22nd Century Group, Inc.
Form 10-K
February 18, 2016

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, 2015

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, 2015, 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 12,124,508 shares held by affiliates), based upon the $0.94 price at which such common stock was last sold on June 30, 2015, was approximately $55.2 million.

As of February 18, 2016, there were 76,009,960 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2016 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, 2015.

22nd Century Group, Inc.

Table of Contents

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 raise additional capital on favorable terms or at all;

· Our ability to achieve profitability and positive cash flows;

· 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 significant revenue for our tobacco products;

· 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 gain market acceptance for our products;

· Any potential negative impact from entering the cannabis space;

· 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 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* in the U.S. as an over-the-counter product labeled as reduced exposure to nicotine as *BRAND A* has 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 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* as a modified risk cigarette with an extremely low tar-to-nicotine ratio;
- The manufacture, marketing 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 international sale of our branded proprietary tobaccos;
- The contract manufacturing of third-party branded tobacco products; and
- The research and development in Canada 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 marijuana 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) domestic and international sales of our brands, including *RED SUN* and *MAGIC*; (iii) further development of our potential modified risk tobacco products and our *X-22* smoking cessation aid; and (iv) 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.

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

We believe our proprietary technology, tobaccos and products will generate multiple significant revenue streams from 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 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 27 issued patents and 21 pending applications and 6 issued patents and 6 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. We also have the exclusive right to license and sublicense these patent rights. With the exception of two patent families, which will expire in 2016 and 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 1 U.S. patent and 20 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 in Canada 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 marijuana markets.

We own various registered trademarks in the United States. 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").

Simultaneous with the signing of the BAT Research Agreement, BAT paid 22nd Century Ltd. a non-refundable fee of $7.0 million. Further, 22nd Century Ltd. 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 licensed by 22nd Century Ltd. to BAT. There are four separate milestones, two of which BAT would pay 22nd Century Ltd. $2.0 million for each milestone achieved, and two of which BAT would pay 22nd Century Ltd. $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 22nd Century Ltd. by BAT upon termination as set forth therein. 22nd Century Ltd. 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 22nd Century Ltd. 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 to 22nd Century Ltd. (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 22nd Century Ltd. $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.

Beginning three years from the start of the Commercial License, both 22nd Century Ltd. and BAT may license/sublicense rights to any unaffiliated third party for use of the technology outside the United States and 22nd Century Ltd. 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. 22nd Century Ltd. 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 to acquire NASCO Products, LLC ("NASCO") and 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. In 2015, we focused our marketing efforts for *RED SUN* on national and regional distributors, tobacconists, smokeshops and other tobacco outlets in the U.S. In 2015, we also introduced our *MAGIC* cigarettes to distributors and retailers in Spain, 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

In December 2013, Goodrich Tobacco 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. In January 2014, Goodrich Tobacco purchased additional miscellaneous equipment, factory items, office furniture and fixtures, vehicles and computers from the bankruptcy estate of Renegade Tobacco Co. ("Renegade") for $210,000. PTM and Renegade were related companies located in North Carolina undergoing Chapter 7 liquidation proceedings in the United States Bankruptcy Court for the Middle District of North Carolina. Goodrich Tobacco subsequently received $631,484 in net proceeds from auctioning off certain cigarette manufacturing equipment and other items not required for operations at the Company's factory in Mocksville, North Carolina.

The warehouse and cigarette manufacturing facility were primarily in a pre-manufacturing stage during 2014 as we sought approval during that time for the Company and its factory to become a subsequent participating manufacturer under the MSA. On August 29, 2014, the Company closed its acquisition of NASCO and became a subsequent participating manufacturer under the MSA. The Company is now manufacturing its cigarette brands in the United States through its wholly-owned subsidiary, NASCO, at the Company's factory in North Carolina. In 2015, we manufactured and sold our *RED SUN* super-premium brand, together with a third-party MSA cigarette brand and third-party filtered cigars, at our factory.

International Sales

The Company makes its *MAGIC* super-premium brand at 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 2015, the Company also entered into new distribution agreements with European partners for the launch of the Company's products in additional European countries. The Company is also evaluating the sale and distribution of its products in Asia.

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 granted 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 requires 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 will not 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.

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. We intend to work diligently with the FDA to obtain a reduced exposure marketing authorization for *BRAND A* to be marketed in the U.S. We also intend to seek FDA authorization in the future 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. 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).

In a June 16, 2010 press release, Dr. David Kessler, the former FDA Commissioner, recommended that "[t]he 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.

There have been seven (7) independent, scientific clinical studies utilizing our proprietary VLN tobacco cigarettes, with each study showing the efficacy of our VLN tobacco cigarettes 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 seven (7) 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 most recent 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") 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."

Utilizing the results of these and other independent clinical trials, on December 31, 2015, we submitted to the Center for Tobacco Products ("CTP") of the FDA an application for *BRAND A* to 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 a user to 95% less nicotine than conventional cigarettes.

We believe these and other results and future exposure studies the FDA may require will result in a reduced exposure marketing order to be granted by the FDA for *BRAND A*. We further believe smokers who desire to smoke fewer cigarettes per day while also satisfying cravings and reducing exposure to nicotine will find *BRAND A* beneficial.

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. *BRAND B* has a "tar" yield between typical "light" and "ultra-light" cigarettes, 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 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.

Our 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. The Company and the CRO met with the CTP on November 12, 2014 to discuss the development plan and proof of concept study for *BRAND B*, a cigarette that produces smoke containing an extraordinarily low amount of "tar" per milligram of nicotine.

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 VLN 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 VLN 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 VLN cigarettes for 6 weeks, *X-22* does not expose the smoker to any new drugs or new side effects.

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, or “NRT,” 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 and $377 million in 2014. 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, worldwide sales of Chantix ® in 2009 to 2014 were approximately $700 million, $755 million, $720 million, $670 million, $648 million and $647 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 31 years and 23 years, respectively, and millions of smokers have already tried NRT products and failed to stop smoking due to the limited effectiveness of these products. According to Perrigo Company plc, a pharmaceutical company that sells NRT products, retail sales of NRT products in the United States were approximately $900 million in its fiscal year ended June 30, 2014.

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 their 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.

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 2015, we incurred approximately $224,000 of expenses for the R&D agreement at UVA and anticipate spending an additional amount of approximately $94,000 through May 31, 2016. We also plan to extent the agreement for an additional year to May 31, 2017 at an expected cost of approximately $225,000.

We have committed to an R&D agreement with NCSU relating to nicotine biosynthesis in tobacco plants with a total budget of approximately $163,000 for the period from February 2014 through January 2016. 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, 2015, 2014 and 2013, we incurred total R&D expenses of $1,669,387, $1,249,007 and $744,230, 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. In 2015, we 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. 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 modified nicotine (from very low to high) cigarettes 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 NIDA to researchers free of charge. 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 from RTI approximately 5 million *SPECTRUM* research cigarettes 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. Clinical studies have demonstrated that smokers who smoke 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).

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 an application for *BRAND A* as a Modified Risk Cigarette.

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. *BRAND B* has a “tar” yield between typical “light” and “ultra-light” cigarettes, but a nicotine yield of typical full flavor cigarettes.

Our 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. The Company and the CRO met with the CTP on November 12, 2014 to discuss the development plan and proof of concept study for *BRAND B*, a cigarette that produces smoke containing an extraordinarily low amount of "tar" per milligram of nicotine.

We believe that these two cigarette products in development, which we refer to as *BRAND A* and *BRAND B*, will qualify as Modified Risk Cigarettes. 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.

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 VLN 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 VLN 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 VLN cigarettes for 6 weeks, *X-22* does not expose the smoker to any new drugs or new side effects. Our Investigational New Drug Application for *X-22*, a kit of VLN cigarettes, 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 VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases quit rates.

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 8 and 30 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 seven (7) independent studies listed below have demonstrated that VLN cigarettes 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 seven (7) independent studies listed below are indeed remarkable for their results, 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

·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 VLN cigarettes are an 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. Upon identifying a suitable joint venture partner or licensee, we will then request a meeting with the FDA, and thereafter we plan to resume our own sponsored *X-22* clinical trials.

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 entity, 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 will scientifically evaluate 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 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 ®, Native 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., Commonwealth Brands, Inc., 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 the organic material, usually 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 in Canada

Botanical Genetics 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, that closed on April 14, 2014. On September 15, 2014, Botanical Genetics was granted a sublicense by Anandia to 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, 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.

We do not conduct any activities related to cannabis in the United States. Our research facilities for cannabis are located exclusively in Canada. Through licenses granted by the Canadian government to Anandia, we conduct research and development in Canada with Anandia 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 marijuana 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.

As of December 31, 2015, there are 23 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, Colorado, Oregon and Washington 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.

Employees

We currently employ thirty-nine (39) 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 $11.0 million, $15.6 million, and $26.1 million during the years ended December 31, 2015, 2014 and 2013, respectively. At December 31, 2015, we had current assets of $7,227,948, current liabilities of $3,236,120, and cash on hand of $3,760,297. Excluding contract growing of our proprietary tobacco with farmers, costs associated with an additional modified risk application with the FDA, patent and trademark costs, discretionary expenses such as potential clinical trials, capital expenses for our factory, and possible sponsored research, our monthly cash expenditures are approximately $650,000. Including cash on hand at December 31, 2015 of $3,760,297 plus net proceeds of approximately $5,140,000 in additional cash raised from a registered direct offering of our common stock and warrants on February 5, 2016, 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 approximately October of 2016. While our current cash balance is adequate to sustain operations through approximately October of 2016, 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. These 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 $7.3 million during the year ended December 31, 2015. As indicated above, we believe our current cash position is adequate to sustain operations and meet all current obligations

as they come due through approximately October of 2016. 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 product 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 RED SUN and MAGIC cigarettes and our BRAND A and BRAND B 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 *RED SUN and MAGIC* cigarettes or other cigarettes we may introduce to the market such as our *BRAND A* and *BRAND B* cigarettes as Modified Risk Cigarettes, upon FDA authorization. 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. Domestic competitors include Philip Morris USA Inc., Reynolds American Inc., Commonwealth Brands, Inc., Liggett Group LLC, and Vector Tobacco Inc. International competitors include Philip Morris International Inc., JT International SA, 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.

During 2015, we grew from twenty-three (23) employees to thirty-nine (39) 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 are 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 are 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.

19

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, 2015, 23 states and the District of Columbia allow their citizens to use medical marijuana. Additionally, the states of Alaska, Colorado, Oregon and Washington 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 do not currently conduct any activities related to cannabis in the United States. Our research facilities for cannabis are located exclusively in Canada. In Canada, licenses to cultivate, possess and supply cannabis for medical research are granted by agencies of the federal government in Canada. 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 marijuana laws and regulations are broad in scope and subject to evolving interpretations, which could require us to incur substantial costs associated with compliance requirements. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our operations. In addition, it is possible that regulations may be enacted in the future that will be directly applicable to our proposed business regarding cannabinoid production. 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. 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.

We submitted a request for Fast Track designation for *X-22*, and on August 18, 2011, the FDA informed us that it would not grant the designation of *X-22* as a Fast Track product at that time because we had not yet demonstrated that *X-22* showed potential to address an unmet medical need. Except for our Phase IIb clinical trial, all smoking cessation studies with VLN cigarettes containing our proprietary tobacco were independent studies and were not sponsored by us under our own IND application. We plan to reapply for Fast Track designation, but not until results of a clinical trial conducted by us demonstrates an advantage (over currently approved smoking cessation products) in one of the following areas: efficacy, safety or improvement in some other factor such as compliance (a patient using a product as directed) or convenience. There is no guarantee that the FDA will grant Fast Track designation to *X-22*. We may also not obtain Priority Review of our *X-22* New Drug Application ("NDA"), which would further delay FDA approval of *X-22*. The length of the FDA's review of a NDA without a Priority Review designation is normally ten months from the date of filing of the NDA, although it is possible in certain cases for such review time to be longer. However, the FDA's goal for reviewing a product with Priority Review status is normally six months from the date of the filing of a NDA. If we do not obtain Priority Review of our NDA, we would then expect the timing of FDA approval of *X-22* to be extended several additional months. Even if *X-22* is approved by the FDA, the FDA may require the product to only be prescribed to patients who have already failed to quit smoking with another approved therapy. Further, failure to comply with applicable regulatory requirements can, among other things, result in the suspension of regulatory approval as well as possible civil and criminal sanctions.

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. 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.

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 *X-22* smoking cessation aid 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 consist 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 will comprise the top 50 percent of the front and rear panels of cigarette packages. The graphic health warnings will occupy 20 percent of a cigarette advertisement and will be located at the top of the advertisement. Each warning is accompanied by a smoking cessation phone number, 1-800-QUIT-NOW. 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 *MAGIC* and *RED SUN* , as well as *X-22* , *BRAND A* and *BRAND B* , if and when implemented by the FDA. *MAGIC*, *RED SUN*, *BRAND A* and *BRAND B* will be subject to these new packaging and advertising regulations. It is unclear at this time whether the FDA may require *X-22 and SPECTRUM* to be subject to these new packaging and advertising regulations.

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, 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 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 August 31, 2016, with an option to extend this lease for an additional one-year renewal period expiring on August 31, 2017. Scheduled rent remaining as of December 31, 2015 is $45,007 for 2016 and $30,600 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 one-year lease extension term that will expire on October 31, 2016. The lease expense for the years ended December 31, 2015, 2014 and 2013 amounted to $126,588, $97,593 and $0, respectively. The future minimum lease payments if we exercise each of the additional extensions are approximately as follows:

Year ended December 31, 2016 - $146,000
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. Future minimum lease payments for the years ended December 31, 2016, 2017, 2018 and 2019 are $45,000, $45,000, $45,000 and $37,500, respectively, if we exercise the optional renewal periods.

Item 3. Legal Proceedings.

From time to time we may be involved in claims arising in the ordinary course of business. To our knowledge, 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.

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 16, 2016, there were 104 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 (i) the OTC Bulletin Board Information Center for the period prior to March 11, 2014, when our common stock was quoted on the OTC Bulletin Board, and (ii) the NYSE MKT for the period beginning on March 11, 2014, when our common stock commenced being listed and quoted on the NYSE MKT.

Quarter Ended	High	Low
December 31, 2015	$1.75	$0.82
September 30, 2015	$1.13	$.056
June 30, 2015	$1.55	$.071
March 31, 2015	$1.78	$0.65
December 31, 2014	$2.67	$1.50
September 30, 2014	$3.35	$1.90
June 30, 2014	$3.87	$2.14
March 31, 2014	$6.36	$1.75

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

On December 30, 2015, we issued 40,000 shares of common stock, par value $0.00001 per share, pursuant to the exercise of outstanding warrants. The exercise of warrants generated gross proceeds of $50,688.

The common stock offered and sold was pursuant to an exemption from the registration requirements under Section 4(2) of the Securities Act.

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.

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 remaining to be issued under all outstanding equity compensation plans as of December 31, 2015:

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	2,881,642 (1)	$ 1.16 (2)	2,710,802
Equity compensation plans not approved by security holders	-	N/A	-
Total	2,881,642		2,710,802

(1) Includes 120,000 restricted stock awards that are issued but not vested as of December 31, 2015.

(2) Weighted average exercise price only applies to the 2,761,624 shares issuable upon exercise of outstanding stock options.

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 January 26, 2011 (the first day trading of the Company’s common stock) through December 31, 2015. The NASDAQ US Small Cap Biotechnology Index began trading on June 6, 2011, and as such, the graph reflects the return on this index from June 6, 2011 through December 31, 2015. The comparison of total return assumes that a fixed investment of $100 was invested on January 25, 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.

29

Item 6. Selected Financial Data.

The selected consolidated financial data for each of the five years in the period ending December 31, 2015 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,				
	2015	2014	2013	2012	2011
Consolidated Statements of Operations data:					
Revenue	$8,521,998	$528,991	$7,278,383	$18,775	$1,012,141
Gross (loss) profit	$(580,562)	$30,555	$6,816,712	$(49,192)	$593,970
Operating expenses (1)	$10,787,032	$11,335,147	$4,859,976	$2,996,551	$4,169,556
Equity based compensation included in operating expenses	$3,585,540	$4,524,468	$2,361,962	$1,254,171	$376,437
Operating (loss) profit	$(12,043,883)	$(11,767,364)	$1,812,447	$(3,244,149)	$(3,755,539)
Warrant liability gain (loss) - net (2)	$144,550	$(3,827,794)	$(27,339,024)	$(1,998,043)	$2,511,750
Net loss	$(11,031,931)	$(15,595,358)	$(26,153,158)	$(6,736,737)	$(1,347,787)
Loss per common share - basic and diluted	$(0.16)	$(0.26)	$(0.60)	$(0.22)	$(0.05)
Common shares used in basic earnings per share calculation	68,143,284	59,993,413	43,635,182	30,419,556	26,391,204
Consolidated Balance Sheet data:					
Working capital	$3,991,828	$8,033,399	$6,759,781	$(3,321,643)	$(1,902,531)
Total assets	$18,370,512	$21,953,515	$12,286,744	$2,644,871	$2,388,623
Total debt	$616,520	$1,100,655	$174,925	$2,685,729	$1,418,811
Total shareholders' equity (deficit)	$11,728,500	$15,219,737	$7,522,888	$(6,131,217)	$(1,212,160)
Other data:					
Net cash used in (provided by) operating activities	$(7,321,811)	$(6,582,730)	$3,855,834	$(1,764,445)	$(3,449,430)
Net cash used in investing activities	$(450,661)	$(2,707,992)	$(3,742,789)	$(162,774)	$(607,297)
Net cash provided by financing activities	$5,130,082	$9,862,810	$5,717,366	$1,675,158	$4,308,666
Acquisition of patents and trademarks (3)	$413,180	$726,989	$290,336	$162,774	$598,191
Depreciation	$319,699	$230,012	$3,028	$1,832	$1,244
Amortization (4)	$454,612	$265,284	$141,261	$196,574	$178,709

(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, 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. 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 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. We focused on tobacco harm reduction and smoking cessation products. We own or exclusively control more than 200 issued patents plus more than an additional 50 pending patent applications.

Our long-term focus is the research, development, licensing, manufacturing, and selling of our products to reduce the harm caused by smoking. Annual worldwide tobacco product sales, cigarettes and smokeless products, are approximately $800 billion and most of which are cigarette sales according to Euromonitor International.

- The international licensing of our technology, proprietary tobaccos, trademarks;
- The international sale of our branded proprietary tobaccos;
- The manufacture, marketing and distribution of *RED SUN* and *MAGIC* proprietary cigarettes;
- The production of *SPECTRUM* research cigarettes for NIDA, a part of NIH;
- The research and development of potentially less harmful or modified risk tobacco products and novel tobacco plant varieties;
- The development of *X-22*, a prescription-based smoking cessation aid consisting of VLN cigarettes;
- The pursuit of necessary regulatory approvals and clearances from the FDA to market in the U.S. *X-22* as a prescription smoking cessation aid and *BRAND A* and *BRAND B* as reduced-risk or Modified Risk Cigarettes;
- The contract manufacturing of third-party branded tobacco products; and
- The research and development in Canada 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, (ii) plants with high levels of cannabidiol, or CBD, and other non-THC cannabinoids for the legal medical marijuana markets and (iii) plants with high levels of THC for the legal recreational cannabis market.

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

Recent Developments

During the fourth quarter of 2015, the following occurred:

- We submitted our Modified Risk Tobacco Product application with the Center for Tobacco Products of the FDA seeking a reduced exposure order so that our *"BRAND A"* VLN cigarettes may be introduced into commerce in the United States with packaging and marketing that discloses to consumers that *BRAND A* cigarettes have 95% less nicotine that conventional cigarettes and, as a result, reduces smokers' exposure to nicotine. *BRAND A* cigarettes contain less than 0.6 milligrams of nicotine per cigarette and less than 0.05 milligrams of nicotine yield per cigarette. We are the only entity in the world capable of growing virtually nicotine-free tobacco plants.

- *The New England Journal of Medicine* published two different articles related to our proprietary *SPECTRUM* research cigarettes. The first article reported on the results of a landmark, double-blind, parallel, randomized clinical trial involving 840 smokers at ten locations that demonstrated the Company's very low nicotine cigarettes were found to reduce exposure to, and dependence on, nicotine and to reduce cravings. The study was funded by the FDA and the National Institute on Drug Abuse ("NIDA"). The study found that smokers of our *SPECTRUM* cigarettes consumed far fewer cigarettes per day and doubled their quit attempts versus smokers of conventional cigarettes, all with minimal withdrawal symptoms and without compensatory smoking or any serious adverse events.

- We completed and shipped a substantial portion of the most recent purchase order from NIDA of approximately 5 million *SPECTRUM* research cigarettes for use in further independent clinical studies on smoking cessation and the nicotine addictive threshold in cigarettes.

- We strategically hired Dr. Paul Rushton as our new Vice President of Plant Biotechnology. Dr. Rushton is uniquely qualified to grow and commercialize our patent portfolio relating to both tobacco and cannabis. Dr. Rushton has extensive experience in tobacco biotechnology, including work at the University of Virginia on our sponsored research projects, as well as nearly a decade working at the world-renowned Max Planck Institute for Plant Breeding in Germany.

- We entered into a new cannabis research collaboration with strategic partner Anandia. As a part of this research collaboration, Anandia will develop and grow proprietary cannabis strains under its licenses in Canada that express highly desirable characteristics and that we expect will lead to exciting commercialization opportunities. We announced last year that we had entered into a worldwide license agreement with Anandia that granted exclusive rights to us in the United States to four genes required for cannabinoid production in the cannabis plant. The license also granted us co-exclusive rights with Anandia to this proprietary technology in all countries outside of the U.S. and Canada. Anandia retained exclusive rights in Canada. The proprietary technology licensed from Anandia allows for the development of cannabis strains that demonstrate either an increase or decrease in the production and content of all, or certain subsets of, cannabinoids. The long-term goals of our research activities relating to cannabis are to develop, protect and commercially produce unique cannabis plant varieties that include high levels of non-THC cannabinoids, such as CBD, for the legal medical marijuana markets, as well as virtually cannabinoid-free cannabis for the commercial hemp industry.

31

- We strategically hired a full-time FDA expert, Gregg Gellman, as our new Director of Business Development and Regulatory Affairs. Mr. Gellman was a key member of our team of professionals who worked diligently on creating, completing and submitting our Modified Risk Tobacco Product application with the FDA seeking a reduced exposure order so that our *"BRAND A"* very low nicotine cigarettes may be introduced into commerce in the United States with packaging and marketing that discloses to consumers that *BRAND A* has 95% less nicotine that conventional cigarettes and, as a result, reduces smokers' exposure to nicotine.

- We exported multiple varieties of our proprietary tobacco seeds to Central America for testing and expanded agricultural production of our proprietary tobacco plants for the purpose of making additional seeds for future plantings of increased amounts of our proprietary tobacco in the U.S. and other parts of the world. The United States Department of Agriculture ("USDA") issued a phytosanitary certificate to us to facilitate our export of our proprietary tobacco seeds to growers in Central America.

- We commenced our search for and collaboration discussions with universities in Western New York at which we are seeking to open specialized laboratories dedicated to new scientific research at substantially lower costs than sponsored research projects at third-party universities. Dr. Paul Rushton, our Vice President of Plant Biotechnology, will lead this new scientific initiative. The new laboratories are intended to accelerate the development of new nicotine-free tobacco varieties as well as the invention of other important tobacco products.

In the year 2016, we anticipate that we will be able to achieve the following:

- We will continue to work to have our Modified Risk Tobacco Product application approved in 2016 so that our *"BRAND A"* very low nicotine cigarettes may be introduced into commerce in the United States with packaging and marketing that discloses to consumers that *BRAND A* has 95% less nicotine that conventional cigarettes and, as a result, reduces smokers' exposure to nicotine.

- We will plan "proof of concept" exposure studies for *"BRAND B"* extremely low tar-to-nicotine ratio cigarettes. If the results of these exposure studies allow, and provided sufficient funds are available, we will begin work on a Modified Risk Tobacco Product application for *"BRAND B"* cigarettes that may ultimately be introduced into commerce in the United States with packaging and marketing that discloses to consumers that the *"BRAND B"* exposes smokers to substantially less "tar" and substantially less smoke than the current market leading brands in the United States.

We will continue to identify and meet with pharmaceutical companies, national retail chains and other significant potential strategic partners in our on-going efforts to contract with a third party to fund Phase III clinical trials for *X-22*. We believe *X-22* is more effective than any current smoking cessation therapy on the market and presents smokers with no new side effects and minimal or no withdrawal symptoms. We also believe that smokers will overwhelmingly prefer the prospect of attempting to quit smoking using our very low nicotine cigarettes over Chantix® and all nicotine replacement therapies ("NRT's").

We will further continue to work on expanding our *RED SUN* product sales in the United States and *MAGI*C brand sales in Europe while exploring opportunities for our products in Asia. Several important regional distributors have already inquired about securing distribution rights for our VLN products in Asia. Asia represents a significant market for our Company's unique tobacco products.

We will work to bring in additional work into our factory in North Carolina, which is now underutilized because our factory capacity is greater in size and cost than what is currently required by our operations. However, the vertical integration provided by our factory allows us to promptly, accurately and strategically produce our own proprietary, highly specialized products and the factory gives us the independence and self-determination to produce our proprietary products in a very competitive, increasingly regulated retail marketplace. Our factory also allows us to fulfill our contracts to produce *SPECTRUM* research cigarettes, and to bring in new contract manufacturing business.

We will further continue to work on expanding our product sales in Europe and launching our products in Asia and in the Middle East. Several important regional distributors have already inquired about securing distribution rights for our VLN products in Asia and the Middle East. Both Asia and the Middle East represent significant markets for our Company's unique tobacco products.

Registered Direct Offering

On February 5, 2016, we closed a registered direct offering of 5,000,000 shares of common stock and warrants to purchase up to 2,500,000 shares of common stock at an exercise price of $1.21 per share. The purchase price per unit was $1.10 and resulted in net proceeds of approximately $5.1 million. We expect cash on hand and the results of this offering to be sufficient to fund operations through October 2016. Accordingly, we will be required to raise additional capital to fund operations and achieve FDA approval of our products.

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, 2015 Compared to Year Ended December 31, 2014 and Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Revenue - Sale of products.

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.

2014 vs. 2013

We realized revenue of $528,991 from the sale of products during the year ended December 31, 2014, as compared to revenue of $278,383 during the year ended December 31, 2013, an increase of $250,608 or 90%. The revenue of $528,991 for the year ended December 31, 2014, consisted of $447,535 in revenue derived from the sale of 5.5 million *SPECTRUM* research cigarettes during January 2014 and from the production of filtered cigars in our North Carolina manufacturing facility in the amount of $81,456. The revenue for the year ended December 31, 2013, was derived from the sale of our proprietary VLN tobacco to a customer in the Netherlands in the amount of $52,500 and from the sale of our VLN tobacco to the FDA as a subcontractor under a government contract between RTI and the FDA in the amount of $225,883.

Revenue - Royalties from licensing.

2015 vs. 2014

During the years ended December 31, 2015 and 2014, we realized no revenue from licensing activities.

2014 vs. 2013

During the year ended December 31, 2014, we realized no revenue from licensing activities. During the year ended December 31, 2013 we realized royalty revenue of $7,000,000 from the worldwide Research License and Commercial Option Agreement entered into with BAT.

***Costs of goods sold - Products*.**

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. The cost of goods sold consisted of $177,696 relating to the production of the *SPECTRUM* research cigarettes and $74,306 relating to the manufacture of the filtered cigars.

2014 vs. 2013

In the year ended December 31, 2014, costs of goods sold were $252,002 or 47.6% of revenue. The cost of goods sold consisted of $177,696 relating to the production of the *SPECTRUM* research cigarettes and $74,306 relating to the manufacture of the filtered cigars. In the year ended December 31, 2013, cost of goods sold were $48,105 or 17.3% of revenue.

Costs of goods sold - Royalties for licensing.

2015 vs. 2014

During the years 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. See the discussion below in the 2014 vs. 2013 comparison for additional details.

2014 vs. 2013

During the year ended December 31, 2014, we revised the estimate of the royalty fee due to the National Research Council of Canada (“NRC”) in connection with the $7,000,000 fee received from BAT in the fourth quarter of 2013. The new amount due to NRC of $660,000 exceeded the estimate of $413,566, originally recorded in the year ended December 31, 2013, by $246,434.

Research and development expense.

2015 vs. 2014

Research and development expense was $1,669,387 for the year ended December 31, 2015, an increase of $420,380 or 33.7%, from $1,249,007 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, a net increase in R&D contract costs, sponsored research costs, and patent maintenance costs of approximately $209,000, and an increase in the amortization of various license fees of approximately $65,000, 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.

2014 vs. 2013

Research and development expense was $1,249,007 for the year ended December 31, 2014, an increase of $504,777, or 67.8%, from $744,230 for the year ended December 31, 2013. This increase was primarily the result of increases in stock based compensation of approximately $220,000, research and development payroll and related benefits of approximately $104,000, royalty and license fees of approximately $187,000, and $15,000 of costs associated with an FDA modified-risk application, partially offset by a decrease in contractual research and development costs of approximately $39,000 during the year ended December 31, 2014 as compared to the year ended December 31, 2013.

***General and administrative expense*.**

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.

2014 vs. 2013

General and administrative expense was $8,823,534 in the year ended December 31, 2014, an increase of $4,716,840, or 114.9%, from $4,106,694 in the year ended December 31, 2013. The increase was primarily due to increases in employee equity based compensation of approximately $1,047,000, employee related costs of approximately $693,000, legal and professional fees of approximately $986,000, costs relating to press releases of approximately $78,000, the write off of an uncollectible advance in the approximate amount of $43,000, NYSE MKT related costs of approximately $176,000, costs associated with severance liability of approximately $637,000, director fee costs of approximately $157,000, the expense associated with the Crede consulting agreement in the approximate amount of $2,091,000, and other administrative costs of approximately $202,000, partially offset by decreases in equity based compensation and cash payments to third-party service providers of approximately $1,318,000 and $75,000, respectively, during the year ended December 31, 2014 as compared to the year ended December 31, 2013.

Pre-manufacturing facility costs.

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.

2014 vs. 2013

On August 29, 2014, we completed the transaction to purchase all of the issued and outstanding membership interests of NASCO. The purchase transaction was subject to various conditions, including the required consents of the 46 Settling States of the MSA to an amendment of NASCO's existing adherence agreement to the MSA, with the Company becoming a signatory to such amended adherence agreement as part of our acquisition of NASCO. On August 29, 2014, the Company became a signatory to the amended adherence agreement. NASCO operates our cigarette manufacturing facility in North Carolina. Prior to the closing of our acquisition of NASCO, the factory was primarily in a pre-manufacturing stage, incurring various expenses relating to preparing and upgrading the warehouse and manufacturing facility for production. Those expenses included salaries and benefits for employees, sub-contract labor, rent, utilities and other miscellaneous costs and amounted to $1,176,676 during the year ended December 31, 2014. There were no expenses relating to the cigarette manufacturing facility during the year ended December 31, 2013.

***Sales and marketing costs*.**

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.

2014 vs. 2013

Sales and marketing costs were $85,930 for the year ended December 31, 2014, an increase of $76,878, or 849.3%, from $9,052 for the year ended December 31, 2013. The increase is primarily the result of costs associated with participation in tobacco industry trade shows, *RED SUN* packaging design costs, and materials used for marketing trips to Europe and Asia.

Depreciation.

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.

2014 vs. 2013

Depreciation expense for the year ended December 31, 2014 amounted to $230,012, an increase of $226,984 from $3,028 for the year ended December 31, 2013. This increase is primarily due to approximately $2.9 million of cigarette manufacturing equipment placed in service during the second quarter of 2014.

Amortization.

2015 vs. 2014

Amortization expense, relating to amortization taken on capitalized patent costs, for the year ended December 31, 2015 amounted to $356,590, an increase of $123,830, or 53.2%, from $232,760 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.

37

2014 vs. 2013

Amortization expense, relating to amortization taken on capitalized patent costs, for the year ended December 31, 2014 amounted to $232,760, an increase of $91,499, or 64.8%, from $141,261 for the year ended December 31, 2013. The increase is primarily due to an adjustment to the 2013 amortization that was recorded in the first quarter of 2014 and due to amortization on additional investments in patent costs during the years ended December 31, 2014 and 2013 in the amount of $1,780,596 and $269,742, respectively, partially offset by a change in the estimated useful lives of one of the patent families during the year ended December 31, 2013.

Warrant liability gain (loss) - net.

2015 vs. 2014

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 the warrants during the period. 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.

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 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.

2014 vs. 2013

The warrant liability loss of $3,676,691 for the year ended December 31, 2014 was described in the above comparison of 2015 to 2014.

In a private placement in the first quarter of 2013, we issued warrants which were accounted for as derivatives and upon issuance a liability at the estimated fair value was recorded. At the date of issuance of these warrants, the value exceeded that total consideration received by an aggregate of $3,987,655 resulting in an immediate charge to expense

for this amount. In connection with the exercise of 1,101,034 Series B Warrants in July 2013, we issued a like number of Series C Warrants which were accounted for as derivatives and upon issuance a liability at the estimated fair value was recorded. At the date of issuance of these warrants, the value was estimated to be $1,622,069 which exceeded the sum of the net proceeds received in the exercise and the reclassification of warrant liability to capital by $343,079 resulting in an immediate charge to expense for this amount. These two charges added to the loss on warrant liability of $19,271,977, resulting from an increase in the fair value during the year ended December 31, 2013 for all warrants we have issued, resulting in a total loss on warrant liability-derivative for the year of $23,602,711. The loss on warrant liability of $19,271,977 was primarily the result of an increase in the Company's underlying stock price from $0.75 per share at December 31, 2012, as compared to $2.14 per share at December 31, 2013.

Warrant amendment inducement expense.

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. 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.

2014 vs. 2013

During the fourth quarter of 2013, we initiated a warrant amendment program with existing warrant holders with the goal of reducing our warrant liability by offering certain financial inducements to such warrant holders. 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 $3,736,313 for the year ended December 31, 2013. As discussed above, the warrant amendment inducement expense was $144,548 for the year ended December 31, 2014.

Litigation proceeds.

2015 vs. 2014

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.

2014 vs. 2013

There were no litigation proceeds received during the years ended December 31, 2014 and 2013.

Loss on equity investment.

2015 vs. 2014

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. See below for a discussion of the loss on equity investment for the year ended December 31, 2014.

2014 vs. 2013

The loss on equity investment of $101,165 for the year ended December 31, 2014, consists of (i) our 25% share of Anandia's net loss from our initial April 11, 2014 investment in Anandia through December 31, 2014 in the amount of $84,350, plus (ii) amortization of the intangible asset represented by the difference between our equity investment in Anandia and our portion of the book value of the net assets of Anandia in the amount of $16,815. There was no loss on equity investment for the year ended December 31, 2013.

Interest income.

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.

2014 vs. 2013

Interest income for the year ended December 31, 2014 was $30,383 and was earned from excess cash invested in a money market account. There was no interest income earned for the year ended December 31, 2013.

Interest expense.

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 $24,123 from the accretion of interest on a note payable and $20,998 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.

2014 vs. 2013

Interest expense (including the amortization of debt discount and debt issuance costs for the year ended December 31, 2013) decreased during the year ended December 31, 2014 to $7,094 from $748,605 during the year ended December 31, 2013. This decrease of $741,511 or 99.1% was primarily the result of a decrease in the amortization of debt discount and debt issuance costs relating to convertible notes issued on August 9, 2012 that were converted into common stock in August of 2013, payment of the majority of the Company’s interest bearing debt in the fourth quarter of 2013, and the recording as interest expense the excess of the fair value of warrants issued during the year ended December 31, 2013 over the proceeds realized in the amount of approximately $509,000.

39

***Net loss*.**

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.

2014 vs. 2013

We had a net loss for the year ended December 31, 2014 of $15,595,358 as compared to a net loss of $26,153,158 for the year ended December 31, 2013. The decrease in the net loss of $10,557,800 or 40.4%, was primarily the result of a decrease in the warrant liability gain (loss) - net in the amount of approximately $19,926,000, a decrease in interest expense and amortization of debt discount in the amount of approximately $742,000, a decrease in the warrant amendment inducement expense of approximately $3,592,000 and an increase in the gain on the sale of machinery and equipment of approximately $71,000, offset by a decrease in gross profit of approximately $6,786,000, an increase in operating expenses of approximately $6,794,000, and a decrease in other income of approximately $193,000.

Liquidity and Capital Resources

Working Capital

As of December 31, 2015, we had positive working capital of approximately $4.0 million compared to positive working capital of approximately $8.0 million at December 31, 2014, a decrease of approximately $4.0 million. This decrease in working capital is due to a decrease in current assets of approximately $3.5 million plus an increase in current liabilities of approximately $0.5 million. The decrease is primarily due to a decrease in cash of $2.6 million and a decrease in prepaid fees and expenses of approximately $1.5 million, partially offset by an increase in net inventory of approximately $0.6 million. The increase in current liabilities is primarily due to a net increase in accounts payable and accrued expenses of approximately $0.7 million, partially offset by a decrease in the demand bank loan of approximately $0.2 million.

On February 5, 2016, we closed a registered direct offering of 5,000,000 shares of common stock and warrants to purchase up to 2,500,000 shares of common stock at an exercise price of $1.21 per share. The purchase price per unit was $1.10 and resulted in net proceeds of approximately $5.1 million. We expect cash on hand and the results of this offering to be sufficient to fund operations through October 2016. Accordingly, we will be required to raise additional capital to fund operations and achieve FDA approval of our products.

We must successfully execute our business plan to increase revenue in order to achieve positive cash flows to sustain adequate liquidity without requiring additional funds from external sources to meet minimum operating requirements. The Company's Form S-3 universal shelf registration statement was filed with the U.S. Securities and Exchange Commission ("SEC") on April 18, 2014, and became effective on June 5, 2014. The universal shelf registration statement will allow, but not compel, the Company to raise up to approximately $24 million of capital over a three-year period ending June 5, 2017 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, 2015, we experienced an operating loss of approximately $12.0 million and used cash in operations of approximately $7.3 million. Excluding contract growing of our proprietary tobacco with farmers, costs associated with an additional modified risk application with the FDA, patent and trademark costs, discretionary expenses such as potential clinical trials, capital expenses for our factory, and possible sponsored research, our monthly cash expenditures are approximately $650,000. Including cash on hand at December 31, 2015 of $3,760,297 plus net proceeds of approximately $5,140,000 in additional cash raised from a registered direct offering of our common stock and warrants on February 5, 2016, 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 approximately October of 2016.

Net Cash (used in) provided by Operating Activities

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.

40

2014 vs. 2013

In the year ended December 31, 2014, $6,582,730 of cash was used in operating activities compared to $3,855,834 of cash provided by operating activities in the year ended December 31, 2013, a decrease of $10,438,564. This decrease in cash provided by operations was primarily due to the license revenue received from BAT under the Research License and Commercial Option Agreement in the amount of $7,000,000 in 2013 as compared to no revenue from licensing in 2014. In addition, approximately $3,400,000 in additional cash was consumed in operating activities.

Net Cash used in Investing Activities

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.

2014 vs. 2013

In the year ended December 31, 2014, we used $2,707,992, as compared to $3,742,789 of cash used in investing activities during the year ended December 31, 2013, a decrease of $1,034,797. The decrease in cash used in investing activities is primarily due to a decrease in the acquisition of machinery and equipment in the amount of $3,239,966, and an increase in proceeds received on the sale of machinery and equipment in the amount of $631,484, offset by increases in the acquisition of patents and trademarks of $436,653, license fees of $1,450,000, the cash portion of the equity investment in Anandia of $700,000, and the cash portion of the NASCO transaction of $250,000.

Net Cash provided by Financing Activities

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 issuance of common stock 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.

2014 vs. 2013

During the year ended December 31, 2014, we generated $9,862,810 from our financing activities, as compared to $5,717,366 of cash generated from financing activities during the year ended December 31, 2013, an increase of $4,145,444. The $9,862,810 generated during the year ended December 31, 2014 was mainly the 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 exercise of stock warrants and stock options in the amount of $535,251. The $5,717,366 of cash generated during the year ended December 31, 2013 was primarily the result of the net proceeds from the Series A-1 Preferred stock placement in the amount of $2,034,664, net cash proceeds received from the exercise of warrants in the amount of $2,254,999, proceeds received from the issuance of notes payable in the amount of $150,000, proceeds received from the exercise of stock options in the amount of $5,200, and net cash proceeds received from the Warrant Exchange Program in the amount of $3,239,385. These proceeds raised were partially offset by payments on notes payable, convertible notes payable and net payments to related parties and officers in the amount of $1,620,299, $339,250 and $8,993, respectively.

Contractual Obligations

The following table summarizes by category our expected future cash outflows associated with contractual obligations in effect at December 31, 2015:

	Payments Due by Period				
	Total	Year Ended December 31, 2016	Years Ended December 31, 2017 & 2018	Years Ended December 31, 2019 & 2020	More Than Five Years
Note payable	$666,666	$ 333,333	$ 333,333	$ -	$-
Severance payments	428,365	225,000	203,365	-	-
Operating lease obligations	1,228,500	236,000	446,000	405,500	141,000

Consulting agreements	392,000	290,000	72,000	30,000	-
License fees	3,330,000	400,000	515,000	590,000	1,825,000
Sponsored research	667,831	574,081	93,750	-	-
Total	$6,713,362	$ 2,058,414	$ 1,663,448	$ 1,025,500	$1,966,000

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 the First-in, First-out (FIFO) method on all other inventories. 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 at the point the product is shipped to a customer and title has transferred. Revenue from the sale of our products is recognized net of cash discounts, sales returns and allowances. Federal cigarette and filtered cigar excise taxes are included in net sales and accounts receivable billed to customers, except on sales of *SPECTRUM* and exported cigarettes as 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.

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. 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. The remainder of the order was shipped in January of 2016 and will generate revenue of approximately $329,000. Previously, in September 2013, the Company received a purchase order for 5.5 million *SPECTRUM* research cigarettes that was shipped in January 2014 and resulted in the revenue recognition of $447,535. There were no *SPECTRUM* cigarettes delivered during the year ended December 31, 2013.

As described above, we license our patented technology to third parties. Revenue is recognized from licensing arrangements as contractually defined in licensing agreements. We account for milestone elements contained in licensing agreements in accordance with ASC 605. Simultaneous with the signing of the Research License and Commercial Option Agreement, BAT paid us a non-refundable $7,000,000. Revenue was recognized for this amount since delivery of the patented technology took place, we had no further performance obligations, and the fee was fixed. We may be entitled to receive additional payments from BAT, up to an additional $7,000,000, during the Research Term in the event certain milestones are met by BAT with respect to BAT’s research and development of our patent rights licensed by the Company to BAT. There are four separate milestones, two of which BAT would pay us $2 million for each milestone achieved, and two of which BAT would pay us $1.5 million for each milestone achieved. In addition, the Company could earn additional future royalties if BAT elects to exercise the Commercial Option Agreement during the Research Term.

No amount related to the research milestones was recognized during 2015, 2014 or 2013. A portion of the patented technology sublicensed to BAT was exclusively licensed to 22nd Century Ltd. by NRC. Pursuant to the terms of the license agreement with NRC, 22nd Century Ltd. was obligated to make a royalty payment to NRC from the monies received from BAT. During the quarter ended September 30, 2014, 22nd Century Ltd. and NRC mutually agreed on a payment of $660,000 that was paid in December 2014. 22nd Century Ltd. had previously estimated the payment to be $413,566. The difference in the amount of $246,434 has been recorded as Royalty for licensing in the Cost of goods sold section of the Company's Consolidated Statements of Operations for the year ended December 31, 2014.

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., patents and trademarks) are reviewed annually for impairment. We have not recognized any impairment losses during the three-year period ended December 31, 2015.

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

The Company recognizes deferred tax assets and liabilities for any basis differences in its assets and liabilities between tax and U.S. GAAP reporting, and for operating loss and credit carry-forwards. In light of 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, 2015 and 2014.

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, 2015 would have the impact of increasing or decreasing the liability by approximately $8,000.

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, 2015, 2014 and 2013.

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 25% 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 US 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 $2,898,296 on our consolidated balance sheet at December 31, 2015. This liability consists of a $2,810,000 liability relating to the issuance of the Crede Tranche 1A warrants in the third quarter of 2014, and a warrant liability of $88,296 associated with other warrants issued by us. The fair value of the Crede

Tranche 1A warrants is fixed as detailed in Note 6 to our consolidated financial statements. The fair value calculation, as discussed in Note 15 of our consolidated financial statements, of the remaining warrants is exposed to market volatilities, changes in the price of our common stock, and interest rates. Only a small percentage of our outstanding warrants contain an anti-dilution clause that gives rise to the warrant liability (see Note 15 of our consolidated financial statements for additional details), and as such, our exposure to this risk is significantly mitigated. During the year ended December 31, 2015 we experienced a gain of $144,550 in the change in the fair value of the warrant liability.

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

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its Exchange Act (defined below) reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to the Company’s management, including the Company’s president and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our president and chief financial officer, after evaluating the effectiveness of the Company's "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934 ("Exchange Act") Rules 13a-15(e) or 15d-15(e)) as of the end of the period covered by this annual report, has concluded that our disclosure controls and procedures were not effective and that material weaknesses described below exist in our internal control over financial reporting based on his evaluation of these controls and procedures as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, the president and the chief financial officer and effected by our board of directors, management and other personnel, 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.

Our evaluation of internal control over financial reporting includes using the COSO framework, an integrated framework for the evaluation of internal controls issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013, to identify the risks and control objectives related to the evaluation of our control environment.

Based on our evaluation under the frameworks described above, our management concluded that as of December 31, 2015, that our internal controls over financial reporting were not effective and that material weaknesses exist in our internal control over financial reporting. The material weakness consists of controls associated with segregation of duties whereby individuals have incompatable duties within the financial reporting area. To address the material weakness we performed additional analyses and other post-closing procedures to ensure that our consolidated financial statements were prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). Notwithstanding this material weakness, management believes that the financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, result of operations and cash flows for the periods presented.

Freed Maxick CPA's, P.C., the Company's independent registered public accounting firm, has audited the consolidated financial statements as of and for the year ended December 31, 2015, and the effectiveness of the Company's internal control over financial reporting as of December 31, 2015, as stated in their reports, which are included herein.

Changes in Internal Control over Financial Reporting

There was no change in the Company's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

22nd Century Group, Inc.

We have audited 22nd Century Group, Inc. and Subsidiaries (the "Company") internal control over financial reporting as of December 31, 2015, 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.

45

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment.

Material weaknesses related to financial closing and reporting process.

The Company had inadequate segregation of duties consistent with control objectives. The Company’s corporate and financial reporting function is currently composed of a small number of individuals resulting in situations where limitations on segregations of duties exist. As a result we noted instances whereby individuals performed aspects of the financial reporting process which are incompatible duties, including but not limited to access to the underlying records and system, the ability to post and record journal entries, the responsibility to perform and review account reconciliations as well as the responsibility for the preparation of the financial statements.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2015 financial statements, and this report does not affect our report dated February 16, 2016 on those financial statements.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2015, 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, 2015 and 2014 and the related consolidated statements of operations, changes in shareholders’ equity and cash flows of the Company for each of the years in the three year period ending December 31, 2015 and our report dated February 18, 2016 expressed an unqualified opinion.

/s/ FREED MAXICK CPAs, P.C.

Buffalo, New York
February 18, 2016

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 2016 Annual Meeting of Stockholders.

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

Name	Age	Position
Henry Sicignano, III	48	President, Chief Executive Officer and Director
John T. Brodfuehrer	58	Chief Financial Officer & Treasurer
Michael R. Moynihan, Ph.D.	63	Vice President of R&D
Paul Rushton, Ph.D.	53	Vice President of Plant Biotechnology
Thomas L. James, Esq.	57	Vice President, General Counsel and Secretary
Joseph Alexander Dunn, Ph.D.	62	Director*
James W. Cornell	59	Director**
Richard M. Sanders	62	Director***
Nora B. Sullivan	58	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 referenced in this paragraph 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 2016 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 2016 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 2016 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 2016 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements

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, 2015 and 2014, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the years in the three year period ending December 31, 2015. 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, 2015 and 2014, and the results of its operations and cash flows for each of the years in the three year period ending December 31, 2015, 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, 2015, based on criteria established in *Internal Control - Integrated Framework* issued by Committee of Sponsoring Organizations of the Treadway Commission in 2013. Our report dated February 18, 2016 expressed an opinion that 22nd Century Group, Inc. had not maintained effective internal control over financial reporting as of December 31, 2015, 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

February 18, 2016

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

	2015	2014
ASSETS		
Current assets:		
Cash	$3,760,297	$6,402,687
Accounts receivable, net	51,230	-
Due from related party	-	46,069
Inventory, net	2,706,330	2,064,796
Prepaid consulting fees	-	1,978,785
Prepaid expenses and other assets	710,091	214,469
Total current assets	7,227,948	10,706,806
Machinery and equipment, net	2,555,793	2,850,615
Other assets:		
Intangible assets, net	7,364,120	7,077,759
Equity investment	1,222,651	1,318,335
Total other assets	8,586,771	8,396,094
Total assets	18,370,512	$21,953,515
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Demand bank loan	$-	$174,925
Current portion of note payable	308,582	320,513
Accounts payable	1,283,346	884,412
Accrued expenses	1,423,531	1,081,545
Accrued severance	220,661	212,012
Deferred revenue	-	-
Total current liabilities	3,236,120	2,673,407
Long-term portion of note payable	307,938	605,217
Long-term portion of accrued severance	199,658	412,308
Warrant liability	2,898,296	3,042,846
Total liabilities	6,642,012	6,733,778
Commitments and contingencies (Note 17)	-	-
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:		
71,006,844 common shares (64,085,042 at December 31, 2014)	710	641
Capital in excess of par value	78,284,815	70,744,190
Accumulated deficit	(66,557,025)	(55,525,094)
Total shareholders' equity	11,728,500	15,219,737
Total liabilities and shareholders' equity	$18,370,512	$21,953,515

See accompany notes to consolidated financial statements.

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

	2015	2014	2013
Revenue:			
Sale of products	$8,521,998	$528,991	$278,383
Royalties from licensing	-	-	7,000,000
	8,521,998	528,991	7,278,383
Cost of goods sold (exclusive of depreciation shown separately below):			
Products	9,102,560	252,002	48,105
Royalties for licensing	-	246,434	413,566
	9,102,560	498,436	461,671
Gross (loss) profit	(580,562)	30,555	6,816,712
Operating expenses:			
Research and development (including equity based compensation of $167,837, $331,467 and $111,563, respectively)	1,669,387	1,249,007	744,230
General and administrative (including equity based compensation of $3,376,664, $4,165,078 and $2,250,399, respectively)	7,760,127	8,823,534	4,106,694
Pre-manufacturing facility costs (including equity based compensation of $0, $27,923 and $0, respectively)	-	1,176,676	-
Sales and marketing costs (including equity based compensation of $41,039, $0 and $0, respectively)	1,357,518	85,930	9,052
Depreciation	319,699	230,012	3,028
Amortization	356,590	232,760	141,261
	11,463,321	11,797,919	5,004,265
Operating (loss) profit	(12,043,883)	(11,767,364)	1,812,447
Other income (expense):			
Warrant liability gain (loss) - net	144,550	(3,676,691)	(23,602,711)
Warrant amendment inducement expense	-	(144,548)	(3,736,313)
Litigation proceeds	1,000,000	-	-
(Loss) gain on the disposition and sale of machinery and equipment	(15,130)	71,121	-
Loss on equity investment	(95,684)	(101,165)	-
Income tax credit refund	-	-	122,024
Interest income	31,198	30,383	-
Interest expense	(52,982)	(7,094)	(748,605)
	1,011,952	(3,827,994)	(27,965,605)
Loss before income taxes	(11,031,931)	(15,595,358)	(26,153,158)

Income taxes	-	-	-
Net loss	$(11,031,931)	$(15,595,358)	$(26,153,158)
Loss per common share - basic and diluted	$(0.16)	$(0.26)	$(0.60)
Common shares used in basic earnings per share calculation	68,143,284	59,993,413	43,635,182

See accompany notes to consolidated financial statements.

22nd CENTURY GROUP INC. AND SUBSIDIARIES