22nd Century Group, Inc.
Form 10-K
March 08, 2017

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, 2016

or

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

Securities Exchange Act of 1934

Commission File Number: 001-36338

22nd Century Group, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**98-0468420**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)

9530 Main Street, Clarence, New York 14031

(Address of principal executive offices)

(716) 270-1523

Registrant's telephone number, including area code

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

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

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, or a non-accelerated filer.

Large Accelerated Filer ¨ Accelerated Filer x Non-Accelerated Filer ¨ Smaller Reporting Company ¨

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, 2016, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate value of the registrant’s common stock (excluding the 6,547,234 shares held by affiliates), based upon the $0.81 price at which such common stock was last sold on June 30, 2016, was approximately $56.3 million.

As of March 8, 2017, there were 90,698,113 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2017 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, 2016.

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;
- Our ability to raise additional capital on favorable terms or at all;
- Our ability to obtain significant revenue for our tobacco products;
- Our ability to manage our growth effectively;
- Our ability to retain key personnel;
- Our ability to enter into additional licensing transactions;
- The potential for our clinical trials to produce negative or inconclusive results;
- Our ability to obtain U.S. Food and Drug Administration (“FDA”) clearance for our potentially modified risk tobacco products and FDA approval for our *X-22* smoking cessation aid;
- Our ability to obtain FDA clearance to market *BRAND A* and *BRAND B* cigarettes as Modified Risk Products;

- Our ability to gain market acceptance for our products;

- Any potential negative impact from doing business in the legal hemp and medical marijuana space;

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

- 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 levels of cannabinoids in cannabis plants through genetic engineering and plant breeding. Our primary mission is to reduce the harm caused by smoking. We own or exclusively control more than 200 issued patents plus more than 50 pending patent applications.

We are in the process of transitioning from researching and developing our proprietary technology and tobaccos to commercializing our technology and products. We initiated the commercialization of our technology and products in the year 2015. According to Euromonitor International, annual worldwide tobacco product sales, including cigarettes and smokeless products, are approximately $800 billion, most of which are cigarette sales. If we, or our licensee(s), capture a small fraction of this market, we believe our value will increase tremendously.

We are primarily involved in the following activities:

- The research and development of potentially less harmful or modified risk tobacco products and novel tobacco plant varieties;

- The pursuit of necessary regulatory approvals and clearances from the FDA to market *BRAND A* cigarettes in the U.S. as an over-the-counter product labeled to advertise the reduced exposure to nicotine, as *BRAND A* cigarettes contain 95% less nicotine than conventional tobacco cigarettes;

- The development of *X-22*, a prescription-based smoking cessation aid consisting of very low nicotine ("VLN") cigarettes, and the pursuit of regulatory approvals and clearances from the FDA and regulatory agencies in other countries to market *X-22* as a prescription smoking cessation aid;

- The pursuit of necessary regulatory approvals and clearances from the FDA to market *BRAND B* cigarettes as modified risk cigarettes with an extremely low tar-to-nicotine ratio;

- The manufacture, marketing, sales and distribution of *RED SUN* and *MAGIC* proprietary cigarettes;

- The production of *SPECTRUM* research cigarettes for the National Institute on Drug Abuse ("NIDA"), a part of the National Institutes of Health ("NIH");

- The international licensing of our technology, proprietary tobaccos, and trademarks;

- The sale of our branded proprietary tobaccos;

- The contract manufacturing of third-party branded tobacco products; and

- The research and development of unique plant varieties of hemp/cannabis, such as (i) plants with low to no amounts of delta-9-tetrahydrocannabinol, or THC, for the legal hemp industry, and (ii) plants with high levels of cannabidiol, or CBD, and other non-THC cannabinoids for the legal medical cannabis markets.

Our prospects depend on our ability to generate and sustain revenues from (i) licensing and/or sale of our proprietary tobacco, technology and products; (ii) regulatory approval of our *X-22* smoking cessation aid; (iii) further development of our potential modified risk tobacco products; (iv) domestic and international sales of our brands, including *RED SUN* and *MAGIC*; and (v) the manufacture of the filtered cigar and cigarette brands of third-parties at our manufacturing facility in North Carolina. Our ability to generate meaningful revenue from our potential modified risk tobacco products in the United States depends on obtaining FDA authorization to market these products as modified risk or reduced exposure; and our ability to generate meaningful revenue in the United States from *X-22* depends on FDA approval. If these products are authorized and approved by the FDA, we must still meet the challenges of successful marketing, distribution and consumer acceptance.

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We believe our products address unmet needs of smokers; for those smokers who desire to quit, an innovative smoking cessation aid, and for those smokers who are unable or unwilling to quit smoking, cigarettes that may reduce the level of exposure to nicotine and certain tobacco toxins.

We believe our proprietary technology, tobaccos and products will generate multiple significant revenue streams from the licensing of our technology and tobacco and from the sales of our products.

Intellectual Property

Our intellectual property enables us to decrease or increase the level of nicotine and other nicotinic alkaloids in tobacco plants by decreasing or increasing the expression of the gene(s) responsible for nicotine production in the tobacco plant using genetic engineering. 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 own or exclusively control more than 200 issued patents plus more than 50 pending patent applications. A "patent family" is a set of patents granted in various countries to protect a single invention. Our patent coverage in the United States and China, two of the most valuable smoking cessation and cigarette markets in the world, consists of 29 issued patents and 21 pending applications and 10 issued patents and 8 pending patent applications, respectively. We have exclusive rights to all uses of the following genes responsible for nicotine content in tobacco plants: *NBB*, *QPT*, *A622*, *MPO* and several transcription factor genes. We have exclusive rights to plants with altered nicotine content produced from modifying expression of these genes and tobacco products produced from these plants. With the exception of one patent family that will expire in 2018, the majority of the 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.

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 four genes in the 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. As a plant biotechnology company, our entry into the legal hemp/cannabis markets is a natural evolution of our activities in a plant that has important research and commercial value and applications. We intend to engage in research and development activities to create unique plant varieties of hemp/cannabis, 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 cannabis markets.

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 and 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.

Licensing our technology and tobacco

We have been in negotiations with various parties in the tobacco and pharmaceutical industries for licensing our technology and products. On October 1, 2013, our subsidiary, 22nd Century Limited, LLC ("22nd Century Ltd."), entered into a Research License and Commercial Option Agreement (the "BAT Research Agreement") with British American Tobacco (Investments) Limited ("BAT"), a subsidiary of British American Tobacco plc.

Under the terms of the BAT Research Agreement, BAT receives an exclusive worldwide license to certain patent rights (subject to worldwide rights retained by 22nd Century Ltd. for use in its own brands and products) and licensed intellectual property rights (as such terms are defined in the BAT Research Agreement) of 22nd Century Ltd. within the field of use (as defined in the BAT Research Agreement) for a period of up to four (4) years (the "Research Term"). During the Research Term, BAT also has an option, which can be exercised by BAT at any time during the Research Term, to obtain an exclusive worldwide license (subject to worldwide rights retained by 22nd Century Ltd. for use in its own products and brands) to commercialize certain products derived from utilizing the patent rights and licensed intellectual property rights under the terms of a commercial license agreement (the "Commercial License").

Simultaneously with the signing of the BAT Research Agreement, BAT paid us a non-refundable fee of $7.0 million. Further, we may receive payments from BAT of up to an additional $7.0 million during the Research Term in the event certain milestones are met by BAT with respect to its research and development of the patent rights and licensed intellectual property rights. There are four separate milestones, two of which may result in BAT paying us $2.0 million for each milestone achieved, and two of which may result in BAT paying us $1.5 million for each milestone achieved. BAT may terminate the BAT Research Agreement at any time, subject to the requirements for certain payments to us by BAT upon termination as set forth therein. We may also terminate the BAT Research Agreement in the event of certain uncured breaches of the BAT Research Agreement as set forth therein.

BAT also granted to us a worldwide license to any and all registered research results (as such term is defined in the BAT Research Agreement) developed and owned by BAT which results or arises from any research, development or other activities of BAT under the BAT Research Agreement, with the terms of such license from BAT. (i) to be on commercially reasonable terms to be negotiated in good faith between the parties but, in any event, on terms which are no more onerous than the terms of the Commercial License, if any, and (ii) to be dependent on what, if any, research results the Company elects to license.

If BAT exercises the option for a worldwide Commercial License, BAT is required to pay us $3.0 million in aggregate annual license fees over a 2-year ramp-up period, and thereafter a royalty, subject to annual minimums and maximums contained in the Commercial License, of (i) $100 per metric ton of licensed tobacco that is supplied to, or grown and ready for shipment to, BAT and its affiliates (other than Reynolds American, Inc. and Reynolds' affiliates) and all other third parties; and (ii) $200 per metric ton of licensed tobacco supplied to, or grown and processed by, BAT's affiliate Reynolds American, Inc. and Reynolds' affiliates.

Beginning three years from the start of the Commercial License, both we and BAT may license/sublicense rights to any unaffiliated third party for use of the technology outside the United States and we and BAT will equally share all profit from all such licensees/sublicensees. Inside the United States, BAT may only sublicense BAT's commercial rights to Reynolds American, Inc. we may sublicense any party in the United States.

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 the Company 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 the Company's acquisition of NASCO Products, LLC ("NASCO"), allowing us to become a subsequent participating manufacturer under the MSA. During the remainder of 2014, the Company

worked to obtain approvals from regulatory agencies in all 50 States to have our *RED SUN* super-premium 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 the Company's proprietary tobacco products for distribution in the European Union, starting with our *MAGIC* super-premium brand. Both of the *RED SUN* and *MAGIC* brands are available in regular and menthol and all brand styles are king size and packaged in hinge-lid hard packs. Since 2015, we have focused our marketing efforts for *RED SUN* on national and regional distributors, tobacconists, smokeshops and other tobacco outlets in the U.S. Since 2015, we also introduced our *MAGIC* cigarettes to distributors and retailers in select European markets, as explained in greater detail below under "International Sales."

MSA Membership

In September 2013, the Company 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 MSA (the "NASCO Acquisition"). On August 29, 2014, the Company 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, the Company closed the NASCO Acquisition and became a subsequent participating manufacturer under the MSA. NASCO is now a wholly-owned subsidiary of the 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 $3.22 million.

The facility was primarily in a pre-manufacturing stage during 2014 as we sought approval during that time for the Company to become a subsequent participating manufacturer under the MSA. Since August 29, 2014, the Company manufacturers its cigarette brands in the United States through its wholly-owned subsidiary, NASCO, at the Company's factory in North Carolina. Since 2015, we have manufactured and sold our *SPECTRUM* government research cigarettes, our *RED SUN* super-premium brand, together with a third-party MSA cigarette brand, and third-party filtered cigars, at our factory.

The Company outsources the manufacturing of *MAGIC* super-premium brand to Orion, a cigarette manufacturer in Poland that contract manufactures *MAGIC* cigarettes for the Company for distribution in the European Union. Orion is a manufacturer and distributor of smoking tobaccos, cigarettes, filter tubes, and smoking accessories with distribution in more than 20 countries. Distribution of *MAGIC* brand cigarettes commenced in Spain in 2015. In advance of expanding sales of *MAGIC* brand cigarettes in additional European countries and in Asia, the Company is pursuing, on a country-by-country basis, the regulatory approvals associated with marketing to consumers the unique benefits of Very Low Nicotine cigarettes.

The Tobacco Control Act and Our Potentially Modified Risk Cigarettes - BRAND A and BRAND B

In a 2005 analyst report, *The Third Innovation, Potentially Reduced Exposure Cigarettes*, JP Morgan examined the effects of regulation by the U.S. Food and Drug Administration ("FDA") of tobacco, including the market for safer cigarettes. JP Morgan's proprietary survey of over 600 smokers found that 90% of smokers are willing to try a safer cigarette. Among JP Morgan's other conclusions, it stated: "FDA oversight would imbue PREPS ['potential reduced exposure products' which essentially equate to potential modified risk tobacco products] with a regulatory 'stamp of approval' and allow for more explicit comparative health claims with conventional cigarettes. Consumers should trust the FDA more than industry health claims." Prior to the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") becoming law in 2009, no regulatory agency or body had the authority to assess potentially modified risk tobacco products.

The Tobacco Control Act grants the FDA authority over the regulation of all tobacco products. 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. The Tobacco Control Act also banned all sales in the U.S. of cigarettes with characterizing flavors (other than menthol). As of June 2010, all cigarette companies were required to cease the use of the terms “low tar,” “light” and “ultra-light” in describing cigarettes sold in the U.S. Besides numerous other regulations, including certain marketing restrictions, for the first time in history, a U.S. regulatory agency now scientifically evaluates cigarettes that may pose lower health risks as compared to conventional 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 two types of our cigarettes in development, which we refer to as *BRAND A* and *BRAND B*, may 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 (e.g., Marlboro ®, Camel ®, Newport ®, Natural American Spirit ®), which could create opportunities for us to license our proprietary technology and/or our tobaccos to larger competitors.

We believe that our *BRAND A* and *BRAND B* cigarettes will benefit smokers who are unable or unwilling to quit smoking and who may be interested in cigarettes which reduce exposure to nicotine or to certain tobacco smoke toxins and/or pose a lower health risk than conventional cigarettes. This includes approximately one-half of the 42 million adult smokers in the United States who do not attempt to quit in a given year. Compared to commercial cigarettes, the tobacco in *BRAND A* has approximately 95% less nicotine than tobacco in cigarettes previously marketed as “light” cigarettes and *BRAND B* ’s smoke contains an extraordinarily low amount of “tar” per milligram of nicotine. We believe that *BRAND A* and *BRAND B* will achieve market share in the global cigarette market among smokers who are unable or unwilling to quit but are interested in reducing the harmful effects of smoking. We believe this new regulatory environment represents a paradigm shift for the tobacco industry. There is no guarantee, however, that we will (i) have sufficient capital to complete the FDA authorization process for our potential Modified Risk Cigarettes, (ii) obtain FDA authorization to market *BRAND A or BRAND B* as Modified Risk Cigarettes, or (iii) achieve significant share of the market even with FDA authorization to market our products as Modified Risk Cigarettes.

We have worked diligently with the FDA to obtain a reduced exposure marketing authorization for *BRAND A* to be marketed as having less nicotine in the U.S., as described below. We also intend to seek FDA authorization to (i) market *BRAND B* as a Modified Risk Cigarette with an extraordinarily low amount of "tar" per milligram of nicotine and (ii) market *X-22* as a prescription smoking cessation product.

BRAND A Cigarettes

Compared to commercial tobacco cigarettes, *BRAND A* has the lowest nicotine content. The tobacco in *BRAND A* contains approximately 95% less nicotine than conventional cigarette brands. Reducing smokers' exposure to nicotine is the strategy behind *BRAND A*.

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. *BRAND A* cigarettes contain approximately 0.7 milligrams of nicotine in the tobacco contained in the cigarette and a machine smoking yield of less than 0.05 mg of nicotine per cigarette.

The best-known clinical trial utilizing our proprietary VLN tobacco was reported on in the October 2015 issue of *The New England Journal of Medicine* (N Engl J Med 2015; 373:1340-1349), which was funded by the National Institute on Drug Abuse ("NIDA"), which is part of the National Institutes of Health ("NIH"), and the U.S. Food and Drug Administration ("FDA") Center for Tobacco Products ("CTP"). The Center for the Evaluation of Nicotine in Cigarettes led the double-blind, parallel, randomized clinical trial involving 840 smokers at ten locations. The authors concluded that data from the study suggests, as compared with cigarettes of conventional nicotine content, 22nd Century's proprietary VLN cigarettes were "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events."

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 helpful and positive feedback on our combined Modified Risk Tobacco Product Applications (MRTPAs) and Premarket Tobacco Product Applications (PMTAs) 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 new MRTPAs and PMTAs for *BRAND A* that will include additional scientific data and information from already completed clinical studies on our Very Low Nicotine tobacco cigarettes, in addition to smoking cessation research as requested by the FDA. In order to help further expedite the FDA review process, we also intend to bifurcate our application into separate PMTAs and MRTPAs for

BRAND A, as PMTAs have shorter review periods.

We believe *BRAND A* will ultimately receive a marketing order from the FDA to allow *BRAND A* to be marketed and sold in the U.S. as a reduced exposure product that exposes users to 95% less nicotine than conventional cigarettes.

BRAND B 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 some commercially available full flavor cigarette brands. We believe smokers who desire to reduce smoke exposure, but are less concerned about nicotine, will find *BRAND B* beneficial. Although smoking yields, as determined by laboratory smoking machines, are not always indicative of smoke and tar intake by humans, *BRAND B* cigarettes are being designed to have a "tar" yield between typical "light" and "ultra-light" cigarettes (as previously labeled and marketed by conventional tobacco companies), but a nicotine yield of typical full flavor cigarettes.

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 believe that evaluation of *BRAND B* in short-term human exposure studies will confirm that exposure to smoke, including certain tobacco smoke toxins and carbon monoxide, is significantly reduced when smoking *BRAND B* as compared to smoking the leading brands of cigarettes.

Accordingly, 22nd Century has submitted an application with the FDA for the Company's first proposed smoke evaluation exposure study for our *BRAND B* cigarettes. The Company has engaged a major contract research organization ("CRO") with extensive experience in tobacco exposure studies to assist us in certain regulatory activities at the CTP related to the Company's research to support the development of potentially less harmful or modified risk cigarettes. Our first proof of concept study for *BRAND B* is scheduled for the second quarter of 2017, subject to completion of FDA review.

We believe results from this and other exposure studies will warrant a modified risk claim for *BRAND B*.

X-22 Smoking Cessation Aid

X-22 is a tobacco-based botanical medical product for use as an aid to smoking cessation. The *X-22* therapy protocol utilized in our sponsored Phase IIb clinical trial calls for the patient to smoke 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 this therapy protocol has been successful in independent clinical trials because *X-22* cigarettes made from our proprietary 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.

In fact, independent clinical studies have demonstrated that smokers who smoke very low nicotine ("VLN") cigarettes containing our proprietary 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 VLN cigarettes containing our proprietary tobacco (Hatsukami *et al*. 2010).

The independent, clinical studies utilizing our proprietary tobacco cigarettes have shown efficacy when used alone and/or when used in conjunction with existing nicotine replacement therapies ("NRTs"), such as the nicotine patch, gum or lozenge, or Pfizer's Chantix/Champix product. These clinical studies are all summarized below under "Business - Products - *X-22* Smoking Cessation Aid." The results of such clinical studies using cigarettes made from our Company's proprietary VLN tobacco have demonstrated many desirable outcomes, including reduced smoking, reduced nicotine exposure, reduce nicotine dependence, increased abstinence, reduced exposure to toxicants and few adverse events with little evidence of withdrawal-related discomfort or safety concerns. Unlike "light" cigarettes (as previously labeled and marketed by conventional tobacco companies) which reduce machine-smoking nicotine yields by diluting the smoke rather than by reducing the nicotine content of the tobacco itself, VLN cigarettes do not result in compensatory smoking.

The best-known clinical trial utilizing our proprietary VLN tobacco was reported on in the October 2015 issue of *The New England Journal of Medicine* (N Engl J Med 2015; 373:1340-1349), which was funded by the National Institute on Drug Abuse ("NIDA"), which is part of the National Institutes of Health ("NIH"), and the U.S. Food and Drug Administration (FDA) Center for Tobacco Products. The Center for the Evaluation of Nicotine in Cigarettes led the double-blind, parallel, randomized clinical trial involving 840 smokers at ten locations. The authors concluded that data from the study suggests, as compared with cigarettes of conventional nicotine content, 22nd Century's proprietary VLN cigarettes were "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events." The study's lead author, Dr. Eric Donny, explained that "The evidence is getting stronger that reducing nicotine reduces smoking and makes people less addicted to cigarettes and, in doing so, might make them more likely to quit."

Approximately 50% of U.S. smokers attempt to quit smoking each year, but only 2% to 5% actually quit smoking in a given year. It takes smokers an average of 8 to 11 "quit attempts" before achieving long-term success. Approximately 95% of "self-quitters" (i.e., those who attempt to quit smoking without any treatment) relapse and resume smoking. The Institute of Medicine, the health arm of the National Academy of Sciences, in a 2007 report concludes: "There is an enormous opportunity to increase population prevalence of smoking cessation by reaching and motivating the 57 percent of smokers who currently make no quit attempt per year." We believe that our *X-22* smoking cessation aid will be attractive to smokers who have been frustrated in their previous attempts to quit smoking using other therapies.

Use of existing smoking cessation aids results in relapse rates that can be as high as 90% in the first year after a smoker initially "quits." Smokers currently have the following limited choices of FDA-approved products to help them quit smoking:

- varenicline (Chantix® /Champix® outside the U.S.), manufactured by Pfizer Inc.,
- bupropion (Zyban®), manufactured by GlaxoSmithKline plc, and
- nicotine replacement therapy which is available in the U.S. in several forms: gums, patches, nasal sprays, inhalers and lozenges.

Chantix® and Zyban® are pills and are nicotine free. Chantix®, Zyban®, the nicotine nasal spray and the nicotine inhaler are available by prescription only in the U.S. Nicotine gums, nicotine patches, and nicotine lozenges are available over-the-counter in the U.S.

Chantix® was introduced in the U.S. market in the fourth quarter 2006. Since 2007, Chantix® has been the best-selling smoking cessation aid in the United States, with sales, according to Pfizer Inc., of approximately $701 million in 2007, $489 million in 2008, $386 million in 2009, $330 million in 2010, $326 million in 2011, $313 million in 2012, $343 million in 2013 $377 million in 2014, and $426 million in 2015. In July 2009, the FDA required a "Boxed Warning," the most serious type of warning in prescription drug labeling, for both Chantix® and Zyban ® based on the potential side effects of these drugs. Despite this Boxed Warning (which was subsequently eliminated on December 16, 2016), worldwide sales of Chantix ® in 2009 to 2015 were approximately $700 million, $755 million, $720 million, $670 million, $648 million, $647 million, and $671 million, respectively.

Other than Chantix® and Zyban®, the only FDA-approved smoking cessation therapy in the United States is nicotine replacement therapy ("NRT"). These products consist of gums, patches, nasal sprays, inhalers and lozenges. Nicotine gums and nicotine patches have been sold in the U.S. for approximately 32 years and 24 years, respectively, and millions of smokers have already tried NRT products and failed to stop smoking due to the limited effectiveness of these products.

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") 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 the Company to control R&D costs while achieving our desired results, including obtaining exclusive intellectual property rights relating to our outsourced R&D.

Other R&D partners with the same arrangement have included the National Research Council of Canada, Plant Biotechnology Institute in Saskatoon, Canada ("NRC"), and the Nara Institute of Science and Technology in Nara, Japan ("NAIST"). The majority of this R&D has involved the biosynthesis of nicotine in plants. Our R&D agreements with NCSU, NRC and NAIST expired in 2009. In 2010, NAIST assigned to us all of its worldwide patents and patent applications that were previously licensed to us on an exclusive basis. These patents and patent applications were a result of our R&D at NAIST. On December 23, 2014, we purchased from NRC all the patents and patent applications that were previously licensed to us on an exclusive basis by NRC.

In November 2011, we entered into an R&D agreement with the University of Virginia ("UVA") relating to nicotine biosynthesis in tobacco plants with a total budget of $500,000 for the period from November 2011 through December 31, 2013. The term of the R&D agreement with UVA was subsequently extended to May 31, 2016, with a total budget

of $972,727. In 2016, the R&D agreement with UVA was extended again through October 31, 2016. We incurred $224,560, $224,428 and $224,862 of expenses for the R&D agreement at UVA for the years ended December 31, 2016, 2015, and 2014, respectively. In December 2016, we 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 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. This work with UVA will also involve the development and study of medically important cannabinoids to be extracted by UVA from the Company's unique hemp plants. UVA and 22nd Century 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 new agreeements with UVA and UVA LVG grant 22nd Century exclusive rights to commercialize all results of the collaboration in consideration of royalty payments by the 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 year ended December 31, 2016, we expensed $78,541 relating to this extended R&D agreement. We plan to extend and amend our R&D agreement with NCSU in 2017 to continue our research and development activities with NCSU relating to very low nicotine tobacco plants. In this regard, NCSU has granted us a no-cost extension of our existing sponsored research agreement so that we can finalize an amendment and extension of our R&D agreement with NCSU for our continuing R&D activities together.

In August 2016, we opened our own laboratory on the Buffalo Niagara Medical Campus in Buffalo, NY. We intend to conduct more of our proprietary research and development activities in our laboratory when appropriate to do so.

We are currently working with Anandia Laboratories in Canada to extend and expand our research and development activities with Anandia relating to industrial hemp and medical marijuana plants with low-to-no amounts of THC.

Upon identifying a suitable joint venture partner or licensee to fund further *X-22* clinical trials, we plan to carry out additional *X-22* clinical trials.

During the years ended December 31, 2016, 2015 and 2014, we incurred total R&D expenses of $2,340,958, $1,571,365, and $1,216,483, respectively.

Sources of Raw Materials

We obtain a large portion of our tobacco leaf requirements from farmers in multiple U.S. states that are under direct contracts with us. The contracts prohibit the transfer of our proprietary seedlings and plant materials to other parties. We purchase the balance of our tobacco requirements through third parties. As we expand our sales and distribution of our current commercial brands and proceed to market with our *X-22* smoking cessation aid and *BRAND A* and *BRAND B* cigarettes, we plan to increase the amount of tobacco leaf we obtain directly from farmers under contract, both in the United States and in foreign countries.

Products

RED SUN and MAGIC Cigarettes

Goodrich Tobacco introduced two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market. Both brands are available in regular and menthol and all brand styles are king size and packaged in hinge-lid hard packs. Since 2015, we have focused our marketing and sales efforts for *RED SUN* on independent retailers, tobacconists, smokeshops and other tobacco outlets in the U.S. The ban in 2009 by the FDA of all cigarettes with characterizing flavors (with the exception of menthol) has resulted in a product void in these tobacco channels for highly differentiated, super-premium priced products. We believe that certain U.S. cigarette wholesalers and retailers will carry our brands, among other reasons, to increase their margins. *RED SUN* is produced by our NASCO subsidiary at our factory in North Carolina, which is now a subsequent participating manufacturer under the MSA, and *MAGIC* is produced for us by Orion, our contract manufacturer in Poland, for distribution in the European Union.

SPECTRUM Government Research Cigarettes

NIDA, a part of NIH, provides the scientific community with controlled and uncontrolled research chemicals and drug compounds in 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), or Research Cigarette Option, 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") in RTI's contract with NIDA for the Research Cigarette Option, 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, the National Cancer Institute and the Centers for Disease Control and Prevention to finalize certain aspects of the design of these research cigarettes. These government research cigarettes produced by us under the mark *SPECTRUM* were distributed by RTI for NIDA to researchers. The *SPECTRUM* research cigarette contract was renewed in 2015 for an additional 5 years. Goodrich Tobacco has thus far delivered approximately 22 million *SPECTRUM* research

cigarettes. On July 7, 2014, Goodrich Tobacco entered into a Teaming Agreement with RTI to work together to respond to a new request from NIDA for the potential purchase by NIDA from RTI of additional *SPECTRUM* research cigarettes to be produced and sold by Goodrich Tobacco to RTI. In 2015, NIDA ordered approximately 5 million *SPECTRUM* research cigarettes and in 2016 NIDA ordered approximately 2.8 million *SPECTRUM* research cigarettes, all as made and sold by Goodrich Tobacco.

BRAND A and BRAND B

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of 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 requires the FDA to issue specific regulations and guidance regarding applications submitted to the FDA for the authorization to label and market modified risk tobacco products, including Modified Risk Cigarettes. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance.* We believe that two types of our cigarettes in development, which we refer to as *BRAND A* and *BRAND B*, may 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 (e.g., Marlboro ®, Camel ®, Newport ®, Natural American Spirit ®), which could create opportunities for us to license our proprietary technology and/or our tobaccos to larger competitors.

Compared to commercial tobacco cigarettes, *BRAND A* has the lowest nicotine content. The tobacco in *BRAND A* contains approximately 95% less nicotine than conventional cigarette brands. As mentioned above, we are working to receive a marketing order from the FDA to allow *BRAND A* to be marketed as a reduced exposure product.

Utilizing the results of previously conducted independent clinical trials (see below under "X-22 Smoking Cessation Aid"), on December 31, 2015, we submitted to the Center for Tobacco Products ("CTP") of the FDA a combined Modified Risk Tobacco Product Application ("MRTPA") and a Premarket Tobacco Product Application ("PMTA") for *BRAND A* as a Modified Risk Cigarette. In December 2016, we received feedback and guidance from the FDA on our MRTPA and PMTA for *BRAND A*, which resulted in us withdrawing that filing in order to (i) include additional information requested by the FDA and (ii) bifurcate our application into a separate MRTPA to be filed with the FDA for *BRAND A* and a separate PMTA to be filed with the FDA for *BRAND A* in order to benefit from the FDA's shorter review timing for PMTAs as compared to MRTPAs.

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 some commercially available full flavor cigarette brands. We submitted an application with the FDA for the Company's first proposed smoke evaluation exposure study for our *BRAND B* cigarettes. This first proof of concept study for *BRAND B* is scheduled for the second quarter of 2017, subject to completion of FDA review.

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We believe results from this and other exposure studies will warrant a modified risk claim for *BRAND B* and we believe smokers who desire to reduce smoke exposure, but are less concerned about nicotine, will find *BRAND B* beneficial. Although smoking yields, as determined by laboratory smoking machines, are not always indicative of smoke and tar intake by humans, *BRAND B* cigarettes are being designed to have a "tar" yield between typical "light" and "ultra-light" cigarettes (as previously labeled and marketed by conventional tobacco companies), but a nicotine yield of typical full flavor cigarettes.

X-22 Smoking Cessation Aid

X-22 is a tobacco-based botanical medical product for use as an aid to smoking cessation. The *X-22* therapy protocol utilized in our sponsored Phase IIb clinical trial calls for the patient to switch to our *X-22* cigarettes over a six-week treatment period to facilitate the goal of the patient quitting smoking following the treatment period. We believe this therapy protocol has been successful in independent clinical trials because cigarettes made from our proprietary 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 *X-22* cigarettes for 6 weeks, *X-22* does not expose the smoker to any new drugs or new side effects. Our Investigational New Drug Application ("IND") for *X-22* was cleared by the FDA in July 2011 and has been updated annually. Our *X-22* Phase IIb clinical trial was completed in the first quarter of 2012 but did not demonstrate a statistically significant difference in quitting between *X-22* and the active control, a cigarette containing conventional nicotine levels. However, the median number of *X-22* cigarettes smoked during the trial was significantly reduced compared to patients' baseline of usual brand of cigarettes. In evaluating the results of this trial, we believe we may have reduced the nicotine content of *X-22* by too great a percentage, to a level less than half the nicotine content of our VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases quit rates. In preparation for Phase III clinical trials, the Company has requested and has been granted a meeting with the FDA to discuss *X-22*. At the meeting, which is scheduled to take place in June 2017, 22nd Century will discuss a product development program for *X-22* that is expected to outline a path for the Company's one-of-a-kind combustible smoking cessation aid to become a prescription-based treatment option for smokers in the United States.

Due to the limited effectiveness and/or serious side effects of existing FDA-approved smoking cessation products (all of which have been on the market for approximately between 10 and 32 years), we believe that if additional clinical trials demonstrate increased smoking cessation rates, then *X-22* can capture a share of this market by replacing sales and market share from existing smoking cessation aids and by expanding the smoking cessation market by encouraging more smokers to attempt to quit smoking. In contrast to the results of our Phase IIb trial results, the independent studies listed below have demonstrated that cigarettes with very low nicotine content increase quit rates, whether used alone, in conjunction with Chantix ® (varenicline) or in conjunction with nicotine replacement therapy ("NRT") such as nicotine patches, gums or lozenges. The independent clinical studies listed below are indeed remarkable for their results and/or the conclusions reached by the researchers, but were not conducted or monitored by us and are included herein for informational purposes only. We assume no obligation to review any of these independent studies for errors, omissions or other factors.

- Donny, EC et al. Randomized trial of reduced-nicotine standards for cigarettes. 2015. *New Eng. J. Med,* 2015; 373;14:1340-1349.

- Phase II/III clinical trial

- McRobbie, H et al. Evaluating whether the use of a VLN cigarette in combination with Chantix® (or NRT) increases quitting over use of Chantix (or NRT) alone. 2015. *Nicotine & Tobacco Research, June 2015; doi:10.1093/ntr/ntv122*

- Phase II clinical trial

- Reduced nicotine content cigarettes and nicotine patch. Hatsukami DK, Hertsgaard LA, Vogel RI, Jensen JA, Murphy SE, Hecht SS, Carmella SG, al'Absi M, Joseph AM, Allen SS. 2013. Reduced nicotine content cigarettes and nicotine patch. *Cancer Epidemiol Biomarkers Prev* . 22(6):1015-24.

- Phase II clinical trial

- Hatsukami DK, Kotlyar M, Hertsgaard LA, Zhang Y, Carmella SG, Jensen J, Allen SS, Shields PG, MurphySE, Stepanov I, Hecht SS. 2010. Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation. *Addiction* 105:343-355.

- Phase II clinical trial

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- Walker N, Howe C, Bullen C, Grigg M, Glover M, McRobbie H, Laugesen M, Parag V, Whittaker R. 2012. The combined effect of very low nicotine content cigarettes, used as an adjunct to usual Quitline care (nicotine replacement therapy and behavioural support), on smoking cessation: a randomized controlled trial. *Addiction*. 2012 Oct; 107(10):1857-67.

- Phase III/IV clinical trial

- Becker KM, Rose JE, Albino AP. 2008. A randomized trial of nicotine replacement therapy in combination with reduced-nicotine cigarettes for smoking cessation. *Nicotine Tob Res* 10(7):1139-48.

- Phase II clinical trial

- Rezaishiraz H, Hyland A, Mahoney MC, O'Connor RJ, Cummings KM. 2007. Treating smokers before the quit date: can nicotine patches and denicotinized cigarettes reduce cravings? *Nicotine Tob Res*. Nov; 9(11):1139-46.

- Phase II clinical trial

FDA approval must be obtained, as has been the case for decades, before a product can be marketed for quitting smoking. The Tobacco Control Act provides that products for quitting smoking or smoking cessation, such as *X-22*, be considered for "Fast Track" designation by the FDA. The "Fast Track" programs of the FDA are intended to facilitate development and to expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. We believe that upon completion of a Company-sponsored clinical trial demonstrating efficacy, *X-22* will qualify for "Fast Track" designation by the FDA.

We believe that our *X-22* cigarettes can be a highly effective aid to smoking cessation. We are currently in the process of identifying potential joint venture partners or licensees to fund the remaining *X-22* clinical trials. In preparation for Phase III clinical trials, the Company has requested and has been granted a June 2017 meeting with the Center for Drug Evaluation and Research ("CDER") of the FDA to discuss a development program for *X-22*.

Government Regulation

Smoking Cessation Aids

Government authorities in the U.S. and foreign countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing and import and export of pharmaceutical products. FDA approval must be obtained, as has been the case for decades, before a product can be marketed for quitting smoking or reducing withdrawal symptoms. In addition, as with all FDA-approved prescription drugs, the FDA must approve the brand name of our *X-22* smoking cessation aid. The FDA approval process for smoking cessation aids is similar to that required by the FDA for new drug approvals, although the cost to complete clinical trials for a smoking cessation aid such as *X-22* are generally far less than clinical trials for drugs. The primary endpoint of the clinical trial for smoking cessation aids is smoking abstinence, which is generally confirmed by inexpensive, noninvasive biomarker tests. Since potential quitters are already smokers, *X-22* will not expose participants in the clinical trials to any new compounds, unlike a new chemical product, such as Chantix ®.

The process of obtaining governmental approvals and complying with ongoing regulatory requirements requires the expenditure of substantial time and financial resources. In addition, statutes, rules, regulations and policies may change and new legislation or regulations may be issued that could delay such approvals. If we fail to comply with applicable regulatory requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA’s refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

The Affordable Care Act and other government and private sector initiatives targeted to potentially limit the growth of healthcare costs are continuing in the U.S. and many other countries where we intend to sell our products, including our *X-22* smoking cessation aid. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical products.

Government healthcare programs in the United States, including Medicare and Medicaid, private healthcare insurance and managed-care plans have attempted to control costs by limiting the amount of reimbursement for which they will pay for particular procedures or treatments. This may create price sensitivity among potential customers for our *X-22* smoking cessation aid, even if we obtain FDA approval for it. Some third-party payers must also approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the medical devices or therapies. Even though a new medical product may have been cleared for commercial distribution, we may find limited demand for *X-22* until reimbursement approval has been obtained from governmental and private third-party payers.

Modified Risk Cigarettes

The Tobacco Control Act, which became law in June 2009, prohibits the FDA from banning cigarettes outright or mandating that nicotine levels be reduced to zero. However, among other things, it allows the FDA to require the reduction of nicotine or any other compound in cigarettes. In 2009, the Tobacco Control Act 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. We believe this new regulatory environment represents a paradigm shift for the tobacco industry and will create opportunities for us in marketing *BRAND A* and *BRAND B* and in licensing our proprietary technology and/or tobaccos to larger competitors.

For the first time in history, a U.S. regulatory agency now scientifically evaluates cigarettes that may pose lower health risks as compared to conventional cigarettes. The Tobacco Control Act established procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco smoke toxins and/or (ii) pose lower health risks, as compared to conventional cigarettes (“Modified Risk Cigarettes”). The Tobacco Control Act requires the FDA to issue specific regulations and guidance regarding applications that must be submitted to the FDA for the authorization to label and market Modified Risk Cigarettes. We believe that *BRAND A* and *BRAND B* 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 (e.g., Marlboro ®, Camel ®, Newport ®, Natural American Spirit ®) which could create opportunities for us to license our proprietary technology and/or our tobaccos to larger competitors.

In addition to providing our *SPECTRUM* cigarettes to NIDA for researchers, we have been directly supplying our proprietary cigarettes to independent researchers so that additional 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* and *BRAND B* as Modified Risk Cigarettes and to obtain FDA approval for *X-22* as a prescription smoking cessation aid.

Competition

In the market for FDA-approved smoking cessation aids, our principal competitors include Pfizer Inc., GlaxoSmithKline plc, Novartis International AG, and Perrigo Company plc. 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.

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 cigarette taxes, higher absolute prices and larger gaps between price categories, and product regulation that diminishes the ability to differentiate tobacco products. Domestic competitors include Philip Morris USA, Reynolds American Inc., ITG Brands, Liggett Group LLC and Vector Tobacco Inc. International competitors include Philip Morris International Inc., Japan Tobacco Inc., Imperial Tobacco Group plc, and regional and local tobacco companies.

Biomass Products

Biomass products are products such as ethanol made from organic material, which is derived from plants densely grown over a given area. We have funded extensive biomass field trials conducted by NCSU and work on feedstock digestibility and bioconversion at the National Renewable Energy Lab. Bioconversion is the conversion of organic matter into a source of energy, such as ethanol in our own research, through the action of microorganisms. Tobacco has a number of advantages as a starting point for development of novel bioproduct crop systems. Because tobacco is a widely cultivated crop, grown in over 100 countries throughout the world, tobacco agronomy is highly understood. For decades, tobacco has been used as a model system for plant biology, and recently the tobacco genome has been mapped. Tobacco plants rapidly sprout back after each harvest and produce large amounts of leaf and total biomass. Tobacco grown for cigarettes yields about 3,000 pounds of cured leaf per acre (~20% moisture) per year from 7,500 tobacco plants. In our field trials in North Carolina, nicotine-free tobacco grown for biomass yields about 100,000 pounds of fresh weight per acre (which equals 10,000 pounds of dry weight) per year with multiple machine harvests from about 80,000 tobacco plants. The results of our biomass studies have been summarized in a comprehensive feasibility study relating to our nicotine-free tobacco biomass crop (*Verfola*) to produce a variety of bioproducts. First, protein and other plant fractions are extracted, and then biofuels and other products are produced from the remaining cellulosic residue.

In 2009, we put our biomass development projects on hold so that our management could focus its attention and resources on our modified risk cigarette business and our *X-22* smoking cessation business. We do not plan to move forward with potential biomass business activities until some period of time after FDA approval of *X-22* or FDA authorization to market *BRAND A* or *BRAND B* as a Modified Risk Cigarette. We currently are not spending any capital for such potential biomass business activities nor do we have any current plans to do so in the foreseeable future.

Cannabis Research

We currently sponsor cannabis research in Canada and in the United States. In Canada, we conduct sponsored research on cannabis through Botanical Genetics, which is a wholly-owned subsidiary of the Company and was incorporated to facilitate an equity investment in Anandia Laboratories, Inc. ("Anandia"), a plant biotechnology company based in Vancouver, Canada. On September 15, 2014, Botanical Genetics was granted a sublicense by Anandia to 23 patent applications relating to genes in the cannabis plant that are required for the production of cannabinoids, the active ingredients in the 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/cannabis, such as (i) plants with low to no amounts of delta-9-tetrahydrocannabinol, or THC, for the legal hemp industry, and (ii) plants with high levels of cannabidiol, or CBD, and other non-THC cannabinoids for the legal medical cannabis markets. In Canada, licenses to cultivate, possess and supply cannabis for medical research are granted by agencies of the Canadian federal government. In order to carry out research in other countries, similar licenses are required to be issued by the relevant authority in each country.

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 next 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 (thus eliminating the risk to growers of having to destroy non-conforming hemp crops) and (ii) optimizing other desirable hemp plant characteristics to improve the plant's suitability for growing in Virginia and in similar legacy tobacco regions. The collaboration with UVA will also involve the development and study of medically important cannabinoids to be extracted by UVA from the Company's unique hemp plants. UVA and 22nd Century 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 22nd Century exclusive rights to commercialize all results of the collaboration in consideration of royalty payments by the Company to UVA LVG.

As of December 31, 2016, there are 29 states in the United States plus the District of Columbia that have laws and/or regulations that recognize, in one form or another, legitimate medical uses for cannabis and consumer use of cannabis

in connection with medical treatment. Additionally, the states of Alaska, California, Colorado, Maine, Massachusetts, Nevada, Oregon, Washington plus the District of Columbia have legalized cannabis for adult 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 has no medical benefit and a range of activities are prohibited, including cultivation, possession, personal use and interstate distribution of cannabis. In the event the U.S. Department of Justice (the "DOJ") begins strict enforcement of the CSA in states that have laws legalizing medical marijuana and recreational marijuana in small amounts, there may be a direct and adverse impact to any future business or prospects that we have in the cannabis business. However, our work in hemp would continue since hemp R&D and commercialization activities are permitted under applicable federal and state laws, rules and regulations.

Employees

We currently employ forty-six (46) people and we consider our employee relations to be good.

Corporate Information

We are a Nevada corporation and our corporate headquarters is located at 9530 Main Street, Clarence, New York 14031. Our telephone number is (716) 270-1523. Our internet address is www.xxiicentury.com. 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 (i) achieve and sustain profitability or (ii) raise additional capital on favorable terms; or at all.

We have experienced net losses of approximately $11.6 million, $11.0 million, and $15.6 million during the years ended December 31, 2016, 2015 and 2014, respectively. At December 31, 2016, we had current assets of $16,797,435, current liabilities of $3,249,317, and cash on hand of $13,468,188. Excluding discretionary expenses related to R&D, patent and trademark costs, contract growing of our proprietary tobacco, and certain nonrecurring expenses relating to factory capital expenses, investor relations, and marketing costs, our monthly cash expenditures are approximately $750,000. Including cash on hand at December 31, 2016 of $13,468,188, and revenues from ongoing product sales, but not including potential milestone payments of up to $7,000,000 from BAT, we believe resulting cash balances will be adequate to sustain operations and meet all current obligations as they come due through at least May of 2018. While our current cash balance is adequate to sustain operations through at least May of 2018, 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 additional royalty revenue from the licensing 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. There is also no guarantee that we will be able to raise additional capital on favorable terms, or at all. Any inability to raise additional capital could have an impact on our ability to continue to operate our business.

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 from financing activities, including approximately $9.9 million during the year ended December 31, 2016. As indicated above, we believe our current cash position is adequate to sustain operations and meet all current obligations as they come due through at least May of 2018. 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.

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 will likely require additional capital before we can complete the FDA authorization process for our X-22 smoking cessation aid and our Modified Risk Cigarettes.

We are currently seeking a suitable joint venture partner or licensee willing to fund further clinical trials for FDA approval of our *X-22* smoking cessation aid. At that time we will resume our own sponsored *X-22* clinical trials. There is no guarantee that we will identify a joint venture partner or licensee willing to fund further *X-22* clinical trials on terms that are acceptable to us. We estimate the cost of completing two Phase III trials to be approximately $25 million. We will also likely 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 each of our two potential Modified Risk Cigarettes is difficult to estimate since it is currently unknown exactly what the FDA will require, including the number and size of exposure studies. 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 choose to resume and fund our own clinical trials for FDA approval of our *X-22* smoking cessation aid and we cannot raise additional capital on acceptable terms, we may not be able to, among other things:

- complete clinical trials of our *X-22* smoking cessation aid;
- 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 face intense competition in the market for our cigarettes and our failure to compete effectively or to achieve market acceptance of these products could have a material adverse effect on our profitability and results of operations.

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. We are subject to highly competitive conditions in all aspects of our business and we may not be able to effectively market, sell and achieve market acceptance for our proprietary cigarettes. The competitive environment and our competitive position can be significantly influenced by weak economic conditions, erosion of consumer confidence, competitors' introduction of low-price products or innovative products, higher cigarette taxes, higher absolute prices and larger gaps between price categories, and product regulation that diminishes the ability to differentiate tobacco products. In addition, most of our competitors have greater resources and brand recognition than us. Domestic competitors include Philip Morris USA Inc., Reynolds American Inc., ITG Brands, Liggett Group LLC, and Vector Tobacco Inc. International competitors

include Philip Morris International Inc., Japan Tobacco, Inc., Imperial Tobacco Group plc and regional and local tobacco companies.

We will mainly depend on third parties to market, sell and distribute our products, and we currently have no commercial arrangements for the marketing, sale or distribution of our X-22 smoking cessation aid.

We expect to depend on third parties to a great extent to market, sell and distribute our products and we currently have no arrangements with third parties in place to provide such services for our *X-22* smoking cessation aid. We cannot be sure that we will be able to enter into such arrangements on acceptable terms, or at all. If we are unable to enter into marketing, sales and distribution arrangements with third parties for our *X-22* smoking cessation aid, we would need to incur significant sales, marketing and distribution expenses in connection with the commercialization of *X-22* and any future potential products. We do not currently have a dedicated sales force, and we have no experience in the sales, marketing and distribution of pharmaceutical products. Developing a sales force is expensive and time-consuming, and we may not be able to develop this capacity. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable.

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 address competitive challenges adequately.

From 2013 to 2016 we grew from nine (9) employees to forty-six (46) 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 and pharmaceutical 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 and/or similar inspections in foreign countries to produce our tobacco products or the final version of our *X-22* smoking cessation aid, or that future changes to cGMP manufacturing standards will not also negatively affect the cost or sustainability of our manufacturing facility.

If our X-22 smoking cessation aid does not gain market acceptance among physicians, patients, third-party payers and the medical community, we may be unable to generate significant revenue.

Our *X-22* smoking cessation aid may not achieve market acceptance among physicians, patients, third-party payers and others in the medical community. If we receive FDA approval for the marketing of *X-22* as a smoking cessation aid in the U.S., the degree of market acceptance could depend upon a number of factors, including:

· limitations on the indications for use for which *X-22* may be marketed;

· the establishment and demonstration in the medical community of the clinical efficacy and safety of our potential products and their potential advantages over existing products;

·the prevalence and severity of any side effects;

·the strength of marketing and distribution support; and

·sufficient third-party coverage or reimbursement.

The market may not accept our *X-22* smoking cessation aid, based on any number of the above factors. Even if the FDA approves the marketing of *X-22* as a smoking cessation aid, there are other FDA-approved products available and there will also be future competitive products which directly compete with *X-22* . The market may prefer such existing or future competitive products for any number of reasons, including familiarity with or pricing of such products. The failure of any of our potential products to gain market acceptance could impair our ability to generate revenue, which could have a material adverse effect on our future business, financial condition, results of operations and cash flows.

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 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 *X* -22 smoking cessation aid or our cigarette brands to compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition, results of operations and cash flows. Our competitors may:

·develop and market products that are less expensive, safer or otherwise more appealing than our products;

. commercialize competing products before we or our partners can launch our products; and

·initiate or withstand substantial price competition more successfully than we can.

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

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

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

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

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

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

Government mandated prices, 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 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. Paul Rushton, our Vice President of Plant Biotechnology, and Thomas James, Esq., 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. We cannot assure you that such claims will not be made in the future.

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

Despite growing support for the cannabis industry and legalization of cannabis in certain U.S. states, many individuals and businesses remain opposed to the cannabis industry. Any negative press resulting from our recent entry into the cannabis 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 cannabis industry.

As of December 31, 2016, 29 states and the District of Columbia allow their citizens to use medical marijuana. Additionally, the states of Alaska, California, Colorado, Maine, Massachusetts, Nevada, Oregon, Washington plus the District of Columbia have legalized cannabis for adult use. The state laws are in conflict with the federal Controlled Substances Act, or CSA, which makes marijuana use, possession and interstate distribution illegal on a federal level.

We currently conduct sponsored research on cannabis through Anandia Laboratories in Canada and 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 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 medical cannabis 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 would effectively terminate our cannabis research in the United States. However, our work in hemp would continue since hemp R&D 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 proposed business.

Risks Related to Regulatory Approvals and Insurance Reimbursement

If we fail to obtain FDA and foreign regulatory approvals for X-22 as a smoking cessation aid and FDA authorization to market BRAND A and BRAND B as Modified Risk Cigarettes, we will be unable to commercialize these potential products in and outside the U.S., other than the sale of our BRAND A and BRAND B cigarettes as conventional cigarettes.

There can be no assurance that our *X-22* smoking cessation aid will be approved by the FDA, European Medicines Agency ("EMA"), or any other governmental body or that *BRAND A* and *BRAND B* will be approved by the FDA to be marketed as Modified Risk Cigarettes. 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 to market for and sale of our potential products. Our ability

to complete the FDA-approval process in a timely manner is dependent, in part, on our ability to obtain “Fast Track” designation for *X-22* by the FDA.

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 EMA and other international FDA equivalent agencies in targeted countries is costly and time consuming, and the time required for such approval is uncertain. Our *X-22* smoking cessation aid must undergo rigorous clinical testing and an extensive regulatory approval process mandated by the FDA or EMA. Such regulatory review includes the determination of manufacturing capability and product performance. Generally, only a small percentage of pharmaceutical products are ultimately approved for commercial sale.

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* and *BRAND B* 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 has experienced delays and took a year to obtain substantial feed back from the FDA. We may be unsuccessful in establishing that *BRAND A* or *BRAND B* are Modified Risk Cigarettes, and we may fail to demonstrate that either *BRAND A* or *BRAND B* significantly reduces exposure to certain tobacco smoke toxins. Even upon demonstrating significant reduced exposure to nicotine and/or certain tobacco smoke toxins, 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* and/or *BRAND B* 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 could force us to remove from the U.S. market our tobacco products such as *RED SUN* or *MAGIC* since these are not grandfathered products under the Tobacco Control Act, and the FDA could force us to remove from the U.S. market *BRAND A* and/or *BRAND B* even after FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes.

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

In addition to seeking approval from the FDA for our *X-22* smoking cessation aid in the United States, we intend to seek governmental approvals required to market *X-22* 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 the individual country. 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 United States, 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.

Market acceptance of our X-22 smoking cessation aid could be limited if users are unable to obtain adequate reimbursement from third-party payers.

Government health administration authorities, private health insurers and other organizations generally provide reimbursement for FDA-approved smoking cessation products, and our commercial success could depend in part on these third-party payers agreeing to reimburse patients for the costs of our *X-22* smoking cessation aid. Even if we succeed in bringing our *X-22* smoking cessation aid to market, there is no assurance that third-party payers will consider *X-22* cost effective or provide reimbursement in whole or in part for its use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Our *X-22* smoking cessation aid is intended to replace or alter existing therapies or procedures. These third-party payers may conclude that our *X-22* smoking cessation aid is less safe, effective or cost-effective than these existing therapies or procedures. Therefore, third-party payers may not approve *X-22* for reimbursement.

If third-party payers do not approve *X-22* or our potential products for reimbursement or fail to reimburse for them adequately, sales could suffer as some physicians or their patients could opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payers make reimbursement available, these payers' reimbursement policies may adversely affect our ability and the ability of our potential collaborators to sell our potential products on a profitable basis.

The trend toward managed healthcare in the United States, such as the Affordable Care Act enacted on March 23, 2010, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our potential products which could adversely affect our business, financial condition, results of operations and cash flows.

In addition, legislation and regulations affecting the pricing of our potential products may change in ways adverse to us before or after the FDA or other regulatory agencies approve any of our potential products for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agency adopts these proposals, they could materially adversely affect our business, financial condition, results of operations and cash flows.

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

We do not know whether clinical trials of our potential products will demonstrate safety and efficacy sufficiently to result in marketable products. Because our clinical trials for our *X-22* smoking cessation aid and any other potential products may produce negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing for these potential products or cease our clinical trials. If this occurs, 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 and we may also experience significant additional development costs. We may also be required to undertake additional clinical testing if we change or expand the indications for our potential products.

Risks Related to the Tobacco Industry

Our business faces significant governmental action aimed at increasing regulatory requirements with the goal of preventing the use of tobacco products.

Cigarette 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, 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 certain other countries, and we expect that these factors will continue to reduce consumption levels in these countries.

Certain of such actions may have a favorable impact on our *X-22* smoking cessation aid, or on our *BRAND A* and *BRAND B* cigarettes if we are able to market them as Modified Risk Cigarettes. However, there is no assurance of such favorable impact and such actions may have a negative impact on our ability to market *RED SUN* and *MAGIC*.

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 decrease in demand for cigarettes, any significant increase in the cost of complying with new regulatory requirements and requirements that lead to a commoditization of tobacco products such as the implementation of plain packaging in Australia.

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 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 warning 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 supposed to be implemented in September 2012, a federal judge ruled that these warnings are unconstitutional. If and when these graphic health warnings are implemented, 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 our 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 of our *RED SUN* and *MAGIC* cigarettes and, upon FDA authorization, our *BRAND A* and *BRAND B* 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 our sales and profitability and make us less competitive versus certain of our competitors.

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 of our *RED SUN* and *MAGIC* cigarettes and, upon FDA authorization, our *BRAND A* and *BRAND B* 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 to which we may become subject, and we may be materially affected by an unfavorable outcome of 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 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 possibly invalidated by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States or 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.

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 more than 200 issued patents plus more than 50 pending patent applications. We cannot assure you 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 2 U.S. patents and 23 patent applications relating to four genes in the 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 MKT (NYSE MKT) on which the shares of our common stock are currently quoted. However, even if our common stock continues to be quoted on the NYSE MKT, 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 MKT. It may be more difficult to dispose of shares or 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 MKT 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:

·results from and any delays in any clinical trials programs;

·failure or delays in entering potential products into clinical trials;

·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 us 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.

Item 1B Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal administrative offices are located in Clarence, New York. We currently lease 3,800 square feet of office space. The lease expires on August 31, 2017. Scheduled rent remaining as of December 31, 2016, is approximately $31,000 for 2017.

We have a lease for our warehouse and cigarette manufacturing facility located in North Carolina. 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 our option. We are currently in the first of a two-year lease extension term that will expire on October 31, 2018. The lease expense for the years ended December 31, 2016, 2015 and 2014 amounted to approximately $146,000, $127,000 and $98,000, respectively. The future minimum lease payments if we exercise each of the additional extensions are approximately as follows:

Year ended December 31, 2017 - $156,000
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 November 1, 2015, we entered into a one-year lease for 25,000 square feet of warehouse space in North Carolina to store the Company’s proprietary tobacco leaf. The lease calls for a monthly lease payment of $3,750 and contains a three-year renewal option after the initial one-year term. In October of 2016, we exercised the three-year renewal option under this lease. Future minimum lease payments for the years ended December 31, 2017, 2018 and 2019 will be $45,000, $45,000 and $37,500, 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, expires on April 30, 2017 and contains an option to extend the lease for a period of one year through April 30, 2018. Future minimum sublease payments for the years ended December 31, 2017 and 2018 are approximately $18,000 and $6,000, respectively, if the Company exercises the optional renewal period.

On September 1, 2016, we entered into a sublease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment. The sublease calls for a monthly payment of $1,200, expires on August 31, 2017 and contains twelve-month renewal options as long as the sublessor continues to sublease the warehouse. Future minimum sublease payments for the year ending December 31, 2017 are $14,400 per year and for each subsequent year the warehouse space is sublet by the Company.

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 includes 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 of 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 to be filed by the Company.

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 MKT under the symbol “XXII.” As of February 23, 2017, there were 97 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 MKT.

Quarter Ended	High	Low
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
December 31, 2015	$1.75	$0.82
September 30, 2015	$1.13	$0.56
June 30, 2015	$1.55	$0.71
March 31, 2015	$1.78	$0.65

Dividend Policy

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

Recent issuances of Unregistered Securities

None.

Shares authorized for issuance under equity compensation plans

On October 21, 2010, the Company established the 2010 Equity Incentive Plan, or EIP, for officers, employees, directors, consultants and advisors to the Company and its affiliates, consisting of 4,250,000 shares of common stock. The EIP authorized the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, restricted stock and restricted stock units. There are no awards remaining to be issued from the EIP, although awards from the EIP remain outstanding.

On April 12, 2014, the stockholders of the Company approved the 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (the “OIP”). 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 5,000,000 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 our 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 and shares of restricted stock 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 EIP and OIP as of December 31, 2016:

Number of securities

	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)		remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders	5,250,679	(1)	$ 1.07	(2)	421,765	
Equity compensation plans not approved by security holders	-		N/A		-	
Total	5,250,679				421,765	(3)

(1) Includes 100,000 shares from a restricted stock award that are issued but not vested as of December 31, 2016.

(2) Weighted average exercise price only applies to the 5,150,679 shares issuable upon exercise of outstanding stock options.

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

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Stock Performance Graph

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

The performance graph shown below compares the cumulative total shareholder return on the Company's common stock, based on the market price of the common stock, with the total return of the NYSE MKT Composite Index and the NASDAQ US Small Cap Biotechnology Index for the period covering December 31, 2011 through December 31, 2016. The comparison of total return assumes that a fixed investment of $100 was invested on December 31, 2011 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, 2016 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,				
	2016	2015	2014	2013	2012
Consolidated Statements of Operations data:					
Revenue	$12,279,979	$8,521,998	$528,991	$7,278,383	$18,775
Gross (loss) profit	$(429,699)	$(580,562)	$30,555	$6,816,712	$(49,192)
Operating expenses (1)	$10,115,968	$10,689,010	$11,302,623	$4,859,976	$2,996,551
Equity based compensation included in operating expenses	$911,382	$3,585,540	$4,524,468	$2,361,962	$1,254,171
Operating (loss) profit	$(11,387,847)	$(12,043,883)	$(11,767,364)	$1,812,447	$(3,244,149)
Warrant liability gain (loss) - net (2)	$29,615	$144,550	$(3,827,794)	$(27,339,024)	$(1,998,043)
Net loss	$(11,581,430)	$(11,031,931)	$(15,595,358)	$(26,153,158)	$(6,736,737)
Loss per common share - basic and diluted	$(0.15)	$(0.16)	$(0.26)	$(0.60)	$(0.22)
Common shares used in basic earnings per share calculation	79,842,773	68,143,284	59,993,413	43,635,182	30,419,556
Consolidated Balance Sheet data:					
Working capital	$13,548,118	$3,991,828	$8,033,399	$6,759,781	$(3,321,643)
Total assets	$27,642,357	$18,370,512	$21,953,515	$12,286,744	$2,644,871
Total debt	$307,938	$616,520	$1,100,655	$174,925	$2,685,729
Total shareholders' equity (deficit)	$24,334,359	$11,728,500	$15,219,737	$7,522,888	$(6,131,217)
Other data:					
Net cash used in (provided by) operating activities	$(9,887,580)	$(7,321,811)	$(6,582,730)	$3,855,834	$(1,764,445)
Net cash used in investing activities	$(553,770)	$(450,661)	$(2,707,992)	$(3,742,789)	$(162,774)
Net cash provided by financing activities	$20,149,241	$5,130,082	$9,862,810	$5,717,366	$1,675,158
Acquisition of patents and trademarks (3)	$356,541	$413,180	$726,989	$290,336	$162,774
Depreciation	$326,124	$319,699	$230,012	$3,028	$1,832
Amortization (4)	$516,056	$454,612	$265,284	$141,261	$196,574

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

(4) 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, 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 (i) tobacco harm reduction products and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding, and (ii) research and development of unique hemp/cannabis plants through genetic engineering and plant breeding. We currently own or exclusively control more than 200 issued patents and more than 50 pending patent applications around the world. Our management team is focused on monetizing our intellectual property portfolio, obtaining regulatory approval to market our reduced exposure cigarettes and our smoking cessation product in development, and expanding our hemp/cannabis research and development activities to additional geographic regions in North America.

Strategic Objectives

Our strategic objectives include the following:

- Pursuit of authorization from the U.S. Food and Drug Administration ("FDA") and regulatory agencies in other countries to introduce our X-22 smoking cessation aid in development into commerce as a prescription-based smoking cessation medical product. As a part of these efforts, we are also working to establish a strategic joint venture to conduct a Phase III smoking cessation clinical trial for *X-22;*

- Pursuit of reduced exposure authorization from the FDA for our *BRAND A* Very Low Nicotine cigarettes in development that have 95% less nicotine than conventional tobacco cigarettes, and therefore drastically reduce smokers' exposure to nicotine. In response to the FDA's requests, and in conjunction with additional clarifying guidance, the Company intends to bifurcate its combined Modified Risk Tobacco Product application ("MRTPA") into a separate Premarket Tobacco Product application ("PMTA") and a separate MRTPA for *BRAND A* to enjoy the benefit

of the FDA's shorter review timing for PMTAs as compared to MRTPAs;

- Pursuit of FDA reduced exposure authorization for our low tar-to-nicotine *BRAND B* modified risk cigarette in development;

- Research and development of industrial hemp plants with: (i) guaranteed levels of THC below the legal limits and (ii) improved suitability for optimized growing in various regions of North America, which the Company has already commenced in Virginia with the University of Virginia ("UVA"). This alliance with UVA will also involve the development and study of medically important cannabinoids to be extracted by UVA from the Company's unique hemp plants;

- Establishment of substantial multi-year sales contracts around the world for our proprietary high nicotine tobacco leaf and Very Low Nicotine tobacco leaf;

- Commercialization of our proprietary super-premium cigarette brands; and

- Expansion of our growing base of contract manufacturing business at our manufacturing facility in Mocksville, North Carolina.

Recent Developments

For the fourth quarter of 2016, our accomplishments and notable events include:

On October 13, 2016, we announced that a group of leading scientists from the United States and New Zealand published a special paper in an international peer-reviewed journal strongly advocating for a "national nicotine reduction policy." The article, published in the September issue of *Tobacco Control* journal online, outlines the compelling and urgent case for enacting a national nicotine policy in order to dramatically lower smoking rates. Drs. Eric Donny, Natalie Walker, Dorothy Hatsukami, and Chris Bullen authored the special paper which asserts that governments around the world should reduce the nicotine content of cigarettes to "…≤ 0.4 mg per gram of tobacco, a 95-98% reduction in nicotine content relative to what is currently on the market." The authors cite results from many of the 15 major independent scientific clinical studies conducted with 22nd Century's Very Low Nicotine tobacco. The *Tobacco Control* article reinforces the World Health Organization ("WHO") recommendation that WHO-member countries "mandate reductions in nicotine to minimally addictive levels."

On October 14, 2016, the Company entered into an agreement with one existing institutional investor and one new institutional investor to receive approximately $11.4 million in gross proceeds in a registered direct offering through the sale of units consisting of one share of common stock and 0.5 warrants priced at $1.3425 per share, which was $0.0625 above the closing price of the Company's common stock on the NYSE MKT on October 13, 2016.

On October 20, 2016, the Company announced that scientists from the University of Vermont Center on Tobacco Regulatory Science, Brown University, Johns Hopkins University, and Southern Illinois University published online in the October 2016 issue of *Psychopharmacology* a new independent clinical study which concluded that, even among vulnerable populations, 22nd Century's Very Low Nicotine tobacco cigarettes significantly reduce nicotine withdrawal and craving symptoms. Dr. Stephen T. Higgins, *et al.,* conducted the study, which examined the effects of Very Low Nicotine cigarettes on economically disadvantaged women, opioid-dependent individuals, and individuals with affective disorders. Dr. Higgins remarked: "When nicotine content is set very low… dependence decreases, smoking rates decrease, and people are better able to quit if they choose to do so."

In October 2016, 22nd Century announced a strategic new hire: Michael Zercher, the Company's Vice President of Business Development. Mr. Zercher previously headed Santa Fe Natural Tobacco Company's international business operations based in Zurich, Switzerland. From 2003-2009, while serving as Vice President and Managing Director of Santa Fe Natural Tobacco Company International, Mr. Zercher grew the international American Spirit® brand business from $8 Million to more than $100 Million in annual sales. Mr. Zercher will spearhead 22nd Century's efforts to form strategic partnerships with companies capable of widely commercializing 22nd Century's proprietary brands. In addition, Mr. Zercher will pursue sales of the Company's proprietary Very Low Nicotine tobacco leaf and high nicotine tobacco leaf.

On November 2, 2016, the Company announced that *Addiction Journal* published online a new report investigating smokers' cost sensitivity for Very Low Nicotine cigarettes. Led by Dr. Eric Donny of the University of Pittsburg Cancer Institute, the new publication found that, compared to conventional cigarettes, 22nd Century's Very Low Nicotine cigarettes reduced the number of cigarettes that the participants estimated they would smoke at every price range tested. This Phase III study included 839 participants who, over a 6-week period, first smoked their own brand and then were assigned to smoke one of five different nicotine content cigarettes. The researchers exclusively employed 22nd Century's SPECTRUM® brand cigarettes for their study.

On December 20, 2016, the Company announced the execution of a sponsored research agreement with UVA and an exclusive license with the University of Virginia Patent Foundation d/b/a University of Virginia Licensing & Ventures Group. Over the next three years, the Company will invest approximately $1,000,000 in this major scientific collaboration with UVA. The goals of the research include: (i) creating unique industrial hemp plants with guaranteed levels of THC below the legal limits (thus eliminating the risk to growers of having to destroy non-conforming hemp crops) and (ii) optimizing other desirable hemp plant characteristics to improve the plant's suitability for growing in Virginia and in similar legacy tobacco regions. This alliance will also involve the development and study of medically important cannabinoids to be extracted by UVA from the Company's unique hemp plants. 22nd Century enjoys exclusive rights to commercialize all results from this important collaboration, including all industrial hemp plants and medically important cannabinoids.

Subsequent to the close of the fourth quarter of 2016, we also announced:

On January 5, 2017, the Company announced that the FDA provided the Company with helpful and positive feedback on 22nd Century's MRTPA and PMTA for the Company's *BRAND A* Very Low Nicotine tobacco cigarettes. In its filings with the FDA, the Company requested permission from the FDA to be able to state that the Company's proprietary Very Low Nicotine cigarettes reduce smokers' exposure to nicotine since such cigarettes contain 95% less nicotine than conventional cigarette brands. In response to the FDA's guidance, the Company is working to file revised MRTPAs and PMTAs for *BRAND A* that will include additional scientific data and information from already completed clinical studies on the Company's Very Low Nicotine tobacco cigarettes.

The Company is also continuing to separately work with the FDA's Center for Drug Evaluation and Research ("CDER") with respect to the Company's previously-filed New Drug Application ("NDA") for 22nd Century's proposed "X-22" prescription-based smoking cessation aid in development. The Company has a meeting scheduled with CDER at the FDA in June 2017 to discuss the regulatory path forward for X-22.

On February 3, 2017, the Company announced that it prevailed again in the most recent phase of the lawsuit filed by Crede CG III, Ltd. ("Crede"). Crede filed the lawsuit after the Company terminated its failed China joint venture arrangement with Crede and its principal, Terren Peizer, due to non-performance and other serious breaches by Crede and its principals. In the first round of the Crede lawsuit, the Company prevailed when the United States District Court for the Southern District of New York (the "SDNY Court") denied Crede's request for a preliminary injunction to require the Company to issue shares of its common stock to Crede under the now void exchange feature of a Tranche 1-A warrant previously issued to Crede. The SDNY Court held that Crede had not demonstrated a reasonable likelihood that it would prevail on its claims, and that there was likelihood that Crede violated the activity restrictions of the Tranche 1-A warrant. Following the denial by the SDNY Court of Crede's request for the preliminary injunction, the Company filed motions requesting the SDNY Court to sever the Crede lawsuit into two separate cases. On January 20, 2017, the SDNY Court granted such motions by the Company to sever the Crede lawsuit into two separate cases, with the claims relating to the failed China joint venture being transferred to the United States District Court for the Western District of New York (the "WDNY Court"), where the Company's headquarters office is located. The Crede claims relating to the Tranche 1-A warrant to remain in the SDNY Court. We believe that the Crede claims are frivolous, meritless and that the Company has substantial legal and factual defenses to the claims according to the jurisdictional provision of that warrant. On February 14, 2017, Crede dismissed its lawsuit against the Company in the WDNY Court. On February 21, 2017, the SDNY Court granded the Company's request to file a motion for summary judgement in the case, with all discovery in the case to be deferred until after the SDNY Court conducts a hearing and issues its decision on the upcoming summary judgement motion to be filed by us.

Please refer to the "Business" section in this Annual Report on Form 10-K for additional information regarding our business and operations.

Results of Operations

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015 and Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Revenue - Sale of products

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. 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 for 2016 was primarily due to the sale of products from the continued growth of our contract manufacturing operations in our North Carolina factory.

2015 vs. 2014

We realized net revenue from the sale of products in the amount of $8,521,998 during the year ended December 31, 2015, as compared to net revenues of $528,991 during the year ended December 31, 2014, an increase of $7,993,007. Included in net revenue were sales of *SPECTRUM* research cigarettes in the amount of $242,658 and $447,535 for the years ended December 31, 2015 and 2014, respectively. The increase for 2015 was due to the sale of products from the continued growth of the manufacturing operations in our North Carolina factory as we transitioned from our pre-manufacturing status during the majority of 2014.

Costs of goods sold - Products

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.

2015 vs. 2014

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.

In the year ended December 31, 2014, costs of goods sold were $252,002 or 47.6% of revenue.

Costs of goods sold - Royalties for licensing

2016 vs. 2015

We experienced no cost of goods sold relating to royalties from licensing during the years ended December 31, 2016 and 2015.

2015 vs. 2014

During the year ended December 31, 2015 we realized no revenue from licensing activities and accordingly there were no associated costs. We did not realize any revenues from licensing activities during the year ended December 31, 2014, however, we revised an estimate of the royalty fee due in conjunction with licensing revenue received from BAT in 2013 resulting in cost of goods sold in the amount of $246,434.

Research and development expense

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 fee 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.

2015 vs. 2014

Research and development expense was $1,571,365 for the year ended December 31, 2015, an increase of $354,882 or 29.2%, from $1,216,483 for the year ended December 31, 2014. This increase was primarily a result of an increase in costs associated with our *BRAND A* modified risk application filed with the FDA in the approximate amount of $343,000, an increase in payroll related costs of approximately $50,000, and a net increase in R&D contract costs, sponsored research costs, and patent maintenance costs of approximately $115,000, partially offset by a decrease in equity based compensation in the approximate amount of $164,000, during the year ended December 31, 2015, as compared to the year ended December 31, 2014.

General and administrative expense

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 MKT 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 relation to information technology of approximately $40,000, and 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.

2015 vs. 2014

General and administrative expense was $7,760,127 for the year ended December 31, 2015, a decrease of $1,063,407, or 12.1%, from $8,823,534 for the year ended December 31, 2014. The decrease was primarily due to decreases in employee equity based compensation of approximately $909,000, employee related costs of approximately $147,000, legal and accounting fees of approximately $592,000, costs relating to press releases of approximately $91,000, NYSE MKT related costs of approximately $66,000, costs associated with the severance liability of approximately $637,000, and director fee costs of approximately $62,000, partially offset by increases in equity based compensation and cash payments to third-party service providers of approximately $23,000 and $758,000, respectively, and expenses incurred by our factory of approximately $627,000, during the year ended December 31, 2015 as compared to the year ended December 31, 2014.

Pre-manufacturing facility costs

2016 vs. 2015

There were no pre-manufacturing costs during the years ended December 31, 2016 and 2015.

2015 vs. 2014

There were no pre-manufacturing costs for the year ended December 31, 2015. During the year ended December 31, 2014, we incurred various expenses related to preparing the warehouse and manufacturing facility, which amounted to $1,176,676 and consisted primarily of expenses for salaries and benefits for employees, sub-contract labor, rent, utilities and other miscellaneous costs.

Sales and marketing costs

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.

2015 vs. 2014

Sales and marketing costs were $1,357,518 for the year ended December 31, 2015, an increase of $1,271,588, or 1,479.8%, from $85,930 for the year ended December 31, 2014. The increase in the sales and marketing costs were primarily the result of costs incurred to launch our proprietary cigarette brands, *RED SUN* and *MAGIC*, in the U.S.

and Europe, respectively, and to grow our contract manufacturing business. Sales and marketing costs include payroll for sales and customer service personnel, point of sale materials, trade shows, advertising, promotional campaigns and travel related expenses for our sales personnel.

Depreciation

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.

2015 vs. 2014

Depreciation expense for the year ended December 31, 2015 amounted to $319,699, an increase of $89,687, or 39.0%, from $230,012 for the year ended December 31, 2014. This increase is primarily due to a full year of depreciation taken in 2015 on the cigarette manufacturing equipment as compared to depreciation taken in 2014 for only three-quarters of the year.

Amortization

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.

2015 vs. 2014

Amortization expense, relating to amortization taken on capitalized patent costs and license fees, for the year ended December 31, 2015 amounted to $454,612, an increase of $189,328, or 71.4%, from $265,284 for the year ended December 31, 2014. The increase is primarily due to amortization on additional patent costs incurred during the years ended December 31, 2015 and 2014 in the amounts of $654,069 and $1,780,596, respectively, and a full year of amortization capitalized license costs in 2015 on license costs incurred during 2014 in the amount of $1,450,000.

Warrant liability gain (loss) - net

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 the Company's 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 the Company's 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.

2015 vs. 2014

The warrant liability gain of $144,550 for the year ended December 31, 2015 was described in the above comparison of 2016 to 2015.

The warrant liability loss of $3,676,691 for the year ended December 31, 2014 was due to an increase in the warrants liability recorded in the first quarter of 2014 in the amount of $3,841,943 in conjunction with the warrant amendment program (described below) offset by a decrease in the estimated fair value of the warrants during the year in the

amount of $165,252, primarily attributable to the decrease in the Company's underlying stock price from $2.14 per share at December 31, 2013, as compared to $1.65 per share at December 31, 2014.

Warrant amendment inducement expense

2016 vs. 2015

There was no warrant inducement expense for the years ended December 31, 2016 and 2015.

2015 vs. 2014

There was no warrant inducement expense for the year ended December 31, 2015. In March 2014, we entered into warrant amendments with existing warrant holders with the goal of reducing our warrant liability by offering certain financial inducements to such warrant holders in exchange for exercising or amending such warrants. We calculated the cost of inducement as the difference between the fair value of the warrants immediately after the warrant amendments closed, less the fair value of the warrants immediately prior to the closing of the warrant amendments. We estimated the total cost of inducement to be $144,548 for the year ended December 31, 2014.

Settlement proceeds

2016 vs. 2015

There were no settlement proceeds during the year ended December 31, 2016.

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 the second and third quarters of 2015, we received payments under the settlement in the aggregate amount of $1,000,000 in full settlement of the dispute.

2015 vs. 2014

The settlement proceeds of $1,000,000 for the year ended December 31, 2015 was described in the above comparison of 2016 to 2015.

There were no settlement proceeds during the year ended December 31, 2014.

Loss on equity investment

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.

2015 vs. 2014

The loss on equity investment of $95,684 for the year ended December 31, 2015 was described in the above comparison of 2016 to 2015.

The loss on equity investment of $101,165 for the year ended December 31, 2014 consisted of (i) our 25% share of Anandia's net loss for the year ended December 31, 2014 in the amount of $84,350, 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 $16,815.

Interest income

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.

2015 vs. 2014

Interest income for the year ended December 31, 2015 was $31,198, an increase of $815, or 2.7%, interest income of $30,383 for the year ended December 31, 2014. The interest income earned in both 2015 and 2014 was generated from excess cash invested in a money market account.

Interest expense

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.

2015 vs. 2014

Interest expense increased for the year ended December 31, 2015 to $52,982 from $7,094 for the year ended December 31, 2014. This increase of $45,888 consisted primarily of approximately $24,000 from the accretion of interest on a note payable and approximately $21,000 derived from the interest component of severance payments made during the year ended December 31, 2015, where the severance accrual had previously been recorded on a discounted basis using our incremental borrowing rate.

Net loss

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.

2015 vs. 2014

We had a net loss for the year ended December 31, 2015 of $11,031,931 as compared to a net loss of $15,595,358 for the year ended December 31, 2014. The decrease in the net loss of $4,563,427, or 29.3%, was primarily the result of the decrease in the warrant liability gain (loss) - net in the amount of approximately $3,821,000, the decrease in warrant amendment inducement expense of approximately $145,000, the increase in the litigation settlement proceeds of $1,000,000, and a net decrease in operating expenses of approximately $335,000, offset by a decrease in gross profit of approximately $611,000 and a net increase in other expense in the amount of approximately $126,000.

Liquidity and Capital Resources

Working Capital

As of December 31, 2016, we had positive working capital of approximately $13.5 million compared to positive working capital of approximately $4.0 million at December 31, 2015, an increase of approximately $9.6 million. This increase in working capital is due to an increase in current assets of approximately $9.6 million, which is primarily due to an increase in cash of approximately $9.7 million and an increase in net inventory of approximately $0.4 million, partially offset by a decrease in prepaid fees and expenses of approximately $0.5 million. The net increase in cash is primarily the result of the sale of units in three registered direct offerings totaling approximately $20.1 million.

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. We will likely need to raise additional capital to fund (i) our operations and (ii) FDA approval of our products. There can be no assurance that additional capital will be available on acceptable terms or at all.

Cash demands on operations

During the year ended December 31, 2016, we experienced an operating loss of approximately $11.4 million and used cash in operations of approximately $9.9 million. Excluding discretionary expenses related to R&D, patent and trademark costs, contract growing of our proprietary tobacco, and certain nonrecurring expenses relating to factory capital expenses, investor relations, and marketing costs, our monthly cash expenditures are approximately $750,000. Including cash on hand at December 31, 2016 of $13,468,188 and revenues from ongoing product sales, but not including potential milestone payments of up to $7,000,000 from British American Tobacco (“BAT”), we believe resulting cash balances will be adequate to sustain operations and meet all current obligations as they come due through at least May of 2018

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Net Cash (used in) provided by Operating Activities

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.

2015 vs. 2014

In the year ended December 31, 2015, $7,321,811 of cash was used in operating activities as compared to $6,582,730 of cash used in operating activities in the year ended December 31, 2014; an increase of $739,081. 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 $490,704 and an increase in cash used for working capital components related to operations in the amount of $248,377 for the year ended December 31, 2015 as compared to at year end December 31, 2014.

Net Cash used in Investing Activities

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.

2015 vs. 2014

In the year ended December 31, 2015, net cash used in investing activities was $450,661 as compared to $2,707,992 of cash used in investing activities during the year ended December 31, 2014. The decrease in cash used in investing activities of $2,257,331 was primarily due to $2,400,000 used during the year ended December 31, 2014 for the payment of license fees, the acquisition of NASCO Products, LLC, and the equity investment in Anandia, and by a decrease of $488,815 in the acquisition of patents, trademarks and machinery and equipment, partially offset by the net proceeds received on the sale of machinery and equipment during the quarter ending March 31, 2014 in the amount of $631,484.

Net Cash provided by Financing Activities

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 stock 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.

2015 vs. 2014

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 stock 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. During the year ended December 31, 2014, $9,862,810 was provided by financing activities primarily as a result of net cash proceeds received from a common stock private placement in September 2014 in the amount of $9,324,088, and net cash proceeds from the existence of stock warrants and stock options in the amount of $535,251.

Contractual Obligations

The following table summarizes by category our expected future cash outflows associated with contractual obligations in effect at December 31, 2016:

	Payments Due by Period				
	Total	Year Ended December 31, 2017	Years Ended December 31, 2018 & 2019	Years Ended December 31, 2020 & 2021	More Than Five Years
Note payable	$333,333	$ 333,333	$ -	$ -	$-
Severance payments	203,365	203,365	-	-	-
Operating lease obligations	996,100	259,600	426,500	310,000	-
Consulting agreements	410,000	395,000	15,000	-	-
License fees	3,180,000	250,000	545,000	620,000	1,765,000
Sponsored research	1,795,991	1,121,997	673,994	-	-
Total	$6,918,789	$ 2,563,295	$ 1,660,494	$ 930,000	$1,765,000

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.

Inventory

Inventories are valued at the lower of cost or market. 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 the our 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 $7,452,000, $5,703,000 and $0 are included in net sales for the years ended December 31, 2016, 2015 and 2014, 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. We recognize revenue from the sale of our *MAGIC* brand cigarettes in Europe when the cigarettes are sold by the European distributors to the retailers and are sold net of cash discounts, sales returns and allowances, and all applicable taxes.

In 2010, we were chosen to be a subcontractor for a 5-year government contract between RTI International (“RTI”) and the National Institute on Drug Abuse (“NIDA”) to supply NIDA with research cigarettes. The contract was renewed in 2015 for an additional 5 years. These government research cigarettes are distributed under the Company’s mark *SPECTRUM*. In September 2015, we received a purchase order for approximately 5.0 million *SPECTRUM* research cigarettes. Approximately 40% of the order was shipped in December 2015, resulting in the recognition of revenue in the amount of $242,658 during the fourth quarter of 2015. The remainder of the order was shipped in January of 2016 and generated revenue of approximately $329,321. There were no *SPECTRUM* cigarettes delivered during the balance of 2016.

Impairment of Long-Lived Assets

We review the carrying value of amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be appropriate. 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, 2016.

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. 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.

Income taxes

We recognize deferred tax assets and liabilities for any basis differences in its assets and liabilities between tax and U.S. GAAP reporting, and for operating loss and credit carry-forwards. 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 its net deferred tax assets as of December 31, 2016 and 2015.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of 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 statement 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. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. 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 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. A 10% increase or decrease in the volatility factor used as of December 31, 2016 would have the impact of increasing or decreasing the liability by approximately $4,600.

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, 2016, 2015 and 2014.

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 equivalent 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 and cash equivalent short-term investments. We invest excess cash in a money market account that earns interest based on fluctuating interest rates. We believe changes in this money market 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 portion of our sales activity is outside of the U.S., and accordingly, we have foreign exchange exposure to non-U.S. dollar sales revenue. In addition, a small portion of our vendors are paid in foreign currencies. Our 24.4% equity investment in Anandia has foreign currency risk. Anandia is a Canadian company using the Canadian dollar as its functional currency. As such, our portion of Anandia’s net income (loss) is subject to foreign currency risk upon translation from Canadian to U.S. dollars. 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 $58,681 on our consolidated balance sheet at December 31, 2016. This liability consists of a warrant liability associated with warrants issued by us. The fair value calculation, as discussed in Note 12 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 12 of our consolidated financial statements for additional details), and as such, our exposure to this risk is significantly mitigated. During the year ended December 31, 2016, we experienced a gain of $29,615 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, 2016 would have the impact of increasing or decreasing the liability by approximately $4,600.

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 Information section 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, 2016.

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

During the fourth quarter of 2016, we completed the implementation and testing of a remediation plan that was targeted at eliminating our previously reported material weakness in our internal controls over financial reporting primarily resulting from a lack of segregation of duties. Except as set forth herein, there were no changes in the Company's internal controls over financial reporting during the fourth quarter of 2016 that have materially affected, or are 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.

We have audited 22nd Century Group, Inc. and Subsidiaries (the “Company”) internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. 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 included 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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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 *(a)* pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; *(b)* 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 *(c)* 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.

In our opinion, the Company maintained effective internal control over financial reporting as of December 31, 2016, 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), the consolidated balance sheets as of December 31, 2016 and 2015 and the related consolidated statements of operations, shareholders' equity and cash flows of the Company for each of the years in the three year period ending December 31, 2016 and our report dated March 8, 2017 expressed an unqualified opinion.

/s/ FREED MAXICK CPAs, P.C.

Buffalo, New York

March 8, 2017

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 2017 Annual Meeting of Stockholders.

Set forth below is information regarding our directors, executive officers and key personnel.

Name	Age	Position
Henry Sicignano, III	49	President, Chief Executive Officer and Director
John T. Brodfuehrer	59	Chief Financial Officer & Treasurer
Michael R. Moynihan, Ph.D.	64	Vice President of R&D
Paul Rushton, Ph.D.	54	Vice President of Plant Biotechnology
Thomas L. James, Esq.	58	Vice President, General Counsel and Secretary
Joseph Alexander Dunn, Ph.D.	63	Director*
James W. Cornell	60	Director**
Richard M. Sanders	63	Director***
Nora B. Sullivan	59	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 President, c/o 22nd Century Group, Inc., 9530 Main Street, Clarence, New York 14031. 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 2017 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 2017 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 2017 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 2017 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

22nd Century Group, Inc.

We have audited the accompanying consolidated balance sheets of 22nd Century Group, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the years in the three year period ending December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of 22nd Century Group, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the results of its operations and cash flows for each of the years in the three year period ending December 31, 2016, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Accounting Oversight Board (United States), 22nd Century Group, Inc. and Subsidiaries internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control – Integrated Framework* issued by Committee of Sponsoring Organizations of the Treadway Commission in 2013. Our report dated March 8, 2017 expressed an opinion that 22nd Century Group, Inc. had maintained effective internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

/s/ FREED MAXICK CPAs, P.C.

Buffalo, New York

March 8, 2017

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

	2016	2015
ASSETS		
Current assets:		
Cash	$13,468,188	$3,760,297
Accounts receivable, net	40,992	51,230
Inventory, net	3,092,686	2,706,330
Prepaid expenses and other assets	195,569	710,091
Total current assets	16,797,435	7,227,948
Machinery and equipment, net	2,434,663	2,555,793
Other assets:		
Intangible assets, net	7,389,946	7,364,120
Equity investment	1,020,313	1,222,651
Total other assets	8,410,259	8,586,771
Total assets	$27,642,357	$18,370,512
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of note payable	$307,938	$308,582
Accounts payable	1,340,156	1,283,346
Accrued expenses	1,401,566	1,423,531
Accrued severance	199,657	220,661
Total current liabilities	3,249,317	3,236,120
Long-term portion of note payable	-	307,938
Long-term portion of accrued severance	-	199,658
Warrant liability	58,681	2,898,296
Total liabilities	3,307,998	6,642,012
Commitments and contingencies (Note 14)	-	-
Shareholders' equity		
Capital stock authorized:		
10,000,000 preferred shares, $.00001 par value		
300,000,000 common shares, $.00001 par value		
Capital stock issued and outstanding:		
90,698,113 common shares (71,006,844 at December 31, 2015)	907	710
Capital in excess of par value	102,471,907	78,284,815
Accumulated deficit	(78,138,455)	(66,557,025)

Total shareholders' equity	24,334,359	11,728,500
Total liabilities and shareholders' equity	$27,642,357	$18,370,512

See accompanying notes to consolidated financial statements.

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

	2016	2015	2014
Revenue:			
Sale of products, net	$12,279,979	$8,521,998	$528,991
Cost of goods sold (exclusive of depreciation shown separately below):			
Products	12,709,678	9,102,560	252,002
Royalties for licensing	-	-	246,434
	12,709,678	9,102,560	498,436
Gross (loss) profit	(429,699)	(580,562)	30,555
Operating expenses:			
Research and development (including equity based compensation of $136,946, $167,837 and $331,467, respectively)	2,340,958	1,571,365	1,216,483
General and administrative (including equity based compensation of $718,610, $3,376,664 and $4,165,078, respectively)	6,193,269	7,760,127	8,823,534
Pre-manufacturing facility costs (including equity based compensation of $0, $0 and $27,923, respectively)	-	-	1,176,676
Sales and marketing costs (including equity based compensation of $55,826, $41,039 and $0, respectively)	1,581,741	1,357,518	85,930
Depreciation	326,124	319,699	230,012
Amortization	516,056	454,612	265,284
	10,958,148	11,463,321	11,797,919
Operating loss	(11,387,847)	(12,043,883)	(11,767,364)
Other income (expense):			
Warrant liability gain (loss) - net	29,615	144,550	(3,676,691)
Warrant amendment inducement expense	-	-	(144,548)
Settlement proceeds	-	1,000,000	-
(Loss) gain on the disposition and sale of machinery and equipment	-	(15,130)	71,121
Loss on equity investment	(202,338)	(95,684)	(101,165)
Interest income	16,885	31,198	30,383
Interest expense	(37,745)	(52,982)	(7,094)
	(193,583)	1,011,952	(3,827,994)
Loss before income taxes	(11,581,430)	(11,031,931)	(15,595,358)
Income taxes	-	-	-

Net loss	$(11,581,430)	$(11,031,931)	$(15,595,358)
Loss per common share - basic and diluted	$(0.15)	$(0.16)	$(0.26)
Common shares used in basic earnings per share calculation	79,842,773	68,143,284	59,993,413

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
Years Ended December 31, 2016, 2015 and 2014

	Common Shares Outstanding	Par value of Common Shares	Contributed Capital	Accumulated Deficit	Shareholders' Equity
Balance at December 31, 2013	56,902,770	$ 569	$47,452,055	$(39,929,736)	$7,522,888
Stock based compensation	1,282,768	13	2,433,240	-	2,433,253
Warrants issued as compensation for services	-	-	1,260,000	-	1,260,000
Exercise of warrants	1,167,737	12	486,939	-	486,951
Exercise of options	70,000	1	48,299	-	48,300
Common stock issued in September 2014 private placement, net	3,871,767	39	9,324,049	-	9,324,088
Stock issued in connection with acquisition of NASCO Products, LLC	640,000	6	1,951,994	-	1,952,000
Stock issued in connection with equity investment	150,000	1	394,499	-	394,500
Other capital contribution	-	-	25,200	-	25,200
Warrant amendments	-	-	7,367,915	-	7,367,915
Net loss	-	-	-	(15,595,358)	(15,595,358)
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
Stock based compensation	553,896	6	1,623,417	-	1,623,423
Exercise of warrants	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
Stock 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

See accompanying notes to consolidated financial statements.

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

	2016	2015	2014
Cash flows from operating activities:			
Net loss	$(11,581,430)	$(11,031,931)	$(15,595,358)
Adjustments to reconcile net loss to cash used in operating activities:			
Amortization and depreciation	744,157	676,289	462,772
Amortization of license fees	98,022	98,022	32,524
Loss on equity investment	202,338	95,684	101,165
Accretion of interest on note payable and accrued severance	37,745	45,121	-
Loss (gain) on the disposition and sale of machinery and equipment	-	15,130	(71,121)
Warrant liability (gain) loss	(29,615)	(144,550)	3,676,691
Warrant amendment inducement expense	-	-	144,548
Equity based employee compensation expense	880,509	1,326,393	2,293,083
Equity based payments for outside services	30,873	2,259,147	2,231,385
Increase in inventory reserve	145,000	60,000	-
Increase in allowance for doubtful accounts	-	10,000	-
Severance expense	-	-	624,320
Decrease (increase) in assets:			
Accounts receivable	10,238	(61,230)	-
Inventory	(531,356)	(701,534)	(620,660)
Prepaid expenses and other assets	497,856	(478,955)	(214,469)
Increase (decrease) in liabilities:			
Accounts payable	(136,297)	86,332	625,389
Accrued expenses	(21,965)	649,271	(93,985)
Accrued severance	(233,655)	(225,000)	-
Deferred revenue	-	-	(179,014)
Net cash used in operating activities	(9,887,580)	(7,321,811)	(6,582,730)
Cash flows from investing activities:			
Acquisition of patents and trademarks	(356,541)	(413,180)	(726,989)
Acquisition machinery and equipment	(197,229)	(37,481)	(212,487)
Payment of license fees	-	-	(1,450,000)
Acquisition of NASCO Products, LLC	-	-	(250,000)
Proceeds from the sale of machinery and equipment	-	-	631,484
Equity investment	-	-	(700,000)
Net cash used in investing activities	(553,770)	(450,661)	(2,707,992)
Cash flows from financing activities:			
Proceeds from exercise of warrants	196	50,688	486,951
Proceeds from exercise of options	-	-	48,300
Payments on borrowings - demand bank loan	-	(174,925)	-
Payments on borrowings - note payable	(333,333)	(333,333)	-
Net proceeds from September 2014 registered direct offering	-	-	9,324,088
Net proceeds from June 2015 registered direct offering	-	5,576,083	-

Net proceeds from February 2016 registered direct offering	5,091,791	-	-
Net proceeds from July 2016 registered direct offering	4,682,764	-	-
Net proceeds from October 2016 registered direct offering	10,707,823	-	-
Stock cancellation	-	(34,500)	-
Net payments from (to) related party	-	46,069	(4,000)
Net advances from officers	-	-	7,471
Net cash provided by financing activities	20,149,241	5,130,082	9,862,810
Net increase (decrease) in cash	9,707,891	(2,642,390)	572,088
Cash - beginning of period	3,760,297	6,402,687	5,830,599
Cash - end of period	$13,468,188	$3,760,297	$6,402,687

See accompanying notes to consolidated financial statements.

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

	2016	2015	2014
Supplemental disclosures of cash flow information:			
Net cash paid for:			
Cash paid during the period for interest	$37,745	$7,600	$7,094
Cash paid during the period for income taxes	$-	$-	$-
Non-cash transactions:			
Reclassification of derivative liability to equity due to warrant amendments	$-	$-	$7,367,915
Patent and trademark additions included in accounts payable	$185,341	$310,078	$193,454
Patent and trademark additions included in accrued expenses	$-	$17,715	$-
Machinery and equipment additions included in accounts payable	$7,765	$2,525	$10,904
Reclassification of machinery and equipment purchases to inventory	$-	$-	$37,856
Issuance of common stock in connection with equity investment	$-	$325,000	$-
Other capital contribution	$-	$-	$25,200
License fee included in accrued expenses	$-	$-	$300,000
Equity investment included in accrued expenses	$-	$-	$325,000
Issuance of common stock for equity investment	$-	$-	$394,500
Issuance of common stock for the acquisition of NASCO Products, LLC	$-	$-	$1,952,000
Issuance of warrants as a derivative liability issued under a consulting agreement and included in prepaid consulting fees	$-	$-	$2,810,000
Warrants issued under a consulting agreement resulting in an increase in capital and included in prepaid consulting fees	$-	$-	$1,260,000
Patent additions acquired with note payable	$-	$-	$925,730
Reclassification of warrant liability to capital in excess of par	$2,810,000	$-	$-

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2016

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 for the level of nicotine and other nicotinic alkaloids (e.g., nornicotine, anatabine and anabasine) in tobacco plants to be decreased or increased through genetic engineering and plant breeding. The Company currently owns or exclusively controls more than 200 issued patents and more than 50 pending patent applications around the world. Goodrich Tobacco and Heracles Pharma are business units for the Company's (i) premium cigarettes and potential modified risk tobacco products 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 participating member of 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 equity investment more fully described in Note 9.

Reclassifications - Certain items in the 2015 and 2014 financial statements have been reclassified to conform to the 2016 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.

Accounts receivable - The Company periodically reviews aged account balances for collectability. As of December 31, 2016 and 2015, the Company has established an allowance for doubtful accounts in the amount of $10,000.

Inventory - Inventories are valued at the lower of cost or market. 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, 2016 and December 31, 2015 consisted of the following:

	December 31, 2016	December 31, 2015
Inventory – tobacco leaf	$ 1,936,039	$ 1,816,857
Inventory – finished goods		
Cigarettes and filtered cigars	340,523	342,707
Inventory – raw materials		
Cigarette and filtered cigar components	1,071,747	657,389
	3,348,309	2,816,953
Less: inventory reserve	255,623	110,623
	$ 3,092,686	$ 2,706,330

Fixed assets - Fixed assets 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 2019 and 2028 (the assets' estimated lives), respectively. Periodic maintenance or renewal fees are expensed as incurred. Annual minimum license fees are charged to expense. License fees paid for third-party intellectual property are amortized on a straight-line basis over the last to expire patents, which patent expiration dates 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, 2016 and 2015 consist of the following:

	December 31, 2016	December 31, 2015
Intangible assets, net		
Patent and trademark costs	$ 5,688,440	$ 5,146,559
Less: accumulated amortization	2,021,926	1,603,893
Patent and trademark costs, net	3,666,514	3,542,666
License fees, net (see Note 14)	1,450,000	1,450,000
Less: accumulated amortization	228,568	130,546
License fees, net	1,221,432	1,319,454
MSA signatory costs	2,202,000	2,202,000

License fee for predicate cigarette brand	300,000	300,000
	$ 7,389,946	$ 7,364,120

Amortization expense relating to the above intangible assets for the years ended December 31, 2016, 2015 and 2014 amounted to $516,056, $454,612 and $265,284, respectively.

The estimated annual average amortization expense for the next five years is approximately $353,000 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, 2016, 2015 or 2014.

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, 2016 and 2015.

The Company's federal and state tax returns for the years ended December 31, 2013 through December 31, 2015 are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2016.

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 the Company's 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 $7,452,000, $5,703,000 and $0 are included in net sales for the years ended December 31, 2016, 2015 and 2014, 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. The Company recognizes revenue from the sale of its *MAGIC* brand cigarettes in Europe when the cigarettes are sold by the European distributors to the retailers and are sold net of cash discounts, sales returns and allowances, and all applicable taxes.

In 2010, the Company was chosen to be a subcontractor for a 5-year government contract between RTI International ("RTI") and the National Institute on Drug Abuse ("NIDA") to supply NIDA with research cigarettes. The contract was renewed in 2015 for an additional 5 years. These government research cigarettes are distributed under the Company's mark *SPECTRUM*. In September 2015, the Company received a purchase order for approximately 5.0 million *SPECTRUM* research cigarettes. Approximately 40% of the order was shipped in December 2015, resulting in the recognition of revenue in the amount of $242,658 during the fourth quarter of 2015. The remainder of the order was shipped in January of 2016 and generated revenue of $329,321. There were no *SPECTRUM* cigarettes delivered during the balance of 2016.

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 $325,000, $229,000 and $30,000 for the years ended December 31, 2016, 2015 and 2014, 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 - Financial instruments include cash, receivables, accounts payable, accrued expenses, accrued severance, note payable and warrant liability. Other than 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 the warrant liability includes unobservable inputs and is therefore categorized as a Level 3 measurement, as further discussed in Note 12.

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.

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 will implement the applicable revenue recognition ASU's for annual reporting periods beginning after December 15, 2017. As a result of such implementation the Company with exclude certain Federal excise and other regulatory fees from revenue and the cost of goods sold.

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 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 are exercisable for a period of sixty-six (66) months after issuance, are 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 will 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 may 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 may 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.

NOTE 3. – JULY 2016 REGISTERED DIRECT OFFERING

On July 27, 2016, the Company closed a registered direct offering of units 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 provide 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 have 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. 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 (see Note 4 – February 2016 Registered Direct Offering and Note 5 – June 2015 Registered Direct Offering for additional information).

NOTE 4. - FEBRUARY 2016 REGISTERED DIRECT OFFERING

On February 5, 2016, the Company closed a registered direct offering of units 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 (see Note 3 – July 2016 Registered Direct Offering for additional information).

NOTE 5. - 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 (see Note 3 – July 2016 Registered Direct Offering for additional information).

NOTE 6. - 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 amortization of the prepaid consulting fees amounted to $1,978,785 and $2,091,215 for the years ended December 31, 2015 and 2014, respectively, and are included in General and administrative expenses in the Company's Consolidated Statements of Operations. There was no amortization of prepaid consulting fees for the year ended December 31, 2016.

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 warrants 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. (See Note 14 - Commitments and contingencies for additional information).

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 7. - MANUFACTURING FACILITY

The Company's manufacturing operations at its North Carolina factory were not at full production capacity during the years ended December 31, 2016 and 2015, but the Company continued manufacturing a third-party MSA cigarette brand, filtered cigars on a contract basis, and the Company's own proprietary cigarette brand, *RED SUN*. 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 $551,678 and $607,713 for the years ended December 31, 2016 and 2015, respectively.

The Company's manufacturing operations were primarily in a pre-manufacturing stage during the year ended December 31, 2014. During this period the Company incurred various expenses to prepare the facility for production. Pre-manufacturing expenses incurred during the year ended December 31, 2014 amounted to $1,176,676 and are reported as Pre-manufacturing facility costs on the Company's Consolidated Statements of Operations.

NOTE 8. - MACHINERY AND EQUIPMENT

Machinery and equipment at December 31, 2016 and 2015 consists of the following:

	December 31, 2016	December 31, 2015
Cigarette manufacturing equipment	$ 3,193,580	$ 3,016,246
Office furniture, fixtures and equipment	103,945	95,361
Laboratory equipment	19,076	-
	3,316,601	3,111,607
Less: accumulated depreciation	881,938	555,814
Machinery and equipment, net	$ 2,434,663	$ 2,555,793

Depreciation expense was $326,124, $319,699 and $230,012 for the years ended December 31, 2016, 2015 and 2014, respectively.

NOTE 9. - EQUITY INVESTMENT AND ADVANCE

On April 11, 2014, the Company, through its wholly-owned subsidiary, Botanical Genetics, LLC, entered into an investment agreement (the “Agreement”) with Anandia Laboratories, Inc., a Canadian plant biotechnology company (“Anandia”). The Agreement provided for the Company to make an initial investment of $250,000 in Anandia in return for (i) a ten percent (10%) equity interest in Anandia, and (ii) certain rights granted to the Company for four patent families (the “Intellectual Property”). The $250,000 investment was made on April 14, 2014. On September 15, 2014, certain milestones were achieved triggering an additional cash investment in Anandia in the amount of $450,000 in return for (i) an additional fifteen percent (15%) equity interest in Anandia, and (ii) a worldwide sublicense agreement to the Intellectual Property, including exclusive rights within the U.S. In addition, the Company issued 150,000 unregistered shares of the Company’s common stock to Anandia with a value on the day of issuance of September 15, 2014 in the amount of $394,500, and on March 31, 2015, the Company issued to Anandia an additional 377,906 unregistered shares of the Company’s common stock with an aggregate market value of $325,000 at the time of the issuance in accordance with the Agreement.

The Company uses the equity method of accounting to record its 24.4% ownership interest in Anandia (ownership was 25% prior to a dilutive event on September 8, 2016). As of December 31, 2016, and December 31, 2015, the Company’s equity investment balance in Anandia was $1,020,313 and $1,222,651, respectively, and is classified within Other assets on the accompanying Consolidated Balance Sheets. As of September 15, 2014, the carrying value of our investment in Anandia was approximately $1,199,000 in excess of our share of the book value of the net assets of Anandia, with such difference being attributable to intangible assets. This intangible asset is being amortized over

the expected benefit period and this amortization expense of $57,648, $57,648 and $16,815 for the years ended December 31, 2016, 2015 and 2014, respectively, has been included in the Loss on equity investment in the accompanying Consolidated Statements of Operations. In addition, the Company has recorded an equity loss of $144,690, 38,036 and $84,350 for the years ended December 31, 2016, 2015 and 2014, respectively, representing the Company's portion of Anandia's net losses, resulting in a total loss on equity investment of $202,338, $95,684 and $101,165 for the years ended December 31, 2016, 2015 and 2014, respectively.

NOTE 10. - 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 the scheduled installment payments of $333,333 made by the Company to NRC on December 22, 2016 and 2015 and the accretion of interest, the remaining present value of the note payable amounts to $307,938; with $307,938 and $0 recorded as the current and long-term portion of the note payable, respectively, at December 31, 2016 ($616,520; with $308,582 and $307,938 as the current and long-term portion of the note payable, respectively, at December 31, 2015). 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. NRC has a security interest in these patent rights acquired by the Company from NRC until the note payable has been satisfied.

NOTE 11. - 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, resulting in current and long-term liabilities of $212,012 and $412,308, respectively, at December 31, 2014. Due to alleged breaches of the Employment Agreement by Mr. Pandolfino, payments were suspended by the Company on February 13, 2015. Resulting litigation between Mr. Pandolfino and the Company was settled on November 6, 2015, and pursuant to the settlement agreement Mr. Pandolfino's severance benefits were reinstated, including a catch-up payment through the date of the settlement. As a result of the severance benefit payments made during 2016, the discounted current and long-term balance of the severance liability amounted to $199,657 and $0, respectively, at December 31, 2016 ($220,661 and $199,658, respectively, at December 31, 2015).

NOTE 12. - WARRANT EXCHANGE PROGRAM AND WARRANTS FOR COMMON STOCK

On December 31, 2016, the Company had outstanding warrants to purchase 13,781,921 shares of common stock of the Company, of which only 94,721 warrants contain an anti-dilution feature. The Crede Tranche 2 and Tranche 3 warrants are excluded from the outstanding warrant total of 13,781,921 (see Note 6 – Joint Venture, Consulting Agreement and Associated Warrants for additional information).

On January 25, 2016, warrants to purchase 67,042 shares of common stock were exercised, primarily on a cashless basis, resulting in the issuance of 2,618 shares of the Company's common stock. On January 25, 2016, warrants to purchase 6,831,115 shares of common stock expired without being exercised.

Pursuant to the registered direct offering that closed on October 19, 2016, and discussed in Note 2, the Company issued warrants to purchase 4,250,000 shares of common stock with an exercise price of $1.45 per share. These warrants had a term of sixty-six (66) months, were not exercisable for six months immediately following the date of issuance, did not contain an anti-dilution feature, and had a fair value of approximately $3,380,000 at issuance.

Pursuant to the registered direct offering that closed on July 27, 2016, and discussed in Note 3, the Company issued warrants to purchase 7,043,211 shares of common stock. The warrants provide 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 have a term of 5.5 years and do not contain an anti-dilution feature. 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 (see also Note 4 – February 2016 Registered Direct Offering and Note 5 – June 2015 Registered Direct Offering for additional information).

Pursuant to the registered direct offering that closed on February 5, 2016, and discussed in Note 4, the Company issued warrants to purchase 2,500,000 shares of common stock with an exercise price of $1.21 per share. These warrants had a term of sixty-six (66) months, were not exercisable for six months immediately following the date of issuance, did not contain an anti-dilution feature, and had a fair value of approximately $1,940,000 at issuance. The warrants associated with this transaction were terminated on July 27, 2016 (see Note 3 – July 2016 Registered Direct Offering for additional information).

Pursuant to the registered direct offering that closed on June 2, 2015, and discussed in Note 5, the Company issued warrants to purchase 3,000,000 shares of common stock with an exercise price of $1.25 per share. These warrants had a term of sixty-six (66) months, were not exercisable for six months immediately following the date of issuance, did not contain an anti-dilution feature, and had a fair value of approximately $2,067,000 at issuance. The warrants associated with this transaction were terminated on July 27, 2016 (see Note 3 – July 2016 Registered Direct Offering for additional information).

Outstanding warrants at December 31, 2016 consist of the following:

Warrant Description	**Number of Warrants**	**Exercise Price**	Expiration
December 2011 convertible NP warrants	172,730	$1.1984	February 8, 2017
December 2011 convertible NP warrants	802,215	$1.3816	February 6, 2018
May 2012 PPO warrants	401,700	$0.6000	May 15, 2017
November 2012 PPO warrants	925,100	$0.6000	November 9, 2017
August 2012 convertible NP warrants[(1)]	94,721	$0.9310	August 8, 2018
August 2012 convertible NP warrants	92,244	$0.9060	August 8, 2018
July 2016 registered direct offering warrants	7,043,211	$1.0000	January 27, 2021
October 2016 registered direct offering warrants	4,250,000	$1.4500	April 19, 2022
Total warrants outstanding [(2), (3)]	13,781,921		

(1) Includes anti-dilution features.

(2) Includes warrants to purchase 533,000 shares of common stock (3.9%) held by officers and directors that have had the anti-dilution feature removed.

(3) Includes warrants to purchase 312,730 shares of common stock (2.3%) held by a former officer and director that have had the anti- dilution feature removed.

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 6 - 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, 2013	$3,779,522
Reclassification of warrant liability to equity resulting from Warrant Amendments - Q1 2014	(7,367,915)
Cost of inducement from Warrant Amendments - Q1 2014	144,548
Fair value of warrant liability resulting from issuance of Crede Tranche 1A Warrants - Q3 2014	2,810,000
Loss as a result of change in fair value	3,676,691
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

The aggregate net gain (loss) as a result of the Company’s warrant liability for the years ended December 31, 2016, 2015 and 2014 amounted to $29,615, $144,500 and ($3,676,691), respectively, which are included in Other income (expense) under Warrant liability gain (loss) - net in the accompanying Consolidated Statements of Operations.

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 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.

The following table summarizes the Company's warrant activity since December 31, 2013:

	Number of Warrants
Warrants outstanding at December 31, 2013	10,653,469
Warrants issued in conjunction with consulting agreement	4,250,000
Warrants exercised during 2014	(1,247,443)
Additional warrants due to anti-dilution provisions	18,383
Warrants outstanding at December 31, 2014	13,674,409
Warrants issued in conjunction with registered direct offering	3,000,000
Warrants exercised during 2015	(40,000)
Additional warrants due to anti-dilution provisions	369
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
Composition of outstanding warrants:	
Warrants containing anti-dilution feature	94,721
Warrants without anti-dilution feature	13,687,200
	13,781,921

(1) Crede Tranche 2 Warrants and Tranche 3 Warrants are not exercisable (see Note 6 for additional information).
(2) Crede Tranche 1A Warrants and Crede Tranche 1B Warrants expired unexercised on September 29, 2016.

NOTE 13. - 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, 2016, 2015 and 2014 amounted to $84,499, $56,208 and $27,485, respectively.

NOTE 14. - 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 for 2015 was $75,000 and in 2016 the minimum annual royalty increased to $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, 2016, 2015 and 2014 the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to $84,191, $103,641 and $122,879, 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, 2016 and 2015, the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to $6,075 and $0, respectively. This License continues through the life of the last-to-expire patent, expected to be in 2036.

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 has extended the Agreement through January 31, 2017 at an additional cost of $85,681. The Company plans to extend and amend its Agreement in 2017 with NCSU relating to very low nicotine tobacco plants.

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, 2016, 2015 and 2014 were $447,808, $156,204 and $149,437, 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, Inc. for a license fee of $1,250,000. An initial cash payment of $725,000 was made upon execution of the Precision License with an unconditional obligation to pay the remaining $525,000 in $25,000 increments as materials are provided to the Company. The remaining $525,000 was paid during December 2014. 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. 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, 2016, 2015 and 2014, the aggregated costs incurred related to capitalized patent costs and patent maintenance expense amounted to $43,740, $75,351 and $1,089, 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 9). 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, 2016, 2015 and 2014 amounted to $98,022, $98,022 and $32,524, 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 will conduct research on behalf of the Company relating to the cannabis plant. The Agreement has 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. The Company is currently in negotiations to exercise the first extension option that contains a potential annual budget of approximately $785,000. The Company has paid Anandia $379,800 over the initial term of the Agreement. During the years ended December 31, 2016 and 2015 expenses related to the Agreement amounted to $263,400 and $116,400, respectively, and are included in Research and development costs on the Company's Consolidated Statements of Operations. 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. The Company incurred R&D expenses under the agreement in the amount $224,560, $224,428 and $222,862 for the years ended December 31, 2016, 2015 and 2014, respectively. 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 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 optimize other desirable hemp plant characteristics to improve the plant's suitability for growing in Virginia and other legacy tobacco regions. This work with UVA will also involve the development and study of medically important cannabinoids to be extracted by UVA from the Company's unique 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 new 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.

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 first two-year lease extension term that will expire on October 31, 2017. The lease expense for the years ended December 31, 2016, 2015 and 2014 amounted to approximately $146,000, $127,000 and $98,000, respectively. The future minimum lease payments if the Company exercises each of the additional extensions are approximately as follows:

Year ended December 31, 2017 - $156,000
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

The Company has a lease for its office space in Clarence, New York and extended the lease for an additional one-year renewal period expiring on August 31, 2017. Future minimum lease payments for the year ended December 31, 2017 are approximately $31,000.

On November 1, 2015, the Company entered into a one-year lease for 25,000 square feet of warehouse space in North Carolina to store the Company’s proprietary tobacco leaf. The lease calls for a monthly lease payment of $3,750 and contains a three-year renewal option after the initial one-year term. In October of 2016, the Company exercised the three-year renewal option after the one-year term. Future minimum lease payments for the years ended December 31, 2017, 2018 and 2019 are $45,000, $45,000 and $37,500, respectively, if the Company exercises the optional renewal period.

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, expires on April 30, 2017 and contains an option to extend the lease for a period of one year through April 30, 2018. Future minimum sublease payments for the years ended December 31, 2017 and 2018 are approximately $18,000 and $6,000, respectively, if the Company exercises the optional renewal period.

On September 1, 2016, the Company entered into a sublease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment. The sublease calls for a monthly payment of $1,200, expires on August 31, 2017 and contains twelve-month renewal options as long as the sublessor continues to sublease the warehouse. Future minimum sublease payments for the year ended December 31, 2017 are $14,400 per year for each subsequent year the warehouse space is sublet by the Company.

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 includes 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 of 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 to be filed by the Company.

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 15. - 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, 2016, 2015 and 2014:

	December 31, 2016	December 31, 2015	December 31, 2014
Net loss attributed to common shareholders	$(11,581,430)	$(11,031,931)	$(15,595,358)
Denominator for basic earnings per share-weighted average shares outstanding	79,842,773	68,143,284	59,993,413
Effect of dilutive securities:			
Warrants, restricted stock and options outstanding	-	-	-
Denominator for diluted earnings per common share-weighted average shares adjusted for dilutive securities	79,842,773	68,143,284	59,993,413
Loss per common share - basic and diluted	$(0.15)	$(0.16)	$(0.26)

Securities outstanding that were excluded from the computation of earnings per share for the years ended December 31, 2016, 2015 and 2014 because they would have been anti-dilutive are as follows:

	December 31, 2016	December 31, 2015	December 31, 2014
Warrants	13,781,921	16,634,778	13,674,409
Restricted stock	-	-	250,000
Options	5,650,679	3,161,642	890,000
	19,432,600	19,796,420	14,814,409

NOTE 16. - EQUITY BASED COMPENSATION

On October 21, 2010, the Company established the 2010 Equity Incentive Plan (“EIP”) for officers, employees, directors, consultants and advisors to the Company and its affiliates, which consisted of 4,250,000 shares of common stock. During the first quarter of 2014, the Company issued restricted stock awards from the EIP for 850,000 restricted shares to employees and directors that vested on January 27, 2015. All awards were valued at the closing price of the

Company’s common stock on the measurement date of the award. No additional awards are issuable under the EIP.

On April 12, 2014, the stockholders of the Company approved the 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (the “OIP”). 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 5,000,000 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.

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 award. During the year ended December 31, 2015, the Company issued stock option awards from the OIP for 1,821,642 shares and restricted stock option awards from the OIP for 20,000 shares to eligible individuals having vesting periods ranging from six months to one year 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 MKT on the date of the award.

For the years ended December 31, 2016, 2015 and 2014, the Company recorded compensation expense related to restricted stock and stock option awards granted under the EIP and OIP of $880,509, $1,326,393 and $2,293,082, respectively. During the year ended December 31, 2016, the Company issued stock to third-party service providers in the amount of 15,811 shares and issued stock options in the amount of 100,000 shares to a third-party service provider. During the year ended December 31, 2015, the Company issued restricted stock to third-party service providers in the amount of 279,196 shares and issued stock options to third-party service providers in the amount of 400,000 shares. The Company recorded equity based compensation expense related to the third-party providers for the years ended December 31, 2016, 2015 and 2014 in the amount of $30,873, $280,362 and $140,170, respectively, and does not include equity based compensation under the Crede Consulting Agreement in the amount of $0, $1,978,785 and $2,091,215 for the years ended December 31, 2016, 2015 and 2014, respectively.

As of December 31, 2016, unrecognized compensation expense related to non-vested restricted shares and stock options amounted to approximately $1,383,000 which is expected to be recognized approximately as follows: $447,000, $357,000 and $112,000 during 2017, 2018 and 2019, respectively. Approximately $467,000 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 2016, 2015 and 2014:

	2016		2015		2014	
Risk-free interest rate (weighted average)	1.31	%	1.60	%	1.80	%
Expected dividend yield	0	%	0	%	0	%
Expected stock price volatility	90	%	90	%	90	%
Expected life of options (weighted average)	4.87 years		8.96 years		10 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, 2013 is as follows:

	Weighted	Aggregate

	Number of Options	Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value
Outstanding at December 31, 2013	660,000	$ 0.74		
Granted in 2014	300,000	$ 2.61		
Exercised in 2014	(70,000)	$ 0.69		
Outstanding at December 31, 2014	890,000	$ 1.38		
Reinstated in 2015	50,000	$ 0.69		
Granted in 2015	2,221,642	$ 1.00		
Outstanding at December 31, 2015	3,161,642	$ 1.10		
Granted in 2016	2,489,037	$ 0.97		
Outstanding at December 31, 2016	5,650,679	$ 1.04	7.4 years	$875,845
Exercisable at December 31, 2016	2,711,642	$ 1.07	6.8 years	$433,380

There were stock options granted during the years ended December 31, 2016, 2015 and 2014, to purchase a total of 2,489,037, 2,221,642 and 300,000 shares, respectively. The weighted average grant date fair value of options issued during the years ended December 31, 2016, 2015 and 2014 was $0.66, $0.58 and $2.07, respectively. The total fair value of options that vested during years ended December 31, 2016, 2015, and 2014 amounted to $1,242,110, $206,500 and $103,250, respectively. During the year ended December 31, 2014, 70,000 options were exercised for cash proceeds of $48,300. No options were exercised during the years ended December 31, 2016 and 2015.

NOTE 17. - INCOME TAXES

The following is a summary of the components giving rise to the income tax provision (benefit) for the years ended December 31, 2016, 2015 and 2014.

	2016	2015	2014
Current:			
Federal	$-	$-	$-
State	-	-	-
Total current	-	-	-
Deferred:			
Federal	(2,424,497)	(3,372,964)	(3,494,787)
State	21,452	(155,352)	160,319
Total deferred	(2,403,045)	(3,528,316)	(3,334,468)
Change in valuation allowance	2,403,045	3,528,316	3,334,468
	$-	$-	$-

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 as follows:

	2016	2015	2014
Statutory federal rate	(34.0)%	(34.0)%	(34.0)%
Other items	(0.2)	0.0	0.6
Derivative liability	11.9	(0.5)	8.4
Stock based compensation	1.5	3.1	2.5
State tax provision, net of federal benefit	0.1	(0.9)	1.1
Valuation allowance	20.7	32.3	21.4
Effective tax rate (benefit) provision	0.0 %	0.0 %	0.0 %

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

2016	2015	2014

Deferred tax assets:			
Net operating loss carry-forward	$11,626,143	$7,745,734	$4,775,536
Accounts receivable reserve	3,499	3,499	-
Inventory	96,934	38,707	17,713
Stock-based compensation	282,850	1,599,916	809,319
Start-up expenditures	477,917	514,680	388,130
Loss on equity investment	139,676	68,877	35,398
Severance liability	69,860	147,070	218,450
Other	21,423	9,272	6,561
	12,718,302	10,127,755	6,251,107
Deferred tax liabilities:			
Fixed assets	(316,232)	(227,186)	(80,251)
Patents and trademarks	(807,137)	(767,044)	(624,010)
Other intangible assets	(138,713)	(80,349)	(21,986)
	(1,262,082)	(1,074,579)	(726,247)
Valuation allowance	(11,456,220)	(9,053,176)	(5,524,860)
Net deferred taxes	$-	$-	$-

The Company has incurred a net operating loss ("NOL") of approximately $33,700,000 through December 31, 2016 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, 2016.

NOTE 18. - SELECTED QUARTERLY FINANCIAL DATA (unaudited)

Below is selected quarterly financial data for the years ended December 31, 2016 and 2015:

	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 (loss) profit	$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)

	Three Months Ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Revenue, net	$616,138	$2,306,953	$ 2,667,506	$ 2,931,401
Gross (loss) profit	$(16,442)	$(293,493)	$ (281,422)	$ 10,795
Loss from operations	$(4,119,463)	$(2,346,736)	$ (2,747,501)	$ (2,830,183)

Net loss	$(4,116,739)	$(1,288,703)	$(2,761,691)	$(2,864,798)
Loss per common share - basic and diluted	$(0.06)	$(0.02)	$(0.04)	$(0.04)

NOTE 19. - SUBSEQUENT EVENTS

The Company's Form S-3, universal shelf registration statement, was filed with the U.S. Securities and Exchange Commission ("SEC") on December 30, 2016, and became effective 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.

On January 20, 2017, the United States District Court for the Southern District of New York (the "SDNY Court") granted the Company's 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. Additionally, on February 14, 2017, Crede voluntarily dismissed its lawsuit against the Company in the WDNY Court, determining not to pursue its claims against the Company related to the terminated China joint venture. Also, 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 to be filed by the Company. Please see the Litigation section of Note 14 – Commitments and Contingencies for a detailed discussion of the Crede lawsuit.

Item 15(b). 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;

- 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).

2.2 Purchase Agreement, dated December 22, 2014, by and between 22nd Century Limited, LLC and the National Research Council of Canada (incorporated by reference to Exhibit 2.1 to the Company's Form 8-K filed with the Commission on December 29, 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 3, 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 Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the Commission on December 14, 2011).

4.2 Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Commission on May 18, 2012).

4.3 Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Commission on November 13, 2012).

4.4 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).

4.5 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the Commission on May 29, 2015).

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4.6 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on July 26, 2016)

4.7 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on July 26, 2016)

4.8 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on October 17, 2016)

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† Employment Agreement dated as of March 15, 2011, by and between the Company and Michael R. Moynihan (incorporated by reference to Exhibit 10.18 to the Company's Form S-1 registration statement filed with the Commission on June 6, 2011).

10.4†† 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).

10.4.1 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).

10.5†† License Agreement dated May 1, 2009 between The National Research Council of Canada and 22nd Century Limited, LLC (incorporated by reference to Exhibit 10.22 to the Company's Form S-1 registration statement filed with the Commission on August 26, 2011).

10.6 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).

10.7† Employment Agreement between John Brodfuehrer and the Company dated March 19, 2013 (incorporated by reference to Form 8-K filed on March 25, 2013).

10.8† Form of Restricted Stock Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).

10.9† Form of Stock Option Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).

10.10†† Research License and Commercial Option Agreement with British American Tobacco (Investments) Limited dated October 1, 2013 (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Commission on January 30, 2014).

10.11 † 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (incorporated by reference to Appendix B to the Company's Definitive Proxy Statement filed with the Commission on March 4, 2014).

10.12 † Form of Restricted Stock Award Agreement under 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the Commission on April 14, 2014).

10.13 † Form of Stock Option Award Agreement under 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed with the Commission on April 14, 2014).

10.14 † 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).

10.15† Employment Agreement, dated October 7, 2015, between Dr. Rushton and the Company (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the Commission on October 9, 2015).

10.16 *††† 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.

10.17 *††† 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.

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.

††† Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. 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 8, 2017 By: /s/ Henry Sicignano, III
Henry Sicignano, III
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 8, 2017 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 8, 2017 By: /s/ Henry Sicignano III
Henry Sicignano III
President, Chief Executive Officer and Director

Date: March 8, 2017 By: /s/ Joseph Alexander Dunn, Ph.D.
Joseph Alexander Dunn, Ph.D. Director

Date: March 8, 2017 By: /s/ James W. Cornell
James W. Cornell

Director

Date: March 8, 2017 By: /s/ Richard M. Sanders
Richard M. Sanders
Director

Date: March 8, 2017 By: /s/ Nora B. Sullivan
Nora B. Sullivan

Director

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