarence, New York that was extended for an additional one-year renewal period that expired on August 31, 2017 and was subsequently leased on a month-to-month basis at a monthly lease payment of $5,267. On October 4, 2017, the Company entered a new lease for new office space at a new location with an initial three-year term and with a monthly lease payment of $6,375. The Company moved into the new lease space in February of 2018. Future minimum lease payments under the new office lease will be approximately $64,000, $76,000 and $76,000 for the years ended December 31, 2018, 2019 and 2020, respectively.

On May 1, 2016, the Company entered into a sublease for laboratory space in Buffalo, New York. The sublease calls for a monthly payment of $1,471 through April 30, 2018. Additionally, on February 1, 2017, the Company 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 sublease obligation to $2,690. On April 26, 2017, the Company entered into an 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, the Company 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 years ended December 31, 2018 and 2019 will be approximately $63,000 and $34,000, respectively.

Litigation - In accordance with applicable accounting guidance, the Company establishes an accrued liability for litigation and regulatory matters when those matters present loss contingencies that are both probable and estimable. In such cases, there may be an exposure to loss in excess of any amounts accrued. When a loss contingency is not both probable and estimable, the Company does not establish an accrued liability. As a litigation or regulatory matter develops, the Company, in conjunction with any outside counsel handling the matter, evaluates on an ongoing basis whether such matter presents a loss contingency that is probable and estimable. If, at the time of evaluation, the loss contingency related to a litigation or regulatory matter is not both probable and estimable, the matter will continue to be monitored for further developments that would make such loss contingency both probable and estimable. When a loss contingency related to a litigation or regulatory matter is deemed to be both probable and estimable, the Company will establish an accrued liability with respect to such loss contingency and record a corresponding amount of litigation-related expense. The Company will then continue to monitor the matter for further developments that could affect the amount of any such accrued liability.

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 seeks 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 seeks 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 January 26, 2018, the SDNY Court entered a case management order that such discovery be completed by May 18, 2018 and scheduling a pretrial conference for May 23, 2018.

We believe 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.

NOTE 18. - EARNINGS PER COMMON SHARE

The following table sets forth the computation of basic and diluted earnings per common share for the years ended December 31, 2017, 2016 and 2015:

	December 31, 2017	December 31, 2016	December 31, 2015
Net loss attributed to common shareholders	$(13,029,117)	$(11,581,430)	$(11,031,931)
Denominator for basic earnings per share-weighted average shares outstanding	101,161,380	79,842,773	68,143,284
Effect of dilutive securities:			
Warrants, restricted stock and options outstanding	-	-	-
Denominator for diluted earnings per common share-weighted average shares adjusted for dilutive securities	101,161,380	79,842,773	68,143,284
Loss per common share - basic and diluted	$(0.13)	$(0.15)	$(0.16)

Securities outstanding that were excluded from the computation of earnings per share for the years ended December 31, 2017, 2016 and 2015 because they would have been anti-dilutive are as follows:

	December 31, 2017	December 31, 2016	December 31, 2015
Warrants	12,088,080	13,781,921	16,634,778
Options	8,156,691	5,650,679	3,161,642
	20,244,771	19,432,600	19,796,420

NOTE 19. - EQUITY BASED COMPENSATION

On April 12, 2014, the stockholders of the Company approved the 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (the “OIP”) and the authorization of 5,000,000 shares thereunder. On April 29, 2017, the stockholders approved an amendment to the OIP to increase the number of shares available for issuance by 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. As of December 31, 2017, the Company had available 2,933,956 shares remaining for future awards under the OIP.

During the year ended December 31, 2017, the Company issued stock option awards from the OIP for 2,692,000 shares to eligible individuals having vesting periods ranging from one to three years from the date of the award. During the year ended December 31, 2016, the Company issued stock option awards from the OIP for 2,389,037 shares to eligible individuals having vesting periods ranging from six months to three and one-half years from the date of the awards. All stock option awards were valued using the Black-Scholes option-pricing model on the date of the award, and all restricted stock awards were valued at the closing price of the Company's common stock on the NYSE American on the date of the award.

For the years ended December 31, 2017, 2016 and 2015, the Company recorded compensation expense related to stock option and restricted stock awards of $941,650, $880,509 and $1,326,393, respectively. During the year ended December 31, 2017, there were no issuances of stock or stock options to third-party service providers. During the year ended December 31, 2016, the Company issued restricted stock in the amount of 15,811 shares and issued stock options in the amount of 100,000 shares to a third-party service provider. The Company recorded equity-based compensation expense related to the third-party providers for the years ended December 31, 2017, 2016 and 2015 in the amount of $0, $30,873 and $280,362, respectively, and does not include equity-based compensation under the Crede Consulting Agreement in the amount of $0, $0, and $1,978,785 for the years ending December 31, 2017, 2016 and 2015, respectively.

As of December 31, 2017, unrecognized compensation expense related to non-vested restricted shares and stock options amounted to approximately $3,886,000 which is expected to be recognized approximately as follows: $1,595,000, $951,000 and $569,000 during 2018, 2019 and 2020, respectively. Approximately $771,000 of the unrecognized compensation expense relates to previously issued stock options, with the vesting of such stock options being based on the achievement of a certain milestone, and the attainment of such milestone cannot be determined at this time.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were used for the years ended December 31, 2017, 2016 and 2015:

	2017	2016	2015
Risk-free interest rate (weighted average)	2.05 %	1.31 %	1.60 %
Expected dividend yield	0 %	0 %	0 %
Expected stock price volatility	90 %	90 %	90 %
Expected life of options (weighted average)	5.56 years	4.87 years	8.96 years

The Company estimated the expected volatility based on data used by a peer group of public companies. The expected term was estimated using the contract life of the option. The risk-free interest rate assumption was determined using yield of the equivalent U.S. Treasury bonds over the expected term. The Company has never paid any cash dividends and does not anticipate paying any cash dividends in the foreseeable future. Therefore, the Company assumed an expected dividend yield of zero.

A summary of all stock option activity since December 31, 2015 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2015	3,161,642	$ 1.10		
Granted 2016	2,489,037	$ 0.97		
Outstanding at December 31, 2016	5,650,679	$ 1.04		
Granted in 2017	2,692,000	$ 1.76		
Exercised in 2017	(85,988)	$ 0.79		
Expired in 2017	(100,000)	$ 1.43		
Outstanding at December 31, 2017	8,156,691	$ 1.28	7.3 years	$11,533,400

Exercisable at December 31, 2017	3,617,670	$ 1.10	5.8 years	$6,151,390

There were stock options granted during the years ended December 31, 2017 and 2016, to purchase a total of 2,692,000 and 2,489,037 shares, respectively. The weighted average grant date fair value of options issued during the years ended December 31, 2017 and 2016 was $1.28 and $0.66, respectively. The total fair value of options that vested during years ended December 31, 2017 and 2016 amounted to $750,265 and $1,242,110, respectively. During the year ended December 31, 2017, 85,988 options were exercised on a cashless basis resulting in the issuance of 51,927 shares of the Company’s common stock. No options were exercised during the year ended December 31, 2016.

NOTE 20. - INCOME TAXES

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%. The Company's income tax provision (benefit) reflects the effect of this change in Federal corporate tax rates, primarily from the re-measurement of the Company's deferred tax assets and liabilities, including prior net operating loss carry-forwards. The effect of the rate change attributable to the TCJA on the Company's effective tax rate was a decrease of approximately 46% in the net deferred tax assets before the valuation allowance. Since the Company is in a full valuation allowance situation, the change in the Federal corporate rate had no effect on the calculation of the Company's tax provision, which remained at zero.

The following is a summary of the components giving rise to the income tax provision (benefit) for the years ended December 31, 2017, 2016 and 2015:

	2017	2016	2015
Current:			
Federal	$-	$-	$-
State	-	-	-
Total current	-	-	-
Deferred:			
Federal	1,263,677	(2,424,497)	(3,372,964)
State	214,628	21,452	(155,352)
Total deferred	1,478,305	(2,403,045)	(3,528,316)
Change in valuation allowance	(1,478,305)	2,403,045	3,528,316
	$-	$-	$-

The provision (benefit) for income tax varies from that which would be expected based on applying the statutory federal rate to pre-tax accounting loss, including the effect of the change in the U.S. corporate income tax rates, as follows:

	2017	2016	2015
Statutory federal rate	(34.0)%	(34.0)%	(34.0)%
Other items	(2.4)	(0.2)	0.0
Derivative liability	0.4	11.9	(0.5)
Stock based compensation	2.0	1.5	3.1

Research and development credit carryforward	(1.8)	-	-
State tax provision, net of federal benefit	1.1	0.1	(0.9)
Federal tax rate change	46.1	-	-
Valuation allowance	(11.4)	20.7	32.3
Effective tax rate (benefit) provision	0.0 %	0.0 %	0.0 %

Individual components of deferred taxes consist of the following as of December 31:

	2017	2016	2015
Deferred tax assets:			
Net operating loss carry-forward	$9,917,641	$11,626,143	$7,745,734
Accounts receivable reserve	-	3,499	3,499
Inventory	48,011	96,934	38,707
Stock-based compensation	388,925	282,850	1,599,916
Start-up expenditures	279,709	477,917	514,680
Research and development credit carryforward	232,198	-	-
Loss on equity investment	11,760	139,676	68,877
Severance liability	-	69,860	147,070
Other	4,272	21,423	9,272
	10,882,516	12,718,302	10,127,755
Deferred tax liabilities:			
Machinery and equipment	(220,888)	(316,232)	(227,186)
Patents and trademarks	(558,760)	(807,137)	(767,044)
Other intangible assets	(124,953)	(138,713)	(80,349)
	(904,601)	(1,262,082)	(1,074,579)
Valuation allowance	(9,977,915)	(11,456,220)	(9,053,176)
Net deferred taxes	$-	$-	$-

The Company has incurred a net operating loss ("NOL") of approximately $47,000,000 through December 31, 2017 and this amount is being carried forward to future years and begins to expire in 2031. Due to the uncertainty of the Company's ability to generate sufficient taxable income in the future before they expire, the Company has recorded a valuation allowance to reduce the net deferred tax asset to zero. This NOL is included in the net deferred tax asset that has been fully offset by the valuation allowance. Utilization of the NOL carryforwards may be subject to an annual limitation (or the NOL's may expire unutilized) in the case of equity ownership changes, as defined by tax law.

ASC 740 provides guidance on the financial statement recognition and measurement for uncertain income tax positions that are taken or expected to be taken in a company's income tax return. The Company has no uncertain tax positions as of December 31, 2017.

NOTE 21. - SELECTED QUARTERLY FINANCIAL DATA (unaudited)

Below is selected quarterly financial data for the years ended December 31, 2017 and 2016:

	Three Months Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Revenue, net	$2,231,517	$3,897,206	$4,530,865	$5,940,656
Gross (loss) profit	$(273,897)	$(165,055)	$(340,369)	$71,409
Loss from operations	$(2,969,949)	$(3,282,525)	$(3,274,081)	$(3,773,309)
Net loss	$(2,621,277)	$(3,355,624)	$(3,316,634)	$(3,735,582)
Loss per common share - basic and diluted	$(0.03)	$(0.04)	$(0.03)	$(0.03)

	Three Months Ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Revenue, net	$3,019,056	$2,827,658	$3,097,648	$3,335,617
Gross profit (loss)	$123,646	$(140,913)	$(184,618)	$(227,814)

Loss from operations	$(3,228,404)	$(2,830,830)	$(2,595,812)	$(2,732,801)
Net loss	$(3,252,452)	$(2,902,354)	$(2,679,988)	$(2,746,636)
Loss per common share - basic and diluted	$(0.04)	$(0.04)	$(0.03)	$(0.03)

NOTE 22. - SUBSEQUENT EVENTS

The Company (through its wholly-owned subsidiary, Botonical Genetics) has an equity investment in Anandia (see Note 11 for a discussion of the investment). On January 16, 2018, Anandia closed a private placement financing of common shares raising approximately $10.8 million. Subsequent to this financing, the Company's ownership in Anandia was reduced to approximately 15%.

In January and February of 2018, the Company issued 426,180 shares of common stock to various investors from the cashless exercise of 700,148 warrants to purchase shares of the Company's common stock.

Item 15(b). Financial Statement Schedules

Valuation and Qualifying Accounts

The following table summarizes the Company's valuation and qualifying accounts from December 31, 2014:

	Allowance for doubtful Accounts	Reserve for inventory valuation	Deferred tax valuation allowance
Qualifying account valuation at December 31, 2014	$ -	$ 50,623	$ 5,524,860
Additions charged to costs and expenses during 2015	10,000	60,000	3,528,316
Deductions during 2015	-	-	-
Qualifying account valuation at December 31, 2015	10,000	110,623	9,053,176
Additions charged to costs and expenses during 2016	-	145,000	2,403,044
Deductions during 2016	-	-	-
Qualifying account valuation at December 31, 2016	10,000	255,623	11,456,220
Additions charged to costs and expenses during 2017	-	95,000	-
Deductions during 2017	(10,000)	(155,623)	(1,478,305)
Qualifying account valuation at December 31, 2017	$ -	$ 195,000	$ 9,977,915

Item 15(c). Exhibits

In reviewing the agreements included as exhibits to this report, please remember they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about the Company, its subsidiaries or other parties to the agreements. The agreements contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement and:

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;

- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;

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may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and

- Were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time. We acknowledge that, notwithstanding the inclusion of the foregoing cautionary statements, we are responsible for considering whether additional specific disclosures of material information regarding material contractual provisions are required to make the statements in this report not misleading. Additional information about the Company may be found elsewhere in this report and the Company's other public files, which are available without charge through the SEC's website at http://www.sec.gov.

Exhibit No.	Description
2.1	Investment Agreement, dated April 11, 2014, by and between 22nd Century Group, Inc. and Anandia Laboratories Inc. (incorporated by reference to Exhibit 2.2 to the Company's Form 8-K filed with the Commission on September 18, 2014).
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K for the year ended September 30, 2010 filed with the Commission on December 1, 2010).
3.1.1	Amendment to Certificate of Incorporation of the Company (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement filed with the Commission on March 4, 2014).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Commission on January 30, 2014).
3.2.1	Amendment No. 1 to Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 of the Company's Form 8-K filed with the Commission on April 28, 2015).
4.1	Form of Tranche 1A Warrant (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed with the Commission on September 30, 2014).

4.2	Form of Warrant Agreement (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Commission on June 19, 2017).
10.1†	2010 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.3 to the Company's Form S-8 filed with the Commission on March 30, 2011).
10.2†	Employment Agreement dated as of January 25, 2011, by and between the Company and Henry Sicignano III (incorporated herein by reference to Exhibit 10.16 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.3††	License Agreement dated March 6, 2009 between North Carolina State University and 22nd Century Limited, LLC (incorporated by reference to Exhibit 10.21 to the Company's Form S-1 registration statement filed with the Commission on August 26, 2011).
10.3.1	Amendment dated August 9, 2012 to License Agreement dated March 6, 2009 between North Carolina State University and 22nd Century Limited, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on August 20, 2012).
10.4	Letter Agreement between the Company and North Carolina State University dated November 22, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the Commission on November 23, 2011).
10.5†	Employment Agreement between John Brodfuehrer and the Company dated March 19, 2013 (incorporated by reference to Form 8-K filed on March 25, 2013).
10.6†	Form of Restricted Stock Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).
10.7†	Form of Stock Option Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).
10.8†	Form of Restricted Stock Award Agreement under 22nd Century Group, Inc. 2014 Omnibus Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the Commission on April 14, 2014).
10.9†	Form of Stock Option Award Agreement under 22nd Century Group, Inc. 2014 Omnibus Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed with the Commission on April 14, 2014).
10.10†	Employment Agreement dated May 12, 2014 by and between the Company and Thomas James (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the Commission on May 14, 2014).

10.11 *††	Research Funding Agreement dated December 14, 2016 with The Rector and Visitors of the University of Virginia, a not-for-profit Virginia educational institutional of the Commonwealth of Virginia (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Commission on March 8, 2017).
10.12 *††	Exclusive License Agreement dated December 14, 2016 with the University of Virginia Patent Foundation d/b/a University of Virginia Licensing & Ventures Group, a Virginia non-profit corporation (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Commission on March 8, 2017).
10.13†	22nd Century Group, Inc. 2014 Omnibus Incentive Plan, as amended and restated (incorporated by reference from Appendix A to the Company's definitive proxy statement filed on March 17, 2017).
10.14†	Employment Agreement dated October 31, 2017 between Dr. James E. Swauger and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on November 2, 2017).
21.1*	Subsidiaries.
23.1*	Consent of Freed Maxick CPAs, P.C.
31.1*	Section 302 Certification.
31.2*	Section 302 Certification.
32.1*	Written Statement of Principal Executive Officer and Chief Financial Officer pursuant to 18.U.S.C §1350.
101*	Interactive data files formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, and (iv) the Notes to the Consolidated Financial Statements.

101.INS XBRL Instance Document*

101.SCH XBRL Taxonomy Extension Schema ocument*

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document*

101.DEF XBRL Taxonomy Extension Definition Linkbase Document*

101.LAB XBRL Taxonomy Extension Label Linkbase Document*

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

† Management contract or compensatory plan, contract or arrangement.

†† Certain portions of the exhibit have been omitted pursuant to a confidential treatment order. An unredacted copy of the exhibit has been filed separately with the United States Securities and Exchange Commission pursuant to the request for confidential treatment.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

22nd CENTURY GROUP, INC.

Date: March 7, 2018 By: /s/ Henry Sicignano III
Henry Sicignano III
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 7, 2018 By: /s/ John T. Brodfuehrer
John T. Brodfuehrer
Chief Financial Officer
(Principal Accounting and Financial Officer)

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 7, 2018 By: /s/ Henry Sicignano III
Henry Sicignano III
President, Chief Executive Officer and Director

Date: March 7, 2018 By: /s/ Joseph Alexander Dunn, Ph.D.
Joseph Alexander Dunn, Ph.D. Director

Date: March 7, 2018 By: /s/ James W. Cornell
James W. Cornell

Director

Date: March 7, 2018 By: /s/ Richard M. Sanders
Richard M. Sanders
Director

Date: March 7, 2018 By: /s/ Nora B. Sullivan
Nora B. Sullivan

Director

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