22nd Century Group, Inc.
Form 10-K
April 16, 2012

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, 2011

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 30, 2011, the last business day of the registrant's most recently computed second fiscal quarter, the aggregate value of the registrant's common stock (excluding shares held by affiliates), based upon the price at which such common stock was last sold on June 30, 2011, was approximately $12,727,846.

As of April 9, 2012, there were 29,049,646 shares of Common Stock of 22nd Century Group, Inc. outstanding.

22nd Century Group, Inc.

Table of Contents

Cautionary Note Regarding Forward-Looking Statements

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

- Our ability to raise capital in order to continue as a going concern;
- Our ability to achieve profitability;
- Our ability to manage our growth effectively;
- Our ability to obtain FDA and foreign regulatory approval for our *X-22* smoking cessation product and our Modified Risk Cigarettes;
- 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;
- Our ability to comply with existing and new government regulations;
- Our ability to retain key personnel;
- The potential exposure to product liability claims, product recalls and other claims;
- The potential for our clinical trials to produce negative or inconclusive results;
- Our ability to adequately protect our intellectual property and to avoid infringement on rights of third parties; and
- Our ability to maintain our rights to our intellectual property licenses.

For the discussion of these risks and uncertainties 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 22nd Century Limited, LLC, a Delaware limited liability company, as its wholly-owned subsidiary, taken as a whole, and also refer to the operations of 22nd Century Limited, LLC prior to the closing of the merger on January 25, 2011, as described below.

3

PART I

Item 1. Business.

Background

On January 25, 2011, 22nd Century Group, Inc., a Nevada corporation (the "Parent"), entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") by and among Parent, 22nd Century Limited, LLC, a privately held Delaware limited liability company ("22nd Century Ltd"), and 22nd Century Acquisition Subsidiary, a newly formed, wholly-owned Delaware limited liability company subsidiary of Parent ("Acquisition Sub"). Upon the closing of the merger transaction contemplated under the Merger Agreement (the "Merger"), Acquisition Sub was merged with and into 22nd Century Ltd, and 22nd Century Ltd, as the surviving entity, became a wholly-owned subsidiary of Parent. Just prior to the closing of the Merger, 22nd Century Ltd completed a private placement offering (the "Private Placement Offering") of 5,434,446 securities (the "PPO Securities") at the purchase price of $1.00 per PPO Security, each such PPO Security consisting of one (1) limited liability company membership interest unit (a "Unit") and a five year warrant to purchase one-half of one (1/2) Unit at an exercise price of $1.50 per whole Unit.

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

22nd Century Group, Inc. was incorporated under the laws of the State of Nevada on September 12, 2005 and was a development stage since company its inception that had minimal business operations prior to the Merger. After the Merger, we succeeded to the business of 22nd Century Ltd as our sole line of business.

Overview

22nd Century Ltd, our wholly-owned subsidiary, is a plant biotechnology company and we believe the global leader in technology that allows for the level of nicotine and other nicotinic alkaloids (e.g., nornicotine, anatabine and anabasine) in tobacco plants to be decreased or increased through genetic engineering and plant breeding. We own or exclusively control 101 issued patents in 78 countries where at least 75% of the world's smokers reside. Hercules Pharmaceuticals, LLC and Goodrich Tobacco Company, LLC are subsidiaries of 22nd Century Ltd and are business units for our (i) smoking cessation product and (ii) premium cigarettes and modified risk tobacco products, respectively. We believe that our proprietary technology will enable us to capture a significant share of the global

market for approved smoking cessation aids and the emerging market for modified risk tobacco products.

Our Investigational New Drug Application for *X-22*, a kit of very low nicotine (VLN) cigarettes, was cleared by the FDA in July 2011. 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. In evaluating the results of this trial, we believe we may have gone too far in reducing the nicotine content of *X-22*, which was less than half the nicotine content of VLN cigarettes used in various independent clinical trials that were successful. We continue to believe that VLN cigarettes are effective as a smoking cessation aid. However, we have suspended sponsoring further *X-22* clinical trials pending the results of two independent smoking-cessation Phase II trials utilizing a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than the those used in our own sponsored Phase II-B trial. One of these trials recently concluded and the other trial is expected to conclude in the second quarter of 2012. These results will be compared to our Phase II-B trial to determine which variables optimize cessation. At that time we may resume our own sponsored *X-22* clinical trials.

The *X-22* therapy protocol allows the patient to smoke our VLN cigarettes without restriction over the 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 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. We believe *X-22* will be more attractive to smokers than other therapies since it smokes and tastes like a typical cigarette, involves the same smoking behavior, and does not expose the smoker to any new drugs or new side effects.

In contrast to the results of the Company's Phase II-B trial results, independent studies have demonstrated that VLN cigarettes made from our proprietary VLN tobacco are at least as effective as FDA-approved smoking cessation aids. Due to the limited effectiveness and/or serious side effects of existing FDA-approved smoking cessation products, we believe that we are well positioned to capture a significant share of this market. Since *X-22* is the only smoking cessation product that functions exactly like a regular cigarette, we believe it will not only take sales and market share from existing smoking cessation products, but it will also expand the smoking cessation market by encouraging more smokers to attempt to quit smoking.

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 flavored tobacco (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 modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco toxins and (ii) are reasonably likely to pose lower health risks as compared to conventional cigarettes ("Modified Risk Cigarettes"). The Tobacco Control Act requires the FDA to issue specific regulations or 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 two types of our cigarettes in development, which we refer to as *BRAND A* and *BRAND B*, will qualify as Modified Risk Cigarettes. Compared to other 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 the lowest amount of "tar" per milligram of nicotine.

Within our two product categories, 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 *X-22* will qualify for "Fast Track" designation by the FDA.

Modified Risk Cigarettes

We intend to seek FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes. We believe that *BRAND A* and *BRAND B* will achieve significant market share in the global cigarette market among smokers who will not quit but are interested in reducing the harmful effects of smoking. We believe this new regulatory environment represents a paradigm shift for the tobacco industry. The Tobacco Control Act allows the FDA to mandate the use of reduced-risk technologies across all conventional tobacco products or cigarettes. We expect this to create opportunities for us to license our proprietary technology and/or tobaccos to larger competitors.

RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco Company, LLC ("Goodrich Tobacco"), has 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 the second half of 2012, 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 flavored cigarettes (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 carry our brands, among other reasons, to increase their margins.

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. In 2009, 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 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. The Company has delivered approximately 9 million cigarettes during the year ended December 31, 2011. These government research cigarettes are distributed under the mark *SPECTRUM*.

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 (resinous) 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 of low-tar research cigarettes, similar to *BRAND B*, is greatly curtailed resulting in smokers inhaling less "tar" and carbon monoxide.

Market

Cigarettes and Smoking Cessation Aids

The U.S. cigarette market consists of 45 million adult smokers who spent approximately $80 billion in 2010 on 310 billion cigarettes. The World Health Organization, or WHO, predicts that the current 1.3 billion smokers worldwide will increase to 1.7 billion smokers by the year 2025. Worldwide manufacturer sales in 2010 were over 5.0 trillion cigarettes, resulting in annual retail sales of approximately $600 billion. Our products address unmet needs of smokers; for those who want to quit, an innovative smoking cessation aid, and for those who do not quit, cigarettes that can reduce the level of exposure to tobacco toxins.

In 2010, annual sales of smoking cessation aids in the U.S., all of which must be approved by the FDA, were approximately $1.0 billion. Outside the United States, the smoking cessation market is in its infancy. Visiongain estimates the 2008 global smoking cessation market at approximately $3.0 billion. According to Datamonitor, the prescription smoking cessation market in the United States, Germany, United Kingdom, France, Italy, Spain and Japan is expected to grow at a compound annual rate of 16%, reaching approximately $4.6 billion by 2016. This figure does not consider China, Russia, Brazil, India and other large smoking markets.

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 only 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. Nicotine gums, nicotine patches, and lozenges are available over-the-counter.

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 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 warning, worldwide sales of Chantix® in 2011 were $720 million.

Other than Chantix® and Zyban®, the only FDA-approved smoking cessation therapy in the United States is 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 27 years and 19 years, respectively, and millions of smokers have 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, sales of NRT products in the United States have averaged approximately $500 million annually from 2007 to 2010.

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' equate to 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 agency or body had the regulatory authority to set standards for what constitutes reduced exposure or risk to smokers.

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. Vector Tobacco Inc., or Vector Tobacco, our former licensee, has marketed a cigarette offered in three brand styles with reduced levels of nicotine, called Quest®. Both Accord® and Eclipse®, which are not conventional cigarettes (e.g., they do not burn down), have only achieved limited sales. With the exception of Eclipse®, the above products are no longer being manufactured.

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 and dissolvable tobacco products such as Ariva® and Stonewall® tablets made by Star Scientific Inc., and Camel® Orbs, Camel® Strips and Camel® Sticks recently introduced by R.J. Reynolds Tobacco Company. 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 gum and nicotine lozenges, which have been available over-the-counter in the United States for 16 years and 8 years, respectively, and have not significantly replaced cigarettes.

Products

X-22 Smoking Cessation Aid

X-22 is a tobacco-based botanical medical product for use as a smoking cessation therapy. *X-22* will be a prescription-only kit containing VLN cigarettes made from our proprietary tobacco, which has approximately 95% less nicotine compared to tobacco in existing "light" cigarettes. The therapy protocol allows the patient to smoke our VLN cigarettes without restriction over the 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 because VLN cigarettes made from our proprietary tobacco satisfy smokers' cravings for cigarettes while also: (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine.

We further believe that *X-22* offers the following advantages over existing smoking cessation products:

- *X-22* is more attractive than other therapies since it smokes, tastes and smells like a typical cigarette and involves the same smoking behavior;
- *X-22* does not expose smokers to any new drugs or new side effects; and
- *X-22* is more effective than other smoking cessation aids because:
- *X-22* provides greater relief from withdrawal symptoms than the FDA-approved nicotine lozenge;
- *X-22* reduces cravings more than the FDA-approved prescription nicotine inhaler; and
- *X-22* decreases the likelihood of relapse (in the case of Chantix®, approximately half of those who quit relapse within 8 weeks after the end of treatment).

We have suspended sponsoring further *X-22* clinical trials pending the results of two independent smoking-cessation Phase II trials utilizing a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than the those used in our own sponsored Phase II-B trial. One of these trials recently concluded and the other trial is expected to conclude in the second quarter of 2012. These results will be compared to our Phase II-B trial to determine which variables optimize cessation. At that time we may resume our own sponsored *X-22* clinical trials.

Our 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 attracted to cigarettes which potentially pose a lower health risk than conventional cigarettes. This includes the approximate one-half of the 45 million adult smokers in the U.S. who do not attempt to quit in a given year. 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. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance.*

.

BRAND A Cigarettes

Compared to other 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, including our Phase II-B clinical trial, have demonstrated that smokers who smoke VLN cigarettes containing our proprietary tobacco by and large 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 generally does not occur with VLN cigarettes containing our proprietary tobacco.

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.

A Phase II smoking cessation clinical trial at the University of Minnesota Masonic Comprehensive Cancer Center, which is further described below, 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 findings, results from our Phase II-B clinical trial, and future exposure studies the FDA may require will result in a Modified Risk Cigarette claim for *BRAND A*.

BRAND B Cigarettes

Compared to other commercial tobacco cigarettes, *BRAND B*'s smoke contains the lowest amount of "tar" per milligram of nicotine. Using a proprietary high nicotine tobacco blend in conjunction with a unique cigarette design, *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 full flavor cigarette brands. Unlike low-tar/low-nicotine brands currently on the market (previously labeled "light" or "ultra- light" before the Tobacco Act banned these descriptors in 2010), the nicotine yield of *Brand B* is not reduced. Therefore, *BRAND B* has a "tar" yield of a "light" cigarette and the nicotine yield of a full flavor cigarette.

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." Studies have demonstrated that compensatory smoking (e.g., more and/or larger puffs per cigarette) of low-tar research cigarettes, similar to *BRAND B*, is greatly curtailed resulting in smokers inhaling less "tar" and carbon monoxide. We believe that evaluation of *BRAND B* in short-term human exposure studies will confirm that exposure to smoke, including "tar" 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 Cigarette claim for *BRAND B*.

RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco Company, LLC ("Goodrich Tobacco"), has 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 the second half of 2012, 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 flavored cigarettes (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 carry our brands, among other reasons, to increase their margins.

Smoking Cessation Clinical Trials with VLN Cigarettes

VLN cigarettes have been the subject of various independent studies, including six clinical trials for smoking cessation which were not funded by us. These clinical trials were "intent to treat" trials, meaning that any patients who dropped out of the trials for any reason at any time during treatment or during the follow-up periods were considered failures (still smoking and not abstinent). Dropout rates during smoking cessation trials are generally high since patients either quit smoking or resume smoking their usual brand. In either case, they may believe there is no reason to continue.

A Phase II clinical 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). This clinical trial was led by Dr. Dorothy Hatsukami, Director of the National Transdisciplinary Tobacco Use Research Center, at the University of Minnesota Masonic Cancer Center. For reference, 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. 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 Phase II 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 six (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 (4) weeks of the twelve (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 (4) 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 ($P<0.05$). Five additional biomarkers of smoke exposure were significantly reduced on average from baseline measurements (taken before the six (6)-week treatment period) in patients who used the VLN cigarette containing our proprietary tobacco.

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). 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 variety) either in combination with nicotine patch therapy (a nicotine replacement 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.

Another smoking cessation clinical trial using VLN cigarettes containing our proprietary tobacco was a randomized controlled trial conducted at Roswell Park Cancer Institute, Buffalo, New York, to investigate the effect of smoking a very low nicotine cigarette in combination with a nicotine patch for two (2) weeks prior to the quit date (Rezaishiraz *et al*. 2007). Ninety-eight adult smokers were randomized to two treatments: (i) two (2) weeks of a very low nicotine cigarette (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 very low nicotine cigarettes and a nicotine patch before quitting, had lower combined craving score 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), 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.

Three Independent Smoking Cessation Clinical Trials with VLN Cigarettes that have yet to publish

The University of Minnesota Masonic Cancer Center led by Dr. Dorothy Hatsukami recently completed a follow-up Phase II trial, *Innovative Interventions for Smoking Cessation,* (ClinicalTrials.gov Identifier: NCT01050569). This Phase II trial treated approximately 219 subjects and evaluated smoking cessation across the 3 arms: the exclusive use of our VLN cigarette, the exclusive use of a 21-mg nicotine patch, and the use of the nicotine patch and our VLN cigarette together. The treatment period for all three arms was 6 weeks. Smoking abstinence will be measured at 2 weeks and 6 months post treatment. We expect this study to publish in 2012.

The Clinical Trials Research Unit, University of Auckland Results recently completed a Phase III/IV two-arm smoking cessation trial. This trial treated 1,410 subjects; half received VLN cigarettes plus NRT (patch, gum and/or lozenge) and half received only NRT. Results were presented to the *Society For Research on Nicotine and Tobacco* (SRNT) in 2011. The 705 subjects treated with VLN cigarettes plus NRT had significantly higher cessation rates at all measured time points (3 weeks, 6 weeks, 3 months and 6 months) than subjects treated with NRT only. The manuscript of this study has been accepted by *Addiction*. Unlike the University of Minnesota Masonic Cancer Center's Phase II trial, *Innovative Interventions for Smoking Cessation*, the exclusive use of VLN cigarettes without NRT was not evaluated.

Queen Mary University of London, in collaboration with Pfizer, is conducting a smoking cessation clinical trial with 200 subjects. The ClinicalTrials.gov Identifier is NCT01250301. The study is evaluating whether the use of our VLN cigarettes in combination with Chantix® (or NRT) increases quitting rates over the use of Chantix (or NRT) alone. This trial will be completed in June 2012. (Chantix® is branded Champix® in outside the U.S.) Unlike the University of Minnesota Masonic Cancer Center's Phase II trial, *Innovative Interventions for Smoking Cessation*, the exclusive use of VLN cigarettes (without Chantix® or NRT) was not evaluated.

Technology Platform

Our proprietary technology enables us to decrease or increase the level of nicotine and other nicotinic alkaloids (e.g., nornicotine, anatabine and anabasine) in plants, including tobacco plants, by decreasing or increasing the expression of gene(s) responsible for nicotine production in the plant using genetic engineering. The basic techniques we use include the same as those used in the production of genetically modified varieties of other crops ("Biotech Crops"). In 2011, Biotech Crops were planted in 29 countries on 395 million acres (160 million hectares), an increase of 8% over 2010, according to the International Service for the Acquisition of Agri-Biotech Applications. This includes 88% of the corn, 94% of the soybeans, and 90% of the cotton grown in the United States, according the U.S. Department of Agriculture. A record 16.7 million farmers grew Biotech Crops worldwide in 2011, up 1.3 million from 2010.

During the development of genetically engineered varieties, many candidate lines are evaluated in the field in multiple locations over several years, as in any other plant 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 allows us to identify any 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 an 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 identical characteristics, including nicotine content, as the parent and sibling plants. Tobacco products with either low or high nicotine content are 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 “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 tobacco is grown, cured and processed exactly as conventional tobacco is grown, cured and processed. Levels of tobacco specific nitrosamines (“TSNAs”) are considerably lower in our VLN tobacco as compared to conventional tobacco. Most TSNAs (e.g., NNK) are carcinogenic and are formed from nicotinic alkaloids such as nicotine, nornicotine, anatabine and/or anabasine by the process of nitrosation that occurs during the curing and processing of tobacco.

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 seeds 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, *RED SUN* and *MAGIC*, and proceed to market with our *X-22* smoking cessation aid and *BRAND A* and *BRAND B* cigarettes, we plan to continue to scale up the amount of tobacco leaf we obtain directly from farmers under contract.

Intellectual Property

Our proprietary technology is covered by 12 patent families consisting of 101 issued patents in 78 countries and approximately 38 pending patent applications, which are either owned by or exclusively licensed to us. A “patent family” is a set of patents granted in various countries to protect a single invention. Our patent coverage in the U.S. consists of 14 issued patents and 7 pending applications. In China, the world’s largest cigarette market, our patent coverage consists of 5 issued patents and 3 pending patent applications. We have exclusive worldwide rights to all

uses of the following genes responsible for nicotine content in tobacco plants: QPT, A622, NBB1, MPO and genes for several transcription factors. 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 countries where at least 75% of the world's smokers reside.

We own various registered trademarks in the U.S. We also have exclusive rights to plant variety protection ("PVP"), certificates in the United States (issued by the U.S. Department of Agriculture) and Canada. A PVP certificate prevents anyone other than the owner/licensee from planting a plant variety for twenty (20) years in the U.S. or eighteen (18) years in Canada. The protections of PVP are independent of, and in addition to, patent protection.

Sales and Marketing

X-22 Smoking Cessation Aid

We intend 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 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. We plan to concentrate initially on a "push" strategy to develop demand for *X-22* in the U.S. 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 about *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 modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco toxins and (ii) are reasonably likely to pose lower health risks as compared to conventional cigarettes ("Modified Risk Cigarettes"). On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance.* We believe that two types of our cigarettes in development, which we refer to as *BRAND A* and *BRAND B*, will qualify as Modified Risk Cigarettes. Compared to other 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 the lowest amount of "tar" per milligram of nicotine.

RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco Company, LLC ("Goodrich Tobacco"), has 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 the second half of 2012, 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 flavored cigarettes (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 carry our brands, among other reasons, to increase their margins.

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. In 2009, 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 (5)-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 cigarettes to NIDA. The Company has completed the four developmental stages and delivered approximately 9 million cigarettes during the year ended December 31, 2011 and recognized the related revenue. These government research cigarettes are distributed under the mark *SPECTRUM*.

Healthcare Reimbursement

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, and managed-care arrangements, are continuing in many countries where we intend to sell our *X-22* smoking cessation aid, including the U.S. 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.

Approximately 160 million Americans have private health insurance with prescription coverage and the majority, and an increasing number of these plans, cover pharmacologic treatments for smoking cessation. Healthcare payers, including governmental bodies, are increasingly willing to fund smoking cessation treatments due to the expected savings from reducing the incidence of smoking-related illnesses. Approximately 46 million Americans were covered by Medicare in 2009. Medicare provides insurance coverage for up to two smoking cessation attempts per year and each attempt may include four counseling sessions.

Approximately 47 million Americans were covered by state Medicaid programs in 2009. Approximately 30% of Medicaid recipients are smokers. Medicaid programs in 42 states and the District of Columbia cover at least one form of pharmacologic treatment for smoking cessation (Chantix®, Zyban® or NRT). The new healthcare legislation is expanding Medicaid coverage to all 50 states. The current retail price of the 12-week prescription of Chantix® is over $450, which should give us great latitude in pricing *X-22*. We expect *X-22* to be price competitive with any FDA-approved smoking cessation aid, especially Chantix®, which will not only encourage governmental and private third-party payers to cover *X-22*, but will encourage smokers to attempt to quit with *X-22* since they will not have to purchase their usual brand of cigarettes over the 6-week treatment period.

Manufacturing

We have entered into an agreement with a cigarette manufacture to produce *RED SUN*, *MAGIC*, *SPECTRUM*, *BRAND A*, *BRAND B* and the clinical trial cigarettes for *X-22*.

Competition

In the market for FDA-approved smoking cessation aids, our principal competitors include Pfizer Inc., GlaxoSmithKline PLC, Novartis International AG, and Niconovum AB, a subsidiary of Reynolds American Inc. The industry consists of major domestic and international companies, most of which have existing relationships in the markets into which we plan to sell, as well as financial, technical, marketing, sales, manufacturing, scaling capacity, distribution and other resources, and name recognition substantially greater than ours.

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

Potential Smoking Cessation Aids

Nicotine Vaccines

Nicotine vaccines for smoking cessation 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. Four companies, Cytos Biotechnology AG, Celtic Pharmaceuticals Holdings, Nabi Biopharmaceuticals, L.P. and Independent Pharmaceutica AB 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. Phase III NicVAX® clinical trials commenced in 2010. Both of Nabi Pharmaceuticals' Phase III trials for its NicVAX® failed to show efficacy.

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.

Electronic or E-cigarettes

Although the FDA has not evaluated electronic cigarettes, or e-cigarettes, for quitting smoking, and we are not aware of any published result of a controlled clinical trial of e-cigarettes as a smoking cessation aid, 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 or tobacco products 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 very similar nicotine kinetics and delivery as 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.

The FDA has always contended that e-cigarettes should be regulated as drug-delivery devices, not as tobacco products. The FDA had been confiscating imports of e-cigarettes and has been in litigation with importers of e-cigarettes. A federal appeals court ruled on December 7, 2010 that the FDA can only regulate electronic cigarettes as tobacco products rather than as drug-delivery devices. The FDA desired to appeal this decision; however, the U.S. Court of Appeals for the D.C. Circuit in January 2011 rejected the FDA's request to have the entire court review the December 7, 2010 decision that went against the agency. The FDA did not further appeal this decision by the U.S. Court of Appeals for the D.C. Circuit in *Sottera, Inc. v. Food & Drug Administration*, which held that that e-cigarettes and other nicotine-containing products are not drugs or devices unless they are marketed for therapeutic purposes, but that other nicotine-containing products can be regulated as "tobacco products" under the Federal Food, Drug, and Cosmetic Act. Therefore, the FDA intends to develop regulations for electronic cigarettes. Many countries have outright banned e-cigarettes.

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.

Designation as a Fast Track product expedites a product's development time during the FDA's review. Generally, products that are granted as Fast Track also obtain Priority Review status by the FDA. A product with Priority Review status expedites a product's development time during the FDA's review of a NDA, which is filed after the completion of the Phase III clinical trials. The length of the FDA's review of the NDA without a Priority Review status 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 the NDA. A product that receives Fast Track designation is also eligible for (i) more frequent meetings with the FDA to discuss the product's development plan and ensure collection of appropriate data needed to support product 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", under which the applicant can submit sections of the NDA for review by the FDA before the entire application is complete.

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 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 also may not obtain Priority Review of our *X-22* New Drug Application (NDA), which would further delay FDA approval of *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.

X-22 Clinical Trials

Our Investigational New Drug Application for *X-22*, a kit of very low nicotine (VLN) cigarettes, was cleared by the FDA in July 2011. 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. In evaluating the results of this trial, we believe we may have gone too far in reducing the nicotine content of *X-22*, which was less than half the nicotine content of VLN cigarettes used in various independent clinical trials that were successful. We continue to believe that VLN cigarettes are effective as a smoking cessation aid. However, we have suspended sponsoring further *X-22* clinical trials pending the results of two independent smoking-cessation Phase II trials utilizing a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than the those used in our own sponsored Phase II-B trial. One of these trials recently concluded and the other trial is expected to conclude in the second quarter of 2012. These results will be compared to our Phase II-B trial to determine which variables optimize cessation. At that time we may resume our own sponsored *X-22* clinical trials.

Upon obtaining the FDA approval, we intend to register *X-22* as a Medicinal Product (pharmacological) for smoking cessation with the European Medicines Agency and other international FDA-equivalent agencies in targeted countries. Regulatory approval for *X-22* as a smoking cessation aid is not required in some international markets since, unlike the FDA, some foreign drug regulatory agencies do not require approval to market a product as a smoking cessation aid if the product is allowed to be sold for other purposes.

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 toxins and (ii) are reasonably likely to pose lower health risks as compared to conventional cigarettes (“Modified Risk Cigarettes”). On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance*. We believe that *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 which could create opportunities for us to license our proprietary technology and/or our tobaccos to larger competitors.

We supply our cigarettes to researchers so studies can be conducted to obtain additional information on our products. We expect this information will assist us, along with our own funded studies, in obtaining the necessary FDA authorizations to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes and to obtain FDA approval for *X-22* as a prescription smoking cessation aid.

On March 30, 2012, the FDA also released *Draft Guidance, Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act.* Although we agree with the FDA's requirement that tobacco companies will be required to report levels of 93 harmful and potentially harmful constituents (HPHCs) for every tobacco product sold in the U.S., there are more than 7000 constituents in tobacco smoke. Estimates of the risk from exposure to individual smoke constituents that have been analyzed show that many different compounds contribute to the risk of smoking, and even complete removal of any one compound or class of compounds, such as NNK or all tobacco specific nitrosamines (TSNAs), would do little, if anything, to reduce the risks from smoking (Pankow et al. 2007; Watanabe et al. 2009; Haussmann 2012).

There is a clear dose-response relationship between the level of tobacco smoke and disease; the higher the dose of tobacco smoke, the greater the incidence of disease. We believe that the only types of cigarettes that may significantly reduce risks from smoking are those that reduce exposure to the complex mixture of the thousands of compounds in tobacco smoke through consumption of fewer cigarettes per day and/or inhalations of less smoke per cigarette.

Although there is an overwhelming scientific, medical, public-health and tobacco-industry consensus that use of smokeless tobacco products (such as snus, snuff, chewing tobacco and dissolvable tobacco products) are less hazardous than smoking cigarettes, we strongly believe that the Tobacco Control Act will be limited in promoting public health unless a proactive and aggressive approach is taken by the FDA to mandate less hazardous cigarettes.

There are 6 times more cigarette smokers in the U.S. than users of smokeless tobacco products. According to the U.S. Centers for Disease Control and Prevention, approximately 45 million or 20 percent of adults smoke cigarettes. Only 3.5 percent of adults use smokeless tobacco products. Among certain demographics, smokeless tobacco products are barely used in the U.S. For example, 0.3 percent of women and 1 percent of African Americans use smokeless tobacco products.

We and everybody in the public health community agree that core strategies to reduce tobacco-related harm should be focused on discouraging initiation of tobacco use and promoting cessation. However, some believe that the next best public-health strategy is to encourage smokers to switch to smokeless tobacco products, rather than strategies that encourage the availability of less hazardous cigarettes. We strongly believe the latter will prove much more effective in reducing tobacco-related harm in the U.S. since cigarette smoking is the most hazardous, and by far, the most common form of tobacco consumption.

Biomass Products

Biomass Products are products such as ethanol made from the organic material, usually plants grown over a given area. We have funded extensive biomass field trials conducted by North Carolina State University ("NCSU"), and

studies on feedstock digestibility and bioconversion at the National Renewable Energy Lab. Bioconversion is the conversion of organic matter into a source of energy, ethanol in our research, through the action of microorganisms. 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 2008, we put our biomass development projects on hold so that our management could focus its attention and resources on our modified risk tobacco 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* and *Brand B* as Modified Risk Cigarettes. We currently are not spending any capital for such potential biomass business activities nor do we have any current plans to raise any capital for such potential biomass business activities.

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.

Research and Development

Most research and development (R&D) since our inception have been outsourced to highly qualified groups in their respective fields. Since 1998, 22nd Century Ltd has had multiple R&D agreements with NCSU resulting in exclusive worldwide licenses to various patented technologies. We have utilized the model offered by many public-sector research organizations which entails obtaining an exclusive option or license agreement to any invention arising out of funded research. In all cases, we fund and exclusively control all patent filings as the exclusive licensee. This model of contracting with public-sector researchers has enabled 22nd Century Ltd to control R&D costs while achieving our desired results, including obtaining exclusive intellectual property rights relating to all of 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 the agreements with NCSU, NRC and NAIST have involved the biosynthesis of nicotine in plants. During the years ended December 31, 2011 and 2010, we incurred research and development expenses of approximately $2,098,000 and $364,000, respectively. Our 2011 research and development expenses were predominately attributable to the filing of our *X-22* investigational new drug application and the related expenses for our Phase II-B clinical trial. In 2010, NAIST assigned all of their worldwide patents to us which were a result of our R&D at NAIST and that were previously licensed to 22nd Century Ltd on an exclusive basis. In 2011, we entered into a 3-year research and development agreement with the University of Virginia.

Employees

We currently employ six (6) people, none of whom are represented by a union, and we consider our employee relations to be good.

Item 1A. Risk Factors.

Risks Related to Our Business and Operations

We may not be able to continue as a going concern unless we obtain additional capital in 2012 and future sales of equity securities will cause stockholders to experience substantial dilution.

Recurring losses from operations, our negative working capital of approximately $1.9 million as of December 31, 2011, shareholders' deficit of $1.2 million as of December 31, 2011 and the uncertainty of obtaining additional financing on a timely basis, raise doubt about our ability to continue as a going concern. Our Board of Directors has authorized us to raise capital through the sale of equity securities in order to fund 2012 operating expense and pay liabilities that are either due or that will become due in 2012. It is highly probably as a result of any sales of equity securities our stockholders will experience substantial dilution. It is also possible that the equity securities may have rights, preferences or privileges senior to those of existing stockholders. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2011, includes an emphasis of a matter paragraph expressing substantial doubt whether we can continue as a going concern. We cannot guarantee our ability to continue as a going concern.

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

We experienced net losses of approximately $1.3 million and $1.4 million during the years ended December 31, 2011 and 2010, respectively. We expect to continue to incur net losses and negative operating cash flows in the foreseeable future and cannot be certain that we will ever achieve profitability. Since 2007, we have received only limited licensing revenue from a former licensee and our only significant revenue has been from research cigarettes for which the market is limited. We will need to spend significant capital to fulfill planned operating goals and conduct clinical studies, achieve regulatory approvals and, subject to such approvals, successfully produce products for commercialization. In addition, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company.

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

We had negative cash flow before financing activities of approximately $4,057,000 and $1,018,000 during the years ended December 31, 2011 and 2010, respectively. We anticipate that we will continue to have negative cash flow for the foreseeable future even though we have suspended clinical trials for *X-22* and significantly curtailed inventory purchases because we have significant liabilities that are due or that will become due in 2012 and we will continue to incur expenses for sales and marketing, and general and administrative expenses. Our business will also require significant amounts of working capital to support our growth. Therefore, we will need to raise additional investment capital to achieve growth, and we may not achieve sufficient revenue growth to generate positive future cash flow. An inability to generate positive cash flow for the foreseeable future or raise additional capital on reasonable terms 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 six 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 decrease or increase beyond those currently anticipated, which could harm our operating results and financial condition.

We have no experience in selling smoking cessation products or Modified Risk Cigarettes 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 or drops off sharply, 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 have suspended further clinical trials for FDA approval of our X-22 smoking cessation product and will not resume this process until additional capital is raised and we will need additional capital before we can undertake the FDA authorization process for our Modified Risk Cigarettes.

We will require additional capital in the future before we can resume our own clinical trials for FDA approval of our *X-22* smoking cessation product and begin the FDA authorization process for our Modified Risk Cigarettes. Although our Board of Directors has authorized us to raise additional capital for immediate working capital needs, we do not expect to undertake a capital raise for the purpose of funding further *X-22* clinical trials until the results of an independent Phase II trial is published later in 2012. If we resume our own clinical trials for our *X-22* smoking cessation product, we estimate the cost of completing a Phase II trial will be approximately $1.5 million and the cost of completing two Phase III trials to be approximately $10 million. We estimate that the cost of completing the FDA authorization process for each of our potential Modified Risk Cigarettes is estimated to be at least $1 million. If we raise additional funds through the issuance of equity securities for these activities, 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. 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 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, 2011 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 four 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.

We will depend on third parties to manufacture our products.

We currently do not intend to manufacture any of our products and depend on contract manufacturers to produce our products according to our specifications, in sufficient quantities, on time, in compliance with appropriate regulatory standards and at competitive prices. We currently do not have an arrangement with any contract manufacturer to produce our final version of *X-22* smoking cessation aid once it is approved by the FDA.

Manufacturers supplying our potential 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 at any facility will be 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 contract manufacturer will pass FDA and/or similar inspections in foreign countries to produce the final version of our *X-22* smoking cessation aid, or that future changes to cGMP manufacturing standards will not also affect the manufactures of our other products. Therefore, we may have to build our own manufacturing facility which would require additional capital.

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 otential products and their potential advantages over existing products;
- the prevalence and severity of any side effects;
- the strength of marketing and distribution support; and/or
- 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 choose to continue utilizing 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, Novartis International AG, and Niconovum AB, a subsidiary of Reynolds American Inc. The industry consists of major domestic and international companies, most of which have existing relationships in the markets into which we plan to sell, as well as financial, technical, marketing, sales, manufacturing, scaling capacity, distribution and other resources and name recognition substantially greater than ours. 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. and Star Scientific Inc. International competitors include Philip Morris International Inc., British American Tobacco, JT International SA, Imperial Tobacco Group PLC and regional and local tobacco companies; and in some instances, government-owned tobacco enterprises such as the China National Tobacco Corporation.

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 proposed products;

- commercialize competing products before we or our partners can launch our proposed products;
- operate larger research and development programs or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- 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.

In addition, 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.

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 producers 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 growers. 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 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. Identification of suitable management replacements, if any, could have a material adverse effect on our business, operating results, cash flows and financial condition. 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 cigarettes 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 2014 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 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 New Drug Application without a Priority Review designation is normally ten months from the date of filing of the New Drug Application, 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 the New Drug Application. 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. 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. Furthermore, the FDA could force us to remove from the U.S. market our other tobacco products such as RED SUN or MAGIC and even *BRAND A* and/or *BRAND B* 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 further regulatory risk.

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 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 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, the growth of organizations such as health maintenance organizations 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 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 characterizing 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 them 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 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 palatability and 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.

The FDA requirement regarding graphic health warnings on cigarette packaging and in cigarette advertising in September 2012 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 will 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 recently 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 smokers will probably reduce the demand for MAGIC and RED SUN, as well as X-22, *BRAND A* and *BRAND B*, if and when approved/authorized 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, whether or not we are a party to such 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.

Cigarette 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.

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 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. Consultants and key employees that work with our confidential and proprietary technologies are required to assign all intellectual property rights in their discoveries to us. However, these consultants or 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.

Our 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.

Our 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, and purchased or licensed those we have discovered, 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 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 10 issued patents and we have the exclusive license to an additional 91 issued patents in an aggregate of 78 countries. In addition, we own or exclusively license approximately 38 pending patent applications, of which we own 23 such patent applications and have an exclusive license with regard to 15 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 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. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. 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 in Saskatoon, Canada ("NRC"), each involve multiple patent families. The exclusive rights under each of these two license agreements 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 NCSU license relates predominately to issued patents, and the NCSU license will expire in 2022 when the last patent covered by the NCSU license will expire. The NRC license relates to only patent applications, so if such patent applications result in issued patents, then we expect the NRC license to expire in 2028, which is 20 years from the time when all such patent applications were filed together. However, in the event that none of the NRC patent applications result in issued patents, then the NRC license would expire upon our receipt of the last formal notice of rejection from the subject patent office of the domestic or foreign jurisdiction relating to the last of the NRC patent applications, which is an unknown date in the future that we cannot calculate.

We are currently in default pursuant to the terms of an intellectual property license to which we are a party.

We are currently in payment default for certain patent-related costs pursuant to the terms of our exclusive worldwide license agreement with North Carolina State University ("NCSU"), dated as of March 6, 2009 (the "License Agreement"). We are required to reimburse NCSU for such patent-related costs within 30 days of being invoiced, and a portion of such reimbursements has become past due mainly as a result of (i) an interference proceeding invoked by the U.S. Patent and Trademark Office between NCSU and a former licensee of 22nd Century Ltd and (ii) an arbitration proceeding brought by 22nd Century Ltd against the same former licensee. Both of these actions involved the License Agreement. 22nd Century Ltd at its sole option decided to defend NCSU in this patent interference and pay all related expenses including legal fees. This resulted in NCSU obtaining international rights to a patent family that was incorporated into the License Agreement, thereby mutually benefiting NCSU and 22nd Century Ltd. Separately, the arbitration decision was decisively in 22nd Century Ltd's favor containing multiple awards to 22nd Century Ltd, some of which also benefited NCSU since its technology was involved in the proceeding. The arbitration award was not

disputed and was fulfilled by the defendant in its entirety in 2009. We believe the results of both of these actions, the interference proceeding and arbitration proceeding, greatly benefited NCSU and 22nd Century Ltd beyond 22nd Century Ltd's cumulative net cost of these actions which was approximately $800,000. During 2011 the Company paid NCSU a total of approximately $745,000 for past due amounts as well as current patent costs and royalties. We owe NCSU approximately $753,000 as of December 31, 2011. Management periodically communicates its plans for commercialization of products using the technology licensed from NCSU and believes its relations with NCSU are sound. In order to facilitate our plans to raise capital and commercialize its products NCSU agreed, in a letter dated November 22, 2011, not to invoke its rights to terminate for non-payment or non-performance that it may have under the agreement until October, 15, 2012. However, NCSU may have the right to terminate the License Agreement upon 60 days prior written notice, which includes the opportunity for us to cure the payment default within this timeframe. The intellectual property licensed to us under the License Agreement is crucial to our business, and if NCSU chooses to invoke any right it may have to terminate the License Agreement and we are unable to cure the default, our business would be materially and adversely affected. Furthermore, if NCSU does not agree to continue to defer payment of the balance, we may need to raise additional capital on terms that are not favorable.

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 never develop or 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 or other stock exchanges.

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 such as the NASDAQ Stock Market or the NYSE. 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.

A significant portion of the total outstanding shares of common stock may be sold into the public market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

As of April 9, 2011, we had 29,049,646 shares of common stock issued and outstanding. Of the 29,049,646 shares, 16,074,903 are subject to lock-up agreements preventing the re-sale of such shares for 18 months following the date of the closing of the Merger, except to another individual or entity that is subject to a similar lock-up agreement. In July 2012, this lock-up period expires and such shares may be sold into the public market, which could cause the market price of our common stock to drop significantly.

31

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.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

No securities or industry analysts currently publish research or reports about us. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us in the future change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are controlled by our current officers and directors.

As of April 9, 2012, our directors and executive officers as a group beneficially owned approximately 39% of the shares 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 in the foreseeable future.

We have not paid cash dividends to date. 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 capital stock for the foreseeable future. In addition, 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 three years did own) 10 percent or more 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, 2011 is as follows:

2012	$32,667
2013	$37,833
2014	$28,000

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 April 9, 2012, there were 41 holders of record of shares of our common stock. The following table sets forth the high and low bid prices per share of our common stock, as derived from quotations provided by the OTC Bulletin Board Information Center for periods following the Merger.

Quarter Ended	High Bid	Low Bid
2011		
December 31, 2011	$1.34	$0.25
September 30, 2011	$1.30	$0.51
June 30, 2011	$1.30	$1.10
March 31, 2011*	$1.41	$1.01

* Includes trading activity beginning January 26, 2011.

Dividend Policy

We have not previously and do not plan to declare or pay any cash 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.

Recent issuances of Unregistered Securities

Convertible Notes. The Company issued convertible notes in a negotiated sale with 24 investors in the total face amount of $1,926,250 on December 16, 2011(“Convertible Notes”). The Convertible Notes can be converted, at the option of each note holder, in whole or in part, into shares of the Company’s common stock at $0.75 per share and shall also receive warrants equal to 120% of the number of shares of Company’s common stock into which such Convertible Notes have been then converted. Such warrants will have a term of five years and an exercise price of $1.50 per share of common stock. The Company may prepay all or any portion of the Convertible Notes without penalty at the Company’s determination at any time prior to the December 16, 2012, the maturity date, without the consent of the note holder(s), provided that the Company shall provide the note holder(s) with fifteen (15) days’ prior written notice of such prepayment, during which time the note holder(s) may convert the face amount of the Note(s) which is equal to such prepayment amount. In the event the Company engages in a financing transaction of at least $5,000,000 during the one year term of the Convertible Note and in the further event the securities to be sold in such transaction are either shares of Company common stock with a sale price equal to or greater than $0.80 per share or debt securities which are convertible into shares of Company common stock with a conversion price equal to or greater than $0.80 per share of common stock (“Qualified Subsequent Financing”), then the Company has the right to mandatorily require the conversion of Convertible Notes for the conversion price of $0.75 per common share upon fifteen (15) days prior written notice to the note holders. The shares, in the event of a Qualified Subsequent Financing , the note holders have “piggyback’ registration rights of the common shares and warrants underlying the conversion of the notes. These notes and the underlying common stock supporting the conversion rights have not been registered under the Securities Act of 1933, as amended (“Securities Act”), and were issued and sold in reliance upon exemption from registration contained in Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The proceeds from the sale of the Convertible Notes were used for working capital purposes.

Shares authorized for issuance under equity compensation plans

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 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, 2011:

	Number of securities to be issued upon exercise of outstanding options,	Weighted-average exercise price of outstanding options,	Number of securities remaining available for issuance under equity

	warrants and rights (a)		warrants and rights (b)		compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	735,000	(1)	$1.20	(2)	3,065,000
Equity compensation plans not approved by security holders	0		N/A		0
Total	735,000		$1.20		3,065,000

(1) Includes 700,000 restricted stock awards that are issued but not vested as of December 31, 2011.

(2) Weighted average exercise price only applies to the 35,000 shares to be issued 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.

On January 25, 2011, 22nd Century Ltd completed a reverse merger transaction (the "Merger") with 22nd Century Group, Inc. 22nd Century Ltd is a wholly owned subsidiary of 22nd Century Group, Inc. which continues to operate the business of 22nd Century Ltd. All references to shareholders or common shares include the historical members and membership Units of 22nd Century Ltd because, in the Merger, such Units were exchanged for common shares on a one-for-one basis and from an accounting standpoint, they are equivalent. The Merger is being accounted for as a reverse acquisition and a recapitalization; 22nd Century Ltd is the acquirer for accounting purposes. Consequently, the assets and liabilities and the historical operations that are reflected in the financial statements prior to the Merger are those of 22nd Century Ltd and are recorded at the historical cost basis of 22nd Century Ltd, and the consolidated financial statements since completion of the Merger include the assets and liabilities of 22nd Century Ltd, historical operations of 22nd Century Ltd and operations of 22nd Century Group, Inc. from the closing date of the Merger. 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.

Overview

22nd Century Ltd, our wholly-owned subsidiary, is a plant biotechnology company and we believe the global leader in technology that allows for the level of nicotine and other nicotinic alkaloids (e.g., nornicotine, anatabine and anabasine) in tobacco plants to be decreased or increased through genetic engineering and plant breeding. We own or exclusively control 101 issued patents in 78 countries plus an additional 38 pending patent applications. Hercules Pharmaceuticals, LLC and Goodrich Tobacco Company, LLC are subsidiaries of 22nd Century Ltd and are business units for our (i) smoking cessation product and (ii) premium cigarettes and modified risk tobacco products, respectively. We believe that our proprietary technology will enable us to capture a significant share of the global market for approved smoking cessation aids and the emerging market for modified risk tobacco products.

We have operated at a loss since 2006 when we increased our research and development expenditures. In the year ended December 31, 2011 we realized revenue of $788,601 mainly from our research cigarette program; in 2010, we realized revenue of $49,784 from this program and in 2009 we realized sales of $27,612 from limited test marketing of our cigarettes. We are in the process of transitioning from solely developing proprietary technology and tobacco to developing and commercializing our own products. In March 2011, our subsidiary, Goodrich Tobacco introduced two

of our products, *RED SUN* and *MAGIC* cigarettes into the U.S. market. Goodrich Tobacco intends to focus marketing efforts on tobacconists, smoke shops and tobacco outlets in the second half of 2012.

Our prospects depend on our ability to generate and sustain revenues from sales and licensing of *RED SUN* and *MAGIC*, our *X-22* smoking cessation aid, our potential modified risk cigarettes and our proprietary tobacco. Our ability to generate meaningful revenue from *X-22*, especially in the United States, depends on FDA approval, and our ability to generate meaningful revenue from our proprietary cigarette products depends in large part on obtaining FDA authorization to market these products as modified risk cigarettes. Once our products are approved and authorized by the FDA, we must still meet the challenges of successful marketing and distribution and consumer acceptance.

Accordingly, our cash flow from product sales will be limited, therefore we will need cash from equity or debt financing or in-licensing agreements to continue operations. As additional funds are required, we may raise such funds from time to time through public or private sales of equity or debt securities. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and its financial condition and results of operations. Additional equity financing will be dilutive to the ownership interests of holders of our common stock, and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

At December 31, 2011, the Company had current assets of $971,252 and current liabilities of $2,873,783, including $641,886 of Convertible Notes, with a face amount of $1,926,050, net of amortized discount of $1,284,364, that mature in December 2012. Cash on hand at December 31, 2011 of $252,249 is insufficient to sustain operations and pay outstanding current liabilities as they become due in 2012. The Company has suspended clinical trials for *X-22* in order to reduce expenditures and is seeking licensing agreements for its products with both domestic and international businesses. The Company’s Board of Directors authorized management to seek additional financing involving equity securities which will be dilutive to 22nd Century Group’s existing shareholders’ respective ownership percentages.

Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Revenue. In the year ended December 31, 2011, we realized revenue of $788,601, mainly from our research cigarette program, as compared to revenue of $49,784 in year ended December 31, 2010. As of December 31, 2011 we had no outstanding backlog of orders for our products and through the first quarter of 2012 we did not receive an order for any of our products.

Other income. In the year ended December 31, 2011, we recognized other income of $223,540 from a therapeutic grant award we received in fourth quarter of 2010.

Costs of goods sold. In the year ended December 31, 2011, costs of goods sold were $418,171 or 53% of revenue. Costs of goods sold in the year ended December 31, 2011 include inventories written off in the fourth quarter of 2011 of $178,670 because of changes in the Company's plans that rendered these costs not recoverable. In the year ended December 31, 2010, costs of goods sold were $27,964 or 56% of revenue.

Research and development expense. Research and development expense was $2,097,980 in the year ended December 31, 2011, an increase of $1,734,199, or 477%, from $363,781 in the year ended December 31, 2010. Approximately $1.6 million was for expenditures related to the filing of our Investigational New Drug Application and our Phase II-B clinical trials for *X-22*. We initiated this effort late in the fourth quarter of 2010 so there were minimal costs related to Phase II-B activities in 2010. The balance of the increase in research and development expense in 2011 as compared to 2010 consisted of patent expenses, including maintenance fees related to patent renewals, employee compensation costs and travel expense.

General and administrative expense. General and administrative expense was $1,785,543 in the year ended December 31, 2011, an increase of $1,194,717, or 202%, from $590,826 in the year ended December 31, 2010. Approximately $570,000 of the increase was for compensation costs due to increased administrative headcount, awards under our 2010 Equity Incentive Plan and outside directors' fees. The balance of the year-over-year increase was in various other expense categories such as investor relations consulting services, press release fees and stock transfer fees (approximately $198,000 increase) legal and SEC fees (approximately $286,000 increase), accounting and audit fees (approximately $52,000 increase), directors' and officers' liability insurance (approximately $38,000 increase) and travel (approximately $35,000 increase).

Sales and marketing costs. Sales and marketing costs were $286,033 in the year ended December 31, 2011; we had no costs categorized as such in the year ended December 31, 2010. The costs in 2011 related to product testing, product and packaging, and design, product branding, trade samples, trade shows and advertising.

Amortization and depreciation expense. Amortization and depreciation expense relates almost entirely to capitalized patent and trademark costs. Amortization and depreciation expense increased 9.4% in the year ended December 31, 2011 to $179,953, up from $164,456 in the year ended December 31, 2010. This increase of $15,497 is mainly due to our additional investment in patents and trademarks in 2010 of $147,912 and in 2011 of $98,191.

Gain warrant liability – derivative. In connection with the January 25, 2011 private placement we issued warrants which were accounted for as derivatives; a liability at the estimated fair value was recorded and contributed capital was reduced. The gain of $2,511,750 included in the year ended December 31, 2011 represents the decrease in the estimated fair value of the warrants since January 25, 2011.

Interest expense and debt expense. Interest expense and debt expense, which include interest amortization of debt discount and debt issuance costs, decreased in the year ended December 31, 2011 to $103,998, from $326,404 in the year ended December 31, 2010. This decrease of $222,406 or 68% was mainly a result of reduced borrowings during 2011 compared 2010. In January 2011, a substantial portion of our outstanding interest bearing debt was repaid or converted into shares of our common stock which was the cause of the reduced interest and debt expense. This was partially offset by interest on long term obligations in the amount of $587,000 which were entered into at the end of the first quarter, $215,000 in short term obligations borrowed early in the third and fourth quarters and the Convertible Notes issued on December 16, 2011.

Net loss. We had a net loss in the year ended December 31, 2011 of $1,347,787 as compared to a net loss of $1,423,647 in the year ended December 31, 2010. The decrease in the net loss of $75,860, or 5.3%, was mainly a result of increased revenue of approximately $1 million and the unrealized gain related to warrants and reduced interest and debt expense (totaling $2.7 million) nearly offset by increases in operating expenses (totaling $3.6 million) including clinical trial expenses, sales and marketing costs and increased compensation costs and other administrative expenses in the year ended December 31, 2011, as compared to the year ended December 31, 2010.

Liquidity and Capital Resources

Summary of Balances and Recent Sources and Uses

As of December 31, 2011, we had negative working capital of approximately $1.9 million compared to negative working capital of approximately $4.1 million at December 31, 2010. The $2.2 million reduction in our negative working capital position was mainly a result of the January 25, 2011 Private Placement, offset by our net loss of approximately $1.3 million for the year ended December 31, 2011.

Cash demands on operations

In 2010 and 2011, we operated at a loss and operating activities consumed more than $4.3 million in cash during this two year period. Cash on hand at December 31, 2011 of $252,249 is insufficient to fund operations and meet our obligations as they come due in 2012.

Although we have suspended clinical trial activities for *X-22*, we will need to raise funds through the issuance of equity securities during the next twelve months in order to continue operations. Failure to raise sufficient funds would significantly increase the risk that we would be unable to continue operations. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our plans to commercialize our products, our ability to continue as a going concern and our financial condition and results of operations. Additional equity financing will be dilutive to shareholders of our common stock. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary in certain countries to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to us.

Net Cash used in Operating Activities.

In the year ended December 31, 2011, $3,449,430 of cash was used in operating activities compared to $909,939 of cash used in operating activities in the year ended December 31, 2010. This increased use of cash of $2,539,491 was mainly due to the increase of $2,269,587 in the cash portion of the net loss in the year ended December 31, 2011 as compared to the year ended December 31, 2010. The balance of the increase was a result of the net change in working capital components related to operations.

Net Cash used in Investing Activities.

In the year ended December 31, 2011, we used $607,297 of cash related to third party costs incurred for patents and trademarks and the acquisition of office furniture and fixtures as compared to $108,116 used in the year ended December 31, 2010. This increase was attributable to our payment in 2011 of $500,000 towards outstanding patent costs charges that were deferred in prior periods.

Net Cash From Financing Activities.

During the year ended December 31, 2011, we generated approximately $4.3 million from our financing activities primarily through the issuance of shares of our common stock and warrants to purchase our common stock in the January 25, 2011 Private Placement as well as notes issued to shareholders and the issuance of Convertible Notes on December 16, 2011. These issuances resulted in net proceeds of approximately $4.8 million which were partially offset by payments on note obligations to shareholders and another lender, debt issuance costs, net payments to a related party and payment of amounts due from officers. During the year ended December 31, 2010, we generated net cash of approximately $1.0 million from our financing activities; approximately $1.3 million was generated by the issuance of common stock, notes and warrants partially offset by the payment of deferred Private Placement costs, payments on a demand loan, payment on a note to a shareholder, and net payments to a related party and officers.

A portion of the net proceeds from our financing activities were directed to North Carolina State University ("NCSU"). During the year ended December 31, 2011 we paid NCSU approximately $745,000. At December 31, 2011 we owed NCSU approximately $614,000 for patent costs and $139,000 for minimum royalties. Management periodically communicates its plans for commercialization of products using the technology licensed from NCSU and believes its relations with NCSU are sound. In order to facilitate the Company's plans to raise capital and commercialize its products, NCSU agreed in a letter dated November 22, 2011, not to invoke its rights to terminate for non-payment or non-performance that it may have under the agreement until October 15, 2012. After October 15, 2012, if the Company is still delinquent as to amounts owed, NCSU may have the right to terminate the exclusive license agreement, but can only do so with a 60-day prior written notice, including the opportunity to cure within this timeframe. As our licensor for 12 years, we believe NCSU has a vested interest in 22nd Century Group, Inc. commercializing our products. Since 1998, we have funded approximately $6 million to NCSU in royalties, patent support payments and R&D.

The Company will need to raise additional capital to continue operations and make payments on obligations that are and become due in 2012. The Company's Board of Directors authorized management to seek additional equity financing on a negotiated basis. The ability to complete these financings on acceptable terms will depend on a number of factors, including the general performance of the capital markets, the Company's progress in the manufacture, distribution and sale of its products, and results on independent smoking cessation clinical trials. Failure to raise sufficient funds would significantly increase the risk that we would be unable to continue operations. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our plans to commercialize our products, our ability to continue as a going concern and our financial condition and results of operations. These equity financings will be dilutive to our existing shareholders' respective ownership.

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. Cigarette federal 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 5-year government contract between RTI International ("RTI") and the National Institute on Drug Abuse ("NIDA") to supply NIDA research cigarettes which includes four development stages. The company has completed the four developmental stages and delivered approximately 9 million cigarettes during the year ended December 31, 2011 and recognized the related revenue. These government research cigarettes are distributed under the mark *SPECTRUM*. Future revenue under this sub-contract 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.

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 (trademarks) are reviewed annually for impairment. We have not recognized any impairment losses during the two years ended December 31, 2011 and 2010.

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 patent is generally used to determine the estimated useful life of the related patent costs.

Valuation of our Equity Securities

We have issued shares of our common stock to satisfy obligations to vendors or employees that were due in cash. These shares have been valued based on the cash value of the obligation satisfied by their issuance. We have also issued warrants to purchase shares of our stock in connection with the issuance of debt obligations. These warrants have been valued based on the value ascribed to the underlying shares issued in cash transactions, in settlement of cash obligations or, since the merger on January 25, 2011, the closing price of our common stock.

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 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 16, 2011, 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

Prior to the closing of the Merger, 22nd Century Ltd was organized as a limited liability company and treated as a partnership for income tax purposes; accordingly, prior to the Merger, 22nd Century Ltd was not directly responsible for income taxes (income and losses passed through to its LLC members) and did not have to account for them. Following the Merger on January 25, 2011, we are subject to Federal and State income taxes. Accordingly, since the Merger date we are required to recognize deferred tax assets and liabilities for any differences in basis in assets and liabilities between tax and GAAP reporting. The corresponding asset that resulted has been fully offset by a valuation allowance. The Company incurred a net operating loss from the closing of the Merger to December 31, 2011 and, accordingly, has made no provision for current income taxes. The income tax asset arising from this net operating loss has been fully reserved because it is not probable that it will be realized before its expiration.

Derivative Financial Instruments

The warrants to purchase shares of our stock that were issued in connection with the Merger are treated as derivative instruments for accounting purposes. Accordingly, upon issuance, these instruments are reported as liabilities rather than equity. 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. We use a lattice model approach which for valuing our outstanding warrants classified as derivative instruments which includes probability weighted estimates of future events including volatility of our common stock. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

Inflation

Inflation did not have a material effect on our operating results for the two years ended December 31, 2011 and 2010.

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, 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, 2011, that our internal controls over financial reporting were not effective and that a material weakness exists in our internal control over financial reporting. The material weakness consists of controls associated with segregation of duties. 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, 2011 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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

Name	Age	Position
Joseph Pandolfino	43	Chief Executive Officer and Director
Henry Sicignano, III	44	President, Secretary and Director
Michael R. Moynihan, Ph.D.	59	Vice President of R&D
C. Anthony Rider	60	Chief Financial Officer and Treasurer
Joseph Alexander Dunn, Ph.D.	58	Director
James W. Cornell	55	Director

Our directors and executive officers hold office until the earlier of their death, resignation, removal or until their successors have been duly elected and qualified. Our executive officers are appointed by our Board and serve at the discretion of the Board. There are no family relationships among our directors and executive officers. The current members of our Board are Joseph Pandolfino, Henry Sicignano III, Joseph Alexander Dunn, Ph.D., and James W. Cornell. Our current executive officers are Joseph Pandolfino, Chief Executive Officer, Henry Sicignano III, President, Michael R. Moynihan, Ph.D., Vice President of R&D, and Secretary, and C. Anthony Rider, Chief Financial Officer and Treasurer. Each of Messrs. Pandolfino, Sicignano and Rider were executive officers of 22nd Century Ltd prior to the closing of the Merger.

Joseph Pandolfino, MBA, Chief Executive Officer and Director

Mr. Pandolfino has served as our Chief Executive Officer and as a director since the closing of the Merger. He founded 22nd Century Ltd in 1998 and has over 15 years experience in all aspects of the tobacco industry, including 12 years with genetically-engineered tobacco. He served as President of 22nd Century Ltd from its inception until April 2010 and as Chief Executive Officer of 22nd Century Ltd since April 2010. Mr. Pandolfino oversees our operations, strategy and product development. Mr. Pandolfino holds a B.S. Degree in Business Administration from Medaille College and an M.B.A. Degree from the State University of New York at Buffalo. Mr. Pandolfino's significant experience in all aspect of the tobacco industry as well as his experience leading 22nd Century Ltd led to our conclusion that he should serve as a director of our Company.

Henry Sicignano, III, MBA, President, Secretary and Director

Mr. Sicignano has served as our President and Secretary since the closing of the Merger and served as President of 22nd Century Ltd since April, 2010. From August 2005 to April 2009, Mr. Sicignano served as a General Manager and as the Director of Corporate Marketing for NOCO Energy Corp., a petroleum products company; and from March 2003 to July 2005, as Vice President of Kittinger Furniture Company, Inc., a fine furniture manufacturer. From February 1997 through July 2002, he served as Vice President and Marketing Director of Santa Fe Natural Tobacco Company, a specialty tobacco company, prior to the sale of that company to R.J. Reynolds Tobacco Company in 2002. Mr. Sicignano holds a B.A. Degree in Government from Harvard College and a M.B.A. Degree from Harvard University. Mr. Sicignano's extensive experience in management, including in the tobacco industry, led to our conclusion that he should serve as a director of our Company.

Michael R. Moynihan, Ph.D., Vice President of R&D

Dr. Moynihan has served as our Vice President of R&D since March 2011 and served as Vice President of R&D for 22nd Century Ltd since January, 2007. He has also been a consultant for 22nd Century Ltd since 1999. From 2001 to 2006 he served as Director of Biotechnology Development at Fundacion Chile and from 1995 to 2000 as Senior Project Director at InterLink Biotechnologies LLC. Dr. Moynihan holds a Bachelor of Science Degree in Biology from Brown University and a Master's Degree and Ph.D. in Biology from Harvard University. He previously served as a Visiting Research Fellow at the Institute for Molecular and Cellular Biology, Osaka University, Japan; a Postdoctoral Associate in the Section of Plant Biology, Cornell University; and a Postdoctoral Associate at the Center for Agricultural Molecular Biology, Rutgers University.

C. Anthony Rider, CPA, Chief Financial Officer and Treasurer

Mr. Rider has served as our Chief Financial Officer and Treasurer since the closing of the Merger and served as the Chief Financial Officer of 22nd Century Ltd on a part-time basis since 2007. He has also served, since 2007, as Chief Financial Officer of Locke Acquisition Group LLC, which is unrelated to us. Mr. Rider served as the Chief Financial Officer of Astronics Corporation and MOD-PAC Corp., both public companies, from 2000 to 2005, and as the Chief Financial Officer of IIMAK, a private-equity sponsored international manufacturing company, from 2005 to 2007. Mr. Rider holds a Bachelor of Science Degree from Canisius College. Mr. Rider is a member of the AICPA and the New York State Society of CPAs. From 1973 to 2000, Mr. Rider was employed by Ernst & Young.

Joseph Alexander Dunn, Ph.D., 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. Dr. Dunn has also served as Chief Executive Officer of the National Center for Food and Agricultural Policy in Washington, D.C. since November 1, 2009 and as Chief Executive Officer and Director of Research at OmniPharm Research International, Inc., a drug company, and affiliated entities, Therex Technologies Inc., a drug company, and Therex LLC, a drug company, each located in Buffalo, New York since January, 1994. From May 1, 2008, until January 20, 2009, Dr. Dunn served as Deputy Under Secretary and from August 1, 2006, until April 30, 2008 Dr. Dunn served as Senior Scientific Advisor at the United States Department of Agriculture, Research, Education and Economics Mission Area in Washington, D.C. From December 1, 2006, until April 30, 2008 Dr. Dunn served as Executive Director of the United States Department of Agriculture NAREEE Advisory Board. From July, 1998 until July 1, 2006, Dr. Dunn served as Research Associate Professor in the Department of Oral Biology, School of Dental Medicine, at the State University of New York at Buffalo. Since June 1, 2010, Dr. Dunn has served as a member of the Board of Directors of Brothers of Mercy, Inc., a not-for-profit nursing and rehabilitation concern. Dr. Dunn holds a B.S. Degree in Medical Chemistry and a Ph.D. Degree in Pharmacology, both from the State University of New York at Buffalo School of Pharmacy. Dr. Dunn also served as a Postdoctoral Fellow in the Department of Pharmacology at Harvard Medical

School and as a Staff Fellow at the National Institutes of Health, National Cancer Institute Laboratory of Cellular Carcinogenesis and Tumor Promotion. Dr. Dunn's extensive scientific and regulatory background led to our conclusion that he should serve as a director of our Company.

James W. Cornell, MBA, Director

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. He has served in this capacity since October, 1988. 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. From September 2006 until September 2010, Mr. Cornell served as Managing Director of New York New Jersey Rail, LLC, which is part of the national transportation rail system and moves rail freight by rail barge across New York City Harbor, and he now continues to serve as principal business advisor to that firm. From March 2005 until September 2008, Mr. Cornell served as the Chairman of the Board of Directors of New York Regional Rail Corp., which operates as a short-haul regional trucking company. From April 2006, until February 2007, Mr. Cornell served as Chief Restructuring Officer of Regus Industries, a waste management firm, and from January 2001 until November 2004, he served as Special Advisor to Pinkerton Government Services, Inc. and Securitas Nuclear and Government Services Unit, security services providers to the energy industry and government. Mr. Cornell holds a B.S. Degree in Business, Management, and Economics and an M.B.A. Degree, both from the State University of New York, Empire College. Mr. Cornell's extensive business management, strategy, and leadership experience led to our conclusion that he should serve as a director of our Company.

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 will be provided to any person requesting same without charge. To request a copy of our Code of Ethics, please make written request to our Chief Executive Officer c/o 22nd Century Group, Inc., 9530 Main Street, Clarence, NY 14031.

Stockholder Communications

Stockholders may send communications to the Company's directors as a group or individually, by writing to those individuals or the group: c/o the Chief Executive Officer c/o 22nd Century Group, Inc., 9530 Main Street, Clarence, NY 14031. The Chief Executive Officer will review all correspondence received and will forward all correspondence that is relevant to the duties and responsibilities of the board or the business of the Company to the intended director(s). Examples of inappropriate communication include business solicitations, advertising and communication that is frivolous in nature, relates to routine business matters (such as product inquiries, complaints or suggestions), or raises grievances that are personal to the person submitting the communication. Upon request, any director may review communication that is not forwarded to the directors pursuant to this policy.

Board Committees

Nominating Committee

At of the date of this Annual Report on Form 10-K, the Company does not have a nominating committee. The Company intends to adopt a nominating committee in the future.

As of the date of this Annual Report on Form 10-K, we do not have any defined policy or procedure requirements for stockholders to submit recommendations or nominations for directors. The Company does not currently have any specific or minimum criteria for the election of nominees to the Board, and does not have any specific process or procedure for evaluating such nominees. Our current Board assesses all candidates, whether submitted by management or stockholders, and makes recommendations for election or appointment.

Audit Committee

As of the date of this Annual Report on Form 10-K, the role of audit committee is performed by the Board.

In this capacity, the Board is responsible for: (i) selection and oversight of our independent accountants; (ii) establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal controls and auditing matters; (iii) establishing procedures for the confidential, anonymous submission by our employees of concerns regarding accounting and auditing matters; (iv) engaging outside advisors; and (v) funding for the outside

auditors and any outside advisors engaged by the Board.

The Company has determined that James W. Cornell qualifies as an “audit committee financial expert” as defined in Item 407(d)(5)(ii) of Regulation S-K.

From inception to present date, we believe that the members of our Board are collectively capable of analyzing and evaluating the Company’s financial statements and understanding internal controls and procedures for financial reporting.

Compensation Committee

We have determined that the functions ordinarily handled by such a committee should be handled by our entire Board.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers, and stockholders holding more than 10% of our outstanding common stock to file with the SEC initial reports of ownership and reports of changes in beneficial ownership of our common stock. Executive officers, directors and greater-than-10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based on a review of the Securities and Exchange Commission filed ownership reports during 2011, the Company believes that all Section 16(a) filing requirements were met during 2011 except as set forth below.

On January 25, 2011, Messrs. Richard Saffire and Angelo Tomasello became subject to Section 16 reporting requirements which required filing of a Form 3 within 10 days, and on April 1, 2011, Messrs Joseph Dunn, James Cornell and Steven Katz became subject to Section 16 reporting requirements. Form 3 filings for these reporting persons were not made within the required 10-day period.

In addition, each of the following reporting persons had one late Form 4 filing for the number of transactions indicated during 2011: Messrs. James Cornell (1), Joseph Dunn (1), Steven Katz (1), Michael Moynihan (1), Joseph Pandolfino (1), Charles Rider (1), Henry Sicignano (6) and Angelo Tomasello (1).

Item 11. Executive Compensation.

The following table summarizes the compensation paid by us in each of the last two (2) completed fiscal years ended December 31, 2011 for our principal executive officer and the two most highly compensated executive officers who received annual compensation in excess of $100,000. These officers are referred to herein as our "Named Executive Officers."

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($) (2)	Total ($)
Joseph Pandolfino, Chief Executive Officer	2011	150,000	-	102,000	-	-	-	6,646	258,646
	2010	150,000	-	-	-	-	-	6,646	156,646
Henry Sicignano III, President	2011	150,000	-	357,000	-	-	-	15,174	522,174
	2010	85,000	-	-	-	-	-	6,581	91,581
Michael R. Moynihan, Vice President of R&D	2011	111,290	-	51,000	-	-	-	8,613	170,903
	2010	114,019	-	-	-	-	-	8,780	122,799

(1) The amounts included in this column are the aggregate grant date fair value determined in accordance with FASB ASC 718.

(2) Represents amounts paid by Company for health insurance.

Grants of Plan Based Awards During 2011

Name	**Grant Date of Equity**	**All Other Stock Awards:**	**Grant Date Fair Value**

	Incentive Plan Awards	Number of Shares of Stock (#)	of Stock and Option Awards ($)
Joseph Pandolfino	4/1/2011	200,000	$102,000
Henry Sicignano III	4/1/2011	700,000	$357,000
Michael R. Moynihan	4/1/2011	100,000	$51,000

Outstanding Equity Awards at Fiscal Year-End

		Stock Awards			
Name	Grant Date	Number of Shares or Units of Stock That Have Not Vested (#)(1)	Market Value of Shares or Units of Stock That Have Not Vested ($)(2)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)(1)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)(2)
Henry Sicignano III	4/1/2011	600,000	$252,000	100,000	$42,000

(1) 600,000 of the shares are time-based awards subject to vesting over the next 4 years on April 1 of 2012 to 2015, such that 150,000 shares shall vest on April 1 of each such year; 100,000 of the shares are performance based, which are subject to forfeiture unless certain performance milestones are achieved.

(2) Market value calculated based on the price of our common stock as of the last business day of our fiscal year.

Options Exercised and Stock Vested in 2011

	Option Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
Joseph Pandolfino	0	0	200,000	$ 102,000
Henry Sicignano III	0	0	0	0
Michael R. Moynihan	0	0	100,000	$ 51,000

Agreements with Executive Officers

We have entered into employment agreements with each of Messrs. Pandolfino, Sicignano and Rider that provide for annual compensation of $150,000, $150,000, and $72,000, respectively, subject to increases as contained in such employment agreements and/or as decided by our board of directors. Dr. Moynihan has an employment agreement with 22nd Century Group, Inc. that provides for annual compensation of $110,000. These employment agreements also contain non-compete covenants and change of control provisions.

The employment agreement of Messrs. Pandolfino, Sicignano and Rider provides that during the executive officer's employment by us and for a period of two (2) years after the executive officer ceases to be employed by us, the following non-compete covenants will apply: (i) the executive officer will not (except on behalf of us) provide or offer to provide any goods or services to any entity engaged in the United States in the making, offering, marketing, distributing and/or selling of products made from the tobacco (*Nicotiana*) plant, and/or providing or offering to provide the same or substantially similar services to any customer or prospective customer, (ii) the executive officer will not interfere with our relationships with any customer, prospective customer, supplier, distributor, farmer and/or manufacturer, and (iii) the executive will not induce or attempt to induce any persons employed by us to leave their employment with us, nor hire or employ, or attempt to hire or employ, any persons employed by us, nor assist or facilitate in any way any other person or entity in the hiring of any persons employed by us.

The employment agreement of Dr. Moynihan contains the same non-compete covenants but they are in effect for a period of three (3) years after the executive officer ceases to be employed by us. Dr. Moynihan's employment agreement contains a severance provision which provides that upon the termination of his employment without Cause (as defined in his employment agreement), Dr. Moynihan will receive severance compensation equal to the base salary then in effect beginning on the date of termination and continuing until the later of one year following termination or the expiration of the initial term of his employment agreement.

The employment agreement of Mr. Rider provides that in the event of a change of control (as defined in the employment agreement) of our Company, Mr. Rider may resign his employment with the Company (or, if involuntarily terminated, give notice of his intention to collect benefits) and shall be entitled to receive the base salary set forth therein which remains unpaid for the remainder of the initial term of the employment agreement.

The employment agreements of Messrs. Pandolfino and Sicignano provide that in the event of a change in control (as defined in the employment agreements) of our Company, then during the three (3)-year period following such change in control if certain triggering events occur as defined in such employment agreements, such as if the executive is terminated other than for cause (as defined in each of the employment agreements), death or disability, or if the executive officer's responsibilities are diminished after the change in control as compared to the executive officer's responsibilities prior to the change in control, or if the executive officer's base salary or benefits are reduced, or the executive is required to relocate more than twenty-five (25) miles from his current place of employment, then in any such events the executive officer will have the option, exercisable within ninety (90) days of the occurrence of such an event, to resign his employment with us, in which case the executive officer will be entitled to receive: (A) the greater of either his base salary for the then remaining portion of the initial 5-year term of the agreement or his base salary for three (3) years thereafter; (B) reimbursement for eighteen (18) months of his reasonable costs for medical, dental, life, disability and other benefits and insurance coverage that the executive officer received during his employment; (C) outplacement services for two (2) years; and (D) the immediate vesting of all options and/or restricted stock grants previously granted or to be granted to the executive officer. We also provide each of these individuals with health insurance and vacation benefits.

Director Compensation

Directors that are not members of management receive cash compensation of $10,000 each annually and in 2011 received restricted stock awards of 25,000 shares each which vested immediately. The following table sets forth information regarding the compensation of our non-executive directors for their service on our board of directors for fiscal year 2011.

Name	Fees Earned or Paid in	Stock Awards(1)	Option Awards	Non-Equity Incentive Plan Compensation	**Non-Qualified Deferred**	All Other Compensation	Total

	Cash				**Compensation**		
					Earnings		
James W. Cornell	$ 10,000	$ 12,750	-	-	-	-	$22,750
Joseph A. Dunn	$ 10,000	$ 12,750	-	-	-	-	$22,750
Steven Katz (2)	$ 10,000	$ 12,750	-	-	-	-	$22,750

(1) The amounts included in this column are the aggregate grant date fair value determined in accordance with FASB ASC 718.

(2) Mr. Katz resigned from the Board effective January 19, 2012.

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

Beneficial Ownership Table

The following tables set forth certain information regarding the beneficial ownership of our common stock as of April 9, 2012, by (i) each person who, to our knowledge, owns more than 5% of our common stock, (ii) each of our directors and executive officers, and (iii) all of our executive officers and directors as a group. Shares of our common stock subject to options, warrants, or other rights currently exercisable or exercisable within sixty (60) days of April 9, 2012, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person. Except as otherwise noted below, the address for each person or entity listed in the table below is c/o 22nd Century Group, Inc., 9530 Main Street, Clarence, NY 14031.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned (1)	
Management and Directors:			
Joseph Pandolfino (2)	6,210,396	20.28	%
Henry Sicignano, III (3)	4,774,594	15.78	%
Michael R. Moynihan, Ph.D. (4)	1,117,645	3.82	%
C. Anthony Rider (5)	364,473	1.25	%
Joseph Alexander Dunn, Ph.D. (6)	25,000	*	
James W. Cornell (6)	25,000	*	
All directors and executive officers as a group (6 persons) (2)-(6)	12,967,908	38.9	%
Other 5% Owners:			
Clearwater Partners, LLC (7)	5,144,279	16.98	%
Angelo J. Tomasello (8)	4,375,214	14.52	%

* Less than 1%

(1) Based on 29,049,646 shares of common stock issued and outstanding (including outstanding restricted stock), plus common stock subject to options, warrants, the Convertible Notes or other rights currently exercisable or exercisable within sixty (60) days of April 9, 2012, held by the beneficial owner to whom the disclosure pertains.

(2) Includes (a) 1,579,761 shares of common stock issuable to Mr. Pandolfino upon exercise of warrants and (b) 141,500 shares of common stock subject to an option granted by Mr. Pandolfino to Mark Tompkins to purchase such shares at a price per share equal to 20% of the market value of such shares on the date of exercise, which option becomes exercisable by Mr. Tompkins on July 25, 2012 after the expiration of the lock-up agreement between Mr. Pandolfino and the Company with respect to all shares owned by Mr. Pandolfino, and which option expires on August 26, 2012. All of the shares owned by Mr. Pandolfino are subject to restrictions on transfer or sale as contained in a lock-up agreement with the Company which expires on July 25, 2012.

(3) Consists of 1,032,603 shares of common stock held by Henry Sicignano III (including 550,000 restricted shares issued as equity incentive awards under the Company's EIP), 2,542,347 shares of common stock held by Henry Sicignano III Group, LLC, 69,564 shares of common stock issuable to Mr. Sicignano upon exercise of warrants, 329,667 shares of common stock upon conversion of a $247,250 note, and 800,413 shares of common stock issuable to Henry Sicignano III Group, LLC upon exercise of warrants. Mr. Sicignano is Managing Member of Henry Sicignano III Group, LLC and, accordingly, exercises voting and investment power with respect to the shares held by Henry Sicignano III Group, LLC. 450,000 of the shares issued to Mr. Sicignano under the Company's EIP are time-based awards subject to vesting over the next 3 years on April 1 of 2013 to 2015, such that 150,000 shares shall vest on April 1 of each such year. Mr. Sicignano also holds 100,000 performance based shares of restricted stock issued as equity incentive awards under the Company's EIP, which are subject to forfeiture unless certain performance milestones are achieved. All of the shares owned and/or controlled by Mr. Sicignano are subject to restrictions on transfer or sale as contained in a lock-up agreement with the Company which expires on July 25, 2012.

(4) Includes 243,711 shares of common stock issuable upon exercise of warrants. All of the shares owned by Dr. Moynihan are subject to restrictions on transfer or sale as contained in a lock-up agreement with the Company which expires on July 25, 2012.

(5) Includes 57,970 shares of common stock issuable upon exercise of warrants and 46,000 shares of common stock upon conversion of a $34,500 note. All of the shares owned by Rider are subject to restrictions on transfer or sale as contained in a lock-up agreement with the Company which expires on July 25, 2012.

(6) All of the shares owned by this holder are subject to restrictions on transfer or sale as contained in a lock-up agreement with the Company which expires on July 25, 2012.

(7) Includes 1,238,763 shares of common stock issuable upon exercise of warrants. The address of Clearwater Partners, LLC is 34 Sunburst Circle, East Amherst, New York 14051. All of the shares owned by Clearwater Partners, LLC are subject to restrictions on transfer or sale as contained in a lockup agreement with the Company which expires on July 25, 2012, except that 97,544 of such shares are not subject to restrictions on transfer or sale pursuant to such lock-up agreement.

(8) Includes 1,044,972 shares of common stock issuable upon exercise of warrants and 38,333 shares of common stock and warrants to purchase 46,000 shares of common stock upon conversion of a $28,750 note. The address of Mr. Tomasello is 4720 Spaulding Drive, Clarence, New York 14031. All of the shares owned by Mr. Tomasello are subject to restrictions on transfer or sale as contained in a lock-up agreement with the Company which expires on July 25, 2012, except that 325,000 of such shares are not subject to restrictions on transfer or sale pursuant to such lock-up agreement.

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

Immediately prior to the closing of the Merger, pursuant to the terms of the Split-Off Agreement, 22nd Century Group, Inc. transferred all of our pre-Merger operating assets and liabilities to the Split-Off Subsidiary. We then transferred all of the outstanding capital stock of the Split-Off Subsidiary to David Rector, our sole director and executive officer prior to the Merger, in exchange for $1, such consideration being deemed to be adequate by our Board prior to the Merger. Prior to the closing of the Merger, we paid Mr. Rector $1,500 in consideration for his service as our sole director and executive officer.

Prior to the closing of the Merger, Touchstone Mining Limited utilized office space located at 11923 SW 37 Terrace, Miami, Florida 33175 that was provided to us on a rent-free basis by Nanuk Warman, our former director and executive officer. Also, prior to the closing of the Merger, we cancelled 10,015,200 shares of our common stock held by Mr. Warman and entered into a mutual release agreement with Mr. Warman regarding such cancellation. In each of fiscal years 2009 and 2010, we paid Mr. Warman aggregate compensation of $8,000 in consideration for his services as our sole director and executive officer during those periods. We also paid Mr. Warman aggregate of $1,500 in consideration for his accounting services in preparation of our most recent Form 10-K and Form 10-Q filed prior to the closing of the Merger.

We have conducted transactions with Alternative Cigarettes, Inc. (“AC”), which is 95% owned by three holders of our common stock, including Joseph Pandolfino, our Chief Executive Officer, and Angelo Tomasello, who as of April 9, 2012, beneficially owns approximately over 10% of our common stock. We share office space and employee services with AC. AC has also advanced funds to us from time to time. Since January 1, 2010, the largest net amount due from us to AC was approximately $127,000. No interest has been accrued or paid on these amounts due to AC and there are no repayment terms between the parties. In February 2011, AC was paid $22,500 by 22nd Century Ltd for AC’s

assignment of its MAGIC trademark to 22nd Century Ltd and other minor assets.

In January 2008, we issued convertible promissory notes due and payable on January 15, 2011 to Messrs. Pandolfino and Tomasello in the principal amounts of $77,435 and $100,315, respectively, with 7% interest per annum accruing thereon. In December 2009, Mr. Pandolfino converted the principal balance and accrued interest under his note ($88,172) into 151,760 shares of our common stock. In May 2010, Mr. Tomasello agreed to amend his note to eliminate his right to convert the balance into shares of our common stock, and in January 2011, Mr. Tomasello's note together with all accrued interest thereon was paid in full.

In November 2008, we issued a promissory note due and payable on November 11, 2010 to Mr. Tomasello in the principal amount of $325,000, with 10% interest per annum accruing thereon, and a warrant to purchase 371,006 shares of our common stock, which have since been exercised at a price of $.0001 per share. The note was guaranteed by Virgil Properties, LLC, which is jointly owned by Messrs. Pandolfino and Tomasello. Effective December 1, 2010, the $325,000 promissory note was amended to extend the maturity date until January 10, 2011 and to increase the interest rate to 15% during this extension period. On January 25, 2011, Mr. Tomasello converted the principal amount of this promissory note into 325,000 shares of our common stock through an investment in the Private Placement Offering and cash in the amount of $79,401, which represents the accrued interest on the original $325,000 promissory note. Mr. Tomasello has also made funds available to us in the form of cash advances. The largest net amount outstanding since January 1, 2009 was approximately $166,000. No interest was accrued or paid on such advances and there were no repayment terms between the parties. In December 2009, Mr. Tomasello was issued 504,553 shares of our common stock in lieu of repayment of $135,996 of such advances, and we issued him a promissory note in the amount of $30,054 that was exchanged for 204,639 shares of our common stock in June 2010. On December 16, 2011 Mr. Tomasello acquired $28,750 of our December 16, 2011 Convertible Notes for $25,000 cash.

During the period between January 1 and October 5, 2010, we issued Mr. Pandolfino 455,331 shares of our common stock in lieu of $103,573 due and payable to him for his services. On October 5, 2010, we issued Mr. Pandolfino a promissory note, which was assigned to Mr. Sicignano, due and payable on January 31, 2011 in the principal amount of $58,873, with 15% interest per annum accruing thereon. In January 2011, we made payment in full to Mr. Sicignano on this assigned note together with all accrued interest thereon. Mr. Pandolfino acquired $86,250 of the December 16, 2011 Convertible Notes for $75,000 in cash. In 2012, he converted his Convertible Note.

In September 2010, Henry Sicignano III, our President and Secretary, loaned us $35,000, which amount was due and payable in November 2010, with 15% interest per annum accruing thereon. On December 16, 2010, Mr. Sicignano agreed to extend the maturity date of this loan until January 25, 2011. On December 28, 2010 we issued a promissory note to Mr. Sicignano due and payable on January 15, 2011 in the principal amount of $100,000, with 15% interest per annum accruing thereon. From time to time, Mr. Sicignano deferred guaranteed payments due to him by us as consideration for his services as our President with the largest net amount of such deferred guaranteed payments outstanding since January 1, 2010 being $85,000. On January 28, 2011 we made payment in full to Mr. Sicignano of all deferred guaranteed payments and all principal and accrued interest on all promissory notes then outstanding. Mr. Sicignano is also the managing member of Henry Sicignano III Group, LLC (“Sicignano Group”). On October 5, 2010, Sicignano Group purchased 112,396 shares of our common stock for $30,295 and, in a simultaneous related transaction, made a loan to the Company in the principal amount of $30,295, with 15% interest per annum accruing thereon, for which we issued Sicignano Group a promissory note due and payable on January 31, 2011. On January 25, 2011, Sicignano Group converted the principal amount of this promissory note and the accrued interest thereon into 31,626 shares of our common stock through an investment in the Private Placement Offering. From June 30, 2011 to October 18, 2011, Mr. Sicignano loaned us a total of $215,000 and issued a promissory note with interest at 12%. Mr. Sicignano exchanged these notes to acquire $247,250 of our December 16, 2011 Convertible Notes.

On September 15 and October 15, 2009, we issued promissory notes payable to Clearwater Partners, LLC (“Clearwater”) in the amounts of $15,000 and $10,000, respectively. In conjunction with the $15,000 promissory note, a warrant to purchase 185,503 shares of our common stock, at a price per share of less than $.0001, was issued to Clearwater, and in conjunction with the $10,000 note, a warrant to purchase 92,751 shares of our common stock, at a price per share of less than $.0001, was issued to Clearwater. The promissory notes bear interest at a rate of 10%. These promissory notes had original maturity dates September 15, 2010 and October 15, 2010, respectively. On May 27, 2010, the maturity dates of both promissory notes were extended to January 31, 2012. These notes remain unpaid and Clearwater has demanded payment while we have asked Clearwater for an extension.

On March 1, 2010, we issued a four (4) year warrant to purchase 1,706,626 shares of our common stock to Clearwater, which was exercised in full on May 27, 2010, at a price per share of $0.0001. On May 27, 2010, we further issued to Clearwater an additional four (4) year warrant to purchase 1,409,821 shares of our common stock, which was immediately exercised in full at a price per share of $0.0001, and we issued to Clearwater a promissory note due and payable on January 31, 2012 in the principal amount of $45,000, with 10% interest per annum accruing thereon. These warrants and this promissory note were issued to Clearwater in lieu of repayment of $450,000 principal, and accrued interest thereon, of funds previously advanced to us by Clearwater. On October 5, 2010, Clearwater purchased 176,358 shares of our common stock for $47,535 and, in a simultaneous related transaction, made a loan to the Company in the principal amount of $47,535, with 15% interest per annum accruing thereon, for

which we issued Clearwater a promissory note due and payable on January 31, 2011. On January 25, 2011, Clearwater converted the principal amount of this $47,535 promissory note and the accrued interest thereon, and the principal amount of the $45,000 promissory note and the accrued interest thereon, due and payable on January 31, 2012, into 97,544 shares of our common stock through an investment in the Private Placement Offering.

On December 16, 2011, Mr. Pandolfino, our Chief Executive Officer, Mr. Sicignano, our President, and Mr. Rider, our Chief Financial Officer, acquired $86,250, $247,250 and $34,500, respectively, of our December 16, 2011 Convertible Notes.

Policies and Procedures for Related Party Transactions

Our Board is in the process of adapting a written related person transaction policy, which will set forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will be administered by our Board and covers any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $50,000 and a related person had or will have a direct or indirect material interest. While the policy covers related person transactions in which the amount involved exceeds $50,000, the policy states that related person transactions in which the amount involved exceeds $120,000 are required to be disclosed in applicable filings as required by the Securities Act of 1933, as amended (the "Securities Act"), the Exchange Act and related rules. Our Board set the $50,000 threshold for approval of related party transactions in the policy at an amount lower than that which is required to be disclosed under the Securities Act, the Exchange Act and related rules because we believe it is appropriate for our Board to review transactions or potential transactions in which the amount involved exceeds $50,000, as opposed to $120,000.

Pursuant to this policy, our Board will: (i) review the relevant facts and circumstances of each related person transaction, including if the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the extent of the related person's interest in the transaction, and (ii) take into account the conflicts of interest and corporate opportunity provisions of our code of business conduct and ethics. Management will present to our Board each proposed related person transaction, including all relevant facts and circumstances relating thereto, and will update the Board as to any material changes to any related person transaction. All related person transactions may only be consummated if our Board has approved or ratified such transactions in accordance with the guidelines set forth in the policy. Certain types of transactions have been pre-approved by our Board under the policy. These pre-approved transactions include: (i) certain compensation arrangements; (ii) transactions in the ordinary course of business where the related person's interest arises only (a) from his or her position as a director of another entity that is party to the transaction, and/or (b) from an equity interest of less than 5% in another entity that is party to the transaction, or (c) from a limited partnership interest of less than 5%, subject to certain limitations; and (iii) transactions in the ordinary course of business where the interest of the related person arises solely from the ownership of a class of equity securities in our Company where all holders of such class of equity securities will receive the same benefit on a pro rata basis. No director may participate in the approval of a related person transaction for which he or she is a related person.

Director Independence

Messrs. Cornell and Dr. Dunn qualify as "independent" directors under the applicable definition of the Nasdaq Global Market ("Nasdaq") listing standards.

Item 14. Principal Accounting Fees and Services.

The following table shows the fees billed to us for the audits and other services provided by Freed Maxick CPAs, P.C. (formerly Freed Maxick & Battaglia, CPAs, PC) and RSM McGladrey, Inc. (an affiliate of Freed Maxick & Battaglia, CPAs, P.C.), its independent registered public accounting firm, for the fiscal years ended December 31, 2011 and 2010, respectively. On December 21, 2011, the alternative practice structure with RSM McGladery ceased to exist and any future tax services will be performed by Freed Maxick CPAs, P.C. Touchstone Mining Limited had a different independent public registered accounting firm serving as its independent auditors prior to the Merger. The audit and other fees billed to 22nd Century Limited, LLC ("22nd Century Ltd") for services pertaining to 2010 and to 22nd Century Group, Inc. pertaining to 2011 are presented herein as 22nd Century Ltd's business became our sole operating business immediately following the closing of the Merger.

	2011	2010
Audit fees	$82,500	$36,500
Audit-related fees	37,500	26,000
Tax fees	3,000	19,500
All other fees	-	-
	$123,000	$82,000

Audit Fees consist of the aggregate fees billed for professional services rendered for the audit of our consolidated annual financial statements and the reviews of financial statements and for any other services that are normally provided by our independent public accountants in connection with our statutory and regulatory filings or engagements.

Audit Related Fees consist of the aggregate fees billed for professional services rendered for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements and the financial statements of our subsidiary that were not otherwise included in Audit Fees. Amounts include review of private placement memorandums and 8-K's related to the private placement and Merger.

Tax Fees consist of the aggregate fees billed for professional services rendered for tax advice and tax planning. Included in such Tax Fees were fees for consultancy and advice on tax planning matters.

Policy on Audit Committee Pre-Approval of Audit and Non-Audit Services

Our Board, which performs the equivalent functions of an audit committee, has the responsibilities of appointing our independent registered public accounting firm to serve as our auditor and overseeing the auditor's work. In addition, our Board, in performing the equivalent functions of the audit committee, pre-approves all audit and related services. Should our Board pre-approve any services other than audit and related services, it will evaluate whether those services would compromise our auditors' independence.

Of the services provided in the fiscal years ended December 31, 2010, all fees and services were pre-approved by the Company's chief executive officer, which also performed the equivalent functions of an audit committee of the Company.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements

22ND CENTURY GROUP, INC. AND SUBSIDIARY

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

22nd Century Group, Inc.

We have audited the accompanying consolidated balance sheets of 22nd Century Group, Inc. and Subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of operations, shareholders' 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of 22nd Century Group, Inc. as of December 31, 2011 and 2010, 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.

The accompanying consolidated financial statements have been prepared assuming that 22nd Century Group, Inc. will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, 22nd Century Group, Inc. has suffered recurring losses from operations and as of December 31, 2011 has negative working capital of approximately $1.9 million and a shareholders' deficit of approximately $1.2 million. Additional financing will be required during 2012 in order to satisfy existing current obligations and finance working capital needs, as well as additional losses from operations that are expected in 2012. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ FREED MAXICK CPAs, P.C.
(Formerly Freed Maxick & Battaglia, CPAs, PC)

Buffalo, New York
April 16, 2012

F-2

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2011 and December 31, 2010

	2011	2010
ASSETS		
Current assets:		
Cash	$252,249	$310
Grant receivable	-	223,540
Due from related party	15,491	-
Due from officers	7,714	-
Inventory	678,123	308,662
Prepaid expenses	17,675	211,717
Total current assets	971,252	744,229
Other assets:		
Patent and trademark costs, net	1,387,104	1,467,623
Office furniture and fixtures, net	7,862	-
Deferred private placement costs	-	587,133
Deferred debt isuance costs, net	22,405	-
Deposits	-	1,535
Total other assets	1,417,371	2,056,291
Total assets	$2,388,623	$2,800,520
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Demand bank loans	$174,925	$174,925
Accounts payable	1,064,892	2,900,684
Accrued interest payable to shareholders	21,502	190,977
Accrued expenses	545,578	227,724
Deferred grant revenue	-	223,540
Notes payable to shareholders, net of unamortized discount	25,000	1,095,643
Notes payable	400,000	-
Convertible notes, net of unamortized discount	641,886	-
Due to related party	-	6,942
Due to officers	-	3,200
Total current liabilities	2,873,783	4,823,635
Long term notes payable to shareholders, net of unamortized discount	140,000	65,557
Long term portion of notes payables	37,000	-
Warrant liability	550,000	-
Total liabilities	3,600,783	4,889,192
Commitments and contingencies (Note 11)	-	-
Shareholders' 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 preferred shares	-	-
27,209,646 common shares (16,000,000 at December 31, 2010)	273	-
Capital in excess of par value	5,822,882	3,598,856
Accumulated deficit	(7,041,297)	(5,687,394)
Non-controlling interest - consolidated subsidiary	5,982	(134)
Total shareholders' deficit	(1,212,160)	(2,088,672)
Total liabilities and shareholders' deficit	$2,388,623	$2,800,520

See accompanying notes to consolidated financial statements

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Years Ended December 31, 2011 and December 31, 2010

	2011	2010
Revenue	$788,601	$49,784
Other income - therapeutic grant	223,540	-
Total revenue	1,012,141	49,784
Operating expenses:		
Costs of goods sold	418,171	27,964
Research and development	2,097,980	363,781
General and administrative	1,785,543	590,826
Sales and marketing costs	286,033	-
Amortization and depreciation	179,953	164,456
	4,767,680	1,147,027
Operating loss	(3,755,539)	(1,097,243)
Other income (expense):		
Gain warrant liability - derivative	2,511,750	-
Interest expense and debt expense:		
Shareholders	(45,932)	(265,221)
Other	(58,066)	(61,183)
	2,407,752	(326,404)
Net loss	(1,347,787)	(1,423,647)
Net (income) loss attributable to non-controlling interest	(6,116)	15
Net loss attributed to common shareholders	$(1,353,903)	$(1,423,632)
Loss per common share - basic and diluted	$(0.05)	$(0.11)
Common shares used in basic earnings per share calculation	26,391,204	12,437,983

See accompanying notes to consolidated financial statements

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT
Years Ended December 31, 2011 and December 31, 2010

	Common Shares Outstanding	Par value of Common Shares	Contributed Capital	Accumulated Deficit	Non-controlling Interest	Shareholders' Deficit
Balance at December 31, 2009	7,089,940	$ -	$2,466,138	$(4,263,762)	$ (119)	$(1,797,743)
Warrants issued	-	-	405,000	-	-	405,000
Common Stock issued	3,380,908	-	549,870	-	-	549,870
Common Stock issued in exchange for services	8,132	-	2,192	-	-	2,192
Common Stock issued as compensation in lieu of cash	346,493	-	68,237	-	-	68,237
Common Stock issued as compensation	204,053	-	33,000	-	-	33,000
Expensed portion of warrants as compensation	-	-	43,108	-	-	43,108
Conversion of shareholder note and accrrued interest to common stock	165,951	-	31,311	-	-	31,311
Warrants exercised for common stock	4,804,523	-	-	-	-	-
Net loss	-	-	-	(1,423,632)	(15)	(1,423,647)
Balance at December 31, 2010	16,000,000	$ -	$3,598,856	$(5,687,394)	$ (134)	$(2,088,672)
Distribution of 5,000,000 warrants for common stock, exercise price of $3.00 per share	-	-	(1,550,000)	-	-	(1,550,000)
Common Shares issued in January 25, 2011 private placement	5,434,446	-	2,335,103	-	-	2,335,103
	5,325,200	268	(268)	-	-	-

Merger of 22nd Century Limited and 22nd Century Group						
Stock based compensation	450,000	5	376,432	-	-	376,437
Beneficial conversion feature of convertible debt	-	-	1,062,759	-	-	1,062,759
Net income (loss)	-	-	-	(1,353,903)	6,116	(1,347,787)
Balance at December 31, 2011	27,209,646	$ 273	$5,822,882	$(7,041,297)	$ 5,982	$(1,212,160)

See accompanying notes to consolidated financial statements

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2011 and December 31, 2010

	2011	2010
Cash flows from operating activities:		
Net loss	$(1,347,787)	$(1,423,647)
Adjustments to reconcile net loss to cash used by operating activities:		
Amortization and depreciation	179,953	164,456
Amortization of debt issuance costs	1,095	35,923
Amortization of debt discount	34,087	126,624
Gain warrant liability - derivative	(2,511,750)	-
Equity based employee compensation expense	376,437	144,345
Equity based payments for outside services	-	2,192
Note issued for employee compensation obligation	-	9,537
Note issued for obligation for outside services	-	2,192
Convertible note issued for outside services	60,000	-
(Increase) decrease in assets:		
Grant receivable	223,540	(223,540)
Inventory	(369,461)	(253,639)
Prepaid expenses	194,040	(211,717)
Deposits	1,535	-
Increase (decrease) in liabilities:		
Accounts payable	(222,660)	190,524
Accrued interest payable to shareholders	(162,774)	112,047
Accrued expenses	317,855	191,224
Deferred revenue	(223,540)	223,540
Net cash used by operating activities	(3,449,430)	(909,939)
Cash flows from investing activities:		
Acquisition of patents and trademarks	(598,191)	(108,116)
Acquisition of office furniture and fixtures	(9,106)	-
Net cash used by investing activities	(607,297)	(108,116)
Cash flows from financing activities:		
Payment of deferred private placement costs	-	(60,976)
Payment on demand loan	-	(71,810)
Proceeds from issuance of notes and warrants to shareholders	215,000	723,271
Proceeds from issuance of convertible notes	1,300,000	-
Payment of debt issuance costs	(23,500)	-
Payments on borrowings - notes payable to shareholders	(393,276)	(4,390)
Payments on borrowings - notes payable	(50,000)	
Proceeds from issuance of common stock	-	549,870
Net proceeds from January 25, 2011 private placement	3,293,789	-
Net payments to related party	(22,433)	(120,028)
Net (payments to) advances from officers	(10,914)	2,270
Net cash provided by financing activities	4,308,666	1,018,207
Net increase in cash	251,939	152

Cash - beginning of period	310	158
Cash - end of period	$252,249	$310
Cash paid during the period for interest	$196,539	$16,890
Supplemental disclosure of noncash investing and financing activities:		
Reduction of accounts payable not related to operating activities:		
Payment of accounts payable for patent costs	$500,000	$-
Payment of accounts payable for deferred private placement costs	526,127	-
Accounts payable converted to promisory notes	587,000	-
	$1,613,127	$-
Deferred private placement costs charged to contributed capital	$587,133	$-
Original issue discount on convertible debt	$251,250	$-
Conversion of shareholder note to convertible debt	$215,000	$-
Conversion of note payable to convertible note	$100,000	$-
Beneficial conversion value upon issuance of convertible debt recoded as debt discount and an increase in capital in excess of par value	$1,062,759	$-
Conversion of shareholder note and accrued interest to common shares and warrants	$614,070	$31,311
Issuance of warrants as derivative liability instruments and reduction of capital in excess of par value	$3,061,750	$-
Patent and trademark additions included in accounts payable	$-	$39,796
Deferred private placement cost additions included in accounts payable	$-	$526,157

See accompanying notes to consolidated financial statements

22nd CENTURY GROUP, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2011

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

Introduction - These consolidated financial statements of 22nd Century Group, Inc. ("22nd Century Group") and its direct and indirect subsidiaries (collectively with 22nd Century Group, the "Company") incorporate and reflect the reverse acquisition of 22nd Century Limited, LLC by 22nd Century Group as described below.

On January 25, 2011, 22nd Century Limited, LLC ("22nd Century Ltd") completed a reverse merger transaction (the "Merger") with 22nd Century Group (formerly Touchstone Mining Limited). As a result, 22nd Century Ltd became a wholly owned subsidiary of 22nd Century Group which continues to operate the business of 22nd Century Ltd. In connection with the Merger, 22nd Century Group issued 21,434,446 shares of its common stock to the holders of limited liability company membership interests of 22nd Century Ltd, whose share amount represented 80.1% of the outstanding shares immediately following the Merger. All references contained herein to shareholders or common shares include the historical members and limited liability company membership interests of 22nd Century Ltd because, in the Merger, limited liability company membership interests were exchanged for common shares on a one-for-one basis and from an accounting standpoint they are equivalent.

The Merger is being accounted for as a reverse acquisition and a recapitalization; 22nd Century Ltd is the acquirer for accounting purposes. Consequently, the assets and liabilities and the historical operations that are reflected in the financial statements set forth herein for periods prior to the Merger are those of 22nd Century Ltd and are recorded at the historical cost basis of 22nd Century Ltd, and the consolidated financial statements set forth herein for periods beginning on and following completion of the Merger include the assets and liabilities of 22nd Century Ltd, historical operations of 22nd Century Ltd, and operations of 22nd Century Group from the closing date of the Merger.

Upon the closing of the Merger, 22nd Century Group transferred all of its operating assets and liabilities to Touchstone Split Corp. and split-off Touchstone Split Corp. through the sale of all of the outstanding capital stock of Touchstone Split Corp. (the "Split-Off"). After the completion of the Merger and Split Off, 22nd Century Group's consolidated financial statements include only the assets and liabilities of 22nd Century Ltd.

Immediately prior to the Merger on January 25, 2011, 22nd Century Ltd completed a private placement offering (the "Private Placement") of 5,434,446 securities (the "PPO Securities") at the purchase price of $1.00 per Unit, each such Unit consisting of one (1) limited liability company membership interest of 22nd Century Ltd and a five-year warrant to purchase one-half of one (1/2) limited liability company membership interest of 22nd Century Ltd at an exercise price

of $1.50 per whole common share. In connection with the Private Placement, 22nd Century Ltd approved a prorata distribution of 5,000,000 five-year warrants to purchase one limited liability company membership interest at an exercise price of $3.00. These warrants were valued at $1,550,000 and classified as liabilities resulting in a decrease to contributed capital. Private Placement proceeds included $614,070 from the conversion of 22nd Century Ltd indebtedness into PPO Securities and $395,376 from the conversion of placement agent fees into PPO Securities, resulting in gross cash proceeds of $4,425,000. Private Placement expenses incurred included cash expenses of approximately $1,025,000 and non-cash expenses consisting of the placement agent fees of $395,376 which were converted into PPO Securities and $390,000 for the estimated fair value of 934,755 placement agent and advisor warrants issued to the placement agent. An additional $167,820 of cost was incurred in the second and third quarters of 2011 in connection with the registration process for the common stock issued in the Private Placement. 22nd Century Ltd/Group received net cash proceeds of approximately $3.2 million from the Private Placement and a reduction of debt and accrued interest obligations to shareholders that were on the balance sheet at December 31, 2010 of approximately $614,000, which was exchanged for equity interests in the offering. A portion of the proceeds, amounting to $1,511,750, was allocated to the warrants issued and classified as liabilities (see Note 10).

The unaudited supplemental pro forma revenue and net loss attributed to the shareholders of the Company if the acquisition had taken place as of January 1, 2010 are as follows:

	2011	2010
Revenue	$788,601	$49,784
Net loss attributed to shareholders	$(1,353,903)	$(1,473,632)

Reclassifications – Certain items in the 2010 financial statements have been reclassified to conform to the 2011 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.

Nature of Business - 22nd Century Group is a holding company and is the sole member of 22nd Century Ltd, which is a plant biotechnology company. 22nd Century Ltd owns or exclusively licenses 101 issued patents in 78 countries predominantly related to modifying the content of nicotinic alkaloids in plants, specifically tobacco plants, through genetic engineering and plant breeding.

The overall objectives of 22nd Century Ltd are to reduce smoking-related disease by increasing smoking cessation with *X-22,* its botanical prescription smoking cessation aid in development and reducing the harm to smokers with 22nd Century's potential modified risk tobacco products, for smokers unwilling to quit. 22nd Century Ltd, including its subsidiaries, Goodrich Tobacco Company Ltd. ("Goodrich Tobacco") and Hercules Pharmaceuticals, LLC ("Hercules Pharmaceuticals") is primarily involved in the following activities:

- The development of its botanical smoking cessation aid, *X-22*;
- The development of its modified risk tobacco products;
- The pursuit of necessary regulatory approvals at the U.S. Food and Drug Administration (the "FDA") to market *X-22* as a prescription smoking cessation aid and its proprietary cigarettes as modified risk tobacco products in the U.S.;
- The manufacture, marketing and distribution of *RED SUN* and *MAGIC* proprietary cigarettes in traditional tobacco market channels in the U.S. and for export through its subsidiary Goodrich Tobacco;
- The international licensing of 22nd Century Ltd's trademarks, brands, proprietary tobaccos, and technology; and
- The production of *SPECTRUM* research cigarettes for the National Institute on Drug Abuse ("NIDA").

Principles of Consolidation - The accompanying consolidated financial statements include the accounts of 22nd Century Group, 22nd Century Ltd, and Goodrich Tobacco, a subsidiary of 22nd Century Ltd. 22nd Century Ltd owns 96% of the outstanding membership units of Goodrich Tobacco. All intercompany accounts and transactions have been eliminated.

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. The Company's inventory consisted of the following categories:

	December 31, 2011	December 31, 2010
Materials, mainly tobacco	$ 678,123	$ 292,480
Finished goods	-	16,182
Total	$ 678,123	$ 308,662

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. The Company also capitalized costs as a result of one of its exclusively licensed patent applications being subject to an interference proceeding invoked by the U.S. Patent and Trademark Office, which favorably resulted in the Company obtaining rights to a third party's issued patent. The amounts capitalized relate to patents the Company owns or to which it has exclusive rights and its trademarks, and exclude approximately $1.8 million recovered from a former licensee as direct reimbursements of costs incurred. These capitalized costs are amortized using the straight-line method over the remaining statutory life of the Company's primary patent family, which expires in 2019 (the assets' estimated lives). Periodic maintenance or renewal fees, which are generally due on an annual basis, are expensed as incurred. Annual minimum license fees are charged to expense in the year the licenses are effective. Total patent and trademark costs capitalized and accumulated amortization amounted to $2,063,812 and $676,708 as of December 31, 2011 ($1,965,621 and $497,998 - as of December 31, 2010). The estimated annual amortization expense for the next five years is approximately $185,000.

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 years ended December 31, 2011 and 2010.

Deferred Private Placement Costs - During 2010, the Company incurred costs related to the Private Placement that closed on January 25, 2011. Such costs were accumulated on the balance sheet as of December 31, 2010 and were charged against contributed capital upon closing of the offering. Deferred Private Placement costs were $0 as of December 31, 2011 ($587,133 – December 31, 2010).

Deferred Debt Issuance Costs – In the fourth quarter 2011, the Company incurred costs related to the Private Placement of Convertible Notes that closed on December 16, 2011. These costs were recorded in the balance sheet as a deferred charge and are being amortized over the one –year term of the notes. The unamortized balance at December 31, 2011 is $22,405.

Income Taxes - Prior to the Merger, the Company was treated as a Partnership for federal and state income tax purposes. As a result, there was no entity level income tax for periods prior to the Merger because all taxable income tax deductions and tax credits were passed through to the members of the Company. Following the Merger on January 25, 2011, the Company is treated as a corporation, subject to Federal and State income taxes. Accordingly, as of the Merger date the Company is required to recognize 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 carryforwards. The net deferred tax asset resulting from the change in tax status was approximately $300,000.

In light of the Company's history of cumulative losses management has determined that is it more likely than not that its net deferred tax asset will not be realized. Accordingly the Company established a valuation allowance to fully offset its net deferred tax asset as of the Merger and December 31, 2011.

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 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.

For the Convertible Notes issued December 16, 2011, bifurcation of the embedded conversion feature was not required and the Company 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.

Unearned Grant Revenue - In 2010 22nd Century Ltd received approval of a government grant as partial support for its clinical trial for the FDA. All costs associated with this grant were charged to research and development expense in 2011 and the deferred revenue balance of $223,540 at December 31, 2010 represented proceeds received in advance and was recognized into income and included in other income on the statement of operations for the year ended December 31, 2011 as the costs were incurred. Deferred grant revenue was $0 as of December 31, 2011 (as compared to $223,540 as of December 31, 2010).

Revenue Recognition - The Company recognizes revenue 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* 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 which includes four development stages. The company has completed the four developmental stages and delivered 8,779,000 cigarettes during the year ended December 31, 2011 and recognized the related revenue. These government research cigarettes are distributed under the mark *SPECTRUM*. Future revenue under this sub-contract 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.

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 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.

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.

Recent Accounting Pronouncements - In May 2011, the FASB issued Accounting Standards Update No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. This update results in common principles and requirements for measuring fair value and for disclosing information about fair value measurements in accordance with U.S. GAAP and IFRS. ASU 2011-04 is required to be applied prospectively in interim and annual periods beginning after December 15, 2011. Early application is not permitted. The adoption of ASU 2011 is not expected to have a material impact on the consolidated financial statements.

NOTE 2. - LIQUIDITY AND MANAGEMENT'S PLANS

Since 2006, 22nd Century Ltd has incurred substantial operating losses as it transitioned from being only a licensor of its proprietary technology and tobaccos to commercializing its own tobacco products. At December 31, 2011, the Company had current assets of $971,252 and current liabilities of $2,873,783. Cash on hand at December 31, 2011 of $252,249 is insufficient to sustain operations and pay outstanding current liabilities as they become due in 2012. The Company has suspended clinical trials for *X-22* in order to reduce expenditures and is seeking licensing agreements for its products with both domestic and international businesses. The Company's Board of Directors authorized management to seek additional financing involving equity securities which will be dilutive to 22nd Century Group's existing shareholders' respective ownership percentages.

The Company continues to explore the developing distribution channels for its proprietary cigarettes, *RED SUN* and *MAGIC*, through its subsidiary, Goodrich Tobacco. The Company currently has no distribution arrangements and no orders for these products. Although orders from RTI for *SPECTRUM* are expected in 2012 the Company has no outstanding backlog of orders as of December 31, 2011.

The Company's ability to fund operations and meet its obligations during 2012 will be dependent upon obtaining additional equity financing and signing one or more significant licensing arrangements for its products. There can be no assurance that the Company will be able to raise sufficient equity financing or obtain a significant licensing contract.

NOTE 3. - AMOUNTS OWED NORTH CAROLINA STATE UNIVERSITY ("NCSU")

Pursuant to the terms of an exclusive license agreement with NCSU, the Company owes NCSU approximately $753,000 as of December 31, 2011 for patent costs and license fees (as compared to $1,128,000 owed as of December 31, 2010). These amounts are included in accounts payable and accrued liabilities in the consolidated balance sheets. The Company was required to pay these amounts within thirty days of being invoiced and they are past due. NCSU has the right to claim interest on the balance. During 2011 the Company paid NCSU a total of approximately $745,000 for past due amounts as well as current patent costs and royalties. Management periodically communicates its plans for commercialization of products using the technology licensed from NCSU and believes its relations with NCSU are sound. In order to facilitate the Company's plans to raise capital and commercialize its products NCSU agreed, in a letter dated November 22, 2011, not to invoke its rights to terminate for non-payment or non-performance that it may have under the agreement until October 15, 2012. After October 15, 2012, if the Company is still delinquent as to amounts owed, NCSU may have the right to terminate the exclusive license agreement, but can only do so with a 60-day prior written notice, including the opportunity to cure within this timeframe. As of December 31, 2011, patent costs associated with the exclusive license agreements that could potentially be terminated had a carrying value of approximately $700,000. Additionally, NCSU has not imposed interest charges on past due amounts invoiced to the Company and as such the Company has not recorded accrued interest or interest expense.

NOTE 4. - DEMAND BANK LOANS

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 a shareholder of the Company. This loan had a balance of $174,925 at December 31, 2011 and 2010. 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, 2011 and December 31, 2010. 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 5. - NOTES PAYABLE - SHAREHOLDERS

Notes payable to shareholders consisted of the following:

	2011	2010
Note dated January 25, 2011	$140,000	$-
Notes dated September 15 and October 15, 2009, net of unamortized discount	25,000	20,557
Note dated October 28, 2008	-	325,000
Note dated November 11, 2008	-	325,000
Note dated May 20, 2009	-	30,000
Note dated January 1, 2008	-	100,014
Note dated May 27, 2010	-	45,000
Note dated September 1, 2010	-	35,000
Notes dated October 4, 2010	-	150,000
Note dated December 29, 2010	-	100,000
Note payable to repurchase common shares	-	30,629
	$**165,000**	$1,161,200

The notes payable in the table below are shown in the balance sheet as follows:

	2011	2010
Notes payable to shareholders, net of unamortized discount	$25,000	$1,095,643
Long term notes payable to shareholders, net of unamortized discount	140,000	65,557

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 matured notes that were 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 is due on July 1, 2013 together with accrued interest. As of December 31, 2011, the outstanding principal amount of this note is $140,000.

Notes Dated September 15 and October 15, 2009 (unsecured) - On September 15, 2009 and October 15, 2009, the Company issued two notes payable to the same third party in the amounts of $15,000 and $10,000, respectively. In conjunction with the $15,000 note, a warrant to purchase 185,503 common shares of 22nd Century Ltd at less than $.0001 per unit was issued, and in conjunction with the $10,000 note, a warrant to purchase 92,751 common shares of 22nd Century Ltd at less than $.0001 per unit was issued. The warrants were valued at $11,301 for the $15,000 note

and $6,962 for the $10,000 note, were recorded as discounts to the respective notes payable and are being amortized over the term of each note which significantly adjusts the effective interest rate. The intrinsic value of the warrants at the time of issuance was determined to be $68,750; the debt discount recorded was based on allocating the $25,000 in transaction proceeds proportionally between the notes and the warrants. The notes bear interest at a rate of 10% and the outstanding principal and interest is due and payable at maturity - January 31, 2012 in each case. As of December 31, 2011, the total outstanding principal and unamortized debt discounts for the two notes amounted to $25,000 and $0 (as compared to $25,000 and $4,443 at December 31, 2010), respectively. The warrants were exercised in 2010 prior to the Merger.

Following maturity on January 31, 2012 the notes remain unpaid. The Company has attempted to negotiate an extension and the note holder has demanded payment.

Note Dated October 28, 2008 - On October 28, 2008, the Company issued a note payable to a third party in the amount of $325,000. The interest rate on the note was 10% and the outstanding principal and interest was due and payable on October 28, 2010, the maturity date.

This note matured and remained outstanding at December 31, 2010; however, in January and February 2011 this note together with the $30,000 note dated May 20, 2009 (described below), and all the related accrued interest of $77,300 were satisfied by: (i) conversion of $150,000 into equity in connection with the January 25, 2011 Private Placement; (ii) a cash payment of $142,300; and (iii) a new note dated January 25, 2011 (see Note 6) payable in the amount of $140,000.

Note Dated November 11, 2008 - On November 11, 2008, the Company issued a note payable to a shareholder in the amount of $325,000. The interest rate on the note was 10% and the outstanding principal and interest was due and payable on November 11, 2010, the maturity date. This note was extended as set forth below and remained outstanding at December 31, 2010.

The extended maturity date on the note was January 10, 2011 and the interest rate during the extension period was 15%. Following the maturity of this note on January 10, 2011, the principal amount of $325,000 was converted to equity in connection with the January 25, 2011 Private Placement and the accrued interest was paid in cash.

Note Dated May 20, 2009 (unsecured) - On May 20, 2009, the Company issued a note payable in the amount of $30,000 to the same third party that was issued the October 28, 2008 note. The interest rate on the note was 10% and the outstanding principal and interest was due and payable on May 19, 2010, the maturity date. The $30,000 in principal and accrued interest remained outstanding as of December 31, 2010. This note was satisfied in January and February 2011 together with the October 28, 2008 note as described previously.

Note Dated January 1, 2008 (unsecured) - The Company issued a note to a shareholder on January 1, 2008 payable in the amount of $100,014. The interest rate on the note was 7%; the interest and principal were due on January 15, 2011, the maturity date, and were paid in cash in January 2011.

Note Dated May 27, 2010 (unsecured) - During 2010, the holder of the Notes dated September 15 and October 15, 2009 advanced additional funds, totaling $450,000, to the Company and obtained conversion rights to warrants to acquire shares of common stock. In March 2010, $225,000 was converted into warrants to acquire 1,706,626 shares of common stock and this amount was recorded as equity. Pursuant to an agreement effective on May 27, 2010, in exchange for the remaining $225,000 advanced, the Company issued warrants to acquire 1,409,821 shares of common stock and a note for $45,000. The note bears interest at 10%, which is due with the principal amount on January 31, 2012. The note was satisfied in January 2011 by conversion to equity in connection with the January 25, 2011 private placement.

Note Dated September 1, 2010 (unsecured) - On September 1, 2010, the Company issued a note payable to a shareholder in the amount of $35,000. The interest rate on the note was 15%, and, pursuant to an extension, the interest and principal were due on January 25, 2011, the extended the maturity date. The note was paid in cash in January 2011.

Notes Dated October 4, 2010 (unsecured) - The Company issued notes payable to seven shareholders in the aggregate amount of $150,000. The interest rate on each of these notes was 15%, and the interest and principal were due on the maturity date of January 31, 2011. These notes were satisfied in January 2011 by conversion of $87,367 to equity in connection with the January 25, 2011 Private Placement and by payment of $62,633 in cash.

Note Dated December 29, 2010 (unsecured) – The Company issued a note payable to a shareholder in the amount of $100,000. The interest rate on this note was 15%, and the interest and principal were due on the maturity date of January 29, 2011. The note was paid in cash in January 2011.

Note Payable to Repurchase Common Shares (unsecured) - On December 31, 2010, the Company agreed to repurchase 51,637 common shares previously issued to a shareholder in exchange for a $35,019 note, which $30,629 remained unpaid as of December 31, 2010. The interest rate on the note was 7% and the outstanding principal and interest were due and payable on September 30, 2010, the maturity date. The note remained unpaid at the maturity date; the outstanding principal balance and accrued interest were paid in cash in February 2011.

NOTE 6. - NOTES PAYABLE

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

	2011	2010
Convertible note dated March 31, 2011	$87,000	$ -
Note dated March 30, 2011	350,000	-
	437,000	-
Less long term portion of notes payable	(37,000)	-
Notes Payable (shown in current liabilities)	$400,000	$ -

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 exchanged for $115,000 of the Convertible Notes issued December 16, 2011 so that the remaining principal balance under the note is $87,000 as of December 31, 2011. The note amendment also provided for principal payments together with accrued interest to be due as follows: $50,000, May 1, 2012 and $37,000 January 1, 2013, the maturity date. The note is convertible into common stock of the Company at the option of the holder after December 18, 2011. The conversion rate will be determined at the time of conversion based on the average of the closing price of the Company's common stock on the day of and day after the conversion date.

Note Dated 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 are due on July 1, 2012. This maturity date is automatically accelerated if the Company receives funding of $5,000,000 or more prior to July 1, 2012. As of December 31, 2011, the outstanding principal on this note is $350,000.

NOTE 7. - CONVERTIBLE NOTES ISSUED DECEMBER 16, 2011

The Company issued Convertible Notes on December 16, 2011 in a negotiated sale with 24 investors in the total face amount of $1,926,250. The notes were sold for $1,675,000 - an original issue discount of $251,250. The notes do not bear interest and the total face amount of $1,926,250 is due December 16, 2012. The notes can be converted, at the option of each holder, in whole or in part, into shares of the Company's common stock at $0.75 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 Notes have been then converted. Such warrants will have a term of five years and an exercise price of $1.50 per share of common stock. In the event the Company engages in a subsequent financing transaction of at least $5,000,000 in shares of Company's common stock with a sale price equal to or greater than $0.80 per share or debt securities which are convertible into shares of Company common stock with a conversion price equal to or greater than $0.80 per share of common stock, then the Company will have the right to mandatorily require the conversion of the Notes. Also, in the event of subsequent financing transaction of at least $5,000,000, the note holders have "piggyback' registration rights of the common shares and warrants underlying the conversion of the notes. The notes contain "down round" provisions which provide 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. If the notes are converted the warrants issued at conversion have a "down round provision" and will be classified as derivatives for accounting purposes, which (similarly to the January 25, 2011 Warrants) means they are reported as a liability and marked to market at each balance sheet date.

The Company's common stock closed at $0.90 per share on December 16, 2011, which is greater than the portion of the conversion price under the notes allocated to the underlying common shares. This difference is a beneficial

conversion feature which was valued at $1,062,759 at the issue date and recorded as debt discount and additional paid in capital.

Three officers of the Company acquired a portion of these 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.

The following table summarizes the notes and related discount as of December 31, 2011:

Face value of Convertible Notes payable upon issuance and through maturity	$1,926,250
Less original issue discount	(251,250)
Less discount related to BCF	(1,062,759)
Plus amount of discount amortized to interest and debt expense in 2011	29,645
Convertible notes, net of unamortized debt discount as of December, 31, 2011	$**641,886**

Subsequent to December 31, 2011, notes amounting to $86,250 were converted into 115,000 shares of common stock resulting in the issuance of 138,000 common stock warrants. This conversion triggered the “down round” provision of the January 25, 2011 warrants resulting in an adjustment to the exercise price, as well as number of shares issuable under the warrants.

NOTE 8. - DUE FROM or TO 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; other activity during 2011 and 2010 consisted mainly of repayments and advances. The net amount due from AC amounted to $15,491 as of December 31, 2011 (as compared with the Company owing AC $6,942 as of December 31, 2010). No interest has been accrued or paid on amount due from or to AC and there are no repayment terms.

NOTE 9. - DUE FROM or DUE TO OFFICERS

The amount due from officers of $7,714 at December 31, 2011 (as compared with $0 due from officers as of December 31, 2010) is primarily related to employee portion of FICA on restricted stock awards to be recovered from the employee.

Amount due to officers is a result of advances to the Company for working capital purposes and Company expenses paid directly by the officers net of advances or reimbursements. As of December 31, 2011, the net amount due to officers was $0 (as compared with $3,200 due to officers as of December 31, 2010). No interest has been accrued or paid on any amount due to officers and there are no repayment terms.

NOTE 10. - WARRANTS FOR COMMON STOCK

Prior to December 31, 2010, 22nd Century Ltd granted warrants to purchase common shares of 22nd Century Group in connection with borrowings as an additional incentive for providing financing to the Company and as additional compensation to officers, consultants and advisors. The warrants were granted with a conversion price of less than $.0001, and the number of warrants issued was negotiated based on the agreement at the time of the grant. These warrants had been issued for terms of two to five years. All of these warrants were exercised prior to December 31, 2010.

In connection with the January 25, 2011 Private Placement and Merger, the Company issued 8,651,978 five year warrants (“January 25, 2011 Warrants”) to purchase shares of common stock of 22nd Century Group as follows: 5,000,000 with an exercise price of $3.00 per share, and 3,651,978 with an exercise price of $1.50 per share. These warrants contain “down round” provisions 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 is a guarantee of value which requires that 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. The original amount of the warrant liability related to the 5,000,000 $3.00 warrants was $1,550,000 and was recorded as a reduction of equity on January 25, 2011; the original amount of the warrant liability related to the 3,651,978 $1.50 warrants is $1,511,750, and, because it was recorded as a liability, the portion of proceeds from the Private Placement that was recorded as contributed capital was reduced accordingly. As of December 31, 2011 there are 3,651,978 January 25, 2011 Warrants with an exercise price of $1.50 and 5,000,000 January 25, 2011 Warrants with an exercise price of $3.00.

The Company estimated the initial value of the warrant liability at January 25, 2011 using the binomial lattice model to allocate total enterprise value to the warrants and other securities in the Company's capital structure based upon the enterprise value implied in the January 25, 2011 Private Placement. Consideration was also given to the impact of expected future capital raises and issuances of securities under the Company's 2010 Equity Investment Plan ("EIP"). 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 fair value of this warrant liability as of December 31, 2011 was estimated to be $550,000 which was determined using the binomial lattice model with updated for the factors used in the initial valuation performed as of January 25, 2011, principally: the equity value of the Company, the remaining exercise period and the decrease in the risk free interest rate. As a result a gain of $2,511,750 was recorded as other income in the statement of operations during 2011. The following table is a roll-forward of the warrant liability from the initial valuation:

Fair value of warrant liability as of January 25, 2011	$3,061,750
Gain as a result of change in fair value	(2,511,750)
Fair value at December 31, 2011	$550,000

ASC 820 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 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 and are classified within Level 3 of the valuation hierarchy.

The following table summarizes the warrant activity since December 31, 2009:

	Number of Warrants
Warrants outstanding at December 31, 2009	1,688,076
Warrants issued during 2010	3,116,447
Warrants exercised during 2010	(4,804,523)
Warrants outstanding at December 31, 2010	-
January 25, 2011 Warrants issued	8,651,978
Warrants exercised during 2011	-
Warrants outstanding at December 31, 2011	8,651,978
Warrants exercisable at December 31, 2011	8,651,978

NOTE 11. - COMMITMENTS

License Agreements - Under its exclusive license agreement with 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 each of the calendar years 2010 through 2013 is $75,000, and in 2014 the annual minimum royalty increases to $200,000. The license agreement continues through the life of the last-to-expire patent, which is expected to be 2022. These minimum royalty payments are due each February following the end of the applicable calendar year and are reduced by any running royalties paid or payable for that year. The agreement also requires a milestone payment of $150,000 upon FDA approval 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, 2011, the costs incurred related to patent costs and patent maintenance amounted to $93,343 (as compared to $125,956 during the year ended December 31, 2010).

The Company has two other exclusive license agreements which require aggregate annual license fees of approximately $55,000, which are credited against running royalties on sales of licensed products. Each license agreement continues through the life of the last-to-expire patent.

The Company entered into a three year lease for approximately 3,800 square feet of office space in Clarence, NY, which commenced September 1, 2011. Scheduled rent remaining as of December 31, 2011 is as follows:

2012	$32,667
2013	$37,833
2014	$28,000

NOTE 12. - 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, 2011 and 2010:

	2011	2011
Net loss attributed to common shareholders	$(1,353,903)	$(1,423,632)
Denominator for basic earnings per share-weighted average shares outstanding	26,391,204	12,437,983
Effect of dilutive securities: Warrants, restricted stock and options outstanding	-	-
Denominator for diluted earnings per common share - weighted average shares adjusted for dilutive securities	26,391,204	12,437,983
Loss per common share - basic	$(0.05)	$(0.11)
Loss per common share- diluted	$(0.05)	$(0.11)

Securities outstanding that were excluded from the computation because they would have been anti-dilutive are as follows:

	2011	2010
Warrants	8,651,978	-
Convertible Debt Issued December 16, 2011(number of shares including related warrants upon conversion of 3,082,000)	5,650,333	-
Restricted Stock	700,000	-
Convertible Note	246,707	-
Options	35,000	-
	15,284,018	-

NOTE 13. - 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. The EIP also contains a provision which restricts the plan to granting awards relating to no more than 1,600,000 shares of common stock of 22nd Century Group during the first twelve months following the effective date of the Merger. On March 31, 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.

The number of shares of common stock of 22nd Century Group subject to the EIP, any number of shares subject to any numerical limit in the EIP, and the number of shares and terms of any incentive award will be adjusted in the event of any change in outstanding common stock of 22nd Century Group by reason of any stock dividend, spin-off, split-up, stock split, reverse stock split, recapitalization, reclassification, merger, consolidation, liquidation, business combination or exchange of shares or similar transaction.

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.

All awards made under the EIP may be subject to vesting and other contingencies as determined by the Administrator and will be evidenced by agreements approved by the Administrator which set forth the terms and conditions of each award.

The Company accounts for stock-based compensation under the provisions of ASC Topic 718, "*Compensation — Stock Compensation.*" The Company recognizes compensation cost in its financial statements for all share based payments granted, modified, or settled during the period. For awards with graded vesting, compensation cost is recognized on a straight-line basis over the requisite service period, generally the related vesting period.

On April 1, 2011, under our EIP, the Board granted an aggregate of 1,150,000 shares of common stock of 22nd Century Group to officers and directors of which 450,000 shares vested immediately and incentive stock options to key employees to purchase an aggregate of 35,000 shares of 22nd Century Group's common stock. The Company has non-vested awards for 700,000 restricted shares outstanding; 600,000 of the outstanding restricted shares vest at the rate of 150,000 shares annually over the four-year period ending April 1, 2015 and the remaining 100,000 restricted shares vest based on achieving a performance milestone which is annual sales of $3 million in cigarettes (not *SPECTRUM* or *X-22*) by December 31, 2013.

For the year ended December 31, 2011, the Company recorded compensation expense $376,437 ($51,000 included in research and development expense and $325,437 included in general and administrative expense).

On February 1, 2009, the Company granted an award for service to an executive officer of 445,207 warrants to purchase common shares, vesting over a one year service period ending February 1, 2010. The related compensation cost of $258,662 was determined by the intrinsic value of the underlying common shares at the time of the award of $0.58 per unit and was charged to expense on a straight line basis over the service period. The cost was fully amortized in the first quarter of 2010 with a charge of $43,090.

As of December 31, 2011, unrecognized compensation expense related to non-vested restricted shares with annual vesting amounted to $186,469 and non-vested stock options amounted to $9,135. No expense was recorded for restricted stock grants with milestone vesting not considered probable, which had a fair value at grant date of $51,000.

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 year ended December 31, 2011:

	2011	
Risk-free interest rate	3.5	%
Expected dividend yield	0	%
Expected stock price volatility	90	%
Expected life of options	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 the equivalent U.S. Treasury bonds yield 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 for the year ended 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, 2010	-	$ -		
Granted in 2011	35,000	$ 1.20		
Outstanding at December 31, 2011	35,000	$ 1.20	9.67 years	$ -
Exercisable at December 31, 2011	-	$ -	-	$ -

The weighted average grant date fair value of options granted during the year ended December 31, 2011 was $1.04.

NOTE 14 - INCOME TAXES

The following is a summary of the components giving rise to the income tax provision (benefit) for the years ended December 31, 2011.

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

	2011
Current:	
Federal	$-
State	-
Total current	-
Deferred:	
Federal	(1,284,145)
State	(288,654)
Total deferred	(1,572,799)
Change in valuation allowance	1,572,799
	$-

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:

	2011
Statutory federal rate	(34.0)%
Permanent items	0.2
Change in tax status	(20.8)
State tax provision, net of federal benefit	(4.7)
Valuation allowance	59.3
Effective tax rate	0.0 %

Individual components of deferred taxes consist of the following:

Deferred tax assets:	
Net operating loss carryforwards	$2,033,122
Derivative liability	212,773
	2,245,895
Deferred tax liabilities:	
Prepaid expenses	(6,838)
Patents and trademarks	(180,795)
Stock-based compensation	(81,265)
Beneficial conversion feature of convertible debt	(404,198)
	(673,096)
Valuation allowance	(1,572,799)
Net deferred taxes	$-

As of December 31, 2011 the Company has a deferred tax liability of $404,198, which is based on the tax effect of the difference in basis between GAAP and tax purposes for the beneficial conversion feature on the convertible notes issued December 16, 2011. The Company's valuation allowance was also offset to account for the deferred tax liability. This deferred tax liability will decrease as the as the beneficial conversion feature is amortized over the term of the notes. When the Company determines that the valuation allowance can be eliminated in its entirety, the tax effect of the beneficial conversion feature of $411,139 will reverse into contributed capital.

The Company incurred a net operating loss of approximately $5,300,000 from the Merger to December 31, 2011 and this amount is being carried forward to future years and expires on December 31, 2031. Due to the uncertainty of the Company's ability to generate sufficient taxable income in the future before they expire, the company has recorded a valuation allowance to reduce the net deferred tax asset to zero. This NOL is included in the net deferred tax asset that has been fully offset by the valuation allowance

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, 2011.

The Company's federal and state tax returns for the years ended December 31, 2009 to December 31, 2011, including the pre-Merger short period from January 1, 2011 through January 25, 2011, are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2011.

NOTE 15. - SUBSEQUENT EVENT

In January 2012, the Company entered into an Agreement (the "Agreement") with one of its vendors to resolve payables of approximately $259,000. Pursuant to the terms of the Agreement, the Company paid $50,000 and issued 1,000,000 shares of its common stock to the vendor which satisfied the outstanding amount payable and established a credit for the Company for future services of approximately $172,000. The shares of common stock issued were valued at the average of the closing sale prices of such common stock on the Over-The-Counter Bulletin Board (OTCBB) for a ten (10) trading day period (resulting in an approximate value of $381,000).

(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).
2.2	Certificate of Merger dated as of January 25, 2011 Acquisition Sub. with and into 22nd Century (incorporated herein by reference to Exhibit 2.2 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
3.1	Amended and Restate 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	Bylaws of the Company (incorporated herein by reference to Exhibit 4.2 to the Company's Form S-8 filed with the SEC on March 30, 2011).
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	Form of Securities Purchase Agreement dated as of January 25, 2011 by and among 22nd Century, the purchaser(s) identified on the signature pages thereto and Parent, solely for the purposes of Section E and Section G thereof, as amended (incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.3	Form of Conversion Agreement (incorporated herein by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.4	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).
10.5	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).
10.6	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).
10.7	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).
10.8	Advisory Agreement dated as of January 25, 2011 by and between the Company and the Placement Agent (incorporated herein by reference to Exhibit 10.8 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.9	Placement Agency Agreement dated as of December 1, 2010 by and between 22nd Century and the Placement Agent (incorporated herein by reference to Exhibit 10.9 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.10	Escrow Agreement dated as of December 2, 2010 by and among 22nd Century, the Placement Agent and Bank of America, National Association (incorporated herein by reference to Exhibit 10.10 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).

10.11	Split-Off Agreement dated as of January 25, 2011 by and among the Company, Touchstone Split. Corp and David Rector (incorporated herein by reference to Exhibit 10.11 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.12	Letter from Paramount Strategy Corp dated as of December 21, 2010 regarding loan forgiveness (incorporated herein by reference to Exhibit 10.12 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.13	Letter from Milestone Enhanced Fund Ltd. dated as of December 28, 2010 regarding loan forgiveness (incorporated herein by reference to Exhibit 10.13 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.14	Letter from Mark Tompkins dated as of January 25, 2011 regarding loan forgiveness (incorporated herein by reference to Exhibit 10.14 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.15†	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).
10.16†	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).
10.17†	Employment Agreement dated as of January 25, 2011 by and between the Company and C. Anthony Rider (incorporated herein by reference to Exhibit 10.17 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.18†	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).
10.19	Form of Lock-Up Agreement (incorporated herein by reference to Exhibit 10.18 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
10.20	Restated Promissory Note dated June 30, 2011, payable by the Company to Henry Sicignano III in the principal amount of $150,000 (incorporated by reference to Exhibit 10.20 to the Company's Form S-1 registration statement filed with the Commission on July 20, 2011).
10.21†	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).
10.22†	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).
10.23	

	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).
10.24	Form of Securities Purchase Agreement, dated as of December 14, 2011, by and between 22nd Century Group, Inc. and the purchasers thereto (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the Commission on December 16, 2011).
14.1	Code of Ethics (incorporated herein by reference to Exhibit 14.1 of the Company's Annual Report on Form 10-KSB for the year ended September 30, 2006 filed with the Commission on December 20, 2006).

16.1	Letter from Child, Van Wagoner & Bradshaw, PLLC regarding change in independent registered public accountants (incorporated herein by reference to Exhibit 16.1 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
17.1	Letter from David Rector dated as of January 25, 2011 resigning as a director and officer of Parent (incorporated herein by reference to Exhibit 17.1 of the Company's Current Report on Form 8-K filed with the Commission on February 1, 2011).
21.1*	Subsidiaries of the Company
23.1*	Consent of Freed Maxick CPAs, P.C.
31.1.1*	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) and 15d-14(a)
31.1.2*	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) and 15d-14(a)
32.1.1*	Certification of Principal Executive Officer Pursuant to 14 U.S.C 1359 (furnished herewith)
32.1.2*	Certification of Principal Financial Officer Pursuant to 14 U.S.C 1359 (furnished herewith)
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 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: April 16, 2012 By: /s/ Joseph Pandolfino
Joseph Pandolfino
(Principal Executive Officer)

By: /s/ C. Anthony Rider
C. Anthony Rider
(Principal 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: April 16, 2012 By: /s/ Joseph Pandolfino
Joseph Pandolfino
Chief Executive Officer and Director

Date: April 16, 2012 By: /s/ Henry Sicignano, III
Henry Sicignano, III
President, Secretary and Director

Date: April 16, 2012 By: /s/ C. Anthony Rider
C. Anthony Rider
Chief Financial Officer and Treasurer

Date: April 16, 2012 By: /s/ Joseph Alexander Dunn, Ph.D.
Joseph Alexander Dunn, Ph.D.
Director

Date: April 16, 2012 By: /s/ James W. Cornell
James W. Cornell
Director