22nd Century Group, Inc.
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PROSPECTUS

22nd CENTURY GROUP, INC.

Up to 6,250,000 Shares of Common Stock

This prospectus relates to the resale at various times by the selling stockholders identified in this prospectus of up to 6,250,000 shares of common stock, par value $0.00001 per share, issuable (i) upon conversion of our Series A-1 Preferred Stock and (ii) upon the exercise of Series B Warrants. These shares were privately issued to the selling stockholders in connection with a private placement transaction. We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Series B Warrants, if exercised.

The selling stockholders have advised us that they will sell the shares of common stock from time to time in broker's transactions, in the open market, on the OTC Bulletin Board, in privately negotiated transactions or a combination of these methods, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices. We will pay the expenses incurred to register the shares for resale, but the selling stockholders will pay any underwriting discounts, commissions or agent's commissions related to the sale of their shares of common stock.

Our common stock is traded on the OTC Bulletin Board under the symbol "XXII.OB". On March 26, 2013, the closing sale price of our common stock was $0.91 per share.

Investing in our common stock involves risks. Before making any investment in our securities, you should read and carefully consider risks described in the "Risk Factors" section beginning on page 11 of this prospectus.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information. This prospectus may only be used where it is legal to sell these securities. The information in this prospectus is only accurate on the date of this prospectus, regardless of the time of any sale of securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

This date of this prospectus is March 29, 2013

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with information that is different from that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. The selling stockholders are offering to sell and seeking offers to buy these securities only in jurisdictions where offers and sales are permitted. You should assume that the information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

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Prospectus Summary

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all the information that should be considered before investing in our common stock. Investors should read the entire prospectus carefully, including the more detailed information contained herein under the "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" sections and our consolidated financial statements and the notes to those financial statements.

As used in this prospectus, unless the context otherwise requires, the "Company," "we," "us" and "our" refer to 22nd Century Group, Inc., a Nevada corporation, as well as its subsidiaries, 22nd Century Limited, LLC, a Delaware limited liability company, Goodrich Tobacco Company, LLC, a Delaware limited liability company, and Hercules Pharmaceuticals, LLC, a Delaware limited liability company, taken as a whole, and also refer to the operations of 22nd Century Limited, LLC, as discussed below.

Our Company

Background

22nd Century Group, Inc. was incorporated under the laws of the State of Nevada on September 12, 2005 under the name Touchstone Mining Limited. On January 25, 2011, we entered into a reverse merger transaction with 22nd Century Limited, LLC, which we refer to herein as the Merger. Upon the closing of the Merger, 22nd Century Limited, LLC became our wholly-owned subsidiary. We changed our name to 22nd Century Group, Inc. on November 23, 2010 in anticipation of the Merger with 22nd Century Limited, LLC. After the Merger, we succeeded to the business of 22nd Century Limited, LLC as our sole line of business.

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

Overview

22nd Century Limited, LLC ("22nd Century Ltd"), our wholly-owned subsidiary, is a plant biotechnology company focused on tobacco harm reduction and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding. The Company exclusively controls 107 issued patents and exclusively controls an additional 39 patent applications; of these, we own 12 issued patents plus 22 patent applications and we license on an exclusive basis, 95 issued patents and 17 patent applications. Hercules Pharmaceuticals LLC ("Hercules Pharmaceuticals") and Goodrich Tobacco Company, LLC ("Goodrich Tobacco") are wholly-owned subsidiaries of 22nd Century Ltd. Hercules Pharmaceuticals is focused on *X-22,* a prescription smoking cessation aid currently in development. Goodrich Tobacco is focused on commercial tobacco products and potential modified risk cigarettes.

The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 expresses substantial doubt regarding whether we can continue as a going concern and we cannot guarantee our ability to continue as a going concern. **As of March 15, 2013, we had cash on hand of approximately $380,000 due to the capital raises described under "Recent Developments," which should be sufficient to fund operations for approximately 4 months**.

The Company is primarily involved in the following activities:

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

Licensing

The Company has been in discussions with various parties in the tobacco and pharmaceutical industries for licensing its technology and products since the first quarter of 2012. Management is exploring licensing arrangements on a country-by-country basis in the U.S., Europe and Asia. The Company expects to close at least one licensing agreement for its technology and products before the end of the third quarter of 2013.

X-22

The *X-22* therapy protocol utilized in the Company's sponsored Phase II-B clinical trial calls for the patient to smoke our very low nicotine ("VLN") cigarettes over a six-week treatment period to facilitate the goal of the patient quitting smoking by the end of the treatment period. We believe this therapy protocol has been successful in independent clinical trials because VLN cigarettes made from our proprietary tobacco satisfy smokers' cravings for cigarettes while (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine. *X-22* involves the same smoking behavior as conventional cigarettes and because patients are simply switching to VLN cigarettes for 6 weeks, *X-22* does not expose the smoker to any new drugs or new side effects. Our Investigational New Drug Application for *X-22*, a kit of VLN cigarettes, was cleared by the FDA in July 2011. Our *X-22* Phase II-B clinical trial was completed in the first quarter of 2012 and did not demonstrate a statistically significant difference in quitting between *X-22* and the active control, a cigarette containing conventional nicotine levels. However, the median number of *X-22* cigarettes smoked during the trial was significantly reduced compared to patients' baseline of usual brand of cigarettes. In evaluating the results of this trial, we believe we may have reduced the nicotine content of *X-22* by too great a percentage, to a level less than half the nicotine content of VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases quit rates.

In contrast to the results of the Company's Phase II-B trial results, independent studies have demonstrated that VLN cigarettes, whether used alone or in conjunction with nicotine replacement therapy (NRT), increase quitting rates. Due to the limited effectiveness and/or serious side effects of existing FDA-approved smoking cessation products, we believe that if additional clinical trials demonstrate increased smoking cessation rates, *X-22* can capture a share of this market by replacing sales and market share from existing smoking cessation aids and expanding the smoking cessation market by encouraging more smokers to attempt to quit smoking. We are currently in the process of identifying potential joint venture partners to fund the remaining *X-22* clinical trials. We estimate the cost of completing the remaining *X-22* clinical trials to be approximately $14 million and the marketing expenses to bring *X-22* to market in the U.S. are estimated to be approximately $5 million. There is no guarantee that we will (i) obtain the funds necessary to complete additional clinical trials, (ii) identify potential joint venture partners to fund the remaining *X-22* clinical trials, (iii) obtain FDA approval, or (iv) capture significant share of the smoking cessation market upon FDA approval.

We continue to believe that our VLN cigarettes are effective as a smoking cessation aid. However, we have suspended sponsoring further *X-22* clinical trials pending a complete analysis of results of two independent smoking-cessation trials that were completed in 2012 (ClinicalTrials.gov Identifiers NCT01050569 and NCT01250301), which utilized a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than that used in our own sponsored Phase II-B trial. A portion of the results of these two trials has been disclosed at the annual meeting of the Society for Research on Nicotine and Tobacco ("SRNT") held in Boston on March 13 to 16, 2013.

Regarding the NCT01050569 clinical trial, results only in terms of gender differences in abstinence rates were disclosed at the SRNT annual meeting. Dorothy Hatsukami, PhD, was principal investigator of the study. Within the female population at the end of treatment (week 12), the group assigned our VLN cigarette had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned a 21mg nicotine patch. Within the male population at the end of treatment (week 12), the group assigned a 21mg nicotine patch had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned our VLN cigarette.

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

The full set of results of these 2 independent clinical trials are expected to be published in peer reviewed journals and will be compared to results of other independent clinical trials of our VLN cigarettes and results of our Phase II-B trial to determine which variables optimize cessation. One preliminary hypothesis, in conjunction with results of various other studies of our VLN cigarettes, is that having two types of prescription VLN cigarettes available may be advantageous for increased smoking cessation in the general population; one having a higher nicotine content than the other. Upon identifying a suitable joint venture partner to fund further *X-22* clinical trials, we will then request a meeting with the U.S. Food and Drug Administration ("FDA"), and thereafter we may resume our own sponsored *X-22* clinical trials.

Potential Modified Risk Cigarettes and the Tobacco Control Act

The 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") granted the FDA authority over the regulation of all tobacco products. While it prohibits the FDA from banning cigarettes outright, it allows the FDA to require the reduction of nicotine or any other compound in tobacco and cigarette smoke. The Tobacco Control Act also banned all sales in the U.S. of cigarettes with characterizing flavors (other than menthol). As of June 2010, all cigarette companies were required to cease the use of the terms "low tar," "light" and "ultra light" in describing cigarettes sold in the U.S. Besides numerous other regulations, including certain marketing restrictions, for the first time in history, a U.S. regulatory agency will scientifically evaluate cigarettes that may pose lower health risks as compared to conventional cigarettes.

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of 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*, may qualify as Modified Risk Cigarettes. Compared to commercial cigarettes, the tobacco in *BRAND A* has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes, and *BRAND B*'s smoke contains an extraordinary low amount of "tar" per milligram of nicotine.

Goodrich Tobacco intends to seek FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes and expect to file applications with the FDA in 2013, the exact timing will depend on the timing of obtaining additional capital. After filing our modified risk applications with the FDA, we will need significant additional capital to complete the FDA authorization process for our Modified Risk Cigarettes. The exact amount of capital is currently unknown since it is uncertain how many exposure studies the FDA will require for *BRAND A* and *BRAND B*. However, we estimate that the cost of completing the FDA authorization process for each of our potential Modified Risk Cigarettes to be at least $2 million. We believe that *BRAND A* and *BRAND B* will achieve market share in the global cigarette market among smokers who will not quit but are interested in reducing the harmful effects of smoking. There is no guarantee that we will (i) obtain additional capital to complete the FDA authorization process for our potential Modified Risk Cigarettes, (ii) obtain FDA authorization to market *BRAND A or BRAND B* as Modified Risk Cigarettes, or (iii) achieve significant market with FDA authorization to market our products as Modified Risk Cigarettes.

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. Although *X-22* has failed previously to qualify for "Fast Track," we believe that upon completion of a company-sponsored clinical trial demonstrating efficacy, *X-22* will qualify for "Fast Track" designation by the FDA. However, there is no guarantee that the FDA will grant "Fast Track" designation to *X-22*. See "Business – Government Regulation – Fast Track Development."

Modified Risk Cigarettes

We believe this new regulatory environment represents a paradigm shift for the tobacco industry. Besides the fact that the Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, the Tobacco Control Act allows the FDA to mandate the use of reduced-risk technologies across all conventional tobacco products or cigarettes. We believe the Tobacco Control Act may create opportunities for us to license our proprietary technology and/or tobaccos to larger competitors.

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 (e.g., more and/or larger puffs per cigarette) of low-tar research cigarettes, similar to *BRAND B (*though *BRAND B* was not used in such studies), is greatly curtailed resulting in smokers inhaling less "tar" and carbon monoxide. Additional studies will be necessary to establish whether *BRAND B* cigarettes achieve similar results.

RED SUN and MAGIC Cigarettes

Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the "Master Settlement Agreement" or "MSA," a settlement among 46 states and the tobacco industry administered by the National Association of Attorneys General ("NAAG"). Our subsidiary, Goodrich Tobacco, introduced in a limited capacity two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. There have been *de minimis* sales of these brands in 2011 and 2012 since we have intentionally have not expanded marketing and distribution of these brands to facilitate Goodrich Tobacco becoming a participating manufacturer of the MSA. The more *RED SUN* and *MAGIC* sold while these brands are produced by a non-participating manufacturer, the greater the settlement costs Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA. On January 23, 2013, Goodrich Tobacco applied to the Alcohol and Tobacco Tax Trade Bureau ("TTB") for a federal permit to manufacture its own tobacco products. Being a federally licensed tobacco product manufacturer is a primary requirement of becoming a participating manufacturer of the MSA. On February 26, 2013, Goodrich Tobacco applied to the NAAG to become a participating manufacturer to the MSA. Both of these measures, if approved by the TTB and NAAG, will greatly facilitate the sales and distribution potential of *RED SUN* and *MAGIC*. Goodrich Tobacco expects its cigarette factory startup costs to be approximately $250,000 and plans to lease a portion of the machinery required. The costs associated with the MSA settlement are expected to be less than $40,000. The expected marketing costs for *RED SUN* and *MAGIC* in 2013 are $100,000.

SPECTRUM Government Research Cigarettes

As a subcontractor to RTI International ("RTI") in RTI's contract with The National Institute on Drug Abuse for the Research Cigarette Option, we supply modified nicotine (from very low to high) cigarettes to NIDA. These research cigarettes are distributed under the mark *SPECTRUM*.

For more information about our business, see "Business" and "Management's Discussion and Analysis of Financial Condition" in this prospectus.

Current Financial Condition

We have operated at a loss since 2006 when we increased our research and development expenditures. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 expresses substantial doubt regarding whether we can continue as a going concern and we cannot guarantee our ability to continue as a going concern. We had net losses of $6.7 million, $1.3 million and $1.4 million, respectively, in the years ended December 31, 2012, 2011 and 2010. We realized revenue of $18,775 in the year ended December 31, 2012 mainly from the sale of research cigarettes. In the year ended December 31, 2011, we realized revenue of $788,601 mainly from the sale of research cigarettes and in 2010, we realized revenue of $49,784. **As of March 15, 2013, we had cash on hand of approximately $380,000 due to the capital raises described under "Recent Developments," which should be sufficient to fund operations for approximately 4 months.**

Subsequent to December 31, 2012, the Company realized net proceeds of approximately $2.125 million through the sale of preferred shares. Convertible Notes with a carrying value at December 31, 2012 of approximately $1.41 million were converted into common stock and warrants. While these steps significantly improved the Company's financial position, we will need additional capital or one or more licensing arrangements for our technology and products in order to meet cash requirements to fund operations and meet our obligations during 2013. Excluding contract growing of our proprietary tobacco with farmers and extraordinary expenses such as clinical trials and factory setup costs, our monthly cash expenditures are approximately $100,000. In the event the Company does not enter into an out-licensing agreement with a third party in 2013, approximately $1.6 million of additional capital is required through 2013, which includes paying approximately $1 million of obligations that will become due in 2013. The Company expects its cigarette factory start up costs to require an additional $250,000 of capital. It plans to lease a portion of the machinery required. The Company's R&D expenditures in 2013 are expected to be approximately $200,000. Upon the required funding, we expect to carry out exposure studies for our Modified Risk cigarette candidates and will carry out additional clinical trials for *X-22* if Hercules Pharmaceuticals, our subsidiary, identifies a joint venture partner willing to fund these trials.

The ability to complete additional equity or debt 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, licensing of its technology, products and tobacco, and results of independent smoking cessation clinical trials utilizing the Company's products. In addition, our ability to complete additional debt and equity financings is limited by covenants related to our Series A-1 Preferred Stock. However, we can issue securities pursuant to strategic transactions approved by a majority of our disinterested directors, provided that any such issuance shall only be to an entity which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with our business which provides us additional benefits in addition to the investment of funds. See "Risk Factors - Our ability to obtain future debt financing is limited while shares of our Series A-1 Preferred Stock are outstanding" on page 12 of this prospectus. Failure to license the Company's technology, products and tobacco or to raise sufficient capital would significantly increase the risk that we would be unable to continue operations. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technology, tobacco or products or grant licenses on terms that are not favorable to us. There can be no assurance that the Company will be able to raise sufficient financing or obtain a significant licensing contract.

Corporate Information

Our principal executive offices are located at 9530 Main Street, Clarence, New York 14031. The telephone number at our principal executive offices is (716) 270-1523. Our website address is www.xxiicentury.com. Information contained on our website is not deemed part of this prospectus.

Recent Developments

Private Placement of Preferred Stock and Warrants

On January 11, 2013, we entered into and closed the transactions described in a Securities Purchase Agreement with certain accredited investors identified therein (collectively, the "Purchasers"), whereby we sold 2,500 shares of newly created Series A-1 10% Convertible Preferred Stock (the "Series A-1 Preferred Stock") and Warrants (as defined below) for an aggregate purchase price of $2,500,000. We also entered into a Registration Rights Agreement whereby we agreed to file a registration statement to register the resale of the shares of our common stock that are potentially issuable under each of the securities described below.

The shares of Series A-1 Preferred Stock are initially convertible into a total of 4,166,666 shares of the Company's common stock at a conversion price of $0.60 per share (the "Conversion Price"), subject to future adjustments. The Series A-1 Preferred Stock will pay a 10.0% annual cash dividend, which may be payable in shares of our common stock in certain circumstances, and will have a liquidation preference equal to the stated value of the Series A-1 Preferred Stock of $1,000 per share plus any accrued and unpaid dividends thereon. The Series A-1 Preferred Stock has no voting rights. The Conversion Price of the Series A-1 Preferred Stock is subject to adjustment as follows:

(i) on the effective date of this registration statement, the Conversion Price will be reduced to the lesser of (1) the then Conversion Price, as adjusted and taking into consideration any prior resets, (2) the greater of $0.35 (subject to adjustment for reverse and forward stock splits and the like) and 70% of the average of the five (5) trading day volume weighted average prices, or VWAPs, immediately prior to each such effective date or (3) $0.60 (subject to adjustment for forward and reverse stock splits and the like);

(ii) if on the 180th day immediately following the closing date of January 11, 2013 (the "Closing Date"), 70% of the average of the five (5) trading day VWAPs immediately prior to such date is less than the then Conversion Price, then on such 180th day the Conversion Price shall be reduced, and only reduced, to the lesser of (1) the then Conversion Price, as adjusted and taking into consideration any prior resets, (2) the greater of $0.15 (subject to adjustment for reverse and forward stock splits and the like) and 70% of the average of the five (5) trading day VWAPs immediately prior to each such 180th day immediately following the Closing Date or (3) $0.35 (subject to adjustment for forward and reverse stock splits and the like); and

(iii) if all of the shares required to be registered are not registered pursuant to an effective registration statement within the 120th day anniversary of the Closing Date, then on the 180th day and 270th day following the Closing Date, the Conversion Price shall be reduced, and only reduced, to the lesser of (1) the then Conversion Price, as adjusted and taking into consideration any prior resets, (2) the greater of $0.15 (subject to adjustment for reverse and forward stock splits and the like) and 70% of the average of the five (5) trading day VWAPs immediately prior to each such date or (3) $0.35 (subject to adjustment for forward and reverse stock splits and the like).

The foregoing description of the Series A-1 Preferred Stock is only a summary and is not complete. For additional information about the terms of the Series A-1 Preferred Stock, including the anti-dilution features, liquidated damages provisions for certain events and negative covenants, see the section entitled "Description of Securities – Preferred Stock" in this prospectus.

We also issued to the Purchasers a Series A warrant (the "Series A Warrant"), a Series B warrant (the "Series B Warrant"), and a Series C warrant (the "Series C Warrant") (with the Series A Warrant, Series B Warrant and Series C Warrant being collectively referred to herein as the "Warrants"). The Series A Warrant allows the Purchasers the right to acquire, initially before any adjustments to the conversion price, up to an additional 4,166,666 shares of the Company's common stock at an exercise price of approximately $0.72 per share over a period of five (5) years. The Series A Warrant also allows for such warrant to be exercised on a cashless basis. The Series B Warrant allows the Purchasers a one-year period to exercise an overallotment option as contained in the Series B Warrant to purchase, initially before any adjustments to the conversion price, up to an additional aggregate of 2,083,334 shares of the Company's common stock at a price of $0.60 per share. The Series B Warrant may not be exercised on a cashless basis except only in certain limited circumstances. In the event the Purchasers exercise, in whole or in part the overallotment option as contained in the Series B warrant, then the Purchasers shall have the right to exercise on a pro rata basis the portion of the Series C Warrant issued to the Purchasers to acquire, initially before any adjustments to the conversion price, up to an additional aggregate of 2,083,334 shares of the Company's common stock at an exercise price of approximately $0.72 per share over a period of five (5) years. The Series C Warrant allows for such warrant to be exercised on a cashless basis.

The foregoing description of the Warrants is only a summary and is not complete. For additional information about the terms of the Warrants, including the anti-dilution features, see the section entitled "Description of Securities – Warrants and Convertible Notes" in this prospectus.

The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of the outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be).

The Series A-1 Preferred Stock and the Warrants were offered and sold pursuant to an exemption from the registration requirements under Sections 4(2), Section 4(6) and Regulation S of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

We paid Chardan Capital Markets LLC a commission equal to (i) ten percent (10%) of the cash received by us and (ii) 416,666 shares of common stock. In the event the Purchasers exercise for cash any of the Warrants, then we will also pay an additional cash commission to Chardan Capital Markets LLC equal to eight percent (8%) (with no additional equity) of any such additional cash amounts received by us. After deducting fees and expenses, the aggregate net proceeds from the sale of the Series A-1 Preferred Shares and the Warrants were approximately $2.125 million. We intend to use the net proceeds for the payment of certain financial obligations and for working capital and other general corporate purposes.

Modification and Conversion of Convertible Notes Due December 14, 2012

On December 14, 2011, we sold approximately $1.9 million of convertible promissory notes for an aggregate purchase price of approximately $1.7 million in a private placement (the "Convertible Notes"). The notes were issued with an original issue discount of approximately 15% and the original maturity date of the notes was December 14, 2012 (which was extended as set forth below). Upon conversion of all or a portion of the Convertible Notes into common stock, the holder would receive at that time a warrant to purchase at an exercise price of $1.50 per share; such number of shares of common stock from such warrant equal to 120% of such number of shares of common stock issuable upon conversion of the note. All of the Convertible Notes issued on December 14, 2011 have been either converted or paid off in full subsequent to December 31, 2012. At December 31, 2012 notes with a total face and carrying value of $1,805,500 remained outstanding; of this amount $1,523,750 were extended, by agreement with the note holders, to April 14, 2013 at 15% interest per annum. The notes were initially convertible into shares of our common stock at any time prior to maturity at a per share conversion price equal to $0.75. From January 1, 2013 to February 6, 2013, $1,408,750 of the notes (together with accrued interest), with an adjusted conversion price of $0.7004 were converted into 2,035,720 shares of common stock and five-year warrants to purchase 2,662,769 shares of common stock at $1.50 per share; the Company discharged the remaining note principal of $396,750 by payment in

cash of $339,250 and issuing a new note of $57,500 maturing in August 2013. A $247,250 note held by an executive officer and another note of $30,000 were discharged through payments in cash. Subsequent to this repayment, the Company issued a promissory note to the executive officer in the amount of $150,000, with 15% interest per annum and maturing on July 1, 2013. A third note of $115,000 plus interest was discharged through a payment of $58,340 in conjunction with a new note being issued for the same amount. In connection with the issuance of preferred shares in January 2013, the note holders entered into a lock-up agreement with the Company which limits their ability to sell any of the shares received as a result of the conversion of the notes and received additional warrants (five year term at $1.50 exercise price) to purchase 239,900 shares of common stock.

Between December 14, 2012 and January 2, 2013, we entered into agreements with holders of $1,805,500 of the notes that remained outstanding. Holders of $1,408,750 of the notes agreed to extend the maturity date of the notes to April 14, 2013. Holders of $115,000 of the notes elected to convert into shares of the common stock pursuant to the terms of the notes. Holders of $247,250 of the notes elected to enter into a forbearance agreement and were subsequently paid in full. Holders of $34,500 of the notes agreed to be paid over time. On January 24, 2013, we sent out notices to the holders of the notes regarding our intent to repay the notes at the expiration of a 15-day period during which time the holders may convert to common stock and warrants to purchase common stock. From January 1, 2013 through February 6, 2013, the remaining notes were converted into common stock and warrants.

Certain Arrangements

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, which were due on July 1, 2012 have not been paid as of December 31, 2012. The outstanding principal on this note was $350,000 as of December 31, 2012 and 2011. In January 2013 the Company repaid

$175,000 of note principal and all accrued interest; the balance of $175,000 was replaced by a new note which is unsecured, bears interest at 5% and matures July 1, 2014 or sooner if the Company receives license revenue or financing of at least $1,500,000 prior to maturity.

As of March 15, 2013, the Company was in full compliance with the NCSU license agreement. Since December 31, 2012 the Company paid NCSU $400,000 and issued a note dated February 1, 2013 for $474,893; the note is unsecured, bears interest at 5% and matures the earlier of October 1, 2013 or the closing of an in-licensing agreement with up front proceeds of at least $1.5 million. NCSU also agreed to not to invoke any rights to terminate the Company's

license agreement for nonpayment or nonperformance until October 1, 2013.

Appointment of New Chief Financial Officer Effective April 1, 2013

On March 19, 2013, we appointed Mr. John T. Brodfuehrer to be our Chief Financial Officer and Treasurer beginning April 1, 2013. Mr. Brodfuehrer was not appointed to be a Director of the Company. In connection with Mr. Brodfuehrer's appointment, Mr. Henry Sicignano III will step down from his role as interim Chief Financial Officer on April 1, 2013; Mr. Sicignano will continue to serve as President, Secretary and Director of the Company.

Mr. Brodfuehrer, age 55, served as Chief Financial Officer of Latina Boulevard Foods, LLC, an entity formed as the result of a merger of two long-time Western New York wholesale food distributors, from March 2011 until March 2013. From May 2010 to February 2011, Mr. Brodfuehrer was Vice-President of Retail Accounting for United Refining Company, an independent refiner and marketer of petroleum products. Prior to his time at United Refining Company, Mr. Brodfuehrer served in multiple roles over a twenty-four year span with NOCO Incorporated (formerly NOCO Energy Corp.) a diversified distributor of energy products and related services. Mr. Brodfuehrer served as NOCO Incorporated's Chief Financial Officer, Vice-President and as a member of the Board of Directors from 2000 to June 2009 and as a financial consultant to NOCO Incorporated from July 2009 to April 2010. Mr. Brodfuehrer earned a Bachelor of Science in Business Administration, *summa cum laude*, from the State University of New York at Buffalo in 1979 and became a New York State Certified Public Accountant in 1981.

Mr. Brodfuehrer executed an employment agreement with us for an initial term of two years. Pursuant to the employment agreement, Mr. Brodfuehrer will earn an initial base salary of one hundred ten thousand dollars and may become eligible for certain bonuses and equity awards. Further, if Mr. Brodfuehrer's employment is terminated prior to the end of the initial two year term by the Company without "Cause" or by Mr. Brodfuehrer for Good Reason (as such terms are defined in the employment agreement), Mr. Brodfuehrer will be entitled to a severance benefit in the form of a continuation of his then-base salary until the later of (i) six months from the termination date or (ii) the expiration of the initial two year term. Mr. Brodfuehrer was also awarded one hundred thousand (100,000) restricted shares of common stock, which are subject to vesting conditions.

The Offering

Common stock currently outstanding	38,259,365 shares (1) (2)
Common stock offered by us	None.
Common stock offered by the selling stockholders	Up to 6,250,000 shares issuable (i) upon conversion of our Series A-1 Preferred Stock and (ii) upon the exercise of the Series B Warrants.
Use of Proceeds	We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Series B Warrants, if exercised.
Risk Factors	See “Risk Factors” and other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in shares of our common stock.
OTC Bulletin Board Symbol	XXII.OB

(1) As of March 15, 2013.

(2) Unless otherwise indicated, the number of shares in this prospectus does not give effect to:

- up to 4,166,666 shares of common stock that could be issued as a result of the conversion of the shares of Series A-1 Preferred Stock, which is subject to adjustment as described under “Description of Securities – Preferred Stock”;
- up to 950,000 shares of common stock reserved for future issuance under the Equity Incentive Plan;
- up to 680,000 shares of common stock issuable upon exercise of outstanding stock options;
- up to 371,000 shares of common stock currently issuable upon the conversion of convertible notes (subject to adjustment for anti-dilution adjustments);
- up to 22,343,082 shares of common stock currently issuable upon the exercise of outstanding warrants (including the Series A Warrants and Series B Warrants) (subject to adjustment for anti-dilution adjustments); and
- up to 2,454,334 shares of common stock issuable upon exercise of warrants issuable upon conversion or exercise of other instruments (including the Series C Warrants) (subject to adjustment for anti-dilution adjustments).

Cautionary Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements. This prospectus includes statements regarding our plans, goals, strategies, intentions, beliefs or current expectations. These statements are expressed in good faith and based upon a reasonable basis when made, but there can be no assurance that these expectations will be achieved or accomplished. These forward looking statements can be identified by the use of terms and phrases such as “believe,” “plan,” “intend,” “anticipate,” “target,” “estimate,” and “expect.” Items contemplating or making assumptions about, actual or potential future sales, market size, collaborations, and trends or operating results also constitute forward-looking statements.

These forward-looking statements are only predictions, are uncertain and involve substantial known and unknown risks, uncertainties and other factors which may cause our (or our industry’s) actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements. The “Risk Factors” section of this prospectus sets forth detailed risks, uncertainties and cautionary statements regarding our business and these forward-looking statements.

Since our common stock is considered a “penny stock,” we are ineligible to rely on the safe harbor for forward-looking statements provided in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events. You should carefully review and consider the various disclosures made by us in our reports filed with the Securities and Exchange Commission which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operation and cash flows. If one or more of these risks or uncertainties materialize, or if the underlying assumptions prove incorrect, our actual results may vary materially from those expected or projected.

Risk Factors

An investment in shares of our common stock is highly speculative and involves a high degree of risk. We face a variety of risks that may affect our operations or financial results and many of those risks are driven by factors that we cannot control or predict. The following discussion addresses all risks that management believes are material that may affect our operations or financial results. Only those investors who can bear the risk of loss of their entire investment should participate in this offering. Prospective investors should carefully consider the following risk factors in evaluating an investment in our common stock.

Risks Related to Our Business and Operations

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

Recurring losses from operations, our negative working capital of approximately $3.3 million and $1.9 million as of December 31, 2012 and 2011, respectively, shareholders' deficit of $6.1 million and $1.2 million as of December 31, 2012 and 2011, respectively, and the uncertainty of obtaining additional capital on a timely basis, raise doubt about our ability to continue as a going concern. It is highly probable that any sales of equity securities will cause our stockholders to experience substantial dilution. It is also possible that such equity securities will 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, 2012 expresses substantial doubt regarding 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, including adjustment of our warrant liability, of approximately $6.7 million, $1.3 million and $1.4 million during the years ended December 31, 2012, 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. Excluding contract growing of our proprietary tobacco with farmers and extraordinary expenses such as clinical trials and factory setup costs, our monthly cash expenditures are approximately $100,000. In the event the Company does not enter into an out-licensing agreement with a third party in 2013, approximately $1.6 million of additional cash is required through 2013, which

includes paying approximately $1 million of obligations that will become due in 2013. There can be no assurance that the Company will be able to raise sufficient financing or obtain a licensing agreement.

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 $1,927,000, $4,057,000 and $1,018,000 during the years ended December 31, 2012, 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* because we have significant liabilities that are due or that will become due in 2013 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 likely 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 ability to obtain future debt financing is limited while shares of our Series A-1 Preferred Stock are outstanding.

Our Certificate of Designations regarding our Series A-1 Preferred Stock contains restrictive covenants that limit our ability to, among other things, incur or assume additional debt or provide guarantees in respect of obligations of other persons (in each case, so long as 1,000 or more shares of our Series A-1 Preferred Stock are outstanding, and other than with respect to lease obligations and purchase money indebtedness in an amount up to $200,000 in the aggregate), or create, assume, or suffer to exist any liens (other than liens for taxes not yet due, liens contested in good faith, and liens imposed in the ordinary course of business that do not materially impair the operation of the business) without, in each instance, the prior written consent of at least 67% in stated value of the then-outstanding shares of Series A-1 Preferred Stock. A breach of these covenants would trigger the ability of the holders of the Series A-1 Preferred Stock to redeem their shares of Series A-1 Preferred Stock for cash or shares of our common stock or elect to increase the dividend payments to be made on their shares of Series A-1 Preferred Stock to 18% per annum. However, our Certificate of Designations regarding our Series A-1 Preferred Stock allows us to issue securities without restrictions pursuant to strategic transactions approved by a majority of our disinterested directors, provided that any such issuance shall only be to an entity which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with our business which provides us additional benefits in addition to the investment of funds.

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 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, 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 aid and we will need additional capital before we can complete the FDA authorization process for our Modified Risk Cigarettes.

We have suspended further clinical trials for FDA approval of our *X-22* smoking cessation aid until we identify a suitable joint venture partner willing to fund further *X-22* clinical trials. At that time we may resume our own sponsored *X-22* clinical trials. There is no guarantee that we will identify a joint venture partner willing to fund further *X-22* clinical trials. We estimate the cost of completing a Phase II trial will be approximately $2 million and the cost of completing two Phase III trials to be approximately $12 million. We will require additional capital in the future before we can complete the FDA authorization process for our Modified Risk Cigarettes. We estimate that the cost of completing the FDA authorization process for each of our two potential Modified Risk Cigarettes to be at least $2 million. If we raise additional funds through the issuance of equity securities for the FDA authorization process for our Modified Risk Cigarettes, our stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. However, our ability to raise funds through debt financing is limited while any shares of our Series A-1 Preferred Stock is outstanding. We also could elect to seek funds through arrangements with collaborators or licensees. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to us.

If we choose to resume 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, 2012 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 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 manufacturers 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 potential products and their potential advantages over existing products;
- the prevalence and severity of any side effects;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

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

Our principal competitors in the smoking cessation market have, and any future competitors may have, greater financial and marketing resources than we do, and they may therefore develop products or other technologies similar or superior to ours or otherwise compete more successfully than we do.

We have no experience in selling smoking cessation products. Competition in the smoking cessation aid products industry is intense, and we may not be able to successfully compete in the market. In the market for FDA-approved smoking cessation aids, our principal competitors include Pfizer Inc., GlaxoSmithKline PLC, Perrigo Company, 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 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 products;

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

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

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

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

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

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

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

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

Government mandated prices, production control programs, shifts in crops driven by economic conditions and adverse weather patterns may increase the cost or reduce the quality of the tobacco and other agricultural products used to manufacture our products.

We depend upon independent tobacco farmers to grow our specialty proprietary tobaccos with specific nicotine contents for our products. As with other agricultural commodities, the price of tobacco leaf can be influenced by imbalances in supply and demand, and crop quality can be influenced by variations in weather patterns, diseases and pests. We must also compete with other tobacco companies for contract production with independent tobacco farmers. Tobacco production in certain countries is subject to a variety of controls, including government mandated prices and production control programs. Changes in the patterns of demand for agricultural products could cause farmers to plant less tobacco. Any significant change in tobacco leaf prices, quality and quantity could affect our profitability and our business.

Our future success depends on our ability to retain key personnel.

Our success will depend to a significant extent on the continued services of our senior management team, and in particular Joseph Pandolfino, our Chief Executive Officer, Henry Sicignano III, our Chief Financial Officer and President, and Michael Moynihan, Ph.D., our Vice President of R&D. The loss or unavailability of any of these individuals may significantly delay or prevent the development of our potential products and other business objectives by diverting management’s attention to transition matters. While each of these individuals is party to employment agreements with us, they could terminate their relationships with us at any time, and we may be unable to enforce any applicable employment or non-compete agreements.

We also rely on consultants and advisors to assist us in formulating our research and development, manufacturing, distribution, marketing and sales strategies. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us.

Product liability claims, product recalls or other claims could cause us to incur losses or damage our reputation.

The risk of product liability claims or product recalls, and associated adverse publicity, is inherent in the development, manufacturing, marketing and sale of tobacco and smoking cessation products. We do not currently have product liability insurance for our products or our potential products and do not expect to be able to obtain product liability insurance at reasonable commercial rates for these products. Any product recall or lawsuit seeking significant monetary damages may have a material adverse effect on our business and financial condition. A successful product liability claim against us could require us to pay a substantial monetary award. We cannot assure you that such claims will not be made in the future.

Risks Related to Regulatory Approvals and Insurance Reimbursement

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

There can be no assurance that our *X-22* smoking cessation aid will be approved by the FDA, European Medicines Agency, or any other governmental body. In addition, there can be no assurance that all necessary approvals will be granted for our potential products or that review or actions will not involve delays caused by requests for additional information or testing that could adversely affect the time to market for and sale of our potential products. Our ability to complete the FDA-approval process in a timely manner is dependent, in part, on our ability to obtain "Fast Track" designation for *X-22* by the FDA.

We submitted a request for Fast Track designation for *X-22*, and on August 18, 2011, the FDA informed us that it would not grant the designation of *X-22* as a Fast Track product at this time because we did not 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 a NDA. If we do not obtain Priority Review of our New Drug Application, we would then expect the timing of FDA approval of *X-22* to be extended several additional months. Even if *X-22* is approved by the FDA, the FDA may require the product to only be prescribed to patients who have already failed to quit smoking with another approved therapy. Further, failure to comply with applicable regulatory requirements can, among other things, result in the suspension of regulatory approval as well as possible civil and criminal sanctions.

The development, testing, manufacturing and marketing of our potential products are subject to extensive regulation by governmental authorities in the United States and throughout the world. In particular, the process of obtaining approvals by the FDA, European Medicines Agency and other international FDA equivalent agencies in targeted countries is costly and time consuming, and the time required for such approval is uncertain. Our *X-22* smoking cessation aid must undergo rigorous clinical testing and an extensive regulatory approval process mandated by the FDA or EMEA. Such regulatory review includes the determination of manufacturing capability and product performance. Generally, only a small percentage of pharmaceutical products are ultimately approved for commercial sale.

The scope of review, including product testing and exposure studies, to be required by the FDA under the Tobacco Control Act in order for cigarettes such as BRAND A and BRAND B to be marketed as Modified Risk Cigarettes has not yet been fully established. 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 or products that have not yet been cleared for commercial distribution in the United States, such products may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals could impair our ability to generate revenue from international sources.

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

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

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

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

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

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

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

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

Risks Related to the Tobacco Industry

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

Cigarette companies face significant governmental action, especially in the United States pursuant to the Tobacco Control Act, including efforts aimed at reducing the incidence of tobacco use, restricting marketing and advertising, imposing regulations on packaging, warnings and disclosure of flavors or other ingredients, prohibiting the sale of tobacco products with certain flavors or other characteristics, limiting or prohibiting the sale of tobacco products by certain retail establishments and the sale of tobacco products in certain packaging sizes, and seeking to hold retailers and distributors responsible for the adverse health effects associated with both smoking and exposure to environmental tobacco smoke. Governmental actions, combined with the diminishing social acceptance of smoking and private actions to restrict smoking, have resulted in reduced industry volume in the United States and certain other countries, and we expect that these factors will continue to reduce consumption levels in these countries.

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

Significant regulatory developments will take place over the next few years in many markets, driven principally by the World Health Organization's Framework Convention on Tobacco Control ("FCTC"). The FCTC is the first international public health treaty on tobacco, and its objective is to establish a global agenda for tobacco regulation with the purpose of reducing initiation of tobacco use and encouraging cessation. In addition, the FCTC has led to increased efforts by tobacco control advocates and public health organizations to reduce the appeal of tobacco products. Partly because of some or a combination of these efforts, unit sales of tobacco products in certain markets, principally Western Europe and Japan, have been in general decline and we expect this trend to continue. Our operating results could be significantly affected by any significant decrease in demand for cigarettes, any significant increase in the cost of complying with new regulatory requirements and requirements that lead to a commoditization of tobacco products such as the 2012 implementation of plain packaging in Australia.

If implemented in the future, the FDA requirement regarding graphic health warnings on cigarette packaging and in cigarette advertising is likely to have a negative impact on sales of our products.

In November 2010, as required by the Tobacco Control Act, the FDA issued a proposed rule to modify the required warnings that appear on cigarette packages and in cigarette advertisements. These warning were finalized on June 21, 2011 and consist of nine new textual warning statements accompanied by color graphics depicting the negative health consequences of smoking. The FDA selected nine images from the originally proposed 36 images after reviewing the relevant scientific literature, analyzing the results from an 18,000 person study and considering more than 1,700 comments from a variety of groups. The graphic health warnings 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 ruled that these warnings are unconstitutional. If and when these graphic health warnings are implemented, all cigarettes manufactured for sale or distribution in the United States will need to include these new graphic health warnings on their packages. Any reduction in the number of smokers will probably reduce the demand for MAGIC and RED SUN, as well as *X-22*, BRAND A and BRAND B, if and when 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.

Cigarettes are subject to substantial taxes. Significant increases in cigarette-related taxes have been proposed or enacted and are likely to continue to be proposed or enacted in numerous jurisdictions. These tax increases may affect our sales and profitability and make us less competitive versus certain of our competitors.

Tax regimes, including excise taxes, sales taxes and import duties, can disproportionately affect the retail price of manufactured cigarettes versus other tobacco products, or disproportionately affect the relative retail price of our RED SUN and MAGIC cigarettes and, upon FDA authorization, our BRAND A and BRAND B cigarettes versus lower-priced cigarette brands manufactured by our competitors. Increases in cigarette taxes are expected to continue to have an adverse impact on sales of cigarettes resulting in (i) lower consumption levels, (ii) a shift in sales from manufactured cigarettes to other tobacco products or to lower-price cigarette categories, (iii) a shift from local sales to legal cross-border purchases of lower price products, and (iv) illicit products such as contraband and counterfeit.

We may become subject to governmental investigations on a range of matters.

Tobacco companies are often subject to investigations, including allegations of contraband shipments of cigarettes, allegations of unlawful pricing activities within certain markets, allegations of underpayment of custom duties and/or excise taxes, and allegations of false and misleading usage of descriptors such as “lights” and “ultra lights.” We cannot predict the outcome of any to which we may become subject, and we may be materially affected by an unfavorable outcome of future investigations.

Risks Related to Intellectual Property

Our proprietary rights may not adequately protect our intellectual property, products and potential products, and if we cannot obtain adequate protection of our intellectual property, products and potential products, we may not be able to successfully market our products and potential products.

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our technologies, products and potential products. We will only be able to protect our technologies, products and potential products from unauthorized use by third parties to the extent that valid and enforceable patents cover them, or other market exclusionary rights apply.

The patent positions of life sciences companies, like ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. The general patent environment outside the United States also involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may be allowed or that the scope of these patent rights could provide a sufficient degree of future protection that could permit us to gain or keep our competitive advantage with respect to these products and technology. Additionally, life science companies like ours are often dependent on creating a pipeline of products. We may not be able to develop additional potential products or proprietary technologies that produce commercially viable products or that are themselves patentable.

Although there are currently no challenges to any portion of our intellectual property, our issued patents may be subject to challenge and possibly invalidated by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. In addition, others may independently develop similar or alternative products and technologies that may be outside the scope of our intellectual property. Should third parties obtain patent rights to similar products or technology, this may have an adverse effect on our business.

We also rely on trade secrets to protect our technology, products and potential products, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets, however, are difficult to protect. While we believe that we use reasonable efforts to protect our trade secrets, our own or our strategic partners' employees, consultants, contractors or advisors may unintentionally or willfully disclose our information to competitors. We seek to protect this information, in part, through the use of non-disclosure and confidentiality agreements with employees, consultants, advisors and others. These agreements may be breached, and we may not have adequate remedies for a breach. In addition, we cannot ensure that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information or prevent their unauthorized use or disclosure.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our products and potential products, disputes may arise as to the proprietary rights of the information, which may not be resolved in our favor. Key employees are required to assign all intellectual property rights in their discoveries to us. However, these key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. If we were to prosecute a claim that a third party had illegally obtained and was using our trade secrets, it could be expensive and time consuming and the outcome could be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any contractual claim to this information, and our business could be harmed.

The ability to commercialize our potential products will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business.

The ability to commercialize our potential products will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third-party intellectual property rights in our field are complicated, and third-party intellectual property rights in these fields are continuously evolving. While we have conducted searches for such third-party intellectual property rights, we have not performed specific searches for third-party intellectual property rights that may raise freedom-to-operate issues, and we have not obtained legal opinions regarding commercialization of our potential products. As such, there may be existing patents that may affect our ability to commercialize our potential products.

In addition, because patent applications are published up to 18 months after their filing, and because patent applications can take several years to issue, there may be currently pending third-party patent applications and freedom-to-operate issues that are unknown to us, which may later result in issued patents.

If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management's attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- a court order prohibiting us from commercializing our potential products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our potential products to market.

Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

Our patent applications may not result in issued patents, which may have a material adverse effect on our ability to prevent others from commercially exploiting products similar to ours.

We own 12 issued patents and we have the exclusive license to an additional 95 issued patents in an aggregate of 78 countries. In addition, we own or exclusively license approximately 39 pending patent applications, of which we own 24 such patent applications and have an exclusive license 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. 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 the NCSU agreement expires on the date on which the last patent or registered plant variety covered by the subject license expires in the country or countries where such patents or registered plant varieties are in effect. The NCSU license relates predominately to issued patents, and the NCSU license will expire in 2023. The exclusive rights under the NRC agreement expires on the date on which the last patent or covered by the subject license expires in the country or countries where such patents are in effect. The NRC license relates predominately to patent applications, and the NRC license will expire in 2028. Since December 31, 2012 the Company paid NCSU $400,000 and issued a note dated February 1, 2013 for $474,893; the note is unsecured, bears interest at 5% and matures the earlier of October 1, 2013 or the closing of a licensing agreement with up front proceeds of at least $1.5 million. NCSU also agreed to not to invoke any rights to terminate the Company’s license agreement for nonpayment or nonperformance until October 1, 2013. In the event the note is not paid by October 1, 2013, NCSU will have the right to terminate the license agreement. The loss of either of these worldwide exclusive licenses would have a material adverse effect on our operations and business prospects.

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 Stock Market 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.

The conversion of our Series A-1 Preferred Stock and exercise of outstanding warrants, convertible notes and options may depress our stock price and will likely result in significant dilution to our common stockholders.

There are a significant number of outstanding warrants, convertible notes and options to purchase shares of our stock and we have issued shares of Series A-1 Preferred Stock that are convertible into our common stock. If the market price of our common stock exceeds the exercise price of outstanding warrants and options or the conversion price of our convertible notes and shares of Series A-1 Preferred Stock, holders of those securities may be likely to exercise or convert such shares and sell the common stock acquired in the open market. Sales of a substantial number of shares of our common stock in the public market by holders of warrants, convertible notes, options or preferred shares may depress the prevailing market price for our common stock and could impair our ability to raise capital through the future sale of our equity securities. Additionally, if the holders of outstanding options, convertible notes, warrants or preferred shares exercise or convert those shares, as applicable, our common stockholders will incur dilution in their relative percentage ownership. The prospect of this possible dilution may also impact the price of our common stock.

In addition, our Series A-1 Preferred Stock and the majority of our outstanding warrants contain anti-dilution provisions, which may, under certain circumstances, reduce the exercise or conversion price or increase the number of shares issuable, or both.

Any downward adjustment to the conversion price of our Series A-1 Preferred Stock may depress our stock price and will result in significant dilution to our common stockholders.

The conversion price of the Series A-1 Preferred Stock is subject to adjustment in certain events. See "Description of Securities – Preferred Stock" for a discussion of the events that could cause an adjustment of the conversion price of such shares. This potential reduction in conversion price could significantly increase the number of shares that could be issued upon conversion of the Series A-1 Preferred Stock and would result in substantial dilution to the other holders of common stock.

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

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

We are controlled by our current officers and directors.

As of March 15, 2013, our directors and executive officers as a group beneficially owned approximately 38.1% of our common stock. Accordingly, our directors and executive officers will have substantial influence over, and may have the ability to control, the election of our board of directors and the outcome of issues submitted to a vote of our stockholders.

We do not expect to declare any dividends on our common stock in the foreseeable future.

We have not paid cash dividends to date on our common stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our business, and we do not anticipate paying any cash dividends on our common stock for the foreseeable future. In addition, the terms of the Series A-1 Preferred Stock prevent the payment of dividends on our common stock unless holders of at least 67% in stated value of the then-outstanding shares of Series A-1 Preferred Stock consent to such dividend. Additionally, the terms of any future debt facilities may preclude us from paying dividends on the common stock. As a result, capital appreciation, if any, of our common stock could be the sole source of gain for the foreseeable future.

Anti-takeover provisions contained in our articles of incorporation and bylaws, as well as provisions of Nevada law, could impair a takeover attempt.

Our amended and restated articles of incorporation and bylaws currently contain provisions that, together with Nevada law, could have the effect of rendering more difficult or discouraging an acquisition deemed undesirable by our board of directors. Our corporate governance documents presently include the following provisions:

• authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock; and

• limiting the liability of, and providing indemnification to, our directors and officers.

These provisions, alone or together, could delay hostile takeovers and changes in control of us or changes in our management.

As a Nevada corporation, we also may become subject to the provisions Nevada Revised Statutes Sections 78.378 through 78.3793, which prohibit an acquirer, under certain circumstances, from voting shares of a corporation's stock after crossing specific threshold ownership percentages, unless the acquirer obtains the approval of the stockholders of the issuer corporation. The first such threshold is the acquisition of at least one-fifth, but less than one-third of the outstanding voting power of the issuer. We may become subject to the above referenced Statutes if we have 200 or more stockholders of record, at least 100 of whom are residents of the State of Nevada, and do business in the State of Nevada directly or through an affiliated corporation.

As a Nevada corporation, we are subject to the provisions of Nevada Revised Statutes Sections 78.411 through 78.444, which prohibit an "interested stockholder" from entering into a combination with the corporation, unless certain conditions are met. An "interested stockholder" is a person who, together with affiliates and associates, beneficially owns (or within the prior two years did own) 10 percent or more of the corporation's voting stock.

Any provision of our amended and restated articles of incorporation, our bylaws or Nevada law that has the effect of delaying or deterring a change in control of our Company could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Principal Stockholders

The following table sets forth information regarding the beneficial ownership of our common stock as of March 15, 2013, by (i) each person who, to our knowledge, owns more than 5% of our common stock, (ii) each of our current directors and executive officers, and (iii) all of our current directors and executive officers as a group. Derivative securities exercisable or convertible into shares of our common stock within sixty (60) days of March 15, 2013 are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding securities, but are not deemed outstanding for computing the percentage of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*). The address of named beneficial owners that are officers and/or directors is: c/o 22nd Century Group, Inc., 9530 Main Street, Clarence, New York 14031. The following table is based upon information supplied by officers and directors, and with respect to 5% or greater stockholders who are not officers or directors, information filed with the SEC.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Class Beneficially Owned (1)	
Management & Directors			
Joseph Pandolfino (2)	7,880,109	19.6	%
Henry Sicignano III (3)	6,170,673	15.8	%
Michael R. Moynihan, Ph.D. (4)	1,631,657	4.2	%
Joseph Alexander Dunn, Ph.D.(5)	251,500	*	
James W. Cornell (6)	251,500	*	
All directors and executive officers as a group (5 persons) (2)-(6)	16,059,602	38.1	%
Other 5% Owners			
Clearwater Partners, LLC (7)	5,265,941	13.3	%
Angelo J. Tomasello (8)	4,542,491	11.5	%
Sabby Volatility Warrant Master Fund, Ltd. (9)	2,500,000	6.1	%
Sabby Heathcare Volatility Master Fund, Ltd. (10)	4,203,858	9.9	%

(1) Based on 38,259,365 shares of common stock issued and outstanding (including outstanding restricted stock), as of March 15, 2013.

(2) Includes (a) 2,004,574 shares of common stock issuable to Mr. Pandolfino upon exercise of warrants and (b) 5,875,535 shares of common stock.

(3) Consists of (a) 2,252,603 shares of common stock held by Henry Sicignano III (including 550,000 restricted shares issued as equity incentive awards under the Company's Equity Incentive Plan), (b) 2,542,347 shares of common stock held by Henry Sicignano III Group, LLC, (c) 396,441 shares of common stock issuable to Mr. Sicignano upon exercise of warrants, (d) 100,000 shares of common stock issuable to Mr. Sicignano upon exercise of stock options and (e) 879,282 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 Employee Incentive Plan (EIP) are grants that are subject to potential forfeiture over time in the event Mr. Sicignano ceases employment with the Company prior to April 1, 2015. On each anniversary of April 1, 2012 until April 1, 2015, the number of shares subject to forfeiture decreases by 150,000 shares. 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.

(4) Includes (a) 1,038,934 shares of common stock, (b) 417,723 shares of common stock issuable upon exercise of warrants and (c) 175,000 shares issuable upon the exercise of stock options.

(5) Includes (a) 110,000 shares of common stock, (b) 31,500 shares of common stock issuable upon exercise of warrants and (c) 110,000 shares issuable upon the exercise of stock options.

(6) Includes (a) 110,000 shares of common stock, (b) 31,500 shares of common stock issuable upon exercise of warrants and (c) 110,000 shares issuable upon the exercise of stock options.

(7) Includes (a) 3,905,516 shares of common stock and (b) 1,360,425 shares of common stock issuable upon exercise of warrants. Richard G. Saffire, Managing Member of Clearwater Partners, LLC exercises voting and investment power with respect to shares owned by Clearwater Partners, LLC. The address of Clearwater Partners, LLC is 34 Sunburst Circle, East Amherst, New York 14051.

(8) Includes (a) 3,301,909 shares of common stock, (b) 1,220,582 shares of common stock issuable upon exercise of warrants and (c) 20,000 shares of common stock issuable upon exercise of stock options. The address of Angelo Tomasello is 4720 Spaulding Drive, Clarence, New York 14031.

(9) Consists of shares of common stock issuable upon the conversion of an aggregate of 500 shares of Series A-1 Preferred Stock and upon the exercise of Warrants. The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of our outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). However, the 9.99% limitation would not prevent the shareholder from acquiring and selling in excess of 9.99% of our common stock through a series of acquisitions and sales while never beneficially owning more than 9.99% in aggregate. Sabby Management, LLC serves as the investment manager of Sabby Volatility Warrant Master Fund, Ltd. and, as such, Sabby Management, LLC shares voting and investment powers with respect to these shares on behalf of Sabby Volatility Warrant Master Fund, Ltd. The address for Sabby Volatility Warrant Master Fund, Ltd. is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of Sabby Volatility Warrant Master Fund, Ltd. Each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over the securities covered by this prospectus except to the extent of their pecuniary interest therein.

(10) Consists of shares of common stock issuable upon the conversion of an aggregate of 2,000 shares of Series A-1 Preferred Stock and upon the exercise of Warrants. The Series A-1 Preferred Stock and the Warrants contain exercise

and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of our outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). However, the 9.99% limitation would not prevent the shareholder from acquiring and selling in excess of 9.99% of our common stock through a series of acquisitions and sales while never beneficially owning more than 9.99% in aggregate. Sabby Management, LLC serves as the investment manager of Sabby Healthcare Volatility Master Fund, Ltd. and, as such, Sabby Management, LLC shares voting and investment powers with respect to these shares on behalf of Sabby Healthcare Volatility Master Fund, Ltd. The address for Sabby Healthcare Volatility Master Fund, Ltd. is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of Sabby Healthcare Volatility Master Fund, Ltd. Each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over the securities covered by this prospectus except to the extent of their pecuniary interest therein.

Selling Stockholders

On January 11, 2013, Sabby Volatility Warrant Master Fund Ltd. and Sabby Healthcare Volatility Master Fund, Ltd., collectively referred to as the selling stockholders, acquired an aggregate of 2,500 shares of newly created Series A-1 Preferred Stock and Warrants for an aggregate purchase price of $2,500,000.

The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of the outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). However, the 9.99% limitation would not prevent a selling stockholder from acquiring and selling in excess of 9.99% of our common stock through a series of acquisitions and sales while never beneficially owning more than 9.99% in aggregate.

This prospectus relates to the resale by the selling stockholders from time to time of up to an aggregate of 6,250,000 shares that are issuable to the selling stockholders. Pursuant to a Registration Rights Agreement between us and the selling stockholders, this prospectus covers the resale of the number of shares currently issuable (i) upon conversion of our Series A-1 Preferred Stock and (ii) upon the exercise of Series B Warrants. We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Series B Warrants, if exercised.

The table below, which was prepared based on information supplied to us by the selling stockholders, sets forth information regarding the beneficial ownership of outstanding shares of our common stock owned by the selling stockholders and the shares that they may sell or otherwise dispose of from time to time under this prospectus. Each of the selling stockholders, or their respective affiliates, transferees, donees or their successors, may resell, from time to time, all, some or none of the shares of our common stock covered by this prospectus, as provided in this prospectus under the section entitled “Plan of Distribution” and in any applicable prospectus supplement. However, we do not know when, in what amount, or at what specific prices the selling stockholders may offer their shares for sale under this prospectus, if any. Each selling stockholder’s percentage of ownership in the following table is based upon 38,259,365 shares of our common stock outstanding as of March 15, 2013.

Information concerning any of the selling stockholders may change from time to time, and any changed information will be presented in a prospectus supplement as necessary. Please carefully read the footnotes located below the table in conjunction with the information presented in the table.

Selling Stockholder Name	Beneficially Owned Prior to Offering		Shares of Common Stock that may be Offered and Sold Hereby (3)		Beneficially Owned After Offering	
	Number of Shares of Common Stock (1), (2)	Percentage			Number of Shares	Percent
Sabby Volatility Warrant Master Fund, Ltd.	2,500,000	6.1 %	1,250,000	(4)	0	0
Sabby Healthcare Volatility Master Fund, Ltd.	4,203,858	9.9 %	5,000,000	(5)	0	0

(1) Includes all shares beneficially owned by the selling stockholders as of March 15, 2013.

(2) The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of the outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). Accordingly, the number of shares of common stock set forth in the table as being registered for a selling stockholder exceeds the number of shares of common stock that the selling stockholder could own beneficially at any given time through its ownership of the Series A-1 Preferred Stock and the Warrants.

(3) We have assumed (i) that each share of Series A-1 Preferred Stock is convertible into shares of common stock at a conversion price of $0.60 per share of common stock and (ii) that the Series B Warrants are exercisable at the initial exercise price, without adjustment.

(4) Includes (i) 833,333 shares of common stock currently issuable upon conversion of the 500 shares of the Series A-1 Preferred Stock held by this selling stockholder and (ii) 416,667 shares currently issuable upon exercise of the Series B Warrant at $0.60 per share. The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of our outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). However, the 9.99% limitation would not prevent a selling stockholder from acquiring and selling in excess of 9.99% of our common stock through a series of acquisitions and sales while never beneficially owning more than 9.99% in aggregate. Sabby Management, LLC shares voting and investment power with respect to these shares on behalf of this stockholder. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of this stockholder. Each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over the securities covered by this prospectus except to the extent of their pecuniary interest therein.

(5) Includes (i) 3,333,333 shares of common stock currently issuable upon conversion of the 2,000 shares of the Series A-1 Preferred Stock held by this selling stockholder and (ii) 1,666,667 shares currently issuable upon exercise of the Series B Warrant at $0.60 per share. The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of our outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). However, the 9.99% limitation would not prevent a selling stockholder from acquiring and selling in excess of 9.99% of our common stock through a series of acquisitions and sales while never beneficially owning more than 9.99% in aggregate. Sabby Management, LLC shares voting and investment power with respect to these shares on behalf of this stockholder. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of this stockholder. Each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over the securities covered by this prospectus except to the extent of their pecuniary interest therein.

Use of Proceeds

We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Series B Warrants, if exercised. We have agreed to bear the expenses (other than any underwriting discounts or commissions or agent's commissions) in connection with the registration of the common stock being offered hereby by the selling stockholders.

Dividend Policy

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

In addition, the terms of the Series A-1 Preferred Stock prevent the payment of dividends on our common stock unless holders of at least 67% in stated value of the then-outstanding shares of Series A-1 Preferred Stock consent to such dividend. In the event we do declare a dividend, the holders of the Series A-1 Preferred Stock and Warrants will participate in such dividend payment on an as-converted basis to common stock (without regard to the 9.99% beneficial ownership limitation).

Determination of Offering Price

All shares of our common stock being offered will be sold by the selling stockholders without our involvement. As a result, the selling stockholders will determine at what prices they may sell the offered shares, and these sales may be made at prevailing market prices or at privately negotiated prices.

Market for Common Equity and Related Stockholder Matters

Our common stock is quoted on the OTC Bulletin Board under the symbol "XXII.OB." As of March 15, 2013, there were 63 holders of record of shares of our common stock. The following table sets forth, for the quarters indicated, the high and low bid prices per share of our common stock, as derived from quotations provided by the OTC Bulletin Board Information Center.

Quarter Ended	High Bid	Low Bid
December 31, 2012	$0.95	$0.15
September 30, 2012	$0.88	$0.20
June 30, 2012	$1.13	$0.35
March 31, 2012	$0.75	$0.25
December 31, 2011	$1.34	$0.25
September 30, 2011	$1.30	$0.60
June 30, 2011	$1.30	$1.10
March 31, 2011*	$1.41	$1.01

*From January 25, 2011, the date of the Merger.

Trades in our common stock may be subject to Rule 15g-9 of the Exchange Act, which imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, broker/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction before the sale.

The SEC also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than $5.00 (other than securities listed on some national exchanges, provided that the current price and volume information with respect to transactions in that security is provided by the applicable exchange or system). The penny stock rules require a broker/dealer, before effecting a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing before effecting the transaction, and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for shares of common stock. As a result of these rules, investors may find it difficult to sell their shares.

Shares Authorized for Issuance Under Equity Compensation Plans

October 21, 2010, the Company established the 2010 Equity Incentive Plan, or "EIP," for officers, employees, directors, consultants and advisors to the Company and its affiliates, consisting of 4,250,000 shares of common stock. The EIP authorizes the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, restricted stock and restricted stock units.

The following table summarizes the number of stock options issued and shares of restricted stock granted, net of forfeitures and sales, the weighted-average exercise price of such stock options and the number of securities remaining to be issued under all outstanding equity compensation plans as of December 31, 2012:

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted-average exercise price of outstanding options, warrants and rights (b)		Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,015,000	(1)	$ 0.69	(2)	2,055,000
Equity compensation plans not approved by security holders	0		N/A		0
Total	1,015,000				2,055,000

(1) Includes 550,000 restricted stock awards that are issued but not vested as of December 31, 2012.

(2) Weighted average exercise price only applies to the 465,000 shares issuable upon exercise of outstanding stock options.

Business

On January 25, 2011, 22nd Century Limited LLC completed a reverse merger transaction (the "Merger") with 22nd Century Group, Inc. 22nd Century Limited, LLC is a wholly owned subsidiary of 22nd Century Group, Inc. which continues to operate the business of 22nd Century Limited, LLC. All references to shareholders or common shares include the historical members and membership Units of 22nd Century Limited, LLC 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 Limited, LLC 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 Limited, LLC and are recorded at the historical cost basis of 22nd Century Limited, LLC, and the consolidated financial statements since completion of the Merger include the assets and liabilities of 22nd Century Limited, LLC, historical operations of 22nd Century Limited, LLC and operations of 22nd Century Group, Inc. from the closing date of the Merger.

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.

Background

22nd Century Group, Inc. was incorporated under the laws of the State of Nevada on September 12, 2005 under the name Touchstone Mining Limited. On January 25, 2011, we entered into a reverse merger transaction with 22nd Century Limited, LLC, which we refer to herein as the Merger. Upon the closing of the Merger, 22nd Century Limited, LLC became our wholly-owned subsidiary. We changed our name to 22nd Century Group, Inc. on November 23, 2010 in anticipation of the Merger with 22nd Century Limited, LLC. After the Merger, we succeeded to the business of 22nd Century Limited, LLC as our sole line of business.

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

Overview

22nd Century Limited, LLC ("22nd Century Ltd"), our wholly-owned subsidiary, is a plant biotechnology company focused on tobacco harm reduction and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding. The Company exclusively controls 107 issued patents and exclusively controls an additional 39 patent applications; of these, we own 12 issued patents plus 22 patent applications and we license on an exclusive basis, 95 issued patents and 17 patent applications. Hercules Pharmaceuticals LLC ("Hercules Pharmaceuticals") and Goodrich Tobacco Company, LLC ("Goodrich Tobacco") are wholly-owned subsidiaries of 22nd Century Ltd. Hercules Pharmaceuticals is focused on *X-22,* a prescription smoking cessation aid currently in development. Goodrich Tobacco is focused on commercial tobacco products and potential modified risk cigarettes.

The Company is primarily involved in the following activities:

- The international licensing of 22nd Century Ltd's technology, proprietary tobaccos, trademarks and brands;
- The development of its *X-22* prescription smoking cessation aid in development;
- The development of its modified risk tobacco products;
- The pursuit of necessary regulatory approvals and clearances at the U.S. Food and Drug Administration (the "FDA") to market *X-22* as a prescription smoking cessation aid and *BRAND A and BRAND B* as Modified Risk Cigarettes in the U.S.;

- The manufacture, marketing and distribution of *RED SUN* and *MAGIC* proprietary cigarettes; and
- The production of *SPECTRUM* research cigarettes for the National Institute on Drug Abuse ("NIDA").

Licensing

The Company has been in discussions with various parties in the tobacco and pharmaceutical industries for licensing its technology and products since the first quarter of 2012. Management is exploring licensing arrangements on a country-by-country basis in the U.S., Europe and Asia. The Company expects to close at least one licensing agreement for its technology and products before the end of the third quarter of 2013.

X-22

The *X-22* therapy protocol utilized in the Company's sponsored Phase II-B clinical trial calls for the patient to smoke our very low nicotine ("VLN") cigarettes over a six-week treatment period to facilitate the goal of the patient quitting smoking by the end of the treatment period. We believe this therapy protocol has been successful in independent clinical trials because VLN cigarettes made from our proprietary tobacco satisfy smokers' cravings for cigarettes while (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine. *X-22* involves the same smoking behavior as conventional cigarettes and because patients are simply switching to VLN cigarettes for 6 weeks, *X-22* does not expose the smoker to any new drugs or new side effects. Our Investigational New Drug Application for *X-22*, a kit of VLN cigarettes, was cleared by the FDA in July 2011. Our *X-22* Phase II-B clinical trial was completed in the first quarter of 2012 and did not demonstrate a statistically significant difference in quitting between *X-22* and the active control, a cigarette containing conventional nicotine levels. However, the median number of *X-22* cigarettes smoked during the trial was significantly reduced compared to patients' baseline of usual brand of cigarettes. In evaluating the results of this trial, we believe we may have reduced the nicotine content of *X-22* by too great a percentage, to a level less than half the nicotine content of VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases quit rates.

In contrast to the results of the Company's Phase II-B trial results, independent studies have demonstrated that VLN cigarettes, whether used alone or in conjunction with nicotine replacement therapy (NRT), increase quitting rates. Due to the limited effectiveness and/or serious side effects of existing FDA-approved smoking cessation products, we believe that if additional clinical trials demonstrate increased smoking cessation rates, *X-22* can capture a share of this market by replacing sales and market share from existing smoking cessation aids and expanding the smoking cessation market by encouraging more smokers to attempt to quit smoking. We are currently in the process of identifying potential joint venture partners to fund the remaining *X-22* clinical trials. We estimate the cost of completing the remaining *X-22* clinical trials to be approximately $14 million and the marketing expenses to bring *X-22* to market in the U.S. are estimated to be approximately $5 million. There is no guarantee that we will (i) obtain the funds necessary to complete additional clinical trials, (ii) identify potential joint venture partners to fund the remaining *X-22* clinical trials, (iii) obtain FDA approval, or (iv) capture significant share of the smoking cessation

market upon FDA approval.

We continue to believe that our VLN cigarettes are effective as a smoking cessation aid. However, we have suspended sponsoring further *X-22* clinical trials pending a complete analysis of results of two independent smoking-cessation trials that were completed in 2012 (ClinicalTrials.gov Identifiers NCT01050569 and NCT01250301), which utilized a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than that used in our own sponsored Phase II-B trial. A portion of the results of these two trials has been disclosed at the annual meeting of the Society for Research on Nicotine and Tobacco ("SRNT") held in Boston on March 13 to 16, 2013.

Regarding the NCT01050569 clinical trial, results only in terms of gender differences in abstinence rates were disclosed at the SRNT annual meeting. Dorothy Hatsukami, PhD, was principal investigator of the study. Within the female population at the end of treatment (week 12), the group assigned our VLN cigarette had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned a 21mg nicotine patch. Within the male population at the end of treatment (week 12), the group assigned a 21mg nicotine patch had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned our VLN cigarette.

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

The full set of results of these 2 independent clinical trials are expected to be published in peer reviewed journals and will be compared to results of other independent clinical trials of our VLN cigarettes and results of our Phase II-B trial to determine which variables optimize cessation. One preliminary hypothesis, in conjunction with results of various other studies of our VLN cigarettes, is that having two types of prescription VLN cigarettes available may be advantageous for increased smoking cessation in the general population; one having a higher nicotine content than the other. Upon identifying a suitable joint venture partner to fund further *X-22* clinical trials, we will then request a meeting with the U.S. Food and Drug Administration ("FDA"), and thereafter we may resume our own sponsored *X-22* clinical trials.

Potential Modified Risk Cigarettes and the Tobacco Control Act

The 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") granted the FDA authority over the regulation of all tobacco products. While it prohibits the FDA from banning cigarettes outright, it allows the FDA to require the reduction of nicotine or any other compound in tobacco and cigarette smoke. The Tobacco Control Act also banned all sales in the U.S. of cigarettes with characterizing flavors (other than menthol). As of June 2010, all cigarette companies were required to cease the use of the terms "low tar," "light" and "ultra light" in describing cigarettes sold in the U.S. Besides numerous other regulations, including certain marketing restrictions, for the first time in history, a U.S. regulatory agency will scientifically evaluate cigarettes that may pose lower health risks as compared to conventional cigarettes.

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of 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*, may qualify as Modified Risk Cigarettes. Compared to commercial cigarettes, the tobacco in *BRAND A* has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes, and *BRAND B*'s smoke contains an extraordinary low amount of "tar" per milligram of nicotine.

Goodrich Tobacco intends to seek FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes and expect to file applications with the FDA in 2013, the exact timing will depend on the timing of obtaining additional capital. After filing our modified risk applications with the FDA, we will need significant additional capital to complete the FDA authorization process for our Modified Risk Cigarettes. The exact amount of capital is currently unknown since it is uncertain how many exposure studies the FDA will require for *BRAND A* and *BRAND B*. However, we estimate that the cost of completing the FDA authorization process for each of our potential Modified Risk Cigarettes to be at least $2 million. We believe that *BRAND A* and *BRAND B* will achieve market share in the global cigarette market among smokers who will not quit but are interested in reducing the harmful effects of smoking. There is no guarantee that we will (i) obtain additional capital to complete the FDA authorization process for our potential Modified Risk Cigarettes, (ii) obtain FDA authorization to market *BRAND A or BRAND B* as Modified Risk Cigarettes, or (iii) achieve significant market with FDA authorization to market our products as Modified Risk Cigarettes.

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. Although *X-22* has failed previously to qualify for "Fast Track," we believe that upon completion of a company-sponsored clinical trial demonstrating efficacy, *X-22* will qualify for "Fast Track" designation by the FDA. However, there is no guarantee that the FDA will grant "Fast Track" designation to *X-22*. See "Business – Government Regulation – Fast Track Development."

Modified Risk Cigarettes

We believe this new regulatory environment represents a paradigm shift for the tobacco industry. Besides the fact that the Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, the Tobacco Control Act allows the FDA to mandate the use of reduced-risk technologies across all conventional tobacco products or cigarettes. We believe the Tobacco Control Act may create opportunities for us to license our proprietary technology and/or tobaccos to larger competitors.

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 (e.g., more and/or larger puffs per cigarette) of low-tar research cigarettes, similar to *BRAND B (*though *BRAND B* was not used in such studies), is greatly curtailed resulting in smokers inhaling less “tar” and carbon monoxide. Additional studies will be necessary to establish whether *BRAND B* cigarettes achieve similar results.

RED SUN and MAGIC Cigarettes

Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the “Master Settlement Agreement” or “MSA,” a settlement among 46 states and the tobacco industry administered by the National Association of Attorneys General (“NAAG”). Our subsidiary, Goodrich Tobacco, introduced in a limited capacity two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. There have been *de minimis* sales of these brands in 2011 and 2012 since we have intentionally have not expanded marketing and distribution of these brands to facilitate Goodrich Tobacco becoming a participating manufacturer of the MSA. The more *RED SUN* and *MAGIC* sold while these brands are produced by a non-participating manufacturer, the greater the settlement costs Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA. On January 23, 2013, Goodrich Tobacco applied to the Alcohol and Tobacco Tax Trade Bureau (“TTB”) for a federal permit to manufacture its own tobacco products. Being a federally licensed tobacco product manufacturer is a primary requirement of becoming a participating manufacturer of the MSA. On February 26, 2013, Goodrich Tobacco applied to the NAAG to become a participating manufacturer to the MSA. Both of these measures, if approved by the TTB and NAAG, will greatly facilitate the sales and distribution potential of *RED SUN* and *MAGIC*. Goodrich Tobacco expects its cigarette factory startup costs to be approximately $250,000 and plans to lease a portion of the machinery required. The costs associated with the MSA settlement are expected to be less than $40,000.

SPECTRUM Government Research Cigarettes

As a subcontractor to RTI International ("RTI") in RTI's contract with The National Institute on Drug Abuse for the Research Cigarette Option, we supply modified nicotine (from very low to high) cigarettes to NIDA. These research cigarettes are distributed under the mark *SPECTRUM*.

Market

Cigarettes and Smoking Cessation Aids

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.

According to the U.S. Center for Disease Control (CDC), the U.S. cigarette market consists of approximately 45 million adult smokers who spent approximately $80 billion in 2011 on approximately 300 billion cigarettes. Worldwide manufacturer sales in 2011 were over 5.0 trillion cigarettes, resulting in annual retail sales of approximately $610 billion. In 2010, annual manufacturer 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 and is approximately $3.0 billion.

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

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

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

Chantix® and Zyban® are pills and are nicotine free. Chantix®, Zyban®, the nicotine nasal spray and the nicotine inhaler are available by prescription only. 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, according to Pfizer Inc., of $701 million in 2007, $489 million in 2008, $386 million in 2009, $330 million in 2010 and $326 million in 2011. In July 2009, the FDA required a "Boxed Warning," the most serious type of warning in prescription drug labeling, for both Chantix® and Zyban® based on the potential side effects of these drugs. Despite this Boxed Warning, worldwide sales of Chantix® in 2009 to 2011 were approximately $700 million, $755 million, and $720 million, respectively.

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 approximately 28 years and 20 years, respectively, and millions of smokers have already tried NRT products and failed to stop smoking due to the limited effectiveness of these products. According to Perrigo Company, a pharmaceutical company that sells NRT products, retail sales of NRT products in the United States were $800 million in the fiscal year ended June 30, 2012.

Modified Risk Tobacco Products

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

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

Some major cigarette manufacturers have developed and marketed alternative cigarette products. For example, Philip Morris USA developed an alternative cigarette, called Accord®, in which the tobacco is heated rather than burned. R.J. Reynolds Tobacco Company has developed and is marketing an alternative cigarette, called Eclipse®, in which the tobacco is primarily heated, with only a small amount of tobacco burned. Philip Morris and RJ Reynolds have indicated that their products may deliver fewer smoke components compared to conventional cigarettes. Vector Tobacco Inc. ("Vector Tobacco"), which is 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., referred to as "heat not burn" products since they do not burn down) and 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 approximately 28 years and 10 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. Upon U.S. Food and Drug Administration ("FDA") approval, *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 *X-22* therapy protocol calls for the patient to smoke our VLN cigarettes over a six-week treatment period to facilitate the goal of the patient quitting smoking by the end of the treatment period. We believe this therapy protocol has been successful in independent clinical trials because VLN cigarettes made from our proprietary tobacco satisfy smokers' cravings for cigarettes while (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine.

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 reduced the nicotine content of *X-22* by too great a percentage,to a level less than half the nicotine content of VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases quit rates.

Partial results of two independent smoking-cessation clinical trials that were completed in 2012 (ClinicalTrials.gov Identifiers NCT01050569 and NCT01250301) have been disclosed at the annual meeting of the Society for Research on Nicotine and Tobacco ("SRNT") held in Boston on March 13 to 16, 2013.

1. University of Minnesota Masonic Cancer Center - Phase II - 235 subjects

·Follow-up study to Hatsukami et al. 2010
·ClinicalTrials.gov Identifier: NCT01050569
· Evaluating quitting results of six-week treatment period among 3 groups:
(i) exclusive use of a VLN cigarette (a VLN cigarette with slightly higher nicotine content than those used in the 22nd Century trial);

(ii) 21-mg nicotine patch; and

(iii) concurrent use of VLN cigarette and nicotine patch

·Trial included a 6-month follow-up period

2. Queen Mary University of London, in collaboration with Pfizer - 200 subjects

·Same VLN cigarette utilized in above study
·ClinicalTrials.gov Identifier: NCT01250301
· Evaluating whether the use of a VLN cigarette in combination with Chantix® (or NRT) increases quitting over use of Chantix® (or NRT) alone

·Chantix® is branded as Champix® outside the United States

Regarding the NCT01050569 clinical trial, results only in terms of gender differences in abstinence rates were disclosed at the SRNT annual meeting. Dorothy Hatsukami, PhD, was principal investigator of the study. Smokers were randomly assigned (n=235) to one of three treatment groups: (i) our VLN cigarette (n=79); (ii) a 21 mg nicotine patch (n=80) or (iii) a combination of the 21 mg nicotine patch and our VLN cigarette (n=76). Each group received 6 weeks of treatment, an additional 6 weeks of behavioral treatment and 3 follow-up visits. Tobacco and nicotine use self-report and carbon monoxide (CO) were assessed at each visit. Urinary cotinine was assessed at baseline and at weeks 2, 6, 12, 24 and 36. CO and cotinine verified continuous abstinence rates at end of treatment (week 12) varied significantly by treatment group and gender (p=0.029 for the interaction). Within the female population at the end of treatment (week 12), the group assigned our VLN cigarette had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned a 21mg nicotine patch. Within the male population at the end of treatment (week 12), the group assigned a 21mg nicotine patch had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned our VLN cigarette.

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

The full set of results of these 2 independent clinical trials are expected to be published in peer reviewed journals and will be compared to results of other independent clinical trials of our VLN cigarettes and results of our Phase II-B trial to determine which variables optimize cessation. One preliminary hypothesis, in conjunction with results of various other studies of our VLN cigarettes, is that having two types of prescription VLN cigarettes available may be advantageous for increased smoking cessation in the general population; one having a higher nicotine content than the other. Upon identifying a suitable joint venture partner to fund further *X-22* clinical trials, we will then request a meeting with the U.S. Food and Drug Administration ("FDA"), and thereafter we may resume our own sponsored *X-22* clinical trials.

RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco, introduced two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. Both brands are available in regular and menthol and all brand styles are king size and packaged in hinge-lid hard packs. In the second quarter of 2013, we intend to focus our marketing efforts on tobacconists, smoke shops and tobacco outlets in the U.S. The ban in 2009 by the FDA of all cigarettes with characterizing flavors (with the exception of menthol) has resulted in a product void in these specialty tobacco channels for super-premium priced products. We believe that certain U.S. cigarette wholesalers and retailers will carry our brands, among other reasons, to increase their margins.

SPECTRUM Government Research Cigarettes

As a subcontractor to RTI International ("RTI") in RTI's contract with The National Institute on Drug Abuse for the Research Cigarette Option, we supply modified nicotine (from very low to high) cigarettes to NIDA. These research cigarettes are distributed under the mark *SPECTRUM*.

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 interested in cigarettes which reduce exposure to certain tobacco smoke toxins and/or pose a lower health risk than conventional cigarettes. This includes the approximate one-half of the 45 million adult smokers in the United States who do not attempt to quit in a given year. Compared to commercial cigarettes, the tobacco in *BRAND A* has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes and *BRAND B*'s smoke contains an extraordinary low amount of "tar" per milligram of nicotine. 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*, which we will utilize to file our two modified risk applications with the FDA. Goodrich Tobacco intends to seek FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes and expect to file applications with the FDA in 2013, the exact timing will depend on the timing of obtaining additional capital. After filing our modified risk applications with the FDA, we will need significant additional capital to complete the FDA authorization process for our Modified Risk Cigarettes. The exact amount of capital is currently unknown since it is uncertain how many exposure studies the FDA will require for *BRAND A* and *BRAND B*. However, we estimate that the cost of completing the FDA authorization process for each of our potential Modified Risk Cigarettes to be at least $2 million. We believe that *BRAND A* and *BRAND B* will achieve market share in the global cigarette market among smokers who will not quit but are interested in reducing the harmful effects of smoking. There is no guarantee that we will (i) obtain additional capital to complete the FDA authorization process for our potential Modified Risk Cigarettes, (ii) obtain FDA authorization to market *BRAND A or BRAND B* as Modified Risk Cigarettes, or (iii) achieve significant market with FDA authorization to market our products as Modified Risk

Cigarettes.

BRAND A Cigarettes

Compared to commercial tobacco cigarettes, *BRAND A* has the lowest nicotine content. The tobacco in *BRAND A* contains approximately 95% less nicotine than tobacco in leading “light” cigarette brands. Clinical studies have demonstrated that smokers who smoke VLN cigarettes containing our proprietary tobacco smoke fewer cigarettes per day resulting in significant reductions in smoke exposure, including “tar,” nicotine and carbon monoxide. Due to the very low nicotine levels, compensatory smoking does not occur with VLN cigarettes containing our proprietary tobacco (Hatsukami et al. 2010).

In a June 16, 2010 press release, Dr. David Kessler, the former FDA Commissioner, recommended that “[t]he FDA should quickly move to reduce nicotine levels in cigarettes to non-addictive levels. If we reduce the level of the stimulus, we reduce the craving. It is the ultimate harm reduction strategy.” Shortly thereafter in a Washington Post article, Dr. Kessler said that the amount of nicotine in a cigarette should drop from about 10 milligrams to less than 1 milligram. *BRAND A* contains approximately 0.7 milligram of nicotine per cigarette.

A Phase II smoking cessation clinical trial at the University of Minnesota Masonic Comprehensive Cancer Center (Hatsukami et al. 2010) also measured exposure of various smoke compounds in smokers from smoking a VLN cigarette containing our proprietary tobacco over a six (6)-week period. Smokers significantly reduced their smoking as compared to their usual brand of cigarettes. The number of VLN cigarettes smoked per day on average decreased from 19 (the baseline number of cigarettes of smokers' usual brand) to 12 by the end of the six (6)-week period, even though participants were instructed to smoke ad libitum (as many cigarettes as desired) during treatment. Furthermore, besides significant reductions in other biomarkers, carbon monoxide (CO) levels, an indicator of smoke exposure, significantly decreased from 20 parts per million (baseline) to 15 parts per million. Cotinine, a metabolite and biomarker of nicotine, significantly decreased from 4.2 micrograms/mL (baseline) to 0.2 micrograms/mL. All differences were statistically significant ($P<0.05$).

We believe these and other results and future exposure studies the FDA may require will result in a modified risk cigarette claim for *BRAND A*. We further believe smokers who desire to smoke fewer cigarettes per day while also satisfying cravings and reducing exposure to nicotine will find *BRAND A* beneficial. There is no guarantee that *BRAND A* will be classified as a Modified Risk Cigarette by the FDA.

BRAND B Cigarettes

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

In a 2001 report, entitled *Clearing the Smoke, Assessing the Science Base for Tobacco Harm Reduction*, the Institute of Medicine notes that a low "tar"/moderate nicotine cigarette is a viable strategy for reducing the harm caused by smoking. The report states: "Retaining nicotine at pleasurable or addictive levels while reducing the more toxic components of tobacco is another general strategy for harm reduction." We believe that evaluation of *BRAND B* in short-term human exposure studies will confirm that exposure to smoke, including certain tobacco smoke toxins and carbon monoxide, is significantly reduced when smoking *BRAND B* as compared to smoking the leading brands of cigarettes. We believe results from these exposure studies will warrant a modified risk claim for *BRAND B*. There is no guarantee that *BRAND B* will be classified as a Modified Risk Cigarette by the FDA.

Smoking Cessation Clinical Trials with VLN Cigarettes

Partial results of two independent smoking-cessation clinical trials that were completed in 2012 (ClinicalTrials.gov Identifiers NCT01050569 and NCT01250301) have been disclosed at the annual meeting of the Society for Research on Nicotine and Tobacco ("SRNT") held in Boston on March 13 to 16, 2013.

Regarding the NCT01050569 clinical trial, results only in terms of gender differences in abstinence rates were disclosed at the SRNT annual meeting. Dorothy Hatsukami, PhD, was principal investigator of the study. Smokers were randomly assigned (n=235) to one of three treatment groups: (i) our VLN cigarette (n=79); (ii) a 21 mg nicotine patch (n=80) or (iii) a combination of the 21 mg nicotine patch and our VLN cigarette (n=76). Each group received 6 weeks of treatment, an additional 6 weeks of behavioral treatment and 3 follow-up visits. Tobacco and nicotine use self-report and carbon monoxide ("CO") were assessed at each visit. Urinary cotinine was assessed at baseline and at weeks 2, 6, 12, 24 and 36. CO and cotinine verified continuous abstinence rates at end of treatment (week 12) varied significantly by treatment group and gender (p=0.029 for the interaction). Within the female population at the end of treatment (week 12), the group assigned our VLN cigarette had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned a 21mg nicotine patch. Within the male population at the end of treatment (week 12), the group assigned a 21mg nicotine patch had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned our VLN cigarette.

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

Previous to the 2 clinical trials presented at the 2013 SRNT meeting, VLN cigarettes containing our proprietary tobacco have been the subject of various independent studies, including two Phase II clinical trials for smoking cessation which were not funded by us. Both of these Phase II 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.

One of these two Phase II clinical trials compared the quitting efficacy of a VLN cigarette containing our proprietary tobacco versus a low nicotine cigarette and an FDA-approved nicotine lozenge (4 mg) in a total of 165 patients treated for six (6) weeks (Hatsukami *et al.* 2010, *Addiction* 105:343–355). This clinical trial was led by Dr. Dorothy Hatsukami at the University of Minnesota Masonic Comprehensive Cancer Center. Dr. Hatsukami was selected in 2010 as one of the nine voting members of the 12-person Tobacco Products Scientific Advisory Committee ("TPSAC"), within the FDA's Center for Tobacco Products created under the Tobacco Control Act. (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 6-week follow-up after the end of treatment was 47% for the VLN cigarette group, 37% for the nicotine lozenge group and 23% for the low nicotine cigarette group. Furthermore, the VLN cigarette was also associated with greater relief from withdrawal symptoms and cravings of usual brand cigarettes than the nicotine lozenge. Carbon monoxide (CO) levels in patients were tested at each treatment clinic visit to verify smoking abstinence.

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

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

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

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

The major differences between the Vector Tobacco Phase II clinical trial and the University of Minnesota Phase II clinical trial is the duration of time during treatment that VLN cigarettes are smoked and the use of nicotine replacement therapy ("NRT') in combination with VLN cigarettes. In the Vector Tobacco trial, VLN cigarettes were smoked by patients (in two arms of the study) for only two (2) weeks, either in combination with using a nicotine patch or placebo patch, followed by continued use of nicotine patches for the subsequent ten (10) weeks. In the University of Minnesota Phase II clinical trial, VLN cigarettes (in one arm of the study) were smoked for six (6) weeks without any use of NRT before, during or after this 6-week treatment period. We believe that the effectiveness of VLN cigarettes for use in smoking cessation is higher when they are used alone (without NRT or another therapy) and for a longer time period, as in the University of Minnesota trial.

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

A randomized controlled smoking cessation clinical trial using VLN cigarettes was a conducted at Roswell Park Cancer Institute, Buffalo, New York, to investigate the effect of smoking a very low nicotine cigarette ("VLN") in

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

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

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

Technology Platform

Our proprietary technology enables us to decrease or increase the level of nicotine (and other nicotinic alkaloids such as nornicotine, anatabine and anabasine) in tobacco plants by decreasing or increasing the expression of gene(s) responsible for nicotine production in the tobacco plant using genetic engineering. The basic techniques, include but are not limited to those that are used in the production of genetically modified (GM) varieties of other crops. However, our proprietary technology can also be implemented without the resulting plants being GM, as long as no foreign DNA not inherent to a plant species such as *Nicotiana tabacum* is present in the engineered plant. In 2009 GM crops were planted on 330 million acres in 25 countries according to the International Service for the Acquisition of Agri-Biotech Applications. This includes approximately 85% of the corn and soybeans grown in the United States. The only components of the technology that are distinct from those in commercialized genetically modified varieties of major crops are segments of tobacco genes (DNA sequences) that are also present in all conventional tobacco plants. Genetically modified or transgenic tobacco that we use in our products has been deregulated by the USDA. Thus, plants may be grown and used in products in the United States without legal restrictions or labeling requirements related to the genetic modification. Nevertheless, our proprietary tobacco is grown only by farmers under contracts that require segregation and prohibit transfer of material to other parties.

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

Once a genetically-engineered tobacco plant with the desired characteristics is obtained, each plant can produce hundreds of thousands of seeds. When each seed is germinated, the resulting tobacco plant has characteristics similar to the parent and sibling plants and the nicotine content of these plants generally fall within a narrow range. Tobacco products with either low or high nicotine content are easily produced through this method. For example, one of our proprietary tobacco varieties contains the lowest nicotine content of any tobacco ever commercialized, with approximately 95% less nicotine than tobacco in leading “light” cigarette brands. This proprietary tobacco grows with virtually no nicotine without adversely affecting the other leaf constituents important to a cigarette’s characteristics, including taste and aroma.

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 107 issued patents in 78 countries, (of these, we own 12 issued patents and we license 95 issued patents on an exclusive basis) and 39 pending patent applications (of these we own 22 patent applications and we license 17 patent applications on an exclusive basis). A “patent family” is a set of patents granted in various countries to protect a single invention. Our patent coverage in the United States and China, the two most valuable smoking cessation and cigarette markets in the word, consists of 15 issued patents and 9 pending applications and 6 issued patents and 3 pending patent applications, respectively. 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 United States. We also have exclusive rights to plant variety protection, or 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, propagating, selling, importing and exporting a plant variety for twenty (20) years in the U.S. and generally for (20) years in other member countries of the International Union for the Protection of New Varieties of Plants, known as UPOV, an international treaty concerning plant breeders’ rights. There are currently more than 70 countries that are members of UPOV.

Sales and Marketing

X-22 Smoking Cessation Aid

We are currently in the process of identifying potential joint venture partners to fund the remaining *X-22* clinical trials. We can only market *X-22* in the U.S. upon FDA approval. There is no guarantee that we will (i) obtain the funds necessary to complete additional clinical trials, (ii) identify potential joint venture partners to fund the remaining *X-22* clinical trials, (iii) obtain FDA approval, or (iv) capture significant share of the smoking cessation market upon FDA approval. If the FDA approves *X-22* as a smoking cessation aid, Hercules Pharmaceuticals, our subsidiary, intends to enter into arrangements in both the U.S. and international markets with pharmaceutical companies to market and sell *X-22*. We plan to seek marketing partners in the U.S. with existing pharmaceutical sales forces that already call on medical and dental offices in their geographic markets. We estimate the cost of completing the remaining *X-22* clinical trials to be approximately $14 million and the marketing expenses to bring *X-22* to market in the U.S. are estimated to be approximately $5 million.

There are approximately 700,000 physicians in the U.S., including approximately 80,000 general practitioners, many of whom are aware of new medications, even before they achieve FDA approval. There are also approximately 170,000 dentists in the U.S. who can write prescriptions for smoking cessation aids. Upon FDA approval, we plan to develop awareness for *X-22* by educating physicians and dentists about our *X-22* smoking cessation aid. We intend to advertise in professional journals, use direct mail campaigns to medical professionals, and attend trade shows and professional conferences. We also intend to use internet advertising and pharmacy circulars to reach consumers and to encourage them to ask their physicians and dentists about our *X-22* smoking cessation aid. We expect to use public relations to increase public awareness 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.

RED SUN and MAGIC Cigarettes

Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the "Master Settlement Agreement" or "MSA," a settlement among 46 states and the tobacco industry administered by the National Association of Attorneys General ("NAAG"). Our subsidiary, Goodrich Tobacco, introduced in a limited capacity two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. There have been *de minimis* sales of these brands in 2011 and 2012 since we have intentionally have not expanded marketing and distribution of these brands to facilitate Goodrich Tobacco becoming a participating manufacturer of the MSA. The more *RED SUN* and *MAGIC* sold while these brands are produced by a non-participating manufacturer, the greater the settlement costs Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA. On January 23, 2013, Goodrich Tobacco applied to the Alcohol and Tobacco Tax Trade Bureau ("TTB") for a federal permit to manufacture its own tobacco products. Being a federally licensed tobacco product manufacturer is a primary requirement of becoming a participating manufacturer of the MSA. On February 26, 2013, Goodrich Tobacco applied to the NAAG to become a participating manufacturer to the MSA. Both of these measures, if approved by the TTB and NAAG, will greatly facilitate the sales and distribution potential of *RED SUN* and *MAGIC*. Goodrich Tobacco expects its cigarette factory startup costs to be approximately $250,000 and plans to lease a portion of the machinery required. The costs associated with the MSA settlement are expected to be less than $40,000. The expected marketing costs for *RED SUN* and *MAGIC* in 2013 are $100,000.

In the second quarter of 2013, we intend to focus our marketing efforts on tobacconists, smoke shops and tobacco outlets in the U.S. The ban in 2009 by the FDA of all cigarettes with characterizing flavors (with the exception of menthol) has resulted in a product void in these 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 (from very low to high) cigarettes to NIDA. In August 2010, we met with officials from NIDA, FDA, RTI, the National Cancer Institute and the Centers for Disease Control and Prevention to finalize certain aspects of the design of these research cigarettes. These government research cigarettes are distributed under the mark *SPECTRUM*.

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"). 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 of our cigarette products, which we refer to as *BRAND A* and *BRAND B*, will qualify as Modified Risk Cigarettes. Compared to commercial cigarettes, the tobacco in *BRAND A* has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes, and *BRAND B*'s smoke contains an extraordinary low amount of "tar" per milligram of nicotine. The exact amount of capital is currently unknown since it is uncertain how many exposure studies the FDA will require for *BRAND A* and *BRAND B*. However, we estimate that the cost of completing the FDA authorization process for each of our potential Modified Risk Cigarettes to be at least $2 million. We believe that *BRAND A* and *BRAND B* will achieve market share in the global cigarette market among smokers who will not quit but are interested in reducing the harmful effects of smoking. There is no guarantee that we will (i) obtain additional capital to complete the FDA authorization process for our potential Modified Risk Cigarettes, (ii) obtain FDA authorization to market *BRAND A or BRAND B* as Modified Risk Cigarettes, or (iii) achieve significant market with FDA authorization to market our products as Modified Risk Cigarettes.

Healthcare Reimbursement

The Affordable Care Act enacted on March 23, 2010 and other government and private sector initiatives targeted to limit the growth of healthcare costs are continuing in the U.S. and many other countries where we intend to sell our *X-22* smoking cessation aid. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical products.

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

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 Affordable Care Act expands Medicaid coverage to all 50 states in 2014. 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

Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the MSA. After attempting throughout 2012 to negotiate a contract manufacturing agreement with multiple participating manufacturers to the MSA to have *RED SUN* and *MAGIC* produced by a participating manufacturer to the MSA, and not coming to terms, on January 23, 2013, Goodrich Tobacco applied to the Alcohol and Tobacco Tax Trade Bureau ("TTB") for a federal permit to manufacture its own tobacco products. Being a federally licensed tobacco product manufacturer is a primary requirement of becoming a participating manufacturer of the MSA. On February 26, 2013, Goodrich Tobacco applied to the NAAG to become a participating manufacturer to the MSA. Both of these measures, if approved by the TTB and NAAG, will greatly facilitate the sales and distribution potential of *RED SUN* and *MAGIC*. To facilitate Goodrich Tobacco becoming a participating manufacturer of the MSA, we have curtailed the sales and marketing of these products, especially in 2012 because the more *RED SUN* and *MAGIC* that is sold while being produced by a non-participating manufacturer, the greater settlement cost Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA.

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, Reynolds American Inc., Lorillard Inc., Commonwealth Brands, Inc., Liggett Group LCC, Vector Tobacco Inc., and Star Scientific Inc. International competitors include Philip Morris International, British American Tobacco, Japan Tobacco Inc., Imperial Tobacco Group 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 are under development in clinical trials. However, they have not yet achieved the efficacy of other FDA-approved smoking cessation therapies. Nicotine itself is not recognized by the body as a foreign compound since the molecule is too small. In order to stimulate the production of antibodies, nicotine must be attached to a carrier to make the vaccine work. Different vaccine development programs use different carriers. Six companies, Cytos Biotechnology AG, Celtic Pharmaceuticals Holdings, Nabi Biopharmaceuticals, L.P. and Independent Pharmaceutica AB, Selecta Biosciences Inc., and Pfizer Inc. have or have had vaccine candidates in clinical trials.

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

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

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

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

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

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

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

Government Regulation

Smoking Cessation Aids

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

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

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

Preclinical Phase

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

Clinical Phase

The clinical phase of drug development follows an IND submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy, and dosage of the substance in humans, as well as the ability to produce the substance in accordance with the FDA's cGMP requirements. Data from these activities are compiled in an NDA requesting approval to market the drug for a given use, or indication. Clinical trials must be conducted under the supervision of qualified investigators in accordance with good clinical practice, and according to IND-approved protocols detailing, among other things, the study objectives and the parameters, or endpoints, to be used in assessing safety and efficacy. Each trial must be reviewed, approved and conducted under the auspices of an independent Institutional Review Board ("IRB"), and each trial, with limited exceptions, must include all subjects' informed consent. The clinical evaluation phase typically involves the following sequential process:

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

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

hundred subjects or less.

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

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

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

New Drug Application and Review

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

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

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

Fast Track Development

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

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

We submitted a request for Fast Track designation for *X-22*, and on August 18, 2011, the FDA informed us that it would not grant the designation of *X-22* as a Fast Track product at that time because we did not demonstrate that *X-22* shows potential to address an unmet medical need. Except for our Phase II-B clinical trial, all smoking cessation studies with very low nicotine ("VLN") cigarettes containing our proprietary tobacco were independent studies and were not sponsored by 22nd Century Ltd under its own Investigational New Drug ("IND"). We plan to reapply for Fast Track designation, but not until results of a clinical trial sponsored by us demonstrates an advantage (over currently approved smoking cessation products) in one of the following areas: efficacy, safety or improvement in some other factor such as compliance (a patient using a product as directed) or convenience. There is no guarantee that the FDA will grant Fast Track designation to *X-22*.

Post-Approval Phase

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

Company Sponsored X-22 Clinical Trials

We have met with the FDA regarding the remaining *X-22* clinical trials and, based on the FDA's guidance, we developed a plan to conduct a small Phase II-B trial and two larger and concurrent Phase III trials with the same protocols that entail measuring the quitting efficacy of the *X-22* cigarette against a typical cigarette with conventional nicotine content that is visually indistinguishable from *X-22* (the "active control"). Half of the participants smoke *X-22* for six (6) weeks and half of the participants will smoke the active control for six (6) weeks, with all participants instructed to quit on the last day of the six (6)-week treatment period.

Smokers who do not smoke over the four (4)-week period immediately following the conclusion of the six (6)-week treatment period (weeks 7 through 10) are considered abstinent. The abstinence (quit) rates of the *X-22* group and the active control group are compared for statistical significance.

Our Investigational New Drug Application for *X-22*, a kit of 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 reduced the nicotine content of *X-22* by too great a percentage, to a level less than half the nicotine content of VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases quit rates.

We continue to believe that our VLN cigarettes are effective as a smoking cessation aid. However, we have suspended sponsoring further *X-22* clinical trials pending a complete analysis of results of two independent smoking-cessation trials that were completed in 2012 (ClinicalTrials.gov Identifiers NCT01050569 and NCT01250301), which utilized a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than that used in our own sponsored Phase II-B trial. A portion of the results of these two trials has been disclosed at the 2013 annual meeting of the Society for Research on Nicotine and Tobacco. These preliminary results are promising for the further development of *X-22*.

The full set of results of these 2 independent clinical trials are expected to be published in peer reviewed journals and will be compared to results of other independent clinical trials of our VLN cigarettes and results of our Phase II-B trial to determine which variables optimize cessation. One preliminary hypothesis, in conjunction with results of various other studies of our VLN cigarettes, is that having two types of prescription VLN cigarettes available may be advantageous for increased smoking cessation in the general population; one having a higher nicotine content than the other. Upon identifying a suitable joint venture partner to fund further *X-22* clinical trials, we will then request a meeting with the U.S. Food and Drug Administration ("FDA"), and thereafter we may resume our own sponsored *X-22* clinical trials.

Following FDA approval, we intend to register *X-22* as a Medicinal Product (pharmacological) for smoking cessation with the European Medicines Agency ("EMA") 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. For the first time in history, a U.S. regulatory agency will scientifically evaluate cigarettes that may pose lower health risks as compared to conventional cigarettes. The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco smoke toxins and/or (ii) pose lower health risks, as compared to conventional cigarettes ("Modified Risk Cigarettes"). We believe this new regulatory environment represents a paradigm shift for the tobacco industry. Besides the fact that the Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, the Tobacco Control Act allows the FDA to mandate the use of reduced-risk technologies across all conventional tobacco products or cigarettes. We believe the Tobacco Control Act may create opportunities for us to license our proprietary technology and/or tobaccos to larger competitors.

Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the "Master Settlement Agreement" or "MSA," a settlement among 46 states and the tobacco industry administered by the National Association of Attorneys General ("NAAG"). Our subsidiary, Goodrich Tobacco, introduced in a limited capacity two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. There have been *de minimis* sales of these brands in 2011 and 2012 since we have intentionally have not expanded marketing and distribution of these brands to facilitate Goodrich Tobacco becoming a participating manufacturer of the MSA. The more *RED SUN* and *MAGIC* sold while these brands are produced by a non-participating manufacturer, the greater the settlement costs Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA. On January 23, 2013, Goodrich Tobacco applied to the Alcohol and Tobacco Tax Trade Bureau ("TTB") for a federal permit to manufacture its own tobacco products. Being a federally licensed tobacco product manufacturer is a primary requirement of becoming a participating manufacturer of the MSA. On February 26, 2013, Goodrich Tobacco applied to the NAAG to become a participating manufacturer to the MSA. Both of these measures, if approved by the TTB and NAAG, will greatly facilitate the sales and distribution potential of *RED SUN* and *MAGIC*. Goodrich Tobacco expects its cigarette factory startup costs to be approximately $250,000 and plans to lease a portion of the machinery required. The costs associated with the MSA settlement are expected to be less than $40,000.

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

Biomass Products

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

In 2008, we put our biomass development projects on hold so that our management could focus its attention and resources on our modified risk cigarette business and our *X-22* smoking cessation business. We do not plan to move forward with potential biomass business activities until some period of time after FDA approval of *X-22* or FDA authorization to market *Brand A* or *Brand B* as a Modified Risk Cigarette. We currently are not spending any capital for such potential biomass business activities nor do we have any current plans to raise any capital for such potential biomass business activities.

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 has had multiple R&D agreements with North Carolina State University ("NCSU") resulting in exclusive worldwide licenses to various patented technologies. We have utilized the model of many public-sector research organizations which entails obtaining an exclusive option or license agreement to any invention arising out of the 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 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 this R&D has involved the biosynthesis of nicotine in plants. Our R&D agreements with NCSU, NRC and NAIST expired in 2009. We did not have any outsourced R&D projects during 2010. In 2010, NAIST assigned to us all of their worldwide patents and patent applications that were previously licensed to 22nd Century on an exclusive basis. These patents and patent applications were a result of our R&D at NAIST. In November 2011, we entered into an R&D agreement with the University of Virginia (UVA) relating to nicotine biosynthesis in tobacco plants with a total budget of $500,000 for the period from November 2011 through December 2014. In 2012, we incurred approximately $100,000 of expenses for the R&D agreement at UVA. During the years ended December 31, 2012, 2011 and 2010, we incurred research and development expenses of approximately $729,000, $2,098,000 and $364,000, respectively.

Other than the R&D agreement at UVA, we have no other substantial third-party R&D commitments requiring funding. However, we may carry out a minimal amount of R&D in 2013, not to exceed $100,000, for additional field trials of plants from our seed lots that resulted from our R&D at NCSU, NRC, NAIST and UVA. Upon the required funding, we expect to carry out exposure studies for our modified risk cigarette candidates and will carry out additional clinical trials for *X-22* if Hercules Pharmaceuticals, our subsidiary, identifies a joint venture partner willing to fund these trials.

Employees

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

Description of Property

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, 2012 is $37,833 for 2013 and $28,000 for 2014.

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.

Management's Discussion and Analysis of
Financial Condition and Results of Operations

The following discussion highlights the principal factors that have affected our financial condition and results of operations as well as our liquidity and capital resources for the periods described. This discussion contains forward-looking statements. Please see "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" earlier in this prospectus. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere herein, including those discussed in the section entitled "Risk Factors."

On January 25, 2011, 22nd Century Limited, LLC completed a reverse merger transaction (the "Merger") with 22nd Century Group, Inc. 22nd Century Limited, LLC is a wholly owned subsidiary of 22nd Century Group, Inc. which continues to operate the business of 22nd Century Limited, LLC. All references to shareholders or common shares include the historical members and membership Units of 22nd Century Limited, LLC 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 Limited, LLC 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 Limited, LLC and are recorded at the historical cost basis of 22nd Century Limited, LLC, and the consolidated financial statements since completion of the Merger include the assets and liabilities of 22nd Century Limited, LLC, historical operations of 22nd Century Limited, LLC 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 modifying the content of nicotinic alkaloids in tobacco plants through genetic engineering and plant breeding. We own or exclusively control 107 issued patents and exclusively control 39 patent applications; we own 12 issued patents plus 22 patent applications and we license on an exclusive basis 95 issued patents and 17 patent applications. Hercules Pharmaceuticals, LLC ("Hercules Pharmaceuticals") and Goodrich Tobacco Company, LLC ("Goodrich Tobacco") are wholly-owned subsidiaries of 22nd Century Ltd. Goodrich Tobacco is focused on commercial tobacco products and potential Modified Risk cigarettes. Hercules Pharmaceuticals is focused on *X-22, a* prescription smoking cessation aid in development.

We believe that our proprietary technology will enable us to capture a share of the global market for approved smoking cessation aids and the emerging market for modified risk tobacco products. The Company is primarily

involved in the following activities:

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

We have operated at a loss since 2006 when we increased our research and development expenditures. In the years ended December 31, 2012, 2011 and 2010 we realized revenues of $18,775, $788,601 and $49,784, respectively mainly from our research cigarette 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 technology and products.

Our prospects depend on our ability to generate and sustain revenues from (i) sales of *RED SUN* and *MAGIC*, our *X-22* smoking cessation aid, our potential Modified Risk cigarettes and our proprietary tobacco and (ii) licensing of our technology and products. 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 potential Modified Risk cigarettes in the U.S. depends in large part on obtaining FDA authorization to market these products as Modified Risk cigarettes. If our products are approved and authorized by the FDA, we must still meet the challenges of successful marketing and distribution and consumer acceptance. We are currently in the process of identifying potential joint venture partners to fund the remaining *X-22* clinical trials. We estimate the cost of completing the remaining *X-22* clinical trials to be approximately $14 million and the marketing expenses to bring *X-22* to market in the U.S. are estimated to be approximately $5 million. There is no guarantee that we will (i) obtain the funds necessary to complete additional clinical trials, (ii) identify potential joint venture partners to fund the remaining *X-22* clinical trials, (iii) obtain FDA approval, or (iv) capture significant share of the smoking cessation market upon FDA approval.

Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the “Master Settlement Agreement” or “MSA,” a settlement among 46 states and the tobacco industry administered by the National Association of Attorneys General (“NAAG”). Our subsidiary, Goodrich Tobacco, introduced in a limited capacity two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. There have been *de minimis* sales of these brands in 2011 and 2012 since we have intentionally have not expanded marketing and distribution of these brands to facilitate Goodrich Tobacco becoming a participating manufacturer of the MSA. The more *RED SUN* and *MAGIC* sold while these brands are produced by a non-participating manufacturer, the greater the settlement costs Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA. On January 23, 2013, Goodrich Tobacco applied to the Alcohol and Tobacco Tax Trade Bureau (“TTB”) for a federal permit to manufacture its own tobacco products. Being a federally licensed tobacco product manufacturer is a primary requirement of becoming a participating manufacturer of the MSA. On February 26, 2013, Goodrich Tobacco applied to the NAAG to become a participating manufacturer to the MSA. Both of these measures, if approved by the TTB and NAAG, will greatly facilitate the sales and distribution potential of *RED SUN* and *MAGIC*. Goodrich Tobacco expects its cigarette factory startup costs to be approximately $250,000 and plans to lease a portion of the machinery required. The costs associated with the MSA settlement are expected to be less than $40,000.

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 reduced the nicotine content of *X-22* by too great a percentage, to a level less than half the nicotine content of VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases quit rates. We continue to believe that our VLN cigarettes are effective as a smoking cessation aid. However, we have suspended sponsoring further *X-22* clinical trials pending a complete analysis of results of two independent smoking-cessation trials that were completed in 2012 (ClinicalTrials.gov Identifiers NCT01050569 and NCT01250301), which utilized a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than that used in our own sponsored Phase II-B trial. A portion of the results of these two trials has been disclosed at the 2013 annual meeting of the Society for Research on Nicotine and Tobacco. These preliminary results are promising for the further development of *X-22*.

The full set of results of these 2 independent clinical trials are expected to be published in peer reviewed journals and will be compared to results of other independent clinical trials of our VLN cigarettes and results of our Phase II-B trial to determine which variables optimize cessation. One preliminary hypothesis, in conjunction with results of various other studies of our VLN cigarettes, is that having two types of prescription VLN cigarettes available may be advantageous for increased smoking cessation in the general population; one having a higher nicotine content than the other. Upon identifying a suitable joint venture partner to fund further *X-22* clinical trials, we will then request a meeting with the U.S. Food and Drug Administration ("FDA"), and thereafter we may resume our own sponsored *X-22* clinical trials.

The Company expects to file applications in 2013 with the FDA for two types of Modified Risk cigarettes in accordance with the FDA's issued *Modified Risk Tobacco Product Applications Draft Guidance* released on March 30, 2012. This provides the framework for applicants to submit data for modified risk product candidates. Goodrich Tobacco, our subsidiary, has developed two types of potential Modified Risk cigarettes. The first proprietary cigarette, referred to as *BRAND A*, is a VLN cigarette containing approximately 95 percent less nicotine than the leading U.S. cigarette brands. 22nd Century's recent Phase II-B clinical trial and studies by independent researchers have demonstrated that smoke exposure (and cigarettes per day) is significantly reduced with VLN cigarettes. The second proprietary cigarette, referred to as *BRAND B*, is a low-tar cigarette with a relatively high nicotine content, effectively the world's lowest tar-to-nicotine ratio cigarette. Unlike low-tar/low-nicotine brands currently on the market (previously labeled "light" or "ultra- light" before these descriptors were banned in the U.S. by the Tobacco Control Act in 2010), the nicotine yield of *BRAND B* is not reduced. Studies have demonstrated that for those smoking low-tar research cigarettes, similar to *BRAND B*, compensatory smoking is greatly curtailed as compared to those smoking regular cigarettes. Additional studies will be necessary to establish whether *BRAND B* cigarettes achieve similar results.

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. These government research cigarettes are distributed under the Company's mark *SPECTRUM*. The Company delivered approximately 9 million *SPECTRUM* research cigarettes during the year ended December 31, 2011 and delivered an additional 2.7 million *SPECTRUM* research cigarettes in July 2012.

Results of Operations

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Revenue. In the year ended December 31, 2012, we realized revenue of $18,775, mainly from our research cigarette program, as compared to revenue of $788,601 in year ended December 31, 2011. As of December 31, 2012 we had an outstanding backorder of approximately $3,000 for our research cigarettes.

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, 2012, costs of goods sold were $67,967 which exceeded revenue by 262% since we provided RTI with certain *SPECTRUM* research cigarettes without charge mainly due to production delays. 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 due to changes in the Company's manufacturing plans that rendered these costs not recoverable.

Research and development expense. Research and development expense was $729,225 in the year ended December 31, 2012, a decrease of $1,368,755, or 65%, from $2,097,980 in the year ended December 31, 2011. This decrease is mainly the result of suspending our clinical trials for *X-22* early in the first quarter of 2012. In the year ended December 31, 2011 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*.

General and administrative expense. General and administrative expense was $2,205,450 in the year ended December 31, 2012, an increase of $419,907, or 24%, from $1,785,543 in the year ended December 31, 2011. The increase was mainly attributable to the $337,165 increase in equity based compensation costs for administrative personnel which were $662,601 in 2012 as compared to $325,436 in 2011. The remainder of the increase was due to costs associated with investor relations activities.

Sales and marketing costs. Sales and marketing costs were $61,876 in the year ended December 31, 2012, a decrease of $224,157, or 78%, from $286,033 in the year ended December 31, 2011. The costs in 2011 related to the domestic market introduction of *RED SUN* and *MAGIC* and included expenses related to product testing, product and packaging design, product branding, trade samples, trade shows and advertising. Early in 2012, we curtailed marketing of these brands in order to facilitate reaching an agreement to have these products produced by a participating manufacturer of the MSA and, as a result, sales and marketing costs in 2012 were reduced as compared to 2011.

Amortization and depreciation expense. Amortization and depreciation expense relates almost entirely to capitalized patent and trademark costs. Amortization and depreciation expense increased 10% in the year ended December 31, 2012 to $198,406, up from $179,953 in the year ended December 31, 2011. This increase of $18,453 is mainly due to our additional investment in patents and trademarks in 2011 of $98,191and in 2012 of $162,774.

Warrant liability change – net. In multiple private placements in 2012, we issued warrants which were accounted for as derivatives and upon issuance a liability at the estimated fair value was recorded. At the date of issuance of these warrants the value exceeded the total consideration received by an aggregate of $814,500 resulting in an immediate charge to expense for this amount. This charge was in addition to the loss of $1,183,543 resulting from the increase in the estimated fair value during the year ended December 31, 2012 of all warrants we have issued. The market adjustment recorded in the year ended December 31, 2011 was a gain of $2,511,750. The change in the fair value of the warrant liability has been caused mainly by the decrease of the price of our common stock.

Interest expense and amortization of debt discount and expense. Interest expense and amortization of debt discount and debt issuance costs increased in the year ended December 31, 2012 to $1,494,545 from $103,998 in the year ended December 31, 2011. This increase of $1,390,547 or 1,337% was primarily a result of the amortization of debt discount and debt issuance costs related to convertible notes issued on December 14, 2011 and August 9, 2012, which also includes charges interest expense for the value of warrants in excess of the note payable converted, totaling approximately $31,000 related to the partial conversions of the December 14, 2011 Convertible Notes.

Net loss. We had a net loss in the year ended December 31, 2012 of $6,736,737 as compared to a net loss of $1,347,787 in the year ended December 31, 2011, as a result of the warrant liability change and an increase in interest expense and amortization of debt discount and expense as well as a reduction in revenues.

Liquidity and Capital Resources

Summary of Balances and Recent Sources and Uses

As of December 31, 2012, we had negative working capital of approximately $3.3 million as compared to negative working capital of approximately $1.9 million at December 31, 2011. The $1.4 million increase in negative working capital was primarily the result of $1.7 million of cash used in operations and $1.2 million of note discount amortization that resulted in an increase in the carrying value of the convertible notes, which were offset by approximately $1.5 million of proceeds from equity securities we issued during 2012.

Cash demands on operations

In 2012 and 2011, we operated at a loss and operating activities consumed more than $5.2 million in cash during this two year period. Cash on hand at December 31, 2012 of $188 was insufficient to fund operations and meet our obligations as they come due in 2013. The Company has suspended clinical trials for *X-22* and is seeking licensing

agreements for its products with both domestic and international businesses. At December 31, 2012, the Company had current assets of $1,281,305 and current liabilities of $4,602,948.

On January 11, 2013, the Company closed a private placement and realized net proceeds of approximately $2.125 million. From January 1, 2013 through February 6, 2013, the Convertible Notes with a carrying value at December 31, 2012 of approximately $1.41 million were converted into common stock and warrants. While both these steps significantly improved the Company's financial position; we will need additional capital or one or more licensing arrangements for our technology and products in order to meet cash requirements to fund operations and meet our obligations during 2013. Excluding contract growing of our proprietary tobacco with farmers and extraordinary expenses such as clinical trials and factory setup costs, our monthly cash expenditures are approximately $100,000. In the event the Company does not enter into an out-licensing agreement with a third party in 2013, approximately $1.6 million of additional capital is required through 2013, which includes paying approximately $1 million of obligations that will become due in 2013. The Company expects its cigarette factory startup costs to require an additional $250,000 of capital. It plans to lease a portion of the machinery required. There can be no assurance that the Company will be able to raise sufficient capital or obtain a licensing agreement.

Other than the R&D agreement at UVA, the Company has no other substantial third-party R&D commitments requiring funding. The Company may carry out a minimal amount of R&D in 2013, not to exceed $100,000, for additional field trials of plants from our seed lots that resulted from our R&D at NCSU, NRC, NAIST and UVA. Upon the required funding, we expect to carry out exposure studies for our Modified Risk cigarette candidates and will carry out additional clinical trials for *X-22* if Hercules Pharmaceuticals, our subsidiary, identifies a joint venture partner willing to fund these trials.

The ability to complete additional equity or debt 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, licensing of its technology, products and tobacco, and results on independent smoking cessation clinical trials utilizing the Company's products. In addition, our ability to complete additional debt and equity financings is limited by covenants related to our Series A-1 Preferred Stock, unless we issue securities to an entity in a business synergistic to ours. Failure to license the Company's technology, products and tobacco or to raise sufficient capital would significantly increase the risk that we would be unable to continue operations. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technology, tobacco or products or grant licenses on terms that are not favorable to us.

Net Cash used in Operating Activities.

In the year ended December 31, 2012, $1,764,445 of cash was used in operating activities compared to $3,449,430 of cash used in operating activities in the year ended December 31, 2011. This decreased use of cash of $1,684,985 was mainly due to the decrease of clinical trial expenses in 2012 as compared to 2011 and less cash was used in paying down debt in 2012 as compared to 2011.

Net Cash used in Investing Activities.

In the year ended December 31, 2012, we used $162,774 of cash related to third party costs incurred for patents and trademarks and the acquisition of office furniture and fixtures as compared to $607,297 used in the year ended December 31, 2011. This decrease 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, 2012, we generated $1,675,158 from our financing activities mainly as a result of the $1,467,500 proceeds from the May and November 2012 private placements, the $210,000 proceeds from the August 9, 2012 convertible notes, $4,136 in advances from officers and $56,000 in proceeds from the issuance of short term secured notes, partially offset by payments on borrowings of $41,000 and net payments to a related party of $21,478. During the year ended December 31, 2011, we generated net cash of $4,308,666 from our financing activities; we received approximately $3,293,789 in net cash proceeds from the private placement that closed on January 25, 2011, and approximately $1.7 million from the issuance of the December 14, 2011 Convertible Notes and $215,000 from the issuance of notes; these receipts were partially offset by the payments on borrowings of a $443,276, payment of debt issuance costs of $23,500, $10,914 in net advances to officers and net payments to a related party of a related party $22,433.

Critical Accounting Policies and Estimates

Accounting principles generally accepted in the United States of America, or U.S. GAAP, require estimates and assumptions to be made that affect the reported amounts in our consolidated financial statements and accompanying notes. Some of these estimates require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations.

Revenue Recognition

We recognize revenue at the point the product is shipped to a customer and title has transferred. Revenue from the sale of our products is recognized net of cash discounts, sales returns and allowances. Federal cigarette excise taxes are included in net sales and accounts receivable billed to customers, except on sales of *SPECTRUM* and exported cigarettes in which such taxes do not apply.

We were chosen to be a subcontractor for a 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. These government research cigarettes are distributed under the mark *SPECTRUM*. The Company completed the four developmental stages and delivered approximately 9 million cigarettes during the year ended December 31, 2011 and recognized the related revenue. Revenue related to the additional 2.7 million *SPECTRUM* research cigarettes we shipped in July 2012 was recognized at the point the cigarettes were shipped and title transferred. 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 (e.g., patents and trademarks) are reviewed annually for impairment. We have not recognized any impairment losses during the two year period ended December 31, 2012.

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

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.

Convertible Debt

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

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

Income taxes

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. Due to the uncertainty of the Company's ability to generate sufficient taxable income in the future it has determined that it is more likely than not that its net deferred tax asset, which includes net operating loss carryforwards, will not be realized. Accordingly, the Company has recorded a full valuation allowance to reduce the net deferred tax asset to zero for the period from January 25, 2011 through December 31, 2011 and for the 2012 calendar year. The Company incurred net operating losses for each of these periods and accordingly has made no provision for current income taxes.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair market value and then is revalued at each reporting date, with changes in fair value reported in the consolidated statement of operations. The methodology for valuing our outstanding warrants classified as derivative instruments utilizes a lattice model approach which includes probability weighted estimates of future events including volatility of our common stock. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The warrant liability is measured at fair value using certain estimated factors such as volatility and probability which are classified within Level 3 of the valuation hierarchy. Significant unobservable inputs are used in the fair value measurement of the Company's derivative warrant liabilities include volatility. Significant increases (decreases) in the volatility input would result in a significantly higher (lower) fair value measurement. A 10% increase or decrease in the volatility factor used as of December 31, 2012 would have the impact of increasing or decreasing the liability by approximately $875,000.

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

Inflation

Inflation did not have a material effect on our operating results for the two years ended December 31, 2012 and 2011.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by Item 303(a)(4) of Regulation S-K.

Directors and Executive Officers

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

Name	Age	Position
Joseph Pandolfino	44	Chief Executive Officer and Director
Henry Sicignano, III	45	Chief Financial Officer, President, Secretary and Director
Michael R. Moynihan, Ph.D.	60	Vice President of R&D
Joseph Alexander Dunn, Ph.D.	59	Director
James W. Cornell	56	Director

Our executive officers are appointed by the board of directors and serve at the discretion of the board. There are no family relationships among our directors and executive officers.

Our bylaws provide that the number of members of our Board of Directors shall not be less than one nor more than thirteen. The number of authorized directors as of the date of this prospectus is four. Directors hold office for a one year term expiring at the annual meeting in 2013 (or until their respective successors are elected and qualified, or until their earlier death, resignation or removal). The experience, qualifications, attributes and skills that led to the conclusion that the persons should serve as a Director of our Company are described below in each Director nominee's biography.

Joseph Pandolfino, MBA, Chief Executive Officer and Director

Mr. Pandolfino, age 44, has served as our Chief Executive Officer and as a Director since the closing of the merger in January 2011 between the Company and 22nd Century Limited, LLC. He founded 22nd Century Limited, LLC 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 Limited, LLC from its inception until April 2010 and as Chief Executive Officer of 22nd Century Limited, LLC 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 Limited, LLC led to our conclusion that he should serve as a director of our Company.

Henry Sicignano, III, MBA, Chief Financial Officer, President and Director

Henry Sicignano, III, MBA. Mr. Sicignano, age 45, has served as our President and Secretary since the closing of the merger in January 2011 between the Company and 22nd Century Limited, LLC, as a Director since March 4, 2011, and as interim Chief Financial Officer since July 6, 2012. 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 an 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, age 60, has served as our Vice President of R&D since March 2011 and served as Vice President of R&D for 22nd Century Limited, LLC since January, 2007. He has also been a consultant for 22nd Century Limited, LLC 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.

Joseph Alexander Dunn, Ph.D., Director

Dr. Dunn, age 59, has served as a Director since March 4, 2011. 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, Director

Mr. Cornell, age 56, has served as a Director since March 4, 2011. 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.

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Corporate Governance

Board Leadership Structure

As of the date hereof, the Board has not appointed a chairman or a lead independent director. At this time, the Board believes that this structure is appropriate for our Company because we have very few employees and are currently in the development phase for our products. In the future, we expect that the Board will appoint a chairman and, if appropriate, a lead independent director.

Board Role in Risk Oversight

Risk is inherent with every business and we face a number of risks. Management is responsible for the day-to-day management of risks we face, while our Board of Directors is responsible for overseeing our management and operations, including overseeing its risk assessment and risk management functions.

Compensation Policies and Practices and Risk Management

The Board considers, in establishing and reviewing our compensation philosophy and programs, whether such programs encourage unnecessary or excessive risk taking. Base salaries are fixed in amount and consequently the Board does not see them as encouraging risk taking. We also provide our executive officers and other senior managers long-term equity awards to help further align their interests with our interests and those of our stockholders. The Board believes that these awards do not encourage unnecessary or excessive risk taking since the awards are generally provided at the beginning of an employee's tenure or at various intervals to award achievements or provide additional incentive to build long-term value and are subject to vesting schedules to help ensure that executives and senior managers have significant value tied to our long-term corporate success and performance.

The Board believes that our compensation philosophy and programs encourage employees to strive to achieve both short- and long-term goals that are important to our success and building stockholder value, without promoting unnecessary or excessive risk taking. The Board has concluded that our compensation philosophy and practices are not reasonably likely to have a material adverse effect on us.

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 a written request to our Chief Executive Officer c/o 22nd Century Group, Inc., 9530 Main Street, Clarence, New York 14031.

Number of Meetings of the Board of Directors

The Board held four meetings during 2012. Directors are expected to attend Board meetings and to spend time needed to meet as frequently as necessary to properly discharge their responsibilities. Each director attended at least 75% of the aggregate number of meetings of the Board during 2012.

Attendance at Annual Meetings of the Stockholders

The Company has no policy requiring Directors and Director Nominees to attend its annual meeting of stockholders; however, all Directors and Director Nominees are encouraged to attend. All of our directors attended our 2012 annual meeting.

Director Independence

Joseph Alexander Dunn, Ph.D. and James W. Cornell each qualify as “independent” applying the NASDAQ Global Market definition of independent.

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.

Committees of the Board of Directors

As of the date hereof, the Board has not established any committees of the Board. At this time, the Board believes that this structure is appropriate for our Company because we have very few employees and are currently in the development phase for our products. In the future, we expect that the Board will establish Board committees.

Nominating Committee

At of the date hereof, the Company does not have a nominating committee. The Company intends to adopt a nominating committee in the future.

As of the date hereof, 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 hereof, 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.

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 2012:

Name	Fees Earned or paid in cash	Stock Awards	Option Awards(1)	Non-Qualified Non-Equity Incentive Plan Compensation	Deferred Compensation Earnings	All Other Compensation	Total
James W. Cornell	$ 10,000	-	$ 35,400	-	-	-	$45,400
Joseph A. Dunn, Ph.D.	$ 10,000	-	$ 35,400	-	-	-	$45,400

(1) Represents the grant date fair value calculated pursuant to ASC Topic 718. 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:

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

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 2012, the Company believes that all Section 16(a) filing requirements were met during 2012 except as set forth below:

Joseph Pandolfino, Henry Sicignano III, Michael Moynihan and Charles Rider each filed a late Form 4 on May 21, 2012 reporting the acquisition of shares. Michael Moynihan filed a late Form 4 on August 24, 2012 reporting the sale of shares. Henry Sicignano III filed a late Form 4 on August 28, 2012 reporting the acquisition of shares. Joseph Pandolfino filed a late Form 4 on August 30, 2012 reporting the sale of shares. Joseph Dunn, James Cornell, Joseph Pandolfino and Henry Sicignano III each filed a late Form 4 on November 14, 2012 reporting the acquisition of shares.

Executive Compensation

The following table summarizes the compensation paid by us in each of the last two completed fiscal years ended December 31, 2012 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 for Years Ended December 31, 2012 and 2011

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($) (3)	Total ($)
Joseph Pandolfino	2012	150,000							