22nd Century Group, Inc.
Form 10-K
January 30, 2014

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, 2013

or

¨ **Transitional Report under Section 13 or 15(d) of the Securities Exchange Act of 1934**
Commission File Number: 000-54111

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: None

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

Common Stock (Par Value - $0.00001 per share)

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 ¨ Non-Accelerated Filer ¨ Smaller Reporting Company x

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 28, 2013, 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 19,040,893 shares held by affiliates), based upon the $0.71 price at which such common stock was last sold on June 28, 2013, was approximately $18.3 million.

As of January 28, 2014, there were 58,252,770 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2014 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, 2013.

22nd Century Group, Inc.
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Cautionary Note Regarding Forward-Looking Statements

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

- Our ability to manage our growth effectively;
- Our ability to comply with existing and new government regulations;
- Our ability to retain key personnel;
- Our ability to enter into additional licensing transactions;
- The prospect of one of our subsidiaries becoming a member of the U.S. Master Settlement Agreement;
- Our ability to achieve profitability;
- The potential for our clinical trials to produce negative or inconclusive results;
- Our ability to obtain significant revenue for our tobacco products in the U.S.;
- 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;
- Our ability to compete with competitors that may have greater resources than us;
- 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 used biotechnology to regulate the nicotine content in tobacco plants.

Business Overview

22nd Century Limited, LLC ("22nd Century Ltd"), our wholly-owned subsidiary, is a plant biotechnology company focused on tobacco harm reduction and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding. We exclusively control 114 issued patents and an additional 38 patent applications; of these, we own 13 issued patents plus 25 patent applications and we license the remaining patents and patent applications on an exclusive basis. Goodrich Tobacco Company, LLC ("Goodrich Tobacco") and Hercules Pharmaceuticals, LLC ("Hercules Pharmaceuticals") are subsidiaries of 22nd Century Ltd. Goodrich Tobacco is focused on commercial tobacco products and potentially reduced-risk or modified risk tobacco products. Hercules Pharmaceuticals is focused on *X-22,* a prescription smoking cessation aid in development.

Our Strategy

Our long-term focus is the research, development, licensing, manufacturing, and worldwide sales and distribution of our products to reduce the harm caused by smoking. Annual worldwide tobacco product sales, cigarettes and smokeless products, are approximately $700 billion and 90 percent are cigarette sales according to Euromonitor International. Worldwide smoking prevalence has decreased in recent years, but the number of cigarette smokers worldwide has increased to approximately 1 billion due to population growth, according to a 2013 research report from the Institute for Health Metrics and Evaluation (IHME) at the University of Washington.

We believe that the tobacco industry is at the beginning of a paradigm shift towards the development and commercialization of reduced-risk tobacco products which represent a significant step toward achieving the public health objective of harm reduction. Our 15 years of research and development on the tobacco plant, mainly on the nicotine biosynthetic pathway, uniquely positions us to become a major benefactor of this paradigm shift developing in the tobacco industry. Our technology has created, and will continue to develop, a pipeline of products. We are primarily involved in the following activities:

- The international licensing of 22nd Century Ltd's technology, proprietary tobaccos, trademarks;
- The manufacture, marketing and international distribution of *RED SUN* and *MAGIC* proprietary cigarettes;
- The production of *SPECTRUM* research cigarettes for the National Institute on Drug Abuse ("NIDA");
- The research and development of potentially reduced-risk or modified risk tobacco products;
- The development of *X-22*, a prescription-based smoking cessation aid consisting of very low nicotine ("VLN") cigarettes; and

- 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.

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.

Our Technology

Our proprietary technology enables us to decrease or increase the level of nicotine (and other nicotinic alkaloids such as nornicotine, anatabine and anabasine) 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." However, our proprietary technology can also be implemented without the resulting plants being GM, as long as no foreign DNA (not inherent to a plant species such as *Nicotiana tabacum*) is present in the engineered plant.

The year 2012 was the 17th year of commercialization of biotech crops. Biotech crop hectares increased by an unprecedented 100-fold from 1.7 million hectares in 1996 to 170.3 million hectares in 2012, according to the International Service for the Acquisition of Agri-Biotech Applications. The top biotech crops in order of hectarage are the following: soybean, maize, cotton, and canola. Alfalfa, sugarbeet, papaya, squash, poplar, tomato, sweet pepper and tobacco are other biotech crops grown in 2012. Of the 28 countries which planted biotech crops in 2012, 20 were developing countries and 8 were industrial countries. The 5 leading developing countries are Brazil, Argentina, India, China and South Africa, planting 46% of global biotech crops in 2012. The top 5 countries planting biotech crops are United States, Brazil, Argentina, Canada and India.

Approximately 90% of the corn and soybeans grown in the United States are GM. The only components of the technology that are distinct from those in commercialized GM varieties of major crops are segments of tobacco genes (DNA sequences) that are also present in all conventional tobacco plants. GM tobacco that we use in our commercial products has been deregulated by the USDA. Thus, plants may be grown and used in products in the United States without legal restrictions or labeling requirements related to the genetic modification. Nevertheless, our proprietary tobacco is grown only by farmers under contracts that require segregation and prohibit transfer of material to other parties.

During the development of genetically-engineered plant varieties, many candidate plant lines are evaluated in the field in multiple locations over several years, as in any other variety development program. This is carried out in order to identify lines that have not only the specific desired trait, e.g., very low nicotine, but have overall characteristics that are suitable for commercial production of the desired product. This process allows us to determine if there are undesirable effects of the genetic modification approach or the specific genetic modification event, regardless of whether the effects are anticipated or unanticipated. For example, since nicotine is known to be an insecticide that is effective against a wide range of insects, reduction of nicotine content in the plants may be expected to affect susceptibility to insect pests. While there are differences in the susceptibility of VLN tobacco to some insects, all tobacco is attacked by a number of insects. The measures taken to control insect pests of conventional tobacco are adequate to control insect pests in VLN tobacco.

Once a genetically-engineered tobacco plant with the desired characteristics is obtained, each plant can produce hundreds of thousands of seeds. When each seed is germinated, the resulting tobacco plant has characteristics similar to the parent and sibling plants and the nicotine content of these plants generally fall within a narrow range. Tobacco products with either low or high nicotine content are easily produced through this method. For example, one of our proprietary tobacco varieties contains the lowest nicotine content of any tobacco ever commercialized, with approximately 97% less nicotine than tobacco in leading "light" cigarette brands. This proprietary tobacco grows with virtually no nicotine without adversely affecting the other leaf constituents important to a cigarette's characteristics, including taste and aroma.

Our Intellectual Property

Our proprietary technology is covered by 12 patent families consisting 114 issued patents and an additional 38 patent applications; of these, we own 13 issued patents plus 25 patent applications and we license the remaining patents and patent applications on an exclusive basis from third parties. 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 16 issued patents and 8 pending applications and 6 issued patents and 3 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. The patents owned by or exclusively licensed to us are issued in 78 countries where at least 75% of the world’s smokers reside.

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) 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 its technology and products since early 2012. On October 1, 2013, 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 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 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"). BAT and the Company also agreed to collaborate with each other as each party engages in its own independent research during the term of the Research Agreement.

Simultaneous with the signing of the BAT Research Agreement, BAT paid 22nd Century Ltd a non-refundable $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 of (i) $100 per metric ton of licensed tobacco that is supplied to, or grown and ready for shipment to, BAT and is 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.

The minimum and maximum amount of annual royalties under the terms of the Commercial License, which commence after the two-year ramp-up period from the exercise of the option, are $3.0 million and $15.0 million, respectively for a period of three years. Thereafter, the minimum and maximum annual royalties increase to $5.0 million and $25 million, respectively, until September 28, 2028. Thereafter, no further minimum royalties are due and the maximum annual royalties due remain at $25 million until expiration of the Commercial License.

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.

British American Tobacco sells product in approximately 180 countries. In 2012, global production of tobacco leaf was approximately 5,700,000 metric tons, of which BAT utilized approximately 10% for BAT's and its affiliates' brands.

Our RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco, introduced two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. Both brands are available in regular and menthol and all brand styles are king size and packaged in hinge-lid hard packs. In 2014, we intend to focus our marketing efforts on tobacconists, smoke shops and 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 specialty tobacco channels for 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.

Our SPECTRUM Government Research Cigarettes

We were chosen to be a subcontractor for a government contract between RTI International ("RTI") and the National Institute on Drug Abuse ("NIDA") to supply altered nicotine research cigarettes (from very low to high) cigarettes to NIDA. These government research cigarettes are distributed to researchers free of charge under the mark *SPECTRUM*. Goodrich Tobacco has thus far delivered approximately 12 million *SPECTRUM* research cigarettes. We received a purchase order for an additional 5.5 million *SPECTRUM* research cigarettes that will be manufactured and shipped in January 2014.

Rationale for and History of Modified Risk Tobacco Products

A substantial number of adult smokers are unable or unwilling to quit smoking. For example, each year one-half of the adult smokers in the United States do not attempt to quit. Nevertheless, we believe the majority of these smokers are interested in reducing the harmful effects of smoking.

In a 2005 analyst report, *The Third Innovation, Potentially Reduced Exposure Cigarettes*, JP Morgan examined the effects of FDA regulation 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 Tobacco Control Act becoming law in 2009, no regulatory agency or body had the authority to assess potential modified risk tobacco products.

Some major cigarette manufacturers have developed and marketed alternative cigarette products. For example, Philip Morris USA developed an alternative cigarette, called Accord®, in which the tobacco is heated rather than burned. R.J. Reynolds Tobacco Company has developed and is marketing an alternative cigarette, called Eclipse®, in which the tobacco is primarily heated, with only a small amount of tobacco burned. Philip Morris and RJ Reynolds have indicated that their products may deliver fewer smoke components compared to conventional cigarettes. Both Accord® and Eclipse®, which are not conventional cigarettes but cigarette-like devices, have only achieved limited sales. Vector Tobacco Inc. ("Vector Tobacco"), our former licensee, has marketed a cigarette offered in three brand styles with reduced levels of nicotine, called Quest®. With the exception of Eclipse®, the above products are no longer being sold.

Complete cessation from all tobacco and medicinal nicotine products is the ultimate goal of the public health community. However, some public health officials desire to migrate cigarette smokers en masse to medicinal nicotine (also known as NRT) or smokeless tobacco products to replace cigarettes. We believe this is unattainable in the foreseeable future for many reasons, including because the smoking experience is much more complex than simply seeking nicotine. In a 2009 WHO report, statistics demonstrate that approximately 90% of global tobacco users smoke cigarettes. Worldwide cigarette sales (in U.S. dollars) are approximately 12 times greater than sales of smokeless tobacco products and approximately 200 times greater than sales of NRT products. Although a small segment of the smoking population is willing to use smokeless tobacco products in conjunction with cigarettes (known as dual users), a large percentage of smokers is not interested in using smokeless tobacco products exclusively.

There are newer forms of smokeless tobacco products that have been introduced in the market that are less messy to use than chewing tobacco or dry snuff (since spitting is not involved). These products include Swedish-style snus such as Camel® snus made by R.J. Reynolds Tobacco Company and dissolvable tobacco products such as Ariva® and Stonewall® owned by Star Scientific Inc. Although use of such products may be more discreet and convenient than traditional forms of smokeless tobacco, they have the same route of delivery of nicotine as nicotine gums and nicotine lozenges, which have been available over-the-counter in the United States for approximately 30 years and 22 years,

respectively, and have not significantly replaced cigarettes.

Cigarette-like devices are being developed by the largest tobacco companies and are referred to as “next generation products” or “NGPs.” These include heat-not-burn cigarettes in which most if not all of the tobacco is heated and not burned resulting in reduced tobacco toxins. At the Morgan Stanley Global Consumer Conference on November 20, 2013, Philip Morris International presented three platforms of NGPs, the first two of which contain tobacco and are heat-not-burn products and the third uses a chemical reaction to generate a nicotine-containing aerosol. On January 10, 2014, Philip Morris International announced an investment of up to €500 million into its first manufacturing facility in the European Union and an associated pilot plant near Bologna, Italy to produce its potentially reduced-risk tobacco products. Once fully operational by 2016, the factory and pilot plant combined are expected to reach annual production capacity of up to 30 billion units.

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

The 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") granted the FDA authority over the regulation of all tobacco products. While it 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 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 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 have been continuing to gather additional information since the FDA's draft guidance on the subject, including from the FDA, to submit complete applications for our two Modified Risk Cigarette candidates, which we expect to do so in 2014. Depending on how many exposure studies and other information the FDA will require, it is likely that we will require additional capital to complete the entire FDA authorization process for our Modified Risk Cigarettes.

We believe that *BRAND A* and *BRAND B* will qualify as Modified Risk Cigarettes and we intend to seek FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes. 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 certain tobacco smoke toxins and/or pose a lower health risk than conventional cigarettes. This includes the approximate one-half of the 44 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 extraordinary low amount of "tar" per milligram of nicotine.

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 tobacco in leading "light" 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).

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 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* contains approximately 0.7 milligram of nicotine per cigarette.

A Phase II smoking cessation clinical trial at the University of Minnesota Masonic Comprehensive Cancer Center (Hatsukami *et al*. 2010) also measured exposure of various smoke compounds in smokers from smoking a VLN cigarette containing our proprietary tobacco over a six (6)-week period. Smokers significantly reduced their smoking as compared to their usual brand of cigarettes. The number of VLN cigarettes smoked per day on average decreased

from 19 (the baseline number of cigarettes of smokers' usual brand) to 12 by the end of the six (6)-week period, even though participants were instructed to smoke ad libitum (as many cigarettes as desired) during treatment. Furthermore, besides significant reductions in other biomarkers, carbon monoxide (CO) levels, an indicator of smoke exposure, significantly decreased from 20 parts per million (baseline) to 15 parts per million. Cotinine, a metabolite and biomarker of nicotine, significantly decreased from 4.2 micrograms/mL (baseline) to 0.2 micrograms/mL. All differences were statistically significant ($P<0.05$).

We believe these and other results and future exposure studies the FDA will require will result in a modified risk cigarette claim 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. There is no guarantee that *BRAND A* will be classified as a Modified Risk Cigarette by the FDA.

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. We believe results from these exposure studies will warrant a modified risk claim for *BRAND B*. There is no guarantee that *BRAND B* will be classified as a Modified Risk Cigarette by the FDA.

Tar, Nicotine, and Smoking Behavior

The dependence of many smokers on tobacco is largely due to the properties of nicotine, but the adverse effects of smoking on health are mainly due to other components present in tobacco smoke, including “tar” and carbon monoxide. “Tar” is the common name for the total particulate matter minus nicotine and water produced by the burning of tobacco (or other plant material) during the act of smoking. “Tar” and nicotine are commonly measured in milligrams per cigarette trapped on a Cambridge filter pad under standardized conditions using smoking machines. These results are referred to as “yields” or, more specifically, “tar” yield and nicotine yield.

Individual smokers generally seek a certain amount of nicotine per cigarette and can easily adjust how intensely each cigarette is smoked to obtain a satisfactory amount of nicotine. Smoking of low yield (“light” or “ultra light”) cigarettes compared to high yield (“full flavor”) cigarettes often results in taking more puffs per cigarette, larger puffs and/or smoking more cigarettes per day to obtain a satisfactory amount of nicotine, a phenomenon known as “compensation” or “compensatory smoking.” A report by the National Cancer Institute in 2001 stated that due to compensatory smoking, low yield cigarettes are not safer than full flavor cigarettes, which is the reason that the Tobacco Control Act has banned the use of the terms “low tar,” “light” and “ultra-light” in the U.S. market. Studies have shown, however, that smokers generally do not compensate when smoking cigarettes made with our VLN tobacco, and that smoking VLN cigarettes, such as *BRAND A,* actually assist smokers to smoke fewer cigarettes per day and reduce their exposure to “tar” and nicotine. Other studies have demonstrated that compensatory smoking (e.g., more and/or larger puffs per cigarette) of low-tar research cigarettes, similar to *BRAND B (*though *BRAND B* was not used in such studies), is greatly curtailed resulting in smokers inhaling less “tar” and carbon monoxide. Additional studies will be necessary to establish whether *BRAND B* cigarettes achieve similar results.

X-22

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 II-B clinical trial calls for the patient to smoke our very low nicotine (“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 II-B clinical trial was completed in the first quarter of 2012 and 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 approximately between 8 and 30 years), we believe that if additional clinical trials demonstrate increased smoking cessation rates, *X-22* can capture a share of this market by replacing sales and market share from existing smoking cessation aids and expanding the smoking cessation market by encouraging more smokers to attempt to quit smoking. In contrast to the results of our Phase II-B trial results, independent studies have demonstrated that VLN cigarettes increase quit rates, whether used alone, in conjunction with Chantix® (varenicline) or nicotine replacement therapy ("NRT") such as nicotine patches, gums or lozenges.

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A separate and yet unpublished clinical trial evaluated whether the use of our VLN cigarette in combination with Chantix® or in combination with nicotine replacement therapy ("NRT") increases abstinence rates over the use of Chantix® or the use of NRT (NCT01250301). Certain results of this unpublished study were disclosed in a presentation at the 2013 Society for Research on Nicotine and Tobacco ("SRNT") annual meeting given by Hayden McRobbie, Ph.D. of Queen Mary University of London, Wolfson Institute of Preventative Medicine, who was the principal investigator of the study. Pfizer Inc. was also a collaborator of the study. The study included one hundred smokers who were prescribed varenicline (trademarked Chantix, or Champix outside the U.S.) and one hundred smokers who were prescribed NRT. Half the smokers of each of these groups were randomly selected to also use our VLN cigarettes for the first 2 weeks of treatment. All smokers received 9 weekly behavioral support sessions throughout the 12-week study period. The group that used our VLN cigarettes had a 70% quit rate one week after stopping VLN cigarette use compared to a 53% quit rate of the group not using VLN cigarettes after week 1 (p=0.02). The group that used our VLN cigarettes had a 64% four-week continuous abstinence rate during weeks 3 to 6 compared to a 50% four-week continuous abstinence rate during weeks 1 to 4 (p=0.06). Quit rates at 12 weeks post

treatment were not reported in the presentation.

Although we believe that our VLN cigarettes are an effective aid to smoking cessation, we have suspended sponsoring further *X-22* clinical trials and 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 U.S. Food and Drug Administration ("FDA"), and thereafter we may resume our own sponsored *X-22* clinical trials. There is no guarantee that we will (ii) identify a joint venture partner or licensee to fund the remaining *X-22* clinical trials, (ii) obtain the funds necessary to complete additional clinical trials, (iii) obtain FDA approval, or (iv) capture significant share of the smoking cessation market upon FDA approval.

Within our two product categories, smoking cessation and Modified Risk Cigarettes, the Tobacco Control Act offers us the following specific advantages:

Smoking Cessation Aids

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 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. However, there is no guarantee that the FDA will grant "Fast Track" designation to *X-22*. Please see section below, titled, *Fast Track Development*, for a further discussion on the FDA's "Fast Track" program.

Modified Risk Cigarettes

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. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance.* 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®), which could create opportunities for us to license our proprietary technology and/or our tobaccos to larger competitors.

We intend to seek FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes. The Company has continued to gather additional information since the FDA's draft guidance on the subject, including from the FDA, to submit complete applications for our two Modified Risk Cigarette candidates. We expect to submit these applications in 2014. Depending on how many exposure studies and other information the FDA will require, it is likely that we will require additional capital to complete the entire FDA authorization process for our Modified Risk Cigarettes. The amount of capital is currently unknown since it is uncertain how many exposure studies the FDA will require for *BRAND A* and *BRAND B*.

We believe that *BRAND A* and *BRAND B* will achieve significant market share in the global cigarette market among smokers who are unable or unwilling to quit and 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 that we will obtain FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes or that we will achieve a significant market share of this specified subgroup of smokers.

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.

Manufacturing

Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the MSA. We are working to become a participating manufacturer of the Master Settlement Agreement ("MSA"), a settlement among 46 U.S. states and the tobacco industry administered by the National Association of Attorneys General ("NAAG"). To this end, we are following two parallel tracks for becoming a member of the MSA. First, in January 2013, Goodrich Tobacco applied to the Alcohol and Tobacco Tax Trade Bureau ("TTB") for a federal permit to manufacture its own tobacco products. Being a federally licensed tobacco product manufacturer is a primary requirement of becoming a participating manufacturer of the MSA. Goodrich Tobacco's application has been deemed complete by the TTB, including and a successful TTB field inspection of our manufacturing facility. We expect to receive the permit at any time. On February 26, 2013, Goodrich Tobacco applied to the NAAG to become a participating manufacturer to the MSA.

With respect to the second parallel track, on September 17, 2013, we entered into a Membership Interest Purchase Agreement ("Purchase Agreement") to purchase all of the issued and outstanding membership interests of NASCO Products, LLC ("NASCO"), a North Carolina limited liability company ("NASCO") (the "NASCO Transaction"). NASCO already has a TTB permit to manufacture its own tobacco products and is a participating member of the MSA. Consummation of the NASCO Transaction is subject to various conditions including required consents from NAAG and certain attorneys general of the settling states of the MSA. NAAG has been discussing the NASCO Transaction with a small working group of settling states of the MSA for which the Company has answered various rounds of questions. The working group has presented the matter to all the settling states with a recommended course of action which the settling states are evaluating. Upon the entry of a revised adherence agreement of NASCO Products, LLC reflecting the NASCO Transaction, we believe we will be able to close the NASCO Transaction. The NASCO Transaction contains termination rights, including a right for us to terminate the Purchase Agreement, at our sole discretion, if the closing shall not have occurred on or before January 31, 2014. At this time we do not expect to invoke our termination rights.

If we are successful through one of these two parallel tracks to become a licensed tobacco products manufacturer and a participating member of the MSA, the distribution potential of *RED SUN* and *MAGIC* in the U.S. will be increased. Sales and marketing of our commercial cigarettes have been curtailed in order to limit the complexity and settlement costs associated with Goodrich Tobacco becoming a participating manufacturer of the MSA; the more *RED SUN* and *MAGIC* that is sold while being produced by a non-participating manufacturer, the more complex the process becomes and the greater the settlement cost Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA.

In December 2013, Goodrich Tobacco purchased certain (i) cigarette manufacturing equipment, and (ii) equipment parts, factory items, office furniture and fixtures, vehicles and computer software 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 are related companies located in North Carolina undergoing Chapter 7 liquidation proceedings in the United States Bankruptcy Court for the Middle District of North Carolina.

Research and Development

The majority of our research and development (R&D) since our inception have been outsourced to highly qualified groups in their respective fields. Since 1998, 22nd Century has 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 of 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 22nd Century 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 22nd Century on an exclusive basis. These patents and patent applications were a result of our R&D at NAIST.

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 May 2014. In 2013, we incurred approximately $183,000 of expenses for the R&D agreement at UVA. During the years ended December 31, 2013, 2012 and 2011, we incurred research and development expenses of approximately $744,000, $729,000 and $2,098,000, respectively.

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. We will also carry out other R&D in 2014 of up to approximately $700,000, including exposure studies for our potential modified risk candidates. Upon identifying a suitable joint venture partner or licensee to fund further *X-22* clinical trials, we may carry out additional *X-22* clinical trials.

Market

Cigarettes and Smoking Cessation Aids

We believe that 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.

According to the U.S. Center for Disease Control, the U.S. cigarette market consists of approximately 44 million adult smokers who spent approximately $80 billion in 2012 on approximately 300 billion cigarettes. Worldwide annual manufacturer unit sales are approximately 5.5 trillion cigarettes resulting in annual retail cigarette sales of approximately $620 billion. Annual manufacturer sales of smoking cessation aids in the U.S., all of which must be approved by the FDA, are approximately $1 billion. Outside the United States, the smoking cessation market is in its infancy and is approximately $3 billion.

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,
- bupropion (Zyban®), manufactured by GlaxoSmithKline, 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 $701 million in 2007, $489 million

in 2008, $386 million in 2009, $330 million in 2010 and $326 million in 2011. 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 2012 were approximately $700 million, $755 million, $720 million and $670 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 30 years and 22 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, a pharmaceutical company that sells NRT products, retail sales of NRT products in the United States were $900 million in the fiscal year ended June 30, 2012, up from $800 million in the previous fiscal year.

Potential Smoking Cessation Aids

Electronic or E-cigarettes

The FDA has not evaluated electronic cigarettes (e-cigarettes) for quitting smoking. The Company is not aware of any published result of a controlled, double-blinded clinical trial of e-cigarettes as a smoking cessation aid that demonstrated statistically significant quit rates compared to a placebo or FDA-approved approved therapeutic for smoking cessation. A study (Bullen *et al*, 2013) was touted as a success by e-cigarette interest groups and certain members of the press when, in fact, the results demonstrated that an e-cigarette containing nicotine did not achieve statistical significance in quit rates against a placebo e-cigarette (a control without nicotine) or the nicotine patch.

E-cigarettes are included here since there have been unconfirmed claims that these products facilitate cessation. E-cigarettes have been the subject of much controversy for this and various other reasons, including the fact that these products are actually not cigarettes at all but are battery-operated devices filled with nicotine, flavor and other chemicals. They turn nicotine and other chemicals into a vapor that is inhaled. E-cigarettes have nicotine kinetics and delivery very similar to nicotine inhalers, a prescription NRT product already approved by the FDA, which is the reason we believe that using e-cigarettes to quit smoking is not likely to be any more effective than other nicotine replacement products.

In a September 9, 2010 press release, the FDA issued warning letters to five e-cigarette distributors for various violations of the Federal Food, Drug, and Cosmetic Act, including unsubstantiated claims and poor manufacturing practices. The FDA said these e-cigarette companies are illegally marketing their products as tools to help people quit using cigarettes. The FDA believes e-cigarettes "[m]eet the definition of a combination drug-device product under the Federal Food, Drug and Cosmetic Act." In a letter to the Electronic Cigarette Association of the same date, the FDA said the agency intends to regulate electronic cigarettes and related products in a manner consistent with its mission of protecting the public health. Although the number of adverse event reports for tobacco products submitted to the FDA is low, according to the Center for Tobacco Products more than half (46 of 84) of all reports submitted from 2009 through the first quarter of 2012 were for e-cigarettes (Chen, *Nicotine Tob Res* 15:615-6, 2013).

The FDA confiscated imports of e-cigarettes and has been in litigation with importers of these products. A federal appeals court ruled on December 7, 2010 that the FDA can only regulate electronic cigarettes as tobacco products rather than as a drug-delivery device. The FDA appealed this decision; however, the U.S. Court of Appeals for the District of Columbia Circuit on January 2011 rejected the FDA's request to have the court review the December 7, 2010 decision. According to the FDA Public Health Focus web page on e-cigarettes, the Center for Tobacco Products intends to regulate electronic cigarette products that do not make a therapeutic claim as tobacco products. The Department of Health and Humans Services regulatory calendar for 2013 stated that the FDA intended to issue a proposed rule deeming products other than cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco that meet the statutory definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act by April 2013. The target date was later amended to October 31, 2013, and has not been amended as of January 30, 2014, according to the FDA Unified Agenda. The proposed rule has not been published to date. Any e-cigarette product marketed as a smoking cessation aid would still be regulated as a drug-device product by the Center for Drug Evaluation and Research, and efficacy and safety must be evaluated in controlled clinical trials.

Nicotine Vaccines

Nicotine vaccines are under development in clinical trials. However, they have not yet achieved the efficacy of other FDA-approved smoking cessation therapies. Nicotine itself is not recognized by the body as a foreign compound since the molecule is too small. In order to stimulate the production of antibodies, nicotine must be attached to a carrier to make the vaccine work. Different vaccine development programs use different carriers. Six companies, Cytos Biotechnology AG, Celtic Pharmaceuticals Holdings, Nabi Biopharmaceuticals, L.P. and Independent Pharmaceutica

AB, Selecta Biosciences Inc., and Pfizer Inc. have or have had vaccine candidates in clinical trials.

Cytos exclusively licensed its nicotine vaccine candidate to Novartis in 2007 for 35 million Swiss Francs ($30 million) and up to 565 million Swiss Francs ($492 million) in milestone payments and royalties. In October 2009, it was announced that Cytos' nicotine vaccine candidate failed to show efficacy in a Phase II trial.

GlaxoSmithKline Biologicals SA exclusively licensed Nabi's nicotine vaccine candidate, NicVAX®, in an agreement which was approved by Nabi's shareholders in March 2010. Together with an upfront non-refundable fee of $40 million paid by GlaxoSmithKline, Nabi is eligible to receive over $500 million in option fees and milestones, not including potential royalties on global sales. Both of Nabi's Phase III NicVAX® clinical trials subsequently failed in 2010 and 2012.

Selecta Biosciences initiated Phase 1 trials of a nicotine vaccine in 2011. Pfizer initiated Phase 1 trials of a nicotine vaccine in 2012.

These vaccine treatments entail six (6) to seven (7) consecutive monthly injections. Increases in abstinence rates have been reported but only among a minority of trial subjects with the highest levels of anti-nicotine antibodies. To date, not all subjects develop sufficient antibody levels despite receiving multiple injections. Even in those who do develop sufficient antibody levels, cravings for cigarettes are not addressed by this treatment, although the pharmacological reward of nicotine is suppressed. Expectations are that the treatment, if approved, would need to be repeated every 12 to 18 months to assist in preventing relapse.

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 scale up the amount of tobacco leaf we obtain directly from farmers under contract.

Sales and Marketing

RED SUN and MAGIC Cigarettes

Goodrich Tobacco introduced two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. Both brands are available in regular and menthol and all brand styles are king size and packaged in hinge-lid hard packs. In 2014, we intend to focus our marketing efforts on independent retailers, tobacconists, smoke shops and 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 super-premium priced products. We believe that certain U.S. cigarette wholesalers and retailers will broadly carry our brands, among other reasons, to increase their margins. To facilitate Goodrich Tobacco becoming a participating manufacturer of the "Master Settlement Agreement" or "MSA," a settlement among 46 states and the tobacco industry administered by the National Association of Attorneys General ("NAAG"), we have curtailed the sales and marketing of these products. For example, the more *RED SUN* and *MAGIC* that was sold while it was produced by a non-participating manufacturer, the greater settlement cost Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA.

SPECTRUM Government Research Cigarettes

The National Institute on Drug Abuse ("NIDA"), a component of the National Institutes of Health ("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 have 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 are distributed to researchers free of charge under the mark *SPECTRUM*. Goodrich Tobacco has thus far delivered approximately 12 million *SPECTRUM* research cigarettes. The Company received a purchase order for an additional 5.5 million *SPECTRUM* research cigarettes that will be manufactured and shipped in January 2014.

X-22 Smoking Cessation Aid

We are currently in the process of identifying potential joint venture partners to fund the remaining *X-22* clinical trials. If the FDA approves *X-22* as a smoking cessation aid, Hercules Pharmaceuticals intends to enter into arrangements in both the U.S. and international markets with pharmaceutical companies to market and sell *X-22*. We plan to seek marketing partners in the U.S. with existing pharmaceutical sales forces that already call on medical and dental offices in their geographic markets.

There are approximately 700,000 physicians in the U.S., including approximately 80,000 general practitioners, many of whom are aware of new medications, even before they achieve FDA approval. There are also approximately 170,000 dentists in the U.S. who can write prescriptions for smoking cessation aids. Upon FDA approval, we plan to develop awareness of *X-22* by educating physicians and dentists about our *X-22* smoking cessation aid. We intend to advertise in professional journals, use direct mail campaigns to medical professionals, and attend trade shows and professional conferences. We also intend to use internet advertising and pharmacy circulars to reach consumers and to encourage them to ask their physicians and dentists about our *X-22* smoking cessation aid. We expect to use public relations to increase public awareness of *X-22*. We will seek to use federal and state-funded smoking cessation programs and clinics to inform clinicians and patients about, and encourage the use of, *X-22* as a smoking cessation aid. We will also seek to participate in various government-funded programs which purchase approved smoking cessation aids and then distribute these to smokers at no charge or at greatly reduced prices.

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 have been continuing to gather additional information since the FDA's draft guidance on the subject, including from the FDA, to submit complete applications for our two Modified Risk Cigarette candidates, which we expect to do so in 2014. Depending on how many exposure studies and other information the FDA will require, it is likely that we will require additional capital to complete the entire FDA authorization process for our Modified Risk Cigarettes.

We believe that two of our 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 extraordinary low amount of "tar" per milligram of nicotine.

Smoking Cessation Clinical Trials with VLN Cigarettes

The following independent smoking-cessation clinical trials utilized very low nicotine ("VLN") cigarettes:

A phase II trial compared the quitting efficacy of a VLN cigarette containing our proprietary tobacco versus a low nicotine cigarette and an FDA-approved nicotine lozenge (4 mg) in a total of 165 patients treated for six (6) weeks (Hatsukami *et al.* 2010, *Addiction* 105:343 355). This clinical trial was led by Dr. Dorothy Hatsukami at the University of Minnesota Masonic Comprehensive Cancer Center. Dr. Hatsukami was selected in 2010 as one of the nine voting members of the 12-person Tobacco Products Scientific Advisory Committee ("TPSAC"), within the FDA's Center for Tobacco Products created under the Tobacco Control Act. Her term on TPSAC has since expired. (TPSAC will make recommendations and issue reports to the FDA Commissioner on tobacco regulatory matters, including but not limited to, the impact of the use of menthol in cigarettes, altering levels of nicotine in tobacco products, and applications submitted to the FDA for modified risk tobacco products).

Results from this trial conclude that patients exclusively using the VLN cigarette containing our proprietary tobacco achieved a 43% quit rate (confirmed four (4)-week continuous abstinence) as compared to a quit rate of 35% for the group exclusively using the FDA-approved nicotine lozenge and a 21% quit rate for the group exclusively using the low nicotine cigarette. Smoking abstinence at the 6-week follow-up after the end of treatment was 47% for the VLN cigarette group, 37% for the nicotine lozenge group and 23% for the low nicotine cigarette group. Furthermore, the VLN cigarette was also associated with greater relief from withdrawal symptoms and cravings of usual brand cigarettes than the nicotine lozenge. Carbon monoxide (CO) levels in patients were tested at each treatment clinic visit to verify smoking abstinence.

Unlike Phase III clinical trials for other FDA-approved smoking cessation aids, four (4) week continuous abstinence in the University of Minnesota Phase II trial was measured after the treatment period, when patients were "off" medication, rather than during the last four weeks of the treatment period. For example, according to the prescription Chantix® label, four (4)-week continuous abstinence in the Chantix® Phase III clinical trials (the 44 percent quit rate advertised by Pfizer) was measured during the last four weeks of the 12-week treatment period, while patients were still taking Chantix®. In one of these Chantix® Phase III clinical trials, approximately one-third of those who had been abstinent during the last week of treatment returned to smoking within four weeks after they stopped taking Chantix®, and approximately 45% returned to smoking within eight weeks after they stopped taking Chantix®.

Patients who used the VLN cigarette over the six (6)-week treatment period significantly reduced their smoking as compared to their usual brand of cigarettes. The number of VLN cigarettes smoked per day on average decreased from 19 (the baseline number of cigarettes of the smoker's usual brand) to 12 by the end of the six (6)-week treatment period, even though participants in this clinical trial were instructed to smoke ad libitum (as many cigarettes as desired) during treatment. Carbon monoxide (CO) levels, an indicator of smoke exposure, significantly decreased from 20 parts per million (baseline) to 15 parts per million. Cotinine, a metabolite and biomarker of nicotine, significantly decreased from 4.2 micrograms/mL (baseline) to 0.2 micrograms/mL. All differences in the above three measurements were statistically significant ($P<0.05$).

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A Phase III/IV two-arm smoking-cessation clinical trial of 1,410 treatment-seeking smokers was conducted by the University of Auckland, Clinical Trials Research Unit (Walker *et al*. 2012 *Addiction* 107: 857 1867)). The 705 patients who received VLN cigarettes in addition to NRT (patches and/or gum or lozenges) had significantly higher cessation rates at all measured time points (3 weeks, 6 weeks, 3 months and 6 months) than patients treated only with NRT. For those who failed to quit, the median time to relapse was increased to two months in the VLN + NRT group, compared to 13 days in the NRT only group. There was no difference in the frequency of serious adverse events between the groups.

A yet unpublished clinical trial evaluated whether the use of our VLN cigarette in combination with Chantix® or in combination with nicotine replacement therapy ("NRT") increases abstinence rates over the use of Chantix® or the use of NRT (NCT01250301). Certain results of this unpublished study were disclosed in a presentation at the 2013 Society for Research on Nicotine and Tobacco ("SRNT") annual meeting given by Hayden McRobbie, Ph.D. of Queen Mary University of London, Wolfson Institute of Preventative Medicine, who was the principal investigator of the study. Pfizer Inc. was also a collaborator of the study. The study included one hundred smokers who were prescribed varenicline (trademarked Chantix, or Champix outside the U.S.) and one hundred smokers who were prescribed NRT. Half the smokers of each of these groups were randomly selected to also use our VLN cigarettes for the first 2 weeks of treatment. All smokers received 9 weekly behavioral support sessions throughout the 12-week study period. The group that used our VLN cigarettes had a 70% quit rate one week after stopping VLN cigarette use compared to a 53% quit rate of the group not using VLN cigarettes after week 1 (p=0.02). The group that used our VLN cigarettes had a 64% four-week continuous abstinence rate during weeks 3 to 6 compared to a 50% four-week continuous abstinence rate during weeks 1 to 4 (p=0.06). Quit rates at 12 weeks post treatment were not reported in the presentation.

A Phase trial evaluated the efficacy of a VLN cigarette versus an FDA-approved nicotine patch and a combination of VLN cigarette and nicotine patch in 235 smokers (Hatsukami et al. 2013, *Cancer Epidemiol Biomarkers Prev* 22(6):1015-24). Smokers were randomly assigned to one of three treatment groups: (i) a VLN cigarette (n=79); (ii) a 21 mg nicotine patch (n=80) or (iii) a combination of the 21 mg nicotine patch and a VLN cigarette (n=76). Each group received 6 weeks of treatment, an additional 6 weeks of behavioral treatment, and 3 follow-up visits. Tobacco and nicotine use self-report and carbon monoxide ("CO") were assessed at each visit. Urinary cotinine was assessed at baseline and at weeks 2, 6, 12, 24 and 36.

Use of the VLN cigarette alone resulted in abstinence rates that did not differ from those for the nicotine patch or the combination treatment at any time point. Although post-treatment abstinence rates did not differ significantly, the median time to relapse to smoking usual brand cigarettes from treatment onset was significantly longer for the combination treatment 7.1 (6.7 7.7) weeks, 2.6 (1.7 5.9, vs.) weeks for VLN cigarette, and 2.1 (1.6 3.9) weeks for nicotine patch.

The average number of VLN cigarettes smoked per day declined over the treatment period to 16.2 in the VLN cigarette group and 11.3 in the VLN cigarette plus nicotine patch group at 6 weeks, compared to baseline cigarettes/day of 19.4 and 17.7. Nicotine exposure was reduced the most in the VLN cigarette group, falling to 12% of baseline at 6-week treatment period, compared to 46% of baseline for the nicotine patch, 51% for the combination therapy. There were significant declines in levels of urinary NNAL, a metabolite of the tobacco-specific lung carcinogen NNK, in all three groups during treatment, a reduction of 67% in the VLN cigarette group, 81% in the nicotine patch group, and 76% in the VLN cigarette plus patch group.

Gender differences in quitting rates in this study (Hatsukami *et al*. 2013) were disclosed at the 2013 SRNT annual meeting and differed considerably. CO and cotinine verified continuous abstinence rates at end of treatment (week 12) varied significantly by treatment group and gender (p=0.029 for the interaction). Within the female population at the end of treatment (week 12), the group assigned our VLN cigarette had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous

abstinence rate followed by the group assigned a 21mg nicotine patch. Within the male population at the end of treatment (week 12), the group assigned a 21mg nicotine patch had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned our VLN cigarette.

In a separate Phase II clinical trial funded by Vector Tobacco, our former licensee, under Investigational New Drug ("IND") Application 69,185, a randomized double-blind, active controlled, parallel group, multi-center Phase II smoking cessation clinical trial was conducted to evaluate the quitting efficacy of Quest® reduced-nicotine cigarettes as a smoking cessation treatment in 346 patients (Becker *et al*. 2008, *Nicotine & Tobacco Research* 10:1139-48). Treatment consisted of smoking three reduced-nicotine cigarette styles (Quest 1®, Quest 2® and Quest 3®) for two (2) weeks each, with nicotine yields per cigarette of 0.6 mg (a low nicotine cigarette made with a blend of regular tobacco and our proprietary VLN tobacco), 0.3 mg (an extra low nicotine cigarette made with a blend of regular tobacco and our proprietary VLN tobacco) and 0.05 mg (a VLN cigarette made with tobacco only from our proprietary VLN tobacco variety) either in combination with nicotine patch therapy (a nicotine replacement therapy or NRT product) or placebo patches.

In this three-arm clinical trial in which patients were treated over a period of sixteen (16) weeks, use of reduced-nicotine cigarettes in combination with nicotine patches was more effective (the difference was statistically significant) in achieving four (4)-week continuous abstinence than use of nicotine patches alone (32.8% vs. 21.9%), and use of reduced-nicotine cigarettes without nicotine patches yielded an abstinence rate similar (the difference was not statistically significant) to that of nicotine patches (16.4% vs. 21.9%). No serious adverse events were attributable to the investigational product.

A 2008 binding arbitration award, which was completely fulfilled in 2009 by our former licensee, Vector Tobacco, provided us with copies of all of Vector Tobacco's FDA submissions relating to Vector Tobacco's IND for Quest® and awarded to us a right of reference to Vector Tobacco's IND for Quest®, including all results of Vector's Phase II clinical trial. This arbitration award allows us to use all such information in our IND with the FDA for our VLN cigarette that contains our same proprietary tobacco that Vector Tobacco used in its IND submissions to the FDA. This arbitration award has been helpful to us with the FDA, since analytical reports produced by Vector Tobacco pertaining to our proprietary tobacco and cigarettes made from our proprietary tobacco are being utilized by us with the FDA.

A randomized controlled smoking cessation clinical trial using VLN cigarettes was a conducted at Roswell Park Cancer Institute, Buffalo, New York, to investigate the effect of smoking a very low nicotine cigarette ("VLN") in combination with a nicotine patch for 2 weeks prior to the quit date (Rezaishiraz *et al.* 2007 *Nicotine & Tobacco Research* 9:1139-1146). Ninety-eight adult smokers were randomized to two treatments: (i) two (2) weeks of a VLN (Quest 3®) and 21-mg nicotine patch before the quit date and (ii) a reduced nicotine cigarette (Quest 1®) during the two (2) weeks before the quit date. After the quit date, all subjects received counseling for smoking cessation and nicotine patch therapy for up to eight (8) weeks (four (4) weeks of 21-mg patches, two (2) weeks of 14-mg patches, and two (2) weeks of 7-mg patches). Group 1, which used the VLN cigarette and a nicotine patch before quitting, had lower combined craving scores during the two (2) weeks before and after the quit date. Self-reported point prevalence of smoking abstinence at the three (3)- and six (6)-month follow-up points was higher in Group 1 (43% vs. 34% and 28% vs. 21%).

A study at Dalhousie University, Halifax, Nova Scotia (Barrett 2010 *Behavioural Pharmacology* 21:144-52), compared the effects of low nicotine cigarettes and an FDA-approved nicotine inhaler on cravings and smoking behavior of smokers who did not intend to quit. In separate laboratory sessions, each of twenty-two (22) participants used a VLN cigarette (Quest 3®), a reduced nicotine cigarette (Quest 1®, which contains approximately two-thirds conventional tobacco and one-third VLN tobacco), a nicotine inhaler (10 mg; 4 mg deliverable, Pharmacia), or a placebo inhaler (identical in appearance to the nicotine inhaler, but containing no nicotine). Cravings, withdrawal and mood descriptors were rated before and after a twenty (20)-minute treatment session during which subjects were instructed to smoke two cigarettes or to use an inhaler every 10 seconds. The reduction in the rating of intent to smoke (usual cigarette brand) after using the VLN cigarette (-10.0) was significantly greater than the reduction with the nicotine inhaler (-1.9). Use of the VLN cigarette was also associated with significantly increased satisfaction and relaxation compared to the nicotine inhaler.

Healthcare Reimbursement

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.

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., Lorillard Inc., Commonwealth Brands, Inc., Liggett Group LCC and Vector Tobacco Inc. International competitors include Philip Morris International, Inc., Japan Tobacco Inc., Imperial Tobacco Group plc, and regional and local tobacco companies; and in some instances, government-owned tobacco enterprises such as the China National Tobacco Corporation.

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 U.S. regulatory scheme for the development and commercialization of new drugs can be divided into three distinct phases: an investigational phase including both preclinical and clinical investigations leading up to the submission of a New Drug Application ("NDA"); a period of FDA review culminating in the approval or refusal to approve the NDA; and the post-marketing period.

Preclinical Phase

The preclinical phase involves the characterization, product formulation and animal testing necessary to prepare an IND Application for submission to the FDA. The IND must be reviewed and authorized by the FDA before the drug can be tested in humans. Once a new drug agent has been identified and selected for further development, preclinical testing is conducted to confirm pharmacological activity, to generate safety data, to evaluate prototype dosage forms for appropriate release and activity characteristics, and to confirm the integrity and quality of the material to be used in clinical trials. A bulk supply of the active ingredient to support the necessary dosing in initial clinical trials must be secured. Data from the preclinical investigations and detailed information on proposed clinical investigations are compiled in an IND submission and submitted to the FDA before human clinical trials may begin. If the FDA does not formally communicate an objection to the IND within 30 days, the specific clinical trials outlined in the IND may go forward.

Clinical Phase

The clinical phase of drug development follows an IND submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy, and dosage of the substance in humans, as well as the ability to produce the substance in accordance with the FDA's cGMP requirements. Data from these activities are compiled in an NDA requesting approval to market the drug for a given use, or indication. Clinical trials must be conducted under the supervision of qualified investigators in accordance with good clinical practice, and according to IND-approved protocols detailing, among other things, the study objectives and the parameters, or endpoints, to be used in assessing

safety and efficacy. Each trial must be reviewed, approved and conducted under the auspices of an independent Institutional Review Board ("IRB"), and each trial, with limited exceptions, must include all subjects' informed consent. The clinical evaluation phase typically involves the following sequential process:

Phase I clinical trials are conducted in a limited number of healthy subjects to determine the drug's safety, tolerability, and biological performance. The total number of subjects in Phase I clinical trials varies, but is generally in the range of 20 to 80 people (or less in some cases, such as drugs with significant human experience).

Phase II clinical trials involve administering the drug to subjects suffering from the target disease or condition to evaluate the drug's potential efficacy and appropriate dose. The number of subjects in Phase II trials is typically several hundred subjects or less.

Phase III clinical trials are performed after preliminary evidence suggesting effectiveness has been obtained and safety, tolerability, and appropriate dosing have been established. Phase III clinical trials are intended to gather additional data needed to evaluate the overall benefit-risk relationship of the drug and to provide adequate instructions for its use. Phase III trials usually include several hundred to several thousand subjects.

Throughout the clinical testing phase, samples of the product made in different batches are tested for stability to establish shelf life constraints. In addition, increasingly large-scale production protocols and written standard operating procedures must be developed for each aspect of commercial manufacturing and testing.

The clinical trial phase is both costly and time-consuming, and may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical testing as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, institutional review boards, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

New Drug Application and Review

After the completion of Phase III clinical trials, the sponsor of the new drug submits an NDA to the FDA requesting approval to market the product for one or more indications. An NDA is a comprehensive, multi-volume application that includes, among other things, the results of all preclinical and clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging, and labeling the drug. In most cases, the NDA must be accompanied by a substantial user fee. The FDA has 60 days after submission to review the completeness and organization of the application, and may refuse to accept it for continued review, or refuse to file, if the application is found deficient. After filing, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use. Drugs that successfully complete NDA review may be marketed in the United States, subject to all conditions imposed by the FDA.

Prior to granting approval, the FDA generally conducts an inspection of the facilities, including outsourced facilities that will be involved in the manufacture, production, packaging, testing and control of the drug for cGMP compliance. The FDA will not approve the application unless cGMP compliance is satisfactory. If the FDA determines that the marketing application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the marketing application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a "not approvable" letter.

The length of the FDA's review can range from a few months to several years or more. Once an NDA is in effect, significant changes such as the addition of one or more new indications for use generally require prior approval of a supplemental NDA including additional clinical trials or other data required to demonstrate that the product as modified remains safe and effective.

Fast Track Development

The Food and Drug Administration Modernization Act of 1997 (the "Modernization Act"), establishes a statutory program for relatively streamlined approval of "Fast Track" products, which are defined under the Modernization Act as new drugs or biologics intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Fast Track status requires an official designation by the FDA. The Tobacco Control Act provides that products for smoking cessation, such as *X-22*, be considered for "Fast Track" designation by the FDA.

A product that receives Fast Track designation is eligible for (i) more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, and (ii) more frequent written correspondence from the FDA about such things as the design of the proposed clinical trials. A Fast Track product is also eligible for Rolling Review, in which sections of the NDA can be submitted for review by the FDA before the entire application is completed. A Fast Track product would ordinarily meet FDA criteria for Priority Review. The FDA goal for reviewing a drug with Priority Review status is six months from the filing of the NDA.

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 did not demonstrate that *X-22* shows potential to address an unmet medical need. Except for our Phase II-B clinical trial, all smoking cessation studies with very low nicotine ("VLN") cigarettes containing our proprietary tobacco were independent studies and were not sponsored by 22nd Century Ltd under its own Investigational New Drug ("IND"). 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*.

Post-Approval Phase

Once the FDA has approved a new drug for marketing, the product becomes available for physicians to prescribe in the U.S. After approval, we must comply with post-approval requirements, including ongoing compliance with cGMP regulations, delivering periodic reports to the FDA, submitting descriptions of any adverse reactions reported, and complying with drug sampling and distribution requirements. We are required to maintain and provide updated safety and efficacy information to the FDA. We must also comply with requirements concerning advertising, product promotions, and labeling.

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. We will need significant additional capital to complete the FDA authorization process for our Modified Risk Cigarettes. The amount of capital is currently unknown since it is uncertain how many exposure studies the FDA will require for *BRAND A* and *BRAND B*. 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®) 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 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.

Employees

We currently employ nine (9) people and we consider our employee relations to be good.

Item 1A. Risk Factors.

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

Risks Related to Our Business and Operations

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

We have experienced net losses of approximately $26.1 million, $6.7 million and $1.3 million during the years ended December 31, 2013, 2012 and 2011, respectively. Although we experienced operating income and positive cash flow from operating activities for the year ending December 31, 2013, such results were primarily due to $7,000,000 of royalty revenue received from a worldwide Research License and Commercial Option agreement with BAT. At December 31, 2013, we had current assets of $7,744,115, current liabilities of $984,334, and cash on hand of $5,830,599. We believe the cash balance is adequate to sustain operations and meet all current obligations as they come due for a period in excess of 12 months. Excluding contract growing of our proprietary tobacco with farmers, extraordinary expenses such as potential clinical trials and additional factory start-up costs, our monthly cash expenditures are approximately $200,000. While our current cash balance is adequate to sustain operations for a period in excess of 12 months, 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.

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

We had negative cash flow from operating activities, before cash used in investing activities and cash from financing activities, of approximately $1.8 million and $3.4 million during the years ended December 31, 2012 and 2011, respectively. As indicated above, we believe our cash on hand is adequate to sustain operations and meet all current obligations as they come due for a period in excess of 12 months. Continued 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 limited operating history makes it difficult to evaluate our current business and future prospects.

We have been in existence since 1998, but our activities have been limited primarily to licensing and funding research and development activities. Our limited operating history may make it difficult to evaluate our current business and our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced by growing companies in rapidly changing industries, including increasing expenses as we continue to grow our business. If we do not manage these risks successfully, our business will be harmed.

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.

We currently have nine 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.

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

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

We may be unable to become a participating member of the MSA, which would result in Goodrich Tobacco continuing to sell its products as a non-participating member non-participating member of the MSA

We are working to become a participating manufacturer of the Master Settlement Agreement ("MSA"), a settlement among 46 U.S. states and the tobacco industry administered by the National Association of Attorneys General ("NAAG"). As a participating member of the MSA, the distribution potential of *RED SUN* and *MAGIC* in the U.S. will be facilitated and likely increased. Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the MSA. Sales and marketing of our commercial cigarettes have been curtailed in order to limit the complexity and settlement costs associated with Goodrich Tobacco becoming a participating manufacturer of the MSA; the more *RED SUN* and *MAGIC* that is sold while being produced by a non-participating manufacturer, the more complex the process becomes and the greater the settlement cost Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA. There can be no assurance that we will be able to become a member of the MSA. Failure to become a member of the MSA will result in decreased sales potential of our products in the U.S.

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.

We have suspended further clinical trials for FDA approval of our X-22 smoking cessation aid and we will likely require additional capital before we can complete the FDA authorization process for our Modified Risk Cigarettes.

We have suspended further clinical trials for FDA approval of our *X-22* smoking cessation aid until we identify a suitable joint venture partner or licensee willing to fund further *X-22* clinical trials. At that time we may 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. We estimate the cost of completing a Phase II trial will be approximately $2 million and the cost of completing two Phase III trials to be approximately $15 million. We will 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 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 currently are not in compliance with annual "clean-up" provisions under a revolving line of credit.

Included in current liabilities at December 31, 2013 is a demand loan under a revolving credit agreement with a balance outstanding of $174,925, which is payable to a commercial bank and guaranteed by one of our shareholders. This exact same principal amount has been outstanding for over five years on a continuous basis, notwithstanding the fact that we have not complied with annual "clean-up" provisions which require that we repay all amounts outstanding for a period of 30 consecutive days each year. There are no additional amounts available to us under this credit agreement. We have paid interest only since 2008 (currently at the bank's annual prime rate plus 0.75% or 4%) on a monthly basis according to the bank's monthly payment statements. Our plans contemplate that this balance remains outstanding while we continue to pay interest only on a monthly basis. We may incur disruptions in our operations in the event the bank were to demand repayment in full, close the revolving credit agreement, and not allow us sufficient time to locate additional capital.

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.

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.

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 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.

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 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 and sell 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., Lorillard Inc., Commonwealth Brands, Inc., Liggett Group LLC, Vector Tobacco Inc. International competitors include Philip Morris International Inc., JT International SA, Imperial Tobacco Group PLC and regional and local tobacco companies; and in some instances, government-owned tobacco enterprises such as the China National Tobacco Corporation.

Our competitors may develop products that are less expensive, safer or more effective, 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 more effective 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 or more effective 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 upon 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 Joseph Pandolfino, our Chief Executive Officer, Henry Sicignano III, our Chief Financial Officer and President, and Michael Moynihan, Ph.D., our Vice President of R&D. 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.

Risks Related to Regulatory Approvals and Insurance Reimbursement

If we fail to obtain FDA and foreign regulatory approvals of 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, 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 this time because we did not yet demonstrate that *X-22* shows potential to address an unmet medical need. Except for our Phase II-B clinical trial, all smoking cessation studies with very low nicotine ("VLN") cigarettes containing our proprietary tobacco were independent studies and were not sponsored by 22nd Century Ltd under its own Investigational New Drug ("IND"). 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 New Drug Application, 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, European Medicines Agency 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 EMEA. 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 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.

In the future, 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 potential 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 and, 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 recent implementation of plain packaging in Australia.

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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 13 issued patents and we have the exclusive license to an additional 101 issued patents in an aggregate of 78 countries. In addition, we own or exclusively license 38 pending patent applications, of which we own 25 such patent applications and have an exclusive license to 13 such 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 two worldwide exclusive licenses, one from North Carolina State University (“NCSU”) and the other from National Research Council of Canada, Plant Biotechnology Institute (“NRC”), each involve multiple patent families. The exclusive rights under the NCSU agreement expires 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 license relates predominately to issued patents, and our exclusive rights in the NCSU license will expire in 2023. The exclusive rights granted to us under the NRC agreement expire on the date on which the last patent covered by the subject license expires in the country or countries where such patents are in effect. The NRC license relates predominately to patent applications, and our exclusive rights in the NRC license will expire in 2028.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not develop or 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 OTC Bulletin Board, an over-the-counter quotation system, on which the shares of our common stock are currently quoted. However, even if our common stock continues to be quoted on the OTC Bulletin Board, it is unlikely that an active market for our common stock will develop in the foreseeable future. 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 the NASDAQ Stock Market or other stock exchanges.

Although we anticipate filing an application to list our common stock on a national securities exchange, such as NASDAQ or the New York Stock Exchange, there is no guarantee that we will be successful. Even if we are listed on a national securities exchange, there can be no assurance that we can maintain such listing. Accordingly, an active trading market may not be developed or sustained, and you may not be able to sell your shares at or above the price at which you purchased them.

Trading in our common stock is currently limited and our stock price may be highly volatile and could decline in value.

Our common stock is currently traded on the OTC Bulletin Board, and, therefore, the trading volume is currently more limited and sporadic than if our common stock were traded on a national stock exchange. 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.

Our common stock is a "penny stock," which is likely to limit its liquidity.

The market price of our common stock is, and will likely remain for the foreseeable future, less than $5.00 per share, and therefore will be a "penny stock" according to SEC rules, unless our common stock is listed on a national securities exchange. The OTC Bulletin Board is not a national securities exchange. Designation as a "penny stock" requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect the ability of current holders of our common stock to sell their shares. Such rules may also deter broker-dealers from recommending or selling our common stock, which may further limit its liquidity. This may also make it more difficult for us to raise additional capital in the future. Because of such expected illiquidity, it will likely be difficult to re-sell shares of our common stock as desired.

We are controlled by our current officers and directors.

As of January 28, 2014, our directors and executive officers as a group beneficially owned approximately 27.8% of our common stock. Accordingly, our directors and executive officers will have substantial influence over, and may have the ability to control, the election of our board of directors and the outcome of issues submitted to a vote of our stockholders.

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:

• 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 indemnification 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 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 commenced September 1, 2011 and expires August 31, 2014. Scheduled rent remaining as of December 31, 2013 is $28,000 for 2014. One January 25, 2013, the Company entered into a lease for manufacturing space in Depew, New York. The lease commenced on February 1, 2013 and expires July 31, 2015. Scheduled rent remaining as of December 31, 2013 is $17,316 for 2014 and $10,101 for 2015.

On October 9, 2013, we executed a guaranty that guarantees performance by NASCO Products, LLC ("NASCO") of its obligations to the landlord under a certain triple net lease of the same date between NASCO and the landlord for warehouse and cigarette manufacturing facility located in North Carolina. Should the Purchase Agreement close, NASCO will become a wholly owned subsidiary of ours, making the lease our direct obligation. The lease commenced on January 14, 2014, and has an initial term of twelve (12) months (the "Initial Term"). The lease contains four (4) additional extensions; one for an additional one (1) year and three for an additional two (2) years in duration, exercisable at the option of NASCO. The lease also contains an early termination clause that provides NASCO with the right to terminate the lease at any time during the first nine (9) month of the Initial Term by giving ninety (90) days prior written notice to the landlord. Notwithstanding the above sentence, the lease calls for minimum lease payments of $96,000 during the Initial Term, $123,000 for the one (1) year optional extension, $144,525 and $153,750 for each year of the first two (2) year optional extensions, and $169,125 for each year of the final two (2) year optional extensions.

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 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 OTC Bulletin Board under the symbol "XXII.OB." As of January 28, 2014, there were 89 holders of record of shares of our common stock. The following table sets forth, for the quarters indicated, the high and low bid prices per share of our common stock, as derived from quotations provided by the OTC Bulletin Board Information Center.

Quarter Ended	High Bid	Low Bid
December 31, 2013	$ 2.19	$ 0.87
September 30, 2013	$ 1.74	$ 0.70

June 30, 2013	$ 0.90	$ 0.46
March 31, 2013	$ 1.07	$ 0.51
December 31, 2012	$ 0.95	$ 0.15
September 30, 2012	$ 0.88	$ 0.20
June 30, 2012	$ 1.13	$ 0.35
March 31, 2012	$ 0.75	$ 0.25

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

Between October 3, 2013 and December 26, 2013, the Series A Warrant holder exercised on a cashless basis at $0.60 per share 3,678,889 Series A warrants resulting in the issuance of 1,972,976 shares of common stock of the Company, par value $0.00001 per share.

On October 11, 2013, we issued 10,000 shares of its common stock, par value $0.00001 per share, to the keynote speaker at our annual shareholders' meeting held on September 28, 2013.
On November 4, 2013, we issued 10,000 shares of its common stock, par value $0.00001 per share, pursuant to the terms of an agreement between us and IBIS Co. for investor relation services.
On December 12, 2013, we issued 5,504,369 shares of its common stock, par value $0.00001 per share, pursuant to the exercise of warrants. The exercise of warrants generated gross proceeds of $3,559,763.

On December 27, 2013, we issued an aggregate 55,000 shares of common stock pursuant to a contractor agreement with an effective date of October 30, 2012 between us and Angelo Tomasello.

On December 27, 2013, we issued 300,000 shares of common stock pursuant to an agreement dated November 14, 2013 between the us and Chardan Capital Markets, LLC for professional services.

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

Shares authorized for issuance under equity compensation plans

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 authorizes 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.

The following table summarizes the number of stock options issued 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, 2013:

	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	1,160,000	(1)	$ 0.74	(2)	850,000
Equity compensation plans not approved by security holders	0		N/A		0
Total	1,160,000				850,000

(1) Includes 500,000 restricted stock awards that are issued but not vested as of December 31, 2013.

(2)

Weighted average exercise price only applies to the 660,000 shares issuable upon exercise of outstanding stock options.

Item 6. Selected Financial Data.

This item is not applicable to us as a smaller reporting company.

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 Report, 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.

Recent Developments

Warrant Exchange Program

The primary purpose of the Warrant Exchange Program was to reduce 22nd Century Group's "derivative warrant liability" through the exercise or amendment of the Company's outstanding warrants in order for the Company to have sufficient stockholders' equity to have its common stock listed on a national securities exchange such as NASDAQ or NYSE. The Warrant Exchange Program was a success in achieving this goal since as of December 31, 2013, the Company had $7,522,888 of stockholders' equity. The Company plans to file an application with either the NYSE or NASDAQ in early February to have its common stock listed on a national exchange. Prior to the Warrant Exchange Program, as of September 30, 2013, we had 19,616,308 warrants to purchase shares of common stock outstanding. These warrants contain "down round" provisions and anti-dilution features that provide for adjustments to the exercise price and number of warrants outstanding if we issued shares of common stock at a price that is less than the respective warrant exercise prices. These provisions require that these warrants be classified as derivatives for accounting purposes, which means they are reported as a liability and adjusted to fair value at each balance sheet date.

On November 14, 2013, we initiated a warrant exchange program (the "Warrant Exchange Program") with the goal of reducing our warrant liability. The Company offered inducements for warrant holders to (1) exercise their warrant on a cash basis, (2) exercise their warrant on a cashless basis, or (3) agree to have the "down round provision" or anti-dilution feature removed from their warrant. The warrants holders also had the option to maintain the terms and conditions of their original warrant. Our executive officers and directors were prohibited from participating in the Warrant Exchange Program. As a result of the cash and cashless exercise of warrants, there is a reduced number of outstanding warrants, and as a result of the removal of the "down round" provisions and anti-dilution features on other warrants, these warrants are no longer required to be classified as a derivative liability. The Warrant Exchange Program closed on December 12, 2013, generated gross proceeds of $3,559,763, and resulted in the issuance of 5,348,172 shares of our common stock from the cash exercise of warrants. The issuance of an additional 156,197 shares of our common stock resulted from the exercise of 513,949 warrants that were exercised on a cashless basis. As an inducement for warrant holders to agree to remove their "down round" provisions and anti-dilution features from their warrant, 138,666 additional warrants were issued.

As a result of the Warrant Exchange Program, there were 6,732,088 warrants outstanding at December 31, 2013 that do not contain the "down round" provisions or anti-dilution features. We calculated the cost of inducement as the difference between the fair value of the warrants immediately after the Warrant Exchange Program was closed on December 12, 2013, less the fair value of the warrants immediately prior to Warrant Exchange Program completion. We estimated the total cost of inducement to be $3,736,313, and this expense has been recorded as an "Other Expense" on the consolidated statements of operations and as an increase to the derivative warrant liability, and subsequently reversed into capital. We paid $320,378 and issued 300,000 shares of common stock to Chardan Capital Markets, LLC in conjunction with the Warrant Exchange Program. The fair value of the 300,000 shares issued to Chardan in the amount of $462,000 is included as a component of the total cost of inducement.

BAT License

On October 1, 2013, 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 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 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"). BAT and the Company also agreed to collaborate with each other as each party engages in its own independent research during the term of the Research Agreement.

Simultaneous with the signing of the BAT Research Agreement, BAT paid 22nd Century Ltd a non-refundable $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 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 two-year ramp-up period, and thereafter, a royalty of (i) $100 per metric ton of licensed tobacco that is supplied to, or grown and ready for shipment to, BAT and is 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.

The minimum and maximum amount of annual royalties under the terms of the Commercial License, which commence after the two-year ramp-up period from the exercise of the option, are $3.0 million and $15.0 million, respectively for a period of three years. Thereafter, the minimum and maximum annual royalties increase to $5.0 million and $25.0 million, respectively, until September 28, 2028. Thereafter, no further minimum royalties are due and the maximum annual royalties due remain at $25.0 million until expiration of the Commercial License.

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.

British American Tobacco sells products in approximately 180 countries. In 2012, global production of tobacco leaf was approximately 5,700,000 metric tons, of which BAT utilized approximately 10% for BAT's and its affiliates' brands.

NASCO Acquisition

On September 17, 2013, we entered into a Membership Interest Purchase Agreement ("Purchase Agreement") to purchase all of the issued and outstanding membership interests of NASCO Products, LLC ("NASCO"), a North Carolina limited liability company ("NASCO") (the "NASCO Transaction"), for consideration of $1,000,000, consisting of a cash payment of $200,000 and the issuance of $800,000 in value of unregistered shares of our common stock. NASCO already has a TTB permit to manufacture its own tobacco products and is a participating member of the MSA. Consummation of the NASCO Transaction is subject to various conditions including required consents from NAAG and certain attorneys general of the settling states of the MSA. NAAG has been discussing the NASCO Transaction with a small working group of settling states of the MSA for which the Company has answered various rounds of questions. The working group has presented the matter to all the settling states with a recommended course

of action which the settling states are evaluating. Upon the entry of a revised adherence agreement of NASCO Products, LLC reflecting the NASCO Transaction, we believe we will be able to close the NASCO Transaction. The NASCO Transaction contains termination rights, including a right for us to terminate the Purchase Agreement, at our sole discretion, if the closing shall not have occurred on or before January 31, 2014. At this time we do not expect to invoke our termination rights.

Business Overview

22nd Century Ltd, our wholly-owned subsidiary, is a plant biotechnology company focused on tobacco harm reduction and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding. We exclusively control 114 issued patents and an additional 38 patent applications; of these, we own 13 issued patents plus 25 patent applications and we license the remaining patents and patent applications on an exclusive basis. Goodrich and Hercules Pharmaceuticals are subsidiaries of 22nd Century Ltd. Goodrich Tobacco is focused on commercial tobacco products and potentially reduced-risk or modified risk tobacco products. Hercules Pharmaceuticals is focused on *X-22,* a prescription smoking cessation aid in development.

Our long-term focus is the research, development, licensing, manufacturing, and worldwide sales and distribution of our products to reduce the harm caused by smoking. Annual worldwide tobacco product sales, cigarettes and smokeless products, are approximately $700 billion and 90 percent are cigarette sales according to Euromonitor International. Worldwide smoking prevalence has decreased in recent years, but the number of cigarette smokers worldwide has increased to approximately 1 billion due to population growth, according to a 2013 research report from the Institute for Health Metrics and Evaluation (IHME) at the University of Washington.

The tobacco industry is at the beginning of a paradigm shift towards the development and commercialization of reduced-risk tobacco products which represent a significant step toward achieving the public health objective of harm reduction. The Company's 15 years of research and development on the tobacco plant, mainly on the nicotine biosynthetic pathway, uniquely positions us to become a major benefactor of this paradigm shift developing in the tobacco industry. Our technology has created, and will continue to develop, a pipeline of products. The Company is primarily involved in the following activities:

The international licensing of 22nd Century Ltd's technology, proprietary tobaccos, trademarks;
The manufacture, marketing and international distribution of *RED SUN* and *MAGIC* proprietary cigarettes;
The production of *SPECTRUM* research cigarettes for the National Institute on Drug Abuse ("NIDA");
The research and development of potentially reduced-risk or modified risk tobacco products;
The development of *X-22*, a prescription-based smoking cessation aid consisting of very low nicotine ("VLN") cigarettes; and
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.

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.

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, 2013 Compared to Year Ended December 31, 2012

Revenue - Royalties from licensing. In the year ended December 31, 2013, we realized royalty revenue of $7.0 million from the worldwide Research License and Commercial Option Agreement entered into with BAT. There was no licensing revenue for the year ended December 31, 2012.

Revenue - Sale of products. In the year ended December 31, 2013, we recognized revenue from the sale of products in the amount of $278,383. This revenue 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. In the year ended December 31, 2012, we realized revenue of $18,775, mainly from our research cigarette program.

Costs of goods sold - Royalties for licensing. In the year ended December 31, 2013, we recorded a royalty expense for licensing in the amount of $413,566. A portion of the patented technology sublicensed to BAT, as described above, is exclusively licensed to 22nd Century Ltd by a third party licensor. Pursuant to the terms of the license agreement with such licensor, 22nd Century Ltd is obligated to make a royalty payment to the licensor. There was no royalty expense for licensing for the year ended December 31, 2012.

Costs of goods sold - Products. In the year ended December 31, 2013, costs of goods sold were $48,105 or 17% of revenue. In the year ended December 31, 2012, the cost of goods sold were $67,967 and exceeded revenue by 362% since we provided RTI with certain *SPECTRUM* research cigarettes without charge mainly due to production delays.

Research and development expense. Research and development expense was $744,230 in the year ended December 31, 2013, an increase of $15,005, or 2.1%, from $729,225 in the year ended December 31, 2012. This increase is primarily the result of an increase in research and development costs and payroll costs in the amount of $49,802 and $34,360, respectively, partially offset by a decrease in royalty fees and equity based compensation of $35,391 and $33,512, respectively.

General and administrative expense. General and administrative expense was $4,106,694 in the year ended December 31, 2013, an increase of $1,901,244, or 86.2%, from $2,205,450 in the year ended December 31, 2012. The increase was primarily attributable to increases in third-party investor relation services, both cash and equity based, of $1,101,675, equity based employee compensation of $224,049, administrative payroll costs of $238,236, and professional fees of $241,790, for the year ended December 31, 2013, as compared to the year ended December 31, 2012. The increase in administrative payroll costs is the result of hiring a full time CFO, increases in employees' salaries, and bonus to an executive officer. The increase in professional fees is mainly the result of legal fees for services provided in conjunction with the BAT Research License and Commercial Option Agreement and the NASCO Membership Interest Purchase Agreement.

Sales and marketing costs. Sales and marketing costs were $9,052 in the year ended December 31, 2013, a decrease of $52,824, or 85.4%, from $61,876 in the year ended December 31, 2012. Some minor promotional costs were incurred during the year ended December 31, 2013, but we do not intend to incur any significant sales and marketing costs until the national distribution of our products in the U.S.

Amortization and depreciation expense. Amortization and depreciation expense relates almost entirely to capitalized patent and trademark costs. Amortization and depreciation expense decreased 27.3% in the year ended December 31, 2013 to $144,289 from $198,406 in the year ended December 31, 2012. This net decrease of $54,117 is mainly due to a change in an accounting estimate pertaining to the estimated useful life of certain patent families resulting in an increase in the amortization period. This decrease was partially offset by our amortization of additional investment in patents and trademarks in 2013 of $332,826 and in 2012 of $162,774.

Warrant liability loss - net. 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 for the year of $23,602,711. The loss on warrant liability from the change in fair value 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.

In connection with the May 2012 private placement, 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 was estimated to be $1,841,000, which exceeded the total consideration received in the offering by $814,500 resulting in an immediate charge to expense for this amount. This charge was in addition to the loss of $1,183,543 resulting from the increase in the estimated fair value during the year ended December 31, 2012 of all warrants we have issued. The loss on warrant liability of $1,183,543 was primarily the result of an increase in the Company's underlying stock price from $0.42 per share at December 31, 2011 as compared to $0.75 per share at December 31, 2012.

Future periods will reflect a gain or loss based on the change in the fair value of the derivatives, which is based on a number of factors including the Company's stock price.

Interest expense and amortization of debt discount and expense. Interest expense and amortization of debt discount and debt issuance costs decreased in the year ended December 31, 2013 to $748,605 from $1,494,545 in the year ended December 31, 2012. This decrease of $745,940 or 49.9% was primarily a result of a decrease of $1,298,982 in the amortization of debt discount and debt issuance costs. The decrease in the amortization of debt discount and debt issuance costs relates primarily to the Convertible Notes issued on December 14, 2011, which were fully amortized in December 2012. Offsetting the decrease in amortization of debt discounts and debt issuance costs were the fair value of warrants issued in excess of related debt converted to common stock during 2013 in the amount of $526,448, which is treated as a direct charge to interest expense.

Operating income (loss) and Net loss. We had operating income of $1,812,447 in the year ended December 31, 2013, as compared to an operating loss of $3,244,149 in the year ended December 31, 2012. This increase in operating income of $5,056,596 is primarily the result of $7,000,000 in royalty revenue received from BAT under the Research License and Commercial Option Agreement. We had a net loss in the year ended December 31, 2013 in the amount of $26,153,158, as compared to a net loss of $6,736,737 in the year ended December 31, 2012. The increased loss is primarily due to the increase in the warrant liability loss net and inducement costs related the Warrant Exchange Program, partially offset by the royalty revenue received from BAT.

Liquidity and Capital Resources

Working Capital

As of December 31, 2013, we had positive working capital of approximately $6.8 million, as compared to negative working capital of approximately $3.3 million at December 31, 2012. The $10.1 million increase in working capital was primarily the result of net proceeds realized through a series of equity transactions in the amount of $7.5 million and the completion of a worldwide Research License and Commercial Option Agreement with BAT that generated gross revenues of $7.0 million.

Cash demands on operations

In 2013, we had operating income of approximately $1.8 million and generated cash from operations of approximately $3.9 million during the year ended December 31, 2013. Excluding contract growing of our proprietary tobacco with farmers, extraordinary expenses such as potential clinical trials and additional factory start-up costs, our monthly cash expenditures are approximately $200,000. We believe that cash on hand at December 31, 2013 of $5,830,599 is adequate to sustain operations and meet all current obligations as they come due for a period in excess of 12 months.

Net Cash provided by (used in) Operating Activities

In the year ended December 31, 2013, $3,855,834 of cash was provided by operating activities compared to $1,764,445 of cash used in operating activities in the year ended December 31, 2012. This increase in cash provided by operations of $5,620,279 was mainly 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 minimal revenue received in 2012.

Net Cash used in Investing Activities

In the year ended December 31, 2013, we used $3,742,789 of cash related to the acquisition of third party patents and trademarks and the acquisition of various cigarette manufacturing equipment, a portion of which will be held for resale, as compared to $162,774 used in the year ended December 31, 2012. The increase is mainly attributable to the acquisition of various cigarette manufacturing equipment acquired in North Carolina out of bankruptcy that will be used in our cigarette manufacturing business.

Net cash from Financing Activities

During the year ended December 31, 2013, we generated $5,717,366 from our financing activities mainly as a result of net cash proceeds received from the Series A-1 Preferred stock 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. During the year ended December 31, 2012, we generated $1,675,158 from our financing activities mainly as a result of the $1,467,500 proceeds from the May and November 2012 private placements, the $210,000 proceeds from the August 9, 2012 convertible notes, $4,136 in advances from officers and $56,000 in proceeds from the issuance of short term secured notes, partially offset by payments on borrowings of $41,000 and net payments to a related party of $21,478.

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.

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 excise taxes are included in net sales and accounts receivable billed to customers, except on sales of *SPECTRUM* and exported cigarettes in which such taxes do not apply.

We were chosen to be a subcontractor for a government contract between RTI International ("RTI") and the National Institute on Drug Abuse ("NIDA") to supply NIDA research cigarettes. These government research cigarettes are distributed under the Company's mark *SPECTRUM*. Goodrich Tobacco has thus far delivered approximately 12 million *SPECTRUM* research cigarettes during the year ended December 31, 2012 and 2011 and recognized the related revenue of approximately $807,000. There were no *SPECTRUM* cigarettes delivered during the year ended December 31, 2013. Future revenue under this arrangement is expected to be related to the delivery of *SPECTRUM* and will be recognized at the point the product is shipped and title has transferred. In September 2013, we received a purchase order for an additional 5.5 million *SPECTRUM* research cigarettes that will be manufactured and shipped in January 2014. Total revenue from this order will be approximately $448,000 and a down payment on the order was received in the fourth quarter of 2013 in the amount of $179,014. The down payment has been recorded as deferred revenue on the Company's balance sheet at 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 will 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 22nd Century Ltd $2 million for each milestone achieved, and two of which BAT would pay 22nd Century Ltd $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 2013. A portion of the patented technology sublicensed to BAT is exclusively licensed to 22nd Century Ltd by a third party licensor. Pursuant to the terms of the license agreement with such licensor, 22nd Century Ltd is obligated to make a royalty payment to the licensor. 22nd Century Ltd estimates the payment to be approximately $414,000, subject to the mutual agreement of 22nd Century Ltd and the third party licensor.

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 two year period ended December 31, 2013.

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 common shares of 22nd Century Group. 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.

Convertible Debt

When the convertible feature of the conventional convertible debt is issued, the embedded conversion feature is evaluated to determine if bifurcation and derivative treatment is required whether there is a beneficial conversion feature. When the convertible debt provides for an effective rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature (“BCF"). Prior to the determination of the BCF, the proceeds from the debt instrument were first allocated between the convertible debt and any embedded or detachable free standing instruments that are included, such as common stock and warrants. We record a BCF as a debt discount pursuant to FASB ASC Topic 470-20. In those circumstances, the convertible debt will be recorded net of the discount related to the BCF. We amortize the discount to interest expense over the life of the debt.

For the convertible notes issued December 2011 and August 2012, we recorded the OID and the BCF related to these convertible notes as a debt discount and recorded the convertible notes net of the discount related to both the OID and the BCF. Debt discount is amortized to interest expense over the life of the debt.

Income taxes

The Company recognizes deferred tax assets and liabilities for any basis differences in its assets and liabilities between tax and GAAP reporting, and for operating loss and credit carry-forwards. 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, 2013 and 2012.

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, 2013 would have the impact of increasing or decreasing the liability by approximately $450,000.

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, 2013 and 2012.

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.

As a smaller reporting company, we are not required to present the information required by this item.

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).

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 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 chief executive officer 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 chief executive officer 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 exists 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 chief executive officer also acting as 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 1992, 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, 2013, 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 and controls associated with accounting for complex and non-routine transactions relating to certain equity and derivative instruments. 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.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation requirements by the Company's registered public accounting firm pursuant to an exemption provided by the Dodd-Frank Wall Street Reform and Consumer Protection Act.

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, 2013 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

On January 28, 2014, our board of directors approved and adopted amended and restated bylaws. The following description of the sections of the amended and restated bylaws that differ from our prior bylaws is only a summary and is qualified by reference to the amended and restated bylaws, which are filed as part of this Annual Report on Form 10-K.

Meetings of Stockholders. The amended and restated bylaws provide that, for matters to be properly brought before an annual meeting, business must be either (i) specified in the notice of annual meeting (or any supplement or amendment thereto) given by or at the direction of the board of directors, (ii) otherwise brought before the annual meeting by or at the direction of the board of directors, or (iii) otherwise properly brought before the annual meeting by a stockholder. In addition to any other applicable requirements, for business to be properly brought before an annual meeting by a stockholder, the stockholder must have given timely notice thereof in writing to our secretary. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not later than the close of business on the ninetieth (90th) day nor earlier than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than thirty (30) days before or more than seventy (70) days after such anniversary date, notice by the stockholder must be so delivered not earlier than the close of business on the one hundred twentieth (120th) day prior to such annual meeting and not later than the close of business on the later of the ninetieth (90th) day prior to such annual meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made by us.

Quorum. The holders of one-third (33.33%) of the voting power of our stock at any meeting of stockholders, which are present in person or represented by proxy, shall constitute a quorum for the transaction of business except as otherwise provided by law, by the articles of incorporation, or by the bylaws.

Voting. When a quorum is present at any meeting, action of the stockholders on a matter other than the election of directors is approved if the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, unless the question is one upon which by express provision of the statutes, or the articles of incorporation, or the bylaws, a different vote is required in which case such express provision shall govern and control the decision of such question. Directors shall be elected by a plurality of the votes cast by the stockholders.

Special Meetings. Special meetings of the stockholders, for any purpose or purposes, unless otherwise prescribed by statute or by the articles of incorporation, may be called by the Chief Executive Officer and shall be called by the Chief Executive Officer or the Secretary at the request in writing of a majority of the board of directors or by the holders of a majority of the shares of voting stock.

Action by Stockholders. Stockholders may only take action at an annual or special meeting of stockholders. Stockholders may not take action by written consent without a meeting.

Nominations of Directors. Nominations of persons for election to the board at the annual meeting may be made at such meeting by or at the direction of the board, by any committee or persons appointed by the board or by any stockholder entitled to vote for the election of directors at the meeting who complies with the notice procedures set forth in the bylaws. Such nominations by any stockholder shall be made pursuant to timely notice in writing to the Secretary. To be timely, a stockholder's notice shall be delivered to the Secretary at our principal executive offices not later than the close of business on the ninetieth (90th) day nor earlier than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than thirty (30) days before or more than seventy (70) days after such anniversary date, notice by the stockholder must be so delivered not earlier than the close of business on the one hundred twentieth (120th) day prior to such annual meeting and not later than the close of business on the later of the ninetieth (90th) day prior to such annual meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made.

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 2014 Annual Meeting of Stockholders.

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

Name	Age	Position
Joseph Pandolfino	45	Chief Executive Officer and Director
Henry Sicignano, III	46	President, Secretary and Director
John T. Brodfuehrer	56	Chief Financial Officer and Treasurer
Michael R. Moynihan, Ph.D.	61	Vice President of R&D
Joseph Alexander Dunn, Ph.D.	60	Director*
James W. Cornell	57	Director**
Richard M. Sanders	60	Director***

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

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

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

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 Chief Executive Officer 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 2014 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 2014 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 2014 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 2014 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements

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22nd CENTURY GROUP, INC. AND SUBSIDIARY

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
22nd Century Group, Inc.

We have audited the accompanying consolidated balance sheets of 22nd Century Group, Inc. and Subsidiary as of December 31, 2013 and 2012, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for the years then ended. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 Subsidiary as of December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Freed Maxick CPAs, P.C.

Buffalo, New York
January 30, 2014

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

	2013	2012
ASSETS		
Current assets:		
Cash	$ 5,830,599	$ 188
Due from related party	42,069	36,969
Due from officers	7,471	3,578
Inventory	1,406,280	1,230,526
Machinery and equipment held for resale	457,696	-
Prepaid expenses and other assets	-	10,044
Total current assets	7,744,115	1,281,305
Machinery and equipment, net	2,997,760	6,030
Other assets:		
Patent and trademark costs, net	1,544,869	1,353,304
Deferred debt issuance costs, net	-	4,232
Total other assets	1,544,869	1,357,536
Total assets	$ 12,286,744	$ 2,644,871
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Demand bank loan	$ 174,925	$ 174,925
Accounts payable	54,665	1,410,650
Accrued expenses	575,730	503,002
Deferred revenue	179,014	-
Accrued interest payable to related parties	-	3,567
Notes payable	-	617,000
Convertible notes, net of unamortized discount	-	1,893,804
Total current liabilities	984,334	4,602,948
Warrant liability	3,779,522	4,173,140
Total liabilities	4,763,856	8,776,088
Commitments and contingencies (Note 12)	-	-
Shareholders' equity (deficit)		
Capital stock authorized:		
10,000,000 preferred shares, $.00001 par value		
300,000,000 common shares, $.00001 par value		
Capital stock issued and outstanding:		
0 convertible preferred shares, $1,000 stated value,		
10% cumulative (0 at December 31, 2012)	-	-
56,902,770 common shares (34,286,979 at December 31, 2012)	569	344

Capital in excess of par value		47,452,055		7,645,017
Accumulated deficit		(39,929,736)		(13,776,578)
Total shareholders' equity (deficit)		7,522,888		(6,131,217)
Total liabilities and shareholders' equity (deficit)	$	12,286,744	$	2,644,871

See accompany notes to consolidated financial statements.

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

	2013	2012
Revenue:		
Royalties from licensing	$ 7,000,000	$ -
Sale of products	278,383	18,775
	7,278,383	18,775
Cost of goods sold:		
Royalties for licensing	413,566	-
Products	48,105	67,967
	461,671	67,967
Gross profit (loss)	6,816,712	(49,192)
Operating expenses:		
Research and development (including stock based compensation of $111,563 and $145,074, respectively)	744,230	729,225
General and administrative (including stock based compensation of $2,250,399 and $1,109,097, respectively)	4,106,694	2,205,450
Sales and marketing costs	9,052	61,876
Amortization and depreciation	144,289	198,406
	5,004,265	3,194,957
Operating income (loss)	1,812,447	(3,244,149)
Other income (expense):		
Warrant liability loss - net	(23,602,711)	(1,998,043)
Warrant exchange inducement expense	(3,736,313)	-
Income tax credit refund	122,024	-
Interest expense and amortization of debt discount and expense:		
Related parties	(17,889)	(272,758)
Other	(730,716)	(1,221,787)
	(27,965,605)	(3,492,588)
Net loss	(26,153,158)	(6,736,737)
Net loss attributable to non-controlling interest	-	1,456
Net loss attributed to common shareholders	$ (26,153,158)	$ (6,735,281)
Loss per common share - basic and diluted	$ (0.60)	$ (0.22)
Common shares used in basic earnings per share calculation	43,635,182	30,419,556

See accompany notes to consolidated financial statements.

22nd CENTURY GROUP INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY (DEFICIT)

Years Ended December 31, 2013 and 2012

	Preferred Shares Outstanding	Common Shares Outstanding	Par value of Preferred Shares	Par value of Common Shares	Contributed Capital	Accumulated Deficit	Non-controlling Interest	Shareholders' Equity (Deficit)
Balance at December 31, 2011	-	27,209,646	$ -	$ 273	$ 5,822,882	$ (7,041,297)	$ 5,982	$ (1,212,160)
Stock base compensation under Equity Incentive Plan	-	700,000	-	7	722,202	-	-	722,209
Options granted for payment of services	-	-	-	-	10,000	-	-	10,000
Common stock issued as payment of services and accounts payable	-	1,267,500	-	13	517,740	-	-	517,753
Common stock issued upon exercise of Convertible Notes	-	161,000	-	2	(2)	-	-	-
Common stock issued in May 2012 private placement	-	1,710,833	-	17	(17)	-	(4,526)	(4,526)
Beneficial conversion feature of convertible debt	-	-	-	-	116,600	-	-	116,600
	-	3,238,000	-	32	455,612	-	-	455,644

Common stock issued in November 2012 private placement								
Net loss	-	-	-	-	-	(6,735,281)	(1,456)	(6,736,737)
Balance at December 31, 2012	-	34,286,979	$ -	$ 344	$ 7,645,017	$ (13,776,578)	$ -	$ (6,131,217)
Common stock issued upon exercise of Convertible Notes	-	2,406,720	-	24	(24)	-	-	-
Preferred stock issued in January 2013 private placement	2,500	416,666	-	4	(4)	-	-	-
Conversion of preferred stock to common stock	(2,500)	4,166,666	-	42	(42)	-	-	-
Exercise of warrants	-	6,820,218	-	68	14,097,526	-	-	14,097,594
Exercise of options	-	20,000	-	-	5,200	-	-	5,200
Stock based compensation	-	2,820,000	-	28	2,361,934	-	-	2,361,962
Other contributed capital	-	-	-	-	1,660	-	-	1,660
Warrant exchange program	-	5,804,368	-	58	23,340,789	-	-	23,340,847
Common stock issued in payment of accrued dividends	-	161,153	-	1	(1)	-	-	-

Net loss	-	-	-	-	-	(26,153,158)	-	(26,153,158)
Balance at December 31, 2013	-	56,902,770	$ -	$ 569	$ 47,452,055	$ (39,929,736)	$ -	$ 7,522,888

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP INC. AND SUBSIDIARY		
CONSOLIDATED STATEMENTS OF CASH FLOWS		
Years Ended December 31,		
	2013	2012
Cash flows from operating activities:		
Net loss	$ (26,153,158)	$ (6,736,737)
Adjustments to reconcile net loss to cash provided by (used in) operating activities:		
Amortization and depreciation	144,289	198,406
Amortization of debt issuance costs	4,232	18,173
Amortization of debt discount	134,296	1,372,018
Interest due to debt conversion	526,448	31,350
Warrant liability loss	23,602,711	1,998,043
Warrant exchange inducement expense	3,736,313	-
Equity based employee compensation expense	980,162	807,675
Equity based payments for outside services	1,381,800	416,496
Stock issued for director fees	-	30,000
(Increase) decrease in assets:		
Inventory	(175,754)	(552,403)
Prepaid expenses and other assets	10,044	7,630
Increase (decrease) in liabilities:		
Accounts payable	(629,101)	705,415
Accrued interest payable to related parties	(3,567)	(2,470)
Accrued expenses	118,105	(58,041)
Deferred revenue	179,014	-
Net cash provided by (used in) operating activities	3,855,834	(1,764,445)
Cash flows from investing activities:		
Acquisition of patents and trademarks	(290,336)	(162,774)
Purchase of machinery and equipment held for resale	(457,696)	-
Acquisition machinery and equipment	(2,994,757)	-
Net cash used by investing activities	(3,742,789)	(162,774)
Cash flows from financing activities:		
Proceeds from issuance of notes	150,000	56,000
Payments on borrowings - notes payable	(1,620,299)	(41,000)
Payments on borrowings - convertible notes	(339,250)	-
Net proceeds from May and November 2012 private placement	-	1,467,500
Proceeds from issuance of convertible notes	-	210,000
Net proceeds from January 2013 preferred stock private placement	2,034,664	-
Net proceeds from exercise of warrants	2,254,999	-
Net proceeds from warrant exchange program	3,239,385	-
Net proceeds from exercise of options	5,200	-
Other capital contribution	1,660	-
Net payments to related party	(5,100)	(21,478)
Net advances (to) from officers	(3,893)	4,136
Net cash provided by financing activities	5,717,366	1,675,158
Net increase (decrease) in cash	5,830,411	(252,061)
Cash - beginning of year	188	252,249
Cash - end of year	$ 5,830,599	$ 188

Cash paid during the year for interest	$ 135,247	$ 15,317
Cash paid during the year for income taxes	$ -	$ -

Supplemental disclosure of noncash investing and financing activities:		
Reduction of accounts payable not related to operating activities:		
Common stock issued as payment of accounts payable	$ -	$ 359,754
Accounts payable converted to promissory notes	769,377	-
	$ 769,377	$ 359,754
Accrued interest converted to promissory notes	$ 26,422	$ -
Deferred private placement costs charged to contributed capital	$ -	$ 4,526
Notes payable and accrued interest converted to common shares	$ 1,650,305	$ 120,750
Original issue discount on convertible debt	$ -	$ 12,600
Beneficial conversion value upon issuance of convertible debt recorded as debt discount and an increase in capital in excess of par value	$ -	$ 116,600
Common stock issued for fees relating to January 2013 preferred stock private placement	$ 416,666	$ -
Common stock issued for fees relating to December 2013 warrant exchange program	$ 462,000	$ -
Common stock issued in payment of preferred stock dividend payable	$ 93,361	$ -
Refinance of convertible note to note payable	$ 57,500	$ -
Issuance of warrants as derivative liability instruments and reduction of capital	$ 5,675,634	$ 1,532,347
Increase in warrant liability and reduction in capital as a result of lowering the exercise price on certain warrants	$ 626,328	$ -
Issuance of warrants as derivative liability instruments	$ -	$ 92,750
Reclassification of derivative liability to equity due to warrant exercise	$ 14,433,178	$ -
Reclassification of derivative liability to equity due to warrant exchange program	$ 19,639,465	$ -
Patent and trademark additions included in accounts payable	$ 42,490	$ -

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2013

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

Principles of Consolidation - The accompanying consolidated financial statements include the accounts of 22nd Century Group, its wholly owned subsidiary, 22nd Century Ltd, and 22nd Century Ltd's wholly owned subsidiaries, Goodrich Tobacco Company, LLC ("Goodrich Tobacco") and Hercules Pharmaceuticals, LLC ("Hercules Pharma") (collectively, "the Company"). In May 2012, 22nd Century Ltd acquired from an employee the non-controlling membership units of Goodrich Tobacco that it did not own so that Goodrich Tobacco became a wholly owned subsidiary. All intercompany accounts and transactions have been eliminated.

Nature of Business - 22nd Century Ltd, is a plant biotechnology company specializing in technology that allows for the level of nicotine and other nicotinic alkaloids (e.g., nornicotine, anatabine and anabasine) in tobacco plants to be decreased or increased through genetic engineering and plant breeding. The Company owns or exclusively controls 114 issued patents in 78 countries plus an additional 38 pending patent applications. Goodrich Tobacco and Hercules Pharma are business units for the Company's (i) premium cigarettes and potential modified risk tobacco products and (ii) smoking cessation product, respectively.

Reclassifications - Certain items in the 2012 financial statements have been reclassified to conform to the 2013 classification.

Preferred Stock Authorized - the authorization is for "blank check" preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock. On January 11, 2013 the Company designated the rights of and issued 2,500 shares of Series A-1 Preferred Stock. As of June 7, 2013, all 2,500 outstanding shares of Series A-1 Preferred Stock were converted into an aggregate 4,166,666 shares of common stock of the Company (see Note 3) and no shares of preferred stock remain outstanding.

Inventory - Inventories are valued at the lower of cost or market. Cost is determined on the first-in, first-out (FIFO) method. 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. As of December 31, 2013 and 2012, the Company's inventory consisted primarily of raw materials, mainly tobacco.

Fixed assets Fixed assets are recorded at their acquisition cost and depreciated on a straight line basis over their estimated useful lives ranging from 5 to 10 years. Depreciation commences when the asset is placed in service. Cigarette manufacturing equipment purchased in December 2013 in the amount of $2,762,304 was not placed in service at December 31, 2013 and accordingly, no depreciation was taken. Certain cigarette manufacturing equipment with a cost of $457,696 will not be used in the Company's operations and has been recorded as "Machinery and equipment held for resale" on the Company's Balance Sheet at December 31, 2013.

Intangible Assets - Intangible assets are recorded at cost and consist primarily of expenditures incurred with third parties related to the processing of patent claims and trademarks with government authorities, as well as costs to acquire patent rights from third parties. The amounts capitalized relate to intellectual property that the Company owns or to which it has exclusive rights. The Company's intellectual property capitalized costs are amortized using the straight-line method over the remaining statutory life of the primary patent in each of the Company's two largest patent families, which expires in 2019 and 2028 (the assets' estimated lives). Periodic maintenance or renewal fees are expensed as incurred. Annual minimum license fees are charged to expense. Total patent and trademark costs capitalized at December 31, 2013 and 2012 consist of the following:

During the year ended December 31, 2013, the Company changed the estimated useful life of one of the patent families. The change did not have a material impact on the financial statements.

	December 31, 2013	December 31, 2012
Patent and trademark costs	$ 2,559,412	$ 2,226,586
Less: accumulated amortization	1,014,543	873,282
Patent and trademark costs, net	$ 1,544,869	$ 1,353,304

The estimated annual amortization expense for the next five years is approximately $177,000.

Impairment of Long-Lived Assets - The Company reviews the carrying value of its amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable. The Company assesses recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. There was no impairment loss recorded during the year ended December 31, 2013 or 2012.

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

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, 2013 and 2012.

The Company's federal and state tax returns for the years ended September 30, 2011 to December 31, 2012 are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2013.

Refundable taxes and tax credits The Company accounts for income tax refunds or tax refundable tax credits as discrete items and recognized the amount in the period in which the funds are received. During the year ended December 31, 2013, the Company received notice from the New York State Department of Taxation and Finance of a no change audit with respect to its income tax return filed for the period ending September 30, 2011. The subject return contained a refundable credit in the amount of $122,000. The refund was recorded as other income in the Company's consolidated statement of operations. There were no such transactions during the year ended December 31, 2012.

Stock Based Compensation - The Company uses a fair-value based method to determine compensation for all arrangements under which Company employees and others receive shares, options or warrants to purchase common shares of 22nd Century Group. 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.

Debt Discounts - Original issue discount ("OID") is recorded equal to the difference between the cash proceeds, after allocation to warrants issued or issuable upon payment of the debt, and the face value of the debt when issued and amortized as interest expense during the term of the debt.

When the convertible feature of the conventional convertible debt is issued, the embedded conversion feature is evaluated to determine if bifurcation and derivative treatment is required and whether there is a beneficial conversion feature. When the convertible debt provides for an effective rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature ("BCF"). Prior to the determination of the BCF, the proceeds from the debt instrument were first allocated between the convertible debt and any embedded or detachable free standing instruments that are included, such as common stock warrants. The proceeds allocated to any warrants are recorded as a debt discount.

The debt discount is amortized to interest expense over the life of the debt. In the case of any conversion prior to the maturity date there will be an unamortized amount of debt discount that relates to such conversion. The pro rata amount of unamortized discount at the time of such conversion is charged to interest expense as accelerated amortization of the discount. The fair value of warrants issued at the time of conversion is recorded as a reduction of

the amount applied to the common stock issued in the conversion and to the extent that the fair value of warrants exceeds the carrying value of the debt a charge to interest expense results for such excess amount.

Revenue Recognition - The Company recognizes revenue from product sales at the point the product is shipped to a customer and title has transferred. Revenue from the sale of the Company's products is recognized net of cash discounts, sales returns and allowances. Cigarette federal excise taxes are included in net sales and accounts receivable billed to customers, except on sales of *SPECTRUM* research cigarettes and exported cigarettes in which such taxes do not apply.

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 research cigarettes. These government research cigarettes are distributed under the Company's mark, *SPECTRUM*. The Company delivered approximately 12 million *SPECTRUM* research cigarettes during the year ended December 31, 2012 and 2011 and recognized the related revenue of approximately $807,000. There were no *SPECTRUM* cigarettes delivered during the year ended December 31, 2013. Future revenue under this arrangement is expected to be related to the delivery of *SPECTRUM* and will be recognized at the point the product is shipped and title has transferred. In September 2013, the Company received a purchase order for an additional 5.5 million *SPECTRUM* research cigarettes that will be manufactured and shipped in January 2014. Total revenue from this order will be approximately $448,000 and a down payment on the order was received in the fourth quarter of 2013 in the amount of $179,014. The down payment has been recorded as deferred revenue on the Company's balance sheet at December 31, 2013.

The Company licenses its patented technology to third parties. Revenue is recognized from licensing arrangements as contractually defined in licensing agreements. The Company accounts for milestones elements contained in licensing agreements in accordance with ASC 605. On October 1, 2013, 22nd Century Ltd entered into a worldwide Research License and Commercial Option Agreement (the "Agreement") with British American Tobacco (Investments) Limited ("BAT"), a subsidiary of British American Tobacco plc, that grants BAT access to 22nd Century Ltd's patented technology which alters levels of nicotinic alkaloids in tobacco plants. Simultaneous with the signing of the Agreement, BAT paid the Company a non-refundable $7,000,000. The Company will be entitled to receive additional payments from BAT of up to an additional $7,000,000 during the term of the Research License 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 the Company to BAT. No amount related to the additional research milestones were recognized during 2013. During the term of the Research License, BAT will have the option to enter into a Commercial License agreement which will provide for future royalty payments based on sales. A portion of the patented technology sublicensed to BAT is exclusively licensed to 22nd Century Ltd by a third party licensor. Pursuant to the terms of the license agreement with such licensor, 22nd Century Ltd is obligated to make a royalty payment to the licensor. 22nd Century Ltd estimates the payment to be approximately $414,000, subject to the mutual agreement of 22nd Century Ltd and the third party licensor.

Derivatives - 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. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified on the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

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

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

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

material commitments or contingencies that may arise.

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

Fair Value of Financial Instruments - Financial instruments include cash, receivables, accounts payable, accrued expenses, notes payable, demand bank loan, convertible notes payable and warrant liability. Other than warrant liability and convertible notes payable, fair value is assumed to approximate carrying values for these financial instruments, since they are short term in nature, they are receivable or payable on demand, or had stated interest rates that approximate the interest rates available to the Company as of the reporting date. The determination of the fair value of the warrant liability includes unobservable inputs and is therefore categorized as a Level 3 measurement, as further discussed in Note 10. There are no convertible notes outstanding at December 31, 2013.

NOTE 2. FINANCIAL CONDITION

At December 31, 2013, the Company had current assets of $7,744,115 and current liabilities of $984,334 resulting in positive working capital of $6,759,781. Cash on hand at December 31, 2013 was $5,830,599. During the year ended December 31, 2013, the Company has improved its balance sheet and cash position primarily through a series of equity transactions that realized net proceeds of approximately $7,529,000 and completion of a worldwide Research License and Commercial Option Agreement generating gross royalties of $7,000,000. As a result of the above referenced transactions, the Company believes it will have adequate cash reserves to sustain operations and meet all current obligations as they come due for a period in excess of 12 months.

NOTE 3. - JANUARY 2013 PREFERRED STOCK PRIVATE PLACEMENT

On January 11, 2013, the Company sold 2,500 shares of newly created Series A-1 10% Convertible Preferred Stock (the “Series A-1 Preferred Stock”) and warrants for $2.5 million. Net proceeds from this issuance were $2.035 million.

The shares of Series A-1 Preferred Stock were initially convertible into a total of 4,166,666 shares of the Company’s common stock at a conversion price of $0.60 per share (the “Conversion Price”), subject to future adjustments, which have subsequently expired with no change to the conversion price. The Series A-1 Preferred Stock paid a 10.0% annual cash dividend, which was payable in shares of our common stock in certain circumstances, and had a liquidation preference equal to the stated value of the Series A-1 Preferred Stock of $1,000 per share plus any accrued and unpaid dividends thereon. The Series A-1 Preferred Stock had no voting rights.

The preferred stockholders did not have mandatory redemption rights, nor did the Company have an unconditional obligation to issue a variable number of shares. Further, there was a limit on the number of shares that were issuable upon conversion. Accordingly, the Series A-1 Preferred Stock was classified as permanent equity. Based on the fact that the host instrument is more akin to equity, it was further determined that bifurcation of the embedded conversion feature was not required.

The Company also issued to the Purchasers of the Series A-1 Preferred Stock a Series A warrant (the “Series A Warrant”), a Series B warrant (the “Series B Warrant”), and a Series C warrant (the “Series C Warrant”) (with the Series A Warrant, Series B Warrant and Series C Warrant being collectively referred to herein as the “Warrants”). The Series A Warrant allows the Purchasers the right to acquire, initially before any adjustments to the conversion price, up to an additional 4,166,666 shares of the Company’s common stock at an exercise price of approximately $0.72 per share over a period of five (5) years. The Series A Warrant also allows for such warrant to be exercised on a cashless basis. The Series B Warrant allowed the Purchasers a one-year period to exercise an overallotment option as contained in the Series B Warrant to purchase, initially before any adjustments to the conversion price, up to an additional aggregate of 2,083,334 shares of the Company’s common stock at a price of $0.60 per share. Since the Purchasers fully exercised the Series B Warrant, the Purchasers have the right to exercise the Series C Warrant to acquire, initially before any adjustments to the conversion price, an additional aggregate of 2,083,334 shares of the Company’s common stock at an exercise price of approximately $0.72 per share over a period of five (5) years. The Series C Warrant allows for such warrant to be exercised on a cashless basis.

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The warrants have a “down round provision” which results in the warrants being classified and reported as derivative liabilities for accounting purposes and marked to market at each balance sheet date. At the date of the issuance of these warrants, including lock-up warrants, the fair value was estimated to be $6,022,319, which exceeded the net consideration received in the offering of $2,034,664, resulting in an immediate charge to “other expense warrant liability loss net” in the amount $3,987,655. During June 2013, 982,300 Series B Warrant shares were exercised resulting in net proceeds to the Company in the amount of $542,229. In addition, the exercise of the Series B Warrant shares resulted in a reduction in the warrant liability and an increase in capital in the amount of $204,513. The exercise of the 982,300 Series B Warrant shares triggered the issuance of a like amount of Series C Warrant shares. The Series C Warrant shares include a “down round provision” and results in a derivative liability upon issuance. At the date of issuance of the 982,300 Series C Warrant shares the fair value was estimated to be $711,675. During July 2013, 1,101,034 Series B Warrant shares were exercised resulting in net proceeds to the Company in the amount of $607,771. In addition, the exercise of the Series B Warrant shares resulted in a reduction in the warrant liability and an increase in capital in the amount of $671,219. The exercise of the 1,101,034 Series B Warrant shares triggered the issuance of a like amount of Series C Warrant shares. The Series C Warrant shares include a “down round provision” and resulted in a derivative liability upon issuance. At the date of the issuance of these warrants the fair value was estimated to be $1,622,069, which exceeded the sum of the net consideration received in the offering of $607,771 and the reclassification of warrant liability to capital of $671,219, resulting in an immediate charge to “other expense warrant liability loss net” in the amount of $343,079.

As of June 30, 2013, the Company accrued a dividend payable to the preferred shareholders in the amount of $93,361. On May 9, 2013 the Company executed an agreement with the Purchasers of the Series A-1 Preferred Shares to pay certain accrued dividends on the Series A-1 Preferred Stock in shares of the Company’s common stock in lieu of cash. In accordance with the agreement, on July 12, 2013, the Company issued 161,153 shares of common stock to the Purchasers of the Series A-1 Preferred Shares in payment of the accrued dividends payable at June 30, 2013, resulting in an increase in capital in the amount of $93,361. No dividends are accrued or payable subsequent to the payment of this dividend.

On August 1, 2013, the Company entered into an agreement with the holders of its Series A Warrants and Series C Warrants for such holders to exercise a portion of such Series C Warrants to acquire an aggregate of 1,666,666 shares of the Company’s common stock for a cash payment to the Company of $1,000,000 (“Warrant Exercise Agreement”). Prior to the Company and such holders of the Series A Warrants and the Series C Warrants entering into such Warrant Exercise Agreement, the Series A Warrants and the Series C Warrants could have been exercised by such holders on an entirely cashless basis. In exchange for the cash exercise of such portion of the Series C Warrants, the Company reduced the exercise price of all of the Series A Warrants and Series C Warrants from $0.72 to $0.60 per share. The reduced exercised price resulted in an increase in the warrant liability associated with the Series A Warrants and Series C Warrants and a corresponding reduction in capital in the amount of $626,328. In addition, if on a specified date in the future when the shares of common stock of the Company acquired upon this cash exercise of the Series C Warrants become freely tradable pursuant to Rule 144 of the Securities Act of 1933, as amended, the Company’s common stock (as measured by the five trading days before such date) is less than $1.31 per share (the “Measurement Price”), then the Company must reimburse the holders of these warrants up to an amount equal to the difference between $1.31 and the Measurement Price (subject to a floor of $0.60 per share) multiplied by the number of shares of common stock acquired upon the cash exercise of such Series C Warrants pursuant to the terms of the Warrant Exercise Agreement (the “Limited Market Make-Good Provision”). Notwithstanding the foregoing, the Company has no obligation to pay such amounts under the Limited Market Make-Good Provision until and unless the holders of the shares actually incur a loss on the sales of such shares of common stock for a price below the Measurement Price. The Limited Market Make-Good Provision created a contingent liability that must be evaluated and recorded based on its fair value at each reporting date. The maximum exposure related to this obligation is $1,183,333. Upon entering into this agreement, management estimated the fair value of the instrument and recorded a current liability and corresponding reduction in capital of approximately $290,000 as of September 30, 2013. At December 31, 2013, management estimated the fair value of the instrument to be zero primarily as a result of the increase in the underlying

value of the Company's common stock and the short period of time remaining to the date of the Measurement Price. Accordingly, the Company reversed the $290,000 current liability at December 31, 2013 that was established at September 30, 2013. The Series C Warrant holders exercised the cash option on August 5, 2013. The cash exercise of these Series C Warrant shares resulted in a reduction in the warrant liability and an increase in capital in the amount of $3,172,000. As a result of this Warrant Exercise Agreement, an additional $60,000 commission was paid to Chardan Capital Markets, LLC.

On August 6, 2013, the Series A and Series C Warrant holders exercised on a cashless basis at $0.60 per share 147,916 and 416,668 Series A and Series C Warrant shares, respectively, resulting in the issuance of 360,000 shares of common stock of the Company. The cashless exercise of these Series A and Series C Warrant shares resulted in a reduction in the warrant liability and an increase in capital in the amount of $1,074,670. On September 20, 2013, the Series A Warrant holders exercised on a cashless basis at $0.60 per share 339,861 Series A Warrants resulting in the issuance of 177,300 shares of common stock of the Company. This cashless exercise of these Series A Warrant shares resulted in a reduction in the warrant liability and an increase in capital in the amount of $608,419. Between October 3, 2013 and December 26, 2013, the Series A Warrant holder exercised on a cashless basis at $0.60 per share 3,678,889 Series A warrants resulting in the issuance of 1,972,976 shares of common stock of the Company. This cashless exercise of these Series A Warrant shares resulted in a reduction in the warrant liability and an increase in capital in the amount of $7,712,170.

In connection with the issuance of the Series A-1 Preferred Stock, the Company paid Chardan Capital Markets, LLC a commission equal to (i) ten percent (10%) of the cash received by the Company and (ii) 416,666 shares of common stock. In the event the Purchasers exercise for cash any of the Warrants, then the Company will also pay an additional cash commission to Chardan Capital Markets LLC equal to eight percent (8%) (with no additional equity) of any such additional cash amounts received by us. For the year ended December 31, 2013, the Company paid an aggregate total of $160,000 in commissions to Chardan Capital Markets, LLC in conjunction with the cash exercise of Series B and Series C Warrant shares, which has been reflected as a reduction of the equity proceeds.

In conjunction with the Series A-1 Preferred Stock private placement, the Company issued 203,167 lock-up warrants to stockholders that participated in previous private placements. These warrants were valued at $168,402 and are considered liabilities due to a down round provision. This amount was also considered a cost of the Series A-1 Preferred Stock private placement. After deducting fees and expenses, the aggregate net proceeds from the sale of the Series A-1 Preferred Shares and the Warrants were $2.035 million. The net proceeds were earmarked for the payment of certain financial obligations and for working capital and other general corporate purposes.

NOTE 4. - MAY and NOVEMBER 2012 PRIVATE PLACEMENT

On May 15, 2012 the Company issued 1,710,833 shares of its common stock and warrants to purchase up to 1,710,833 shares of its common stock for total consideration of $1,026,500 consisting of: $786,500 in cash, cancellation by a vendor of $150,000 in accounts payable and the exchange by an employee of his 4% minority interest in Goodrich Tobacco for stock and warrants valued at $90,000 in the offering. The warrants issued have an original exercise price of $1.00 per share, a five year term and a “down round provision,” which results in the warrants being classified and reported as derivative liabilities for accounting purposes, and marked to market at each balance sheet date. At the date of issuance of these warrants the value was estimated to be $1,841,000 which exceeded the total consideration received in the offering by $814,500 resulting in an immediate charge to other income and expense - warrant liability - net for this amount. This private placement constituted a “down round” for purposes of all previously issued warrants and the December 14, 2011 Convertible Notes and resulted in adjustments to the exercise price, conversion price and the number of shares issuable upon exercise or conversion of these previously issued securities. Three executive officers of the Company acquired 44,000 shares and warrants for $26,400 in cash.

On November 9, 2012 the Company issued 3,238,000 shares of its common stock and warrants to purchase up to 1,619,000 shares of its common stock for total consideration of $809,500 consisting of: $681,000 in cash, cancellation by vendors of $98,500 in accounts payable and cancellation of $30,000 in directors fees owed to two directors. The warrants issued have an original exercise price of $1.00 per share, a five year term and a “down round provision,” which results in the warrants being classified and reported as derivative liabilities for accounting purposes, and marked to market at each balance sheet date. At the date of issuance of these warrants the value was estimated to be $353,747 which reduced the amount recorded to additional paid in capital. This private placement constituted a “down round” for purposes of all previously issued warrants and the December 14, 2011 Convertible Notes and resulted in adjustments

to the exercise price, conversion price and the number of shares issuable upon exercise or conversion of these previously issued securities. Two executive officers of the Company acquired a total of 1,080,000 shares and 540,000 warrants for $270,000 in cash. Two directors of the Company acquired a total of 120,000 shares and 60,000 warrants in lieu of payment of $30,000 of director fees.

NOTE 5. MACHINERY AND EQUIPMENT

Machinery and equipment at December 31, 2013 and 2012 consists of the following:

	December 31, 2013	December 31, 2012
Cigarette manufacturing equipment	$ 3,220,000	$ -
Office furniture, fixtures and equipment	17,059	9,106
Leasehold improvements	14,500	-
Deposit for purchase of machine parts and other assets	210,000	-
	3,461,559	9,106
Less: cigarette manufacturing equipment held for resale	457,696	-
	3,003,863	9,106
Less: accumulated depreciation	6,103	3,076
Machinery and equipment, net	$ 2,997,760	$ 6,030

On December 11, 2013, the Company closed on a $3,220,000 purchase of certain cigarette manufacturing equipment from a company located in North Carolina that was liquidating under Chapter 7 of the U.S. Bankruptcy Code. A certain portion of the equipment will not be required for the Company's cigarette manufacturing operations and will be subsequently listed for sale in the first quarter of 2014 in order to offset the purchase price of the equipment. The Company allocated $457,696 of the purchase price to these assets and classified them as machinery and equipment held for resale in the current asset section of the balance sheet at December 31, 2013. The remaining cigarette manufacturing equipment, with a cost of $2,762,304, was not placed in service as of December 31, 2013, and accordingly, no depreciation was recorded.

In December 2013, the Company made a $210,000 deposit to the bankruptcy trustee of a company located in North Carolina that is liquidating under Chapter 11 of the U.S. Bankruptcy Code to purchase various cigarette manufacturing equipment parts, office furniture and fixtures, vehicles and computer software and equipment. On January 13, 2014, the transaction closed and the Company successfully purchased the subject assets for the amount of the $210,000 deposit.

NOTE 6. - DEMAND BANK LOAN

The demand loan that is among the Company's short term liabilities is payable to a commercial bank under a revolving credit agreement and is guaranteed by an executive officer of the Company. This loan had a balance of $174,925 at December 31, 2013 and 2012. The Company is required to pay interest monthly at an annual rate of 0.75% above the prime rate, or 4.00% at December 31, 2013 and 2012. The Company is current in meeting this interest payment obligation. The terms of the demand loan includes an annual "clean-up" provision, which requires the Company to repay all principal amounts outstanding for a period of 30 consecutive days every year. The Company has not complied with this requirement; however, the bank has not demanded payment. The bank has a lien on all the Company's assets.

NOTE 7. - NOTES PAYABLE

Notes payable consisted of the following as of the dates set forth below:

	December 31, 2013	December 31, 2012
Note dated March 31, 2011	$ -	$ 77,000
Note dated January 25, 2011	-	140,000
Note dated March 13, 2013 and March 30, 2011	-	350,000
Note dated March 22, 2012 and April 13, 2012	-	50,000
Note dated January 15, 2013	-	-
Note dated January 23, 2013	-	-
Note dated January 24, 2013	-	-
Note dated February 1, 2013	-	-
Notes payable	$ -	$ 617,000

Convertible Note Dated March 31, 2011 (unsecured) - On March 31, 2011, the Company issued a note to a vendor in the original amount of $237,000 as satisfaction of past due invoices previously recorded by the Company in accounts payable. The note bears interest at an annual rate of 9%. In December 2011 the note was amended and the principal was reduced by a cash payment of $50,000 and $100,000 of the notes was exchanged for $115,000 of a portion of the Convertible Notes issued December 14, 2011. The Company made a $10,000 principal payment in May 2012, leaving a remaining balance of $77,000 as of December 31, 2012. On January 18, 2013 the note was paid in full together with accrued interest.

Note Dated January 25, 2011 (unsecured) - On January 25, 2011, the Company issued a note for $140,000 to a shareholder as satisfaction of the balance due for principal and interest on a matured note that was not paid in cash or converted to common stock of 22nd Century Group and warrants to purchase shares of common stock of 22nd Century Group. The note bears interest at 12% and was due on October 1, 2013 together with accrued interest. In July 2013, the Company made a $30,000 payment that was applied to the accrued interest on the note. On October 2, 2013, the Company made a payment to the note holder in the amount of $155,153 in full satisfaction of the note and all accrued interest.

Note Dated March 13, 2013 and March 30, 2011 (unsecured) - On March 30, 2011, the Company issued a note to a vendor in the amount of $350,000 as satisfaction of past due invoices previously recorded by the Company in accounts payable. The note bears interest at an annual rate of 4%. Principal and accrued interest were due on July 1, 2012. As of December 31, 2012, the outstanding principal of $350,000 on this note remained unpaid. In January 2013, the Company repaid $268,286 of the note principal. The remaining unpaid balance of $81,714 plus accrued interest of $25,582 and outstanding accounts payable of $67,704 were refinanced into a new unsecured note with a principal balance of $175,000 dated March 13, 2013, which bears interest at 5% and matures on July 1, 2014 or sooner if the Company receives license revenue or financing of at least $1,500,000 prior to maturity. On October 11, 2013, the Company made a payment to the note holder in the amount of $181,233 in full satisfaction of the note and all accrued interest.

Note Dated March 22, 2012 and April 13, 2012 (secured) - On March 22, 2012 and April 13, 2012, the Company issued two notes in the amount of $25,000 each, originally due on October 1, 2012. The notes were secured by all assets of the Company and its subsidiaries. An officer of the Company is the managing member of the lender. The notes bear interest at an annual rate of 15%. The outstanding principal on this note as of December 31, 2012 was $50,000. Principal and accrued interest of both notes were paid in full by the Company on January 22, 2013.

***Note Dated January 15, 2013 (unsecured)* -** On January 15, 2013, the Company issued a note to a vendor in the amount of $226,780 as satisfaction of past due invoices previously recorded by the Company in accounts payable and accrued interest. The note bears interest at an annual rate of 8%. The outstanding principal and accrued interest was due on October 18, 2013 or sooner if the Company closes an in-licensing agreement in which the Company or a subsidiary receives an up-front payment of at least $1 million. On August 2, 2013, the Company made a $100,000 payment to the note holder that was applied against the note and accrued interest leaving the note principal balance at $136,671. On October 2, 2013, the Company made a payment to the note holder in the amount of $138,469 in full satisfaction of the note and all accrued interest.

***Note Dated January 23, 2013 (unsecured)* -** On January 23, 2013, the Company issued a $150,000 note to an executive officer of the Company. The note bears interest at an annual rate of 15%. The outstanding principal and accrued interest was due on October 1, 2013. On October 2, 2013, the Company made a payment to the note holder in the amount of $165,473 in full satisfaction of the note and all accrued interest.

***Note Dated January 24, 2013 (unsecured)* -** On January 24, 2013, the Company issued a note to a former Convertible Note holder in the amount of $58,340 to discharge $57,500 in Convertible Notes held by the lender plus accrued interest. The note bears interest at an annual rate of 15%. The outstanding principal and accrued interest was due on July 24, 2013. On July 16, 2013, the note was paid in full together with all accrued interest.

***Note Dated February 1, 2013 (unsecured)* -** On February 1, 2013, the Company issued a note to a vendor in the amount of $474,893 as satisfaction of past due invoices previously recorded by the Company in accounts payable. The note bears interest at an annual rate of 5%. The outstanding principal and accrued interest is due on October 1, 2013 or sooner if the Company closes an in-licensing agreement in which the Company or any affiliate receives an up-front payment of at least $1.5 million. On October 2, 2013, the Company made a payment to the note holder in the amount of $490,701 in full satisfaction of the note and all accrued interest.

NOTE 8. - CONVERTIBLE NOTES

ISSUED DECEMBER 14, 2011

The Company issued convertible notes on December 14, 2011 in a negotiated sale with 24 investors in the total face amount of $1,926,250 (“Convertible Notes”). The Convertible Notes were sold for $1,675,000 - an original issue discount of $251,250. The Convertible Notes did not bear interest and the total face amount was due December 14, 2012. The Convertible Notes could be converted, at the option of each holder, in whole or in part, into shares of the Company’s common stock at $0.75 per share at which time the holder shall also receive warrants equal to 120% of the number of shares of Company common stock into which such Convertible Notes have been then converted. The Company could also force the investors to decide whether to convert by sending a 15-day written notice in which each investor is forced to decide whether to convert or receive payment in full. Such warrants have a term of five years and an exercise price of $1.50 per share of common stock. The Convertible Notes contained “down round” provisions which provided for adjustments to the conversion price if the Company issues shares of common stock of 22nd Century Group at a price that is less than the exercise price. The conversion feature was not considered to be a derivative because it does not have a net cash settlement provision as a result of the limited market and trading activity for the underlying stock at this time.

The Company’s common stock closed at $0.90 per share on December 14, 2011, which is greater than the portion of the conversion price under the Convertible Notes allocated to the underlying common shares. This difference is a beneficial conversion feature (BCF) which was valued at $1,062,758 at the issue date and recorded as debt discount and additional paid in capital. This BCF was amortized over the one year life of the Convertible Notes.

Three of the Company’s executive officers at the time of issuance acquired a portion of the Convertible Notes - with a face value of $368,000, for cash of $105,000 and conversion of $215,000 short term unsecured 12% notes issued by the Company earlier in 2011.

As of December 31, 2012, the OID and BCF discounts were fully amortized, and therefore no amortization was recorded during the year ended December 31, 2013. During the year ended December 31, 2012, $1,284,363 of the debt discount was amortized and recorded as interest expense related to the OID and BCF discounts.

During the year ended December 31, 2012, a portion of the Convertible Notes with a face amount of $120,750 (carrying value at time of conversion of approximately $55,000, net of unamortized discount) were

converted into 161,494 shares of common stock and warrants to purchase 193,793 shares of common stock. As a result of the conversion, the unamortized portion of the debt discount amounting to approximately $66,000 was immediately charged to interest and a derivative warrant liability valued at approximately $152,000 was recorded. The difference in the warrant value and debt relieved amounting to approximately $31,000 was also charged to interest expense. Included in conversions of the Convertible Notes during the year ended December 31, 2012 was a note converted by an officer with a face amount of $86,250 converted into 115,000 shares of common stock and warrants to purchase 138,000 shares of common stock.

At December 31, 2012, Convertible Notes with a total face and carrying value of $1,805,500 remained outstanding; of this amount $1,523,750 were extended by agreement with the note holders to April 14, 2013 at 15% interest per annum. Two convertible note holders did not execute agreements to extend their notes. In connection with the issuance of the Series A-1 Preferred Stock in January 2013, the Convertible Note holders entered into lock-up agreements with the Company and received additional warrants (five year term at $1.50 exercise price) to purchase 219,909 shares of common stock, and have the same rights as the warrants in the original December 2011 Convertible Note agreement. The lock-up agreement restricted the Convertible Note holders' ability to sell any of the shares received as a result of the conversion of the Convertible Notes.

Of the $1,805,500 in convertible notes outstanding at December 31, 2012, $1,408,750 of the Convertible Notes (together with accrued interest) were converted into 2,035,720 shares of common stock and five-year warrants (which includes lock-up warrants) to purchase 2,662,769 shares of common stock at $1.50 per share during the period from January 1, 2013 to February 6, 2013. The Company discharged the remaining convertible notes of $396,750 by payments in cash of $339,250 and the Company refinanced $57,500 into a new note that was paid in full in July 2013. Of the Convertible Notes paid in cash, $247,250 was held by an executive officer. The executive officer subsequently issued the Company a new promissory note in the amount of $150,000 that matured on October 1, 2013 (see Note 7). None of the Convertible Notes issued on December 14, 2011 remain outstanding as of December 31, 2013.

ISSUED AUGUST 9, 2012

The Company issued convertible notes on August 9, 2012 in a negotiated sale with 4 investors in the total face amount of $222,600. The convertible notes were sold for $210,000 - an original issue discount (OID) of $12,600. The convertible notes did not bear interest and the total face amount was due August 9, 2013 together with warrants equal to 50% of the number of shares of Company common stock into which such convertible notes are converted. These warrants were valued at $92,750 and represent additional debt discount and warrant liability. The convertible notes can be converted, at the option of each holder, in whole or in part, into shares of the Company's common stock at $0.60 per share at which time the holder shall also receive warrants equal to 100% of the number of shares of Company common stock into which such convertible notes are converted. Additional warrants issued as a result of conversion will be valued and recorded as a warrant liability at that time and will reduce the equity recorded as a result of the conversion. In the event the warrant value exceeds the amount of equity, an immediate charge to other expense will be recorded. The warrants issued upon conversion or maturity will have a term of five years and an exercise price of $1.00 per share of common stock. The conversion feature was not considered to be a derivative because it does not have a net cash settlement provision as a result of the limited market and because of the trading activity for the underlying stock at the time. The warrants to be issued upon conversion or maturity have a "down round provision" and will be classified as derivatives for accounting purposes, and are reported as a liability and marked to market at each balance sheet date.

The Company's common stock closed at $0.45 per share on August 9, 2012, which is greater than the portion of the conversion price under the convertible notes allocated to the underlying common shares. This difference is a beneficial conversion feature (BCF) which was valued at $116,600 at the issue date and recorded as debt discount and additional paid in capital. This BCF is being amortized over the one year life of the convertible notes.

During the years ended December 31, 2013 and 2012, $134,296 and $87,654 of debt discount was amortized and recorded as interest expense related to the OID, warrant and BCF discounts, leaving no unamortized debt discount as of December 31, 2013.

During August 2013, all of the convertible notes issued on August 9, 2012 with a carrying value of $222,600 were converted into 371,000 shares of common stock and five-year warrants to purchase 371,000 shares of common stock at $1.00 per share.

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The warrants issued in conjunction with the note conversions during August 2013 were recorded at fair value at the time of issuance amounting to $731,662. Since the warrants are considered a derivate liability, the excess of the fair value of the warrants at the time of issuance above the face amount of the notes converted was immediately recorded as additional interest expense in the amount of $509,062.

The following table summarizes convertible notes and related discount.

	December 31, 2013	December 31, 2012
Face value of all convertible notes payable through maturity	$ -	$ 2,028,100
Less unamortized original issue discount	-	(63,787)
Less unamortized discount related to BCF	-	(70,509)
Convertible Notes, net of unamortized debt discount	$ -	$ 1,893,804
Carrying value of December 14, 2011 Convertible Notes	$ -	$ 1,805,500
Carrying value of August 9, 2012 Convertible Notes	$ -	$ 88,304

NOTE 9. - DUE FROM RELATED PARTY

The Company has conducted transactions with a related party, Alternative Cigarettes, Inc. (“AC”). AC is entirely owned by certain shareholders of the Company, including the CEO. AC shares office space and employee services with the Company. During the year ended December 31, 2011 the Company acquired its *MAGIC* trademark from AC for a purchase price of $22,500. During the years ended December 31, 2013 and 2012, transactions with AC consisted mainly of repayments and advances. The net amount due from AC amounted to $42,069 as of December 31, 2013 ($36,969 as of December 31, 2012). No interest has been accrued or paid on amount due from or to AC and there are no repayment terms.

NOTE 10. - WARRANT EXCHANGE PROGRAM AND WARRANTS FOR COMMON STOCK

WARRANT EXCHANGE PROGRAM

The Company had 19,616,308 warrants for common stock outstanding at September 30, 2013. These warrants contain “down round” provisions and anti-dilution features that provide for adjustments to the exercise price and number of warrants outstanding if the Company issues common shares of stock of 22nd Century Group at a price that is less than the respective warrant exercise prices. These provisions require that these warrants be classified as derivatives for accounting purposes, which means they are reported as a liability and adjusted to fair value at each balance sheet date. On November 14, 2013, the Company initiated a warrant exchange program (the “Warrant Exchange Program”) with the goal of reducing the Company’s warrant liability. To that end, the Company offered financial inducements to certain warrant holders to (1) exercise their warrant on a cash basis, (2) exercise their warrant on a cashless basis, or (3) agree to have the “down round provision” or anti-dilution feature removed from their warrant in exchange for additional warrant coverage. The warrants holders also had the option to maintain the terms and conditions of their original warrant. Management and the Company’s Board of Directors were prohibited from participating in the Warrant Exchange Program. As a result of the cash and cashless exercise of warrants, there is a reduced number of outstanding warrants, and as a result of the removal of the “down round” provisions and anti-dilution features on other warrants, they are no longer required to be classified as a derivative liability. The Warrant Exchange Program that ended on December 12, 2013, generated gross proceeds of $3,559,763 and resulted in the issuance of 5,348,172 shares of the Company’s common stock from the cash exercise of warrants. The issuance of 156,197 shares of the Company’s common stock resulted from the exercise of 513,949 warrants that were exercised on a cashless basis. As an inducement for warrant holders to agree to remove their “down round” provision and anti-dilutions feature from their

warrant, 138,666 additional warrants were issued. As a result of the Warrant Exchange Program, there are 6,732,088 warrants outstanding at December 31, 2013 that do not contain the "down round" provisions or anti-dilution features. The Company calculated the cost of inducement as the difference between the fair value of the warrants immediately after the Warrant Exchange Program was closed on December 12, 2013, less the fair value of the warrants immediately prior to Warrant Exchange Program completion. The Company estimated the total cost of inducement to be $3,736,313, and this expense has been recorded as an "Other Expense" on the consolidated statements of operations and as an increase to the derivative warrant liability, and subsequently reversed into capital. The Company paid $320,378 and issued 300,000 shares of the Company's common stock to Chardan Capital Markets, LLC ("Chardan") in conjunction with the Warrant Exchange Program. The fair value of the 300,000 shares issued to Chardan in the amount of $462,000 is included as a component of the total cost of inducement.

WARRANTS FOR COMMON SOCK

In connection with the January 25, 2011 Private Placement and reverse merger into a public company, the Company issued five year warrants ("January 25, 2011 Warrants") to purchase shares of common stock of 22nd Century Group. These warrants contain "down round" provisions and anti-dilution features which provide for adjustments to the exercise price if the Company issues common shares of stock of 22nd Century Group at a price that is less than the respective warrant exercise prices. This provision and features require these warrants be classified as derivatives for accounting purposes, which means they are reported as a liability and marked to market at each balance sheet date. As a result of the equity securities issued during 2012, the "down round" provision and anti-dilution feature of the January 25, 2011 Warrants were triggered and the adjusted warrants outstanding as of December 31, 2012 were 5,482,055 with an exercise price of $2.73 per share and 3,947,232 with an exercise price of $1.39 per share. As a result of equity securities issued during the year ended December 31, 2013, the cashless conversion of 1,160,080 warrants during the third quarter of 2013, and the effects of the Warrant Exchange Program, the January 25, 2011 Warrants now amount to 3,455,039 warrants with an exercise price of $2.21 per share, 3,062,665 warrants with an exercise price of $1.96 per share, 110,336 warrants with an exercise price of $1.20 per share and 374,007 warrants with an exercise price of $1.27 per share outstanding as of December 31, 2013. As a result of the Warrant Exchange Program, 3,437,072 of these warrants no longer contain the "down round" provision and anti-dilution feature. The warrants affected by the Warrant Exchange Program resulted in a reduction of the warrant liability and an increase in capital in the amount of $4,612,263 after inducement. The cashless exercise of the 1,160,080 warrants resulted in a reduction of the warrant liability and an increase in capital in the amount of $482,654.

During 2012, 193,200 warrants at an original exercise price of $1.50 were issued upon partial conversion of the December 14, 2011 Convertible Notes, which include "down round" provisions and resulted in a derivative liability upon issuance of approximately $152,000. Due to subsequent issuance of common stock and instruments convertible into common stock, and the effects of the Warrant Exchange Program, the number of warrants issuable and their exercise price has been adjusted. As of December 31, 2013, warrants issued during 2012 related to partial conversion of the December 14, 2011 Convertible Notes now amount to 180,047 warrants outstanding with an exercise price of $1.15 per share. These outstanding warrants have retained their "down round" provision and anti-dilution feature. The warrants affected by the Warrant Exchange Program resulted in a reduction of the warrant liability and an increase in capital in the amount of $158,919 after inducement.

Between January 2, 2013 and February 6, 2013 Convertible Notes issued on December 14, 2011 with a carrying value of $1,408,750 (together with accrued interest) were converted into 2,035,720 shares of common stock and five-year warrants to purchase 2,662,769 shares of common stock at $1.50 per share. The number of warrants issued upon conversion includes 219,909 lock-up warrants with the same rights as the December 14, 2011 Convertible Notes warrants. These warrants include a "down round" provision and resulted in a derivative liability upon conversion of $1,445,091. As a result of equity securities issued in 2013 and the effects of the Warrant Exchange Program there are now 802,215 warrants outstanding with an exercise price of $1.38 per share. As a result of the Warrant Exchange Program these warrants no longer contain their "down round" provision or anti-dilution feature. The warrants affected by the Warrant Exchange Program resulted in a reduction of the warrant liability and an increase in capital in the amount of $7,637,813 after inducement.

In May 2012, the Company issued 1,710,833 five-year warrants to purchase common stock in a private placement with an original exercise price of $1.00. These warrants contain a "down round" provision and anti-dilution feature and resulted in a derivative liability upon issuance of approximately $1,841,000. The Company issued 124,217 lock-up warrants to the holders of May 2012 private placement warrants with the same rights as the warrants originally issued. The exercise price of the May 2012 warrants and lock-up warrants was adjusted as a result of subsequent equity securities issued at a lower price than the original exercise price. As a result of the Warrant Exchange Program and the cash exercise of 275,000 warrants during the third quarter of 2013, there remains 974,201 warrants with an exercise price of $0.60 per share outstanding as of December 31, 2013. As a result of the Warrant Exchange Program these

warrants no longer contain their “down round” provision and anti-dilution feature. The $165,000 cash exercise of the 275,000 warrants resulted in a reduction of the warrant liability and an increase in capital in the amount of $421,817. The warrants affected by the Warrant Exchange Program resulted in a reduction of the warrant liability and an increase in capital in the amount of $3,013,587.

Convertible notes issued in August 2012 entitled the holders to at least 185,500 warrants and up to 371,000 warrants (five-year warrants with an exercise price of $1.00 per share), which resulted in a derivative liability of $92,750 recorded at the time the notes were issued. In connection with the conversion of the August 9, 2012 convertible notes during August 2013, the Company issued 371,000 five-year warrants with an exercise price of $1.00 per share. These warrants include a “down round” provision and resulted in a derivative liability upon conversion of $731,662. As a result of equity securities issued in 2013 and the effects of the Warrant Exchange Program, there are now 184,047 warrants outstanding with exercise prices of $0.96. These outstanding warrants have retained their “down round” provision and anti-dilution feature. The warrants affected by the Warrant Exchange Program resulted in a reduction of the warrant liability and an increase in capital in the amount of $555,165 after inducement.

In November 2012, the Company issued 1,619,000 five-year warrants to purchase common stock in a private placement with an original exercise price of $1.00. These warrants contain “down round” provision and anti-dilution feature and resulted in a derivative liability upon issuance of $353,747. The Company issued 53,950 lock-up warrants to the holders of November 2012 private placement warrants with the same rights as the warrants originally issued. The exercise price of the November 2012 warrants and lock-up warrants was adjusted as a result of subsequent equity securities issued at a lower price than the original exercise price. As a result of the Warrant Exchange Program and the cashless exercise of 63,000 warrants in the third quarter of 2013, 1,518,600 warrants with an exercise price of $0.60 per share remain outstanding as of December 31, 2013. As a result of the Warrant Exchange Program these warrants no longer contain their “down round” provision and anti-dilution feature. The cashless exercise of the 63,000 warrants resulted in a reduction of the warrant liability and an increase in capital in the amount of $111,468. The warrants affected by the Warrant Exchange Program resulted in a reduction of the warrant liability and an increase in capital in the amount of $3,661,718.

The Company issued 6,250,000 warrants to purchase common stock in the January 2013 Series A-1 Preferred Stock private placement, including 4,166,666 Series A Warrants, which are five-year warrants with an exercise price of $0.72 per share and 2,083,334 Series B Warrants, which are one-year warrants with an exercise price of $0.60 per share. These warrants include a “down round” provision and an anti-dilution feature and resulted in a derivative liability upon issuance. The fair value of the Series A Warrants, Series B Warrants and the lock-up warrants issued to the May and November 2012 private placement warrant holders in conjunction with the January 2013 Series A-1 Preferred Stock private placement amounted to $6,022,319. Further, 2,083,334 Series C Warrants are issuable upon exercise of the Series B Warrants. During June and July of 2013, 982,300 and 1,101,034 Series B Warrants, respectively, were exercised on a cash basis. The exercise of these Series B Warrants triggered the issuance of a like amount of Series C Warrants totaling 2,083,334 Series C Warrants. The Series C Warrant shares outstanding are exercisable at $0.72 and include a “down round” provision, which results in a derivative liability upon issuance. The fair value of the 982,300 Series C Warrant shares issued in June 2013, and the fair value of the 1,101,034 Series C Warrants issued in July 2013, amounted to $711,675 and $1,622,069, respectively. On August 1, 2013, the Company entered into a Warrant Exercise Agreement (see Note 3 for a more detailed description of the Agreement) with holders of its Series A Warrants and Series C Warrants for such holders to exercise a portion of such Series C Warrants to acquire an aggregate of 1,666,666 shares of the Company’s common stock for a cash payment to the Company of $1,000,000. In exchange for the cash exercise of such portion of the Series C Warrants, the Company reduced the exercise price of all of the Series A Warrants and Series C Warrants to $0.60 per share. The reduced exercised price resulted in an increase in the warrant liability associated with the Series A Warrants and Series C Warrants and a corresponding reduction in capital in the amount of $626,328. The Series C Warrant holders exercised the cash option on August 5, 2013. In addition, between August and December 2013, the Series A and Series C Warrant holders exercised on a cashless basis at $0.60 per share 4,166,666 and 416,668 Series A and Series C Warrants, respectively. There are no Series A Warrants, Series B Warrants or Series C Warrants outstanding at December 31, 2013.

The Company estimates the value of warrant liability upon issuance of the warrants and at each balance sheet date using the binomial lattice model to allocate total enterprise value to the warrants and other securities in the Company’s capital structure. Volatility was estimated based on historical observed equity volatilities and implied (forward) or

expected volatilities for a sample group of guideline companies and consideration of recent market trends. The following table is a roll-forward summary of the warrant liability:

Fair value at December 31, 2011	$ 550,000
Fair value of warrant liability upon partial conversion of December 14, 2011 Notes	152,100
Fair value of warrant liability upon issuance May 15, 2012	1,841,000
Fair value of warrant liability related to minimum warrants issuable upon maturity of August 9, 2012 convertible notes	92,750
Fair value of warrant liability upon issuance November 9, 2012	353,747
Loss as a result of change in fair value	1,183,543
Fair value at December 31, 2012	$ 4,173,140
Fair value of warrant liability upon conversion of remaining December 14, 2011 Notes - Q1 2013	1,445,091
Fair value of warrant liability upon issuance Q1 2013	6,022,319
Fair value of warrant liability upon issuance Q2 2013	711,675
Fair value of warrant liability upon issuance Q3 2013	1,622,069
Fair value of warrant liability upon conversion of August 9, 2012 Notes - Q3 2013	731,662
Fair value of warrant liability upon reduction of exercise price of Series A and Series C warrants Q3 2013	626,328
Reclassification of warrant liability to equity upon exercise of warrants Q2 2013	(204,513)
Reclassification of warrant liability to equity upon exercise of warrants Q3 2013	(6,542,904)
Reclassification of warrant liability to equity upon exercise of warrants Q4 2013	(7,712,170)
Cost of inducement from Warrant Exchange Program Q4 2013	3,274,313
Reclassification of warrant liability to equity resulting from Warrant Exchange Program Q4 2013	(19,639,465)
Loss as a result of change in fair value	19,271,977
Fair value at December 31, 2013	$ 3,779,522

The aggregate net loss as a result of the Company's warrant liability for the year ended December 31, 2013 amounted to $19,271,977 which is included in other income (expenses) as part of "warrant liability loss - net" in the accompanying consolidated statements of operations. The loss for the year ended December 31, 2013, also includes a charge to other income (expense) in the amount of $4,330,734, as a result of (i) warrant liabilities issued in connection with the Series A-1 Preferred Stock in excess of net proceeds raised in the amount of $3,987,655 in January 2013, and (ii) warrant liabilities issued in connection with the July 2013 issuance of 1,101,034 Series C Warrants in excess of the sum of the net proceeds received upon exercise and the reclassification of the warrant liability to capital, in the amount of $343,079. Warrant liabilities issued in connection with the December 14, 2011 Convertible Notes and the August 9, 2012 convertible notes converted to common stock in excess of the conversion amount by $17,386 and $509,062, respectively, were recorded as additional interest expense.

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

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.
- Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value.

A financial asset's or 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.

The following table summarizes the warrant activity since December 31, 2011:

	Number of Warrants
Warrants outstanding at December 31, 2011	8,668,701
Warrants issued	3,523,033
Additional warrants due to anti-dilution provisions	780,930
Warrants exercised during 2012	-
Warrants outstanding at December 31, 2012	12,972,664
Warrants issued	11,570,274
Warrants issued as part of Warrant Exchange Program	138,666
Additional warrants due to anti-dilution provisions	1,665,400
Warrants exercised during 2013	(9,831,414)
Warrants exercised as part of Warrant Exchange Program	(5,862,121)
Warrants outstanding at December 31, 2013	10,653,469
Composition of outstanding warrants:	
Warrants containing anti-dilution feature	3,921,381
Warrants with anti-dilution feature removed	6,732,088
	10,653,469

NOTE 11. - RETIREMENT PLAN

The Company sponsors a defined contribution plan under IRC Section 401(k). The plan covers all employees who meet the minimum eligibility requirements. Under the 401(k) plan eligible employees are allowed to made voluntary deferred salary contribution to the plan, subject to statutory limits. The Company has elected to make Safe Harbor Non-elective Contributions to the plan for eligible employees in the amount of three percent (3%) of the employee's compensation. Total employer contributions to the plan, including a contribution made for 2012 in the first quarter of 2013, amounted to $34,873 for the year ended December 31, 2013. There were no employer contributions to the plan for the year ended December 31, 2012.

NOTE 12. - COMMITMENTS

License Agreements - Under its exclusive license agreement with North Carolina State University ("NCSU"), the Company is required to pay minimum annual royalty payments, which are credited against running royalties on sales of licensed products. The annual minimum royalty for 2013 is $75,000, and in 2016 the annual minimum royalty increases to $225,000. The license agreement continues through the life of the last-to-expire patent, which is expected to be 2022. The agreement also requires a milestone payment of $150,000 upon FDA approval or clearance of a product that uses the NCSU licensed technology. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. These costs vary from year to year and the Company has certain rights to direct the activities that result in these costs. During the year ended December 31, 2013, the costs incurred related to patent costs and patent maintenance amounted to $101,902 ($104,558 during the year ended December 31, 2012).

The Company has two other exclusive license agreements which require aggregate annual license fees of approximately $75,000, which are credited against running royalties on sales of licensed products. Each license agreement continues through the life of the last-to-expire patent.

Membership Interest Purchase Agreement On September 17, 2013, the Company entered into a Membership Interest Purchase Agreement ("Purchase Agreement") to purchase all of the issued and outstanding membership interests of NASCO Products, LLC, ("NASCO"), a North Carolina limited liability company (the "NASCO

Transaction"). NASCO is a federally licensed tobacco product manufacturer and a participating member of the Tobacco Master Settlement Agreement known as the MSA, an agreement among 46 U.S. states and the tobacco industry administered by the National Association of Attorneys General ("NAAG").

The initial purchase price for the NASCO Transaction is One Million Dollars ($1,000,000) (the "Purchase Price"), subject to potential closing date adjustments for any unpaid liabilities of NASCO. The Purchase Price will be paid as follows: (i) a cash payment of Two Hundred Thousand ($200,000) and (ii) the issuance of Eight Hundred Thousand Dollars ($800,000) in value of unregistered shares of common stock of the Company based on the average of the five (5) day closing price of the Company's common shares on the OTCBB for the five (5) trading days immediately preceding the closing date. In no event shall the number of common shares issued by the Company to NASCO be less than 640,000 or greater than 1,066,667.

The Purchase Agreement contains customary representatives, warranties, covenants and indemnities. Consummation of the NASCO Transaction is subject to various conditions, including receipt of material third party consents and approvals and other customary closing conditions, including required consents from NAAG and certain attorneys general of the settling states of the MSA. NAAG has been discussing the NASCO Transaction with a small working group of settling states of the MSA in which the Company has answered various rounds of questions from. The working group has presented the matter to all the settling states with a recommended course of action which is being evaluated by the settling states. Upon the entry of a revised adherence agreement of NASCO Products, LLC reflecting the NASCO Transaction, the Company believes it will be able to close the NASCO Transaction. The Purchase Agreement contains termination rights, including a right for the Company to terminate the Purchase Agreement, solely up to the Company's discretion, if the closing shall not have occurred on or before January 31, 2014. The Purchase Agreement also contemplates that the Company will enter into a management agreement and sales representation agreement at closing with an affiliate of NASCO.

Lease Agreements - On October 9, 2013, the Company executed a guaranty that guarantees performance by NASCO of its obligations to the landlord under a certain triple net lease of the same date between NASCO and the landlord for a warehouse and cigarette manufacturing facility located in North Carolina. Should the Purchase Agreement close as discussed earlier, NASCO will become a wholly owned subsidiary of the Company, making the lease a direct obligation of the Company. The lease commenced on January 14, 2014, and has an initial term of twelve (12) months (the "Initial Term"). The lease contains four (4) additional extensions; one for an additional one (1) year and three for an additional two (2) years in duration, exercisable at the option of NASCO. The lease also contains an early termination clause that provides NASCO with the right to terminate the lease at any time during the first nine (9) month of the Initial Term by giving ninety (90) days prior written notice to the landlord. The lease calls for minimum lease payments of $96,000, $123,000, $298,275, $338,250 and $338,250 during the Initial Term, the one (1) year optional extension, and each of the three (3), two (2) year optional extensions, respectively. These commitments are not included in the schedule below.

The Company entered into a three year lease for office space in Clarence, New York, which commenced September 1, 2011. On January 25, 2013, the Company entered into a two and a half year lease for manufacturing space in Depew, New York, which commenced February 1, 2013. Scheduled rent commitments remaining as of December 31, 2013 are approximately as follows:

2014	$ 45,000
2015	$ 10,000

Limited Market Make-Good Provision The Company has a contingent obligation to make whole, through a cash payment, shareholders who exercised the Series C Warrants on August 1, 2013, if the holders incur a loss on the sale of common stock received. (See Note 3 for a detailed discussion).

NOTE 13. - EARNINGS PER COMMON SHARE

The following table sets forth the computation of basic and diluted earnings per common share for the year ended December 31, 2013 and 2012:

	December 31, 2013	December 31, 2012
Net loss attributed to common shareholders	$ (26,153,158)	$ (6,735,281)
Denominator for basic earnings per share-weighted average shares outstanding	43,635,182	30,419,556
Effect of dilutive securities:		
Warrants, restricted stock and options outstanding	-	-
Denominator for diluted earnings per common share - weighted average shares adjusted for dilutive securities	43,635,182	30,419,556
Loss per common share - basic	$ (0.60)	$ (0.22)
Loss per common share- diluted	$ (0.60)	$ (0.22)

Securities outstanding that were excluded from the computation of earnings per share for the year ended December 31, 2013 and 2012 because they would have been anti-dilutive are as follows:

	December 31, 2013	December 31, 2012
Warrants	10,653,469	12,972,664
Convertible Debt Issued December 14, 2011 (number of shares including related warrants upon conversion of 3,061,034)	-	4,706,782
Convertible Debt Issued August 9, 2012 (number of shares including related warrants upon conversion of 371,000)	-	742,000
Restricted Stock	500,000	550,000
Options	660,000	465,000
	11,813,469	19,436,446

NOTE 14. - STOCK BASED COMPENSATION

On October 21, 2010, the Company established the 2010 Equity Incentive Plan (“EIP”) for officers, employees, directors, consultants and advisors to the Company and its affiliates, consisting of 4,250,000 shares of common stock. The EIP has a term of ten years and is administered by our Board of Directors (“Board”) or a committee to be established by our Board (the “Administrator”), 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 EIP. On March 30, 2011, the Company filed a Form S-8 registration statement with the SEC to register all of the shares of common stock of 22nd Century Group that it may issue under the EIP.

For year ended December 31, 2013, the Company recorded compensation expense related to restricted stock and stock option awards granted under the EIP of $998,214 ($732,209 for the year ended December 31, 2012). The Company

also recorded stock based compensation for the year ended December 31, 2013, through the issuance of 1,780,000 shares of the Company's common stock, as payment to third parties for services rendered in the amount of $1,363,748 ($521,962 for the year ended December 31, 2012).

During the year ended December 31, 2013, the Company issued restricted stock awards from the EIP for 890,000 restricted shares to employees and directors that vested immediately on February 25, 2013 and for 100,000 restricted shares that will vest one year from the April 1, 2013 grant date. Further, 150,000 shares of a restricted stock award previously granted from the EIP vested during the period. All awards were valued at the closing price on the measurement date of the award.

As of December 31, 2013, unrecognized compensation expense related to non-vested restricted shares and stock options amounted to approximately $100,000, which is expected to be recognized over the next two years.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were used for the years ended December 31, 2013 and 2012:

	2013		2012	
Risk-free interest rate	1.89	%	1.71	%
Expected dividend yield	0	%	0	%
Expected stock price volatility	90	%	90	%
Expected life of options	10 years		10 years	

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

A summary of all stock option activity since December 31, 2011 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2011	35,000	$ 1.20		
Granted in 2012	455,000	$ 0.65		
Forfeited in 2012	(25,000)	$ 0.69		
Outstanding at December 31, 2012	465,000	$ 0.69		
Granted in 2013	215,000	$ 0.80		
Exercised in 2013	(20,000)	$ 0.26		
Outstanding at December 31, 2013	660,000	$ 0.74	8.6 years	$ 923,500
Exercisable at December 31, 2013	660,000	$ 0.74	8.6 years	$ 923,500

The weighted average grant date fair value of options issued in 2013 was $0.68 ($0.56 2012). The total fair value of option that vested during 2013 amounted to $186,959 ($242,160 2011). During the year ended December 31, 2013, 20,000 options were exercised for cash proceeds of $5,200. No options were exercised during the year ended December 31, 2012.

NOTE 15. - INCOME TAXES

The following is a summary of the components giving rise to the income tax provision (benefit) for the years ended December 31, 2013 and 2012.

The provision (benefit) for income taxes consists of the following:

	2013	2012

Current:		
Federal	$ -	$ -
State	-	-
Total current	-	-
Deferred:		
Federal	829,306	(1,370,382)
State	186,414	(308,039)
Total deferred	1,015,720	(1,678,421)
Change in valuation allowance	(1,015,720)	1,678,421
	$ -	$ -

The provision (benefit) for income tax varies from that which would be expected based on applying the statutory federal rate to pre-tax accounting loss as follows:

	2013		2012	
Statutory federal rate	(34.0)	%	(34.0)	%
Permanent items	1.8		2.0	
Derivative liability	35.5		10.1	
State tax provision, net of federal benefit	0.5		(3.0)	
Valuation allowance	(3.9)		24.9	
Effective tax rate (benefit) provision	0.0	%	0.0	%

Individual components of deferred taxes consist of the following:

	2013	2012
Deferred tax assets:		
Net operating loss carry-forward	$ 2,616,624	$ 3,694,817
Derivative liability	21,725	21,725
Inventory reserve	19,584	69,120
Stock-based compensation	131,450	-
Other	1,292	967
	2,790,675	3,776,629
Deferred tax liabilities:		
Inventory	(52,445)	-
Fixed assets	(2,956)	(2,333)
Patents and trademarks	(523,157)	(490,882)
Stock-based compensation	-	(28,300)
Beneficial conversion feature of convertible debt	-	(27,277)
	(578,558)	(548,792)
Valuation allowance	(2,212,117)	(3,227,837)
Net deferred taxes	$ -	$ -

The Company has incurred a net operating loss of approximately $6,800,000 through December 31, 2013 and this amount is being carried forward to future years and expires in 2031 and 2032. Due to the uncertainty of the Company's ability to generate sufficient taxable income in the future before they expire, the company has recorded a valuation allowance to reduce the net deferred tax asset to zero. This NOL is included in the net deferred tax asset that has been fully offset by the valuation allowance.

ASC 740 provides guidance on the financial statement recognition and measurement for uncertain income tax positions that are taken or expected to be taken in a company's income tax return. The Company has no uncertain tax positions as of December 31, 2013.

The Company's federal and state tax returns for the years ended September 30, 2011 to December 31, 2012 are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2013.

NOTE 16. - SUBSEQUENT EVENTS

Effective January 27, 2014, the Company’s board of directors awarded officers, employees and directors an aggregate of 850,000 restricted shares that vest one year from the effective date.

Item 15 (b) Exhibits

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

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;
- may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

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

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization dated as of January 25, 2011 by and among the Company, 22nd Century, and Acquisition Sub (incorporated herein by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K for the year ended September 30, 2010 filed with the Commission on December 3, 2010).
3.2*	Amended and Restated Bylaws of the Company.
4.1	Form of Warrant dated as of January 25, 2011 issued to LLC members of 22nd Century prior to the consummation of the Private Placement Offering upon consummation of the Merger (incorporated herein by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
4.2	Form of Warrant dated as of January 25, 2011 issued to investors in the Private Placement Offering upon consummation of the Merger (Incorporated herein by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
4.3	Form of Warrant dated as of January 25, 2011 issued to the Placement Agent and Sub-Agent upon consummation of the Merger (incorporated herein by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
4.4	

Advisor Warrant dated as of January 25, 2011 issued to the Placement Agent in connection with that certain Advisory Agreement dated as of January 25, 2011 by and between the Company and the Placement Agent (incorporated herein by reference to Exhibit 10.7 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).

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4.5	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the Commission on December 14, 2011).
4.6	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Commission on May 18, 2012).
4.7	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Commission on November 13, 2012).
10.1	2010 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.3 to the Company's Form S-8 filed with the SEC on March 30, 2011).
10.2	Employment Agreement dated as of January 25, 2011 by and between the Company and Joseph Pandolfino (incorporated herein by reference to Exhibit 10.15 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.3	Employment Agreement dated as of January 25, 2011 by and between the Company and Henry Sicignano III (incorporated herein by reference to Exhibit 10.16 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.4	Employment Agreement dated as of March 15, 2011 by and between the Company and Michael R. Moynihan (incorporated by reference to Exhibit 10.18 to the Company's Form S-1 registration statement filed with the Commission on June 6, 2011).
10.5	License Agreement dated March 6, 2009 between North Carolina State University and 22nd Century Limited, LLC (incorporated by reference to Exhibit 10.21 to the Company's Form S-1 registration statement filed with the Commission on August 26, 2011).
10.5.1	Amendment dated August 9, 2012 to License Agreement dated March 6, 2009 between North Carolina State University and 22nd Century Limited, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on August 20, 2012).
10.6	License Agreement dated May 1, 2009 between The National Research Council of Canada and 22nd Century Limited, LLC (incorporated by reference to Exhibit 10.22 to the Company's Form S-1 registration statement filed with the Commission on August 26, 2011).
10.7	Letter Agreement between the Company and NCSU dated November 22, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the Commission on November 23, 2011).
10.8	Employment Agreement between John Brodfuehrer and the Company dated March 19, 2013 (incorporated by reference to Form 8-K filed on March 25, 2013).
10.9	Form of Restricted Stock Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).
10.10	Form of Stock Option Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).
10.11	

		Agreement dated August 1, 2013 between the Company and the holders of the Company's Series A and C Warrants (incorporated by reference to Form 10-Q filed on August 5, 2013).
10.12	*	Research License and Commercial Option Agreement with British American Tobacco (Investments) Limited dated October 1, 2013.
10.13		Membership Interest Purchase Agreement between 22nd Century Group, Inc. and Ralph Angiuoli dated September 17, 2013 (incorporated by reference to Form 8-K filed on September 17, 2013).

21.1*	Subsidiaries
23.1*	Consent of Freed Maxick CPAs, P.C.
31.1*	CEO Certification
31.2*	CFO Certification
32.1*	Written Statement of CEO and CFO pursuant to 18.U.S.C §1350
101*	Interactive data files formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, and (iv) the Notes to the Consolidated Financial Statements.
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

*Filed herewith.

Management contract or compensatory plan, contract or arrangement.

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

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

SIGNATURES

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

22nd Century Group, INC.

Date:	January 30, 2014	By:	/s/ Joseph Pandolfino Joseph Pandolfino Chief Executive Officer and Director (Principal Executive Officer)
Date:	January 30, 2014	By:	/s/ John T. Brodfuehrer John T. Brodfuehrer Chief Financial Officer (Principal Accounting and Financial Officer)

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

Date:	January 30, 2014	By:	/s/ Joseph Pandolfino Joseph Pandolfino Chief Executive Officer and Director
Date:	January 30, 2014	By:	/s/ Henry Sicignano III Henry Sicignano III President, Secretary and Director
Date:	January 30, 2014	By:	/s/ Joseph Alexander Dunn, Ph.D. Joseph Alexander Dunn, Ph.D. Director
Date:	January 30, 2014	By:	/s/ James W. Cornell James W. Cornell Director
Date:	January 30, 2014	By:	/s/ Richard M. Sanders Richard M. Sanders Director