22nd Century Group, Inc.
Form 8-K/A
March 23, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported) March 22, 2011

22nd Century Group, Inc.
(Exact name of registrant as specified in its charter)

Nevada	000-54111	98-0468420
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

8201 Main Street, Suite 6, Williamsville, New York 14221
(Address of principal executive offices)

(716) 270-1523
Registrant’s telephone number, including area code

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Explanatory Note

On February 1, 2011, 22nd Century Group., Inc. (the "Company," we," "us" or "our") filed with the Securities and Exchange Commission (the "SEC") a Current Report on Form 8-K (the "Original Form 8-K"), with respect to our entry into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") by and among us, 22nd Century Limited, LLC, a privately held Delaware limited liability company ("22nd Century"), and 22nd Century Acquisition Subsidiary, a Delaware limited liability company and our wholly-owned subsidiary ("Acquisition Sub"). Upon the closing of the merger transaction contemplated under the Merger Agreement (the "Merger"), Acquisition Sub was merged with and into 22nd Century, and 22nd Century, as the surviving entity, became our wholly-owned subsidiary. Following the Merger, we succeeded to the business of 22nd Century as our sole line of business.

We are filing this amendment to the Original Form 8-K, as a Current Report on Form 8-K/A, to update and supplement information included in the Original Form 8-K, as necessary, to reflect the business, financial condition and results of operations of 22nd Century, as of the fiscal year ended December 31, 2010, including, without limitation, Management's Discussion and Analysis of Financial Condition and Results of Operations relating to the consolidated financial condition and results of operations of 22nd Century as of, and for each of the years ended, December 31, 2009 and 2010, as well as consolidated financial statements and related notes for such periods.

For the convenience of the reader and in accordance with SEC staff guidance, the information included in this amended Form 8-K is being presented utilizing the format provided for in an Annual Report on Form 10-K ("Form 10-K Information"). The Form 10-K Information reflects our information that is required to be disclosed by us as a "smaller reporting company," as that term is defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K/A and other written reports and oral statements made from time to time by us may contain "forward-looking statements," all of which are subject to risks and uncertainties. You can identify these forward-looking statements by their use of words such as "expects," "plans," "will," "estimates," "forecasts," "projects" and ot words of similar meaning. You can identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address our growth strategy, financial results and product and development programs. You must carefully consider any such statement and should understand that many factors could cause actual results to differ from these forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

Information regarding market and industry statistics contained in this Current Report on Form 8-K/A is included based on information available to us that we believes is accurate. It is generally based on industry and other publications that are not produced for purposes of securities offerings or economic analysis. We have not reviewed or included data from all sources, and cannot assure investors of the accuracy or completeness of the data included in this Current Report on Form 8-K/A. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. We do not assume the obligation to update any forward-looking statement. You should carefully evaluate such statements in light of factors described in our filings with the SEC, especially on Forms 10-K, 10-Q and 8-K. In various filings, we have identified important factors that could cause actual results to differ from expected or historic results. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete list of all potential risks or uncertainties.

Item 2.01. Completion of Acquisition or Disposition of Assets

FORM 10-K INFORMATION FOR THE YEAR ENDED DECEMBER 31, 2010

Unless the context otherwise requires, references in this Form 10-K Information section to the "Company," "we," "us," and "our" refer to 22nd Century Group, Inc., a Nevada corporation, and 22nd Century Limited, LLC, a Delaware limited liability company, as its wholly-owned subsidiary, taken as a whole, and also refer to the operations of 22nd Century Limited, LLC prior to the closing of the Merger on January 25, 2011.

PART I

Item 1. Business.

Background

We were incorporated under the laws of the State of Nevada on September 12, 2005 to engage in the acquisition, exploration and development of mineral deposits and reserves. We had been in a development stage since our inception and had minimal business operations prior to the Merger. Prior to the closing of the Merger, we (i) obtained forgiveness of all our outstanding promissory notes in the aggregate principal amount of $162,327, (ii) cancelled the 386,389 shares of our common stock held by Milestone Enhanced Fund Ltd. and the 10,015,200 shares of our common stock held by Nanuk Warman, (iii) entered into contractual agreements with certain of our shareholders pursuant to which an aggregate of 139,800 shares of our common stock will be cancelled as soon as practicable following the closing of the Merger (such 139,800 shares of our common stock being deemed to be no longer issued and outstanding as of January 25, 2011) and (iv) effected a 2.782-for-one forward stock split by way of dividend and subsequent cancellation to ensure that the pre-Merger shareholders of the Company owned an aggregate of 5,325,200 shares of our common stock immediately prior to the closing of the Merger.

In addition, prior to the closing of the Merger, we transferred all of our pre-Merger operating assets and remaining liabilities to Touchstone Split Corp., a Delaware corporation and then wholly-owned subsidiary of the Company (the "Split-Off Subsidiary") pursuant to the terms of that certain Split-Off Agreement dated as of January 25, 2011 by and between the Company, David Rector, and the Split-Off Subsidiary (the "Split-Off Agreement"). Prior to the Merger and pursuant to the terms of the Split-Off Agreement, the Company transferred and sold all of the issued and outstanding shares of capital stock of the Split-Off Subsidiary to Mr. Rector in exchange for $1.00, such consideration being deemed to be adequate by our Board of Directors (the "Board").

22nd Century was formed as a New York limited liability company on February 20, 1998 as 21st Century Limited, LLC, which merged with a newly-formed Delaware limited liability company, 22nd Century Limited, LLC on November 29, 1999. 22nd Century's offices are located in Williamsville, New York. Since beginning operations, 22nd Century has worked to modify the content of nicotine alkaloids in tobacco plants through genetic engineering and plant breeding.

Prior to the closing of the Merger, 22nd Century completed a private placement offering (the "Private Placement Offering") of 5,434,446 securities (the "PPO Securities") at the purchase price of $1.00 per PPO Security, each such PPO Security consisting of one (1) limited liability company membership interest unit (a "Unit") and a five year warrant to purchase one-half of one (1/2) Unit at an exercise price of $1.50 per whole Unit.

After the Merger with the Company, we succeeded to the business of 22nd Century as our sole line of business.

Overview

We are a plant biotechnology company and a global leader in modifying the content of nicotinic alkaloids in tobacco plants through genetic engineering and plant breeding. We own or exclusively control 97 issued patents in 79 countries where at least 75% of the world's smokers reside. We believe that our proprietary technology will enable us to capture a significant share of the global market for approved smoking cessation aids and the emerging market for modified risk tobacco products.

We plan to use a substantial portion of the proceeds of the Private Placement Offering to complete a Phase II-B clinical trial which is necessary to seek approval from the U.S. Food and Drug Administration ("FDA") for X-22, our

prescription smoking cessation aid in development. We have met with the FDA regarding the remaining clinical trials for X-22 and based on the FDA's guidance, we plan to conduct a Phase II-B trial and two larger and concurrent Phase III trials with the same protocols. X-22 will be a prescription-only kit containing very low nicotine ("VLN") cigarettes made from our proprietary tobacco, which has approximately 95% less nicotine compared to tobacco in existing "light" cigarettes. The therapy protocol allows the patient to smoke our VLN cigarettes without restriction over the six-week treatment period to facilitate the goal of the patient quitting smoking by the end of the treatment period. We believe this therapy protocol has been successful because VLN cigarettes made from our proprietary tobacco satisfy smokers' cravings for cigarettes while (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine. We believe X-22 will be more attractive to smokers than other therapies since it smokes and tastes like a typical cigarette, involves the same smoking behavior, and does not expose the smoker to any new drugs or new side effects.

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

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

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco toxins and/or (ii) potentially pose lower health risks as compared to conventional cigarettes ("Modified Risk Cigarettes"). The Tobacco Control Act requires the FDA to issue specific regulations and guidance regarding applications that must be submitted to the FDA for the authorization to label and market Modified Risk Cigarettes. Based in part on the timelines contained in the Tobacco Control Act, we expect the FDA to issue such regulations and guidance in 2011.

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 other commercial cigarettes, the tobacco in BRAND A has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes, and BRAND B's smoke contains the lowest amount of "tar" per milligram of nicotine.

Within our two product categories, the Tobacco Control Act offers us the following specific advantages:

Smoking Cessation Aids

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

Modified Risk Cigarettes

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

RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco Company, LLC (f/k/a Xodus, LLC), has introduced two super-premium priced cigarette brands, RED SUN and MAGIC, into the U.S. market in the first quarter of 2011. Both brands are available in regular and menthol and all four brand styles are king size, packaged in hinge-lid hard packs. We intend to focus our marketing efforts on tobacconists, smoke shops and tobacco outlets. The ban in 2009 by the FDA of all flavored cigarettes (with the exception of menthol) has resulted in a product void in these tobacco channels. Certain wholesalers and retailers are now seeking other specialty cigarettes to replace the banned flavored cigarettes. We believe that certain U.S. cigarette wholesalers and retailers will, among other reasons, purchase RED SUN and MAGIC to replace their lost sales of flavored cigarettes as well as potential lost sales of “light” and “ultra light” cigarettes.

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 high yield 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 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 shown that non-commercial cigarettes with low tar-to-nicotine ratios (tar yield divided by nicotine yield from smoking machines), such as BRAND B, result in smokers inhaling less tar and carbon monoxide (CO).

Market

Cigarettes and Smoking Cessation Aids

The U.S. cigarette market consists of 46 million adult smokers who spent approximately $80 billion in 2010 on 310 billion cigarettes. The World Health Organization, or WHO, predicts that the current 1.3 billion smokers worldwide will increase to 1.7 billion smokers by the year 2025. Worldwide manufacturer sales in 2010 were over 5.0 trillion cigarettes, resulting in annual retail sales of approximately $600 billion. Our products address unmet needs of smokers; for those who want to quit, an innovative smoking cessation aid, and for those who do not quit, cigarettes that can reduce the level of exposure to tobacco toxins.

In 2009, annual sales of smoking cessation aids in the U.S., all of which must be approved by the FDA, were approximately $1.0 billion. Outside the United States, the smoking cessation market is in its infancy. Visiongain estimates the 2008 global smoking cessation market at approximately $3.0 billion. According to Datamonitor, the prescription smoking cessation market in the United States, Germany, United Kingdom, France, Italy, Spain and Japan is expected to grow at a compound annual rate of 16%, reaching approximately $4.6 billion by 2016. This figure does not consider China, Russia, Brazil, India and other large smoking markets.

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

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

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

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

Chantix® was introduced in the U.S. market in the fourth quarter 2006. Since 2007, Chantix® has been the best-selling smoking cessation aid in the United States, with sales of $701 million in 2007, $489 million in 2008, $386 million in 2009 and $330 million in 2010. In July 2009, the FDA required a "Boxed Warning," the most serious type of warning in prescription drug labeling, for both Chantix® and Zyban® based on the potential side effects of these drugs. Despite this warning, worldwide sales of Chantix® in 2009 and 2010 were $700 million and $755 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 26 years and 18 years, respectively, and millions of smokers have tried NRT products and failed to stop smoking due to the limited effectiveness of these products. According to Perrigo Company, a pharmaceutical company that sells NRT products, sales of NRT products in the United States have averaged approximately $500 million annually from 2007 to 2009.

Modified Risk Tobacco Products

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

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

Some major cigarette manufacturers have developed and marketed alternative cigarette products. For example, Philip Morris USA developed an alternative cigarette, called Accord®, in which the tobacco is heated rather than burned. R.J. Reynolds Tobacco Company has developed and is marketing an alternative cigarette, called Eclipse®, in which the tobacco is primarily heated, with only a small amount of tobacco burned. Philip Morris and RJ Reynolds have indicated that their products may deliver fewer smoke components compared to conventional cigarettes. Vector Tobacco Inc., or Vector Tobacco, 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., they do not burn down), have only achieved limited sales. With the exception of Eclipse®, the above products are no longer being manufactured.

Complete cessation from all tobacco and medicinal nicotine products is the ultimate goal of the public health community. However, some public health officials desire to migrate cigarette smokers en masse to medicinal nicotine (also known as NRT) or smokeless tobacco products to replace cigarettes. We believe this is unattainable in the foreseeable future for many reasons, including because the smoking experience is much more complex than simply seeking nicotine. In a 2009 WHO report, statistics demonstrate that approximately 90% of global tobacco users smoke cigarettes. Worldwide cigarette sales (in U.S. dollars) are approximately 12 times greater than sales of smokeless

tobacco products and approximately 200 times greater than sales of NRT products. Although a small segment of the smoking population is willing to use smokeless tobacco products in conjunction with cigarettes (known as dual users), a large percentage of smokers is not interested in using smokeless tobacco products exclusively.

There are newer forms of smokeless tobacco products that have been introduced in the market that are less messy to use than chewing tobacco or dry snuff (since spitting is not involved). These products include Swedish-style snus and dissolvable tobacco products such as Ariva® and Stonewall® tablets made by Star Scientific Inc., and Camel® Orbs, Camel® Strips and Camel ® Sticks recently introduced by R.J. Reynolds Tobacco Company. Although use of such products may be more discreet and convenient than traditional forms of smokeless tobacco, they have the same route of delivery of nicotine as nicotine gum and nicotine lozenges, which have been available over-the-counter in the United States for 16 years and 8 years, respectively, and have not significantly replaced cigarettes.

Products

X-22 Smoking Cessation Aid

X-22 is a tobacco-based botanical medical product for use as a smoking cessation therapy. X-22 will be a prescription-only kit containing VLN cigarettes made from our proprietary tobacco, which has approximately 95% less nicotine compared to tobacco in existing "light" cigarettes. The therapy protocol allows the patient to smoke our VLN cigarettes without restriction over the six-week treatment period to facilitate the goal of the patient quitting smoking by the end of the treatment period. We believe this therapy protocol has been successful because VLN cigarettes made from our proprietary tobacco satisfy smokers' cravings for cigarettes while also: (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine. We also believe X-22 will be more attractive to smokers than other therapies since it smokes and tastes like a typical cigarette, involves the same smoking behavior, and does not expose the smoker to any new drugs or new side effects.

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

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

We have met with the FDA regarding the remaining X-22 clinical trials and, based on the FDA's guidance, we plan to conduct a Phase II-B trial and two larger and concurrent Phase III trials with the same protocols, all of which 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. As depicted below, assuming X-22 is granted Fast Tract status by the FDA, we plan to complete the FDA-approval process for our X-22 smoking cessation aid in the fourth quarter of 2012 at the earliest (as a prescription), and upon such approval launch X-22 in the U.S. market and in other top smoking-cessation markets thereafter.

Our Modified Risk Cigarettes

We believe that our BRAND A and BRAND B cigarettes will benefit smokers who are unable or unwilling to quit smoking and who may be attracted to cigarettes which potentially pose a lower health risk than conventional cigarettes. This includes the approximate one-half of the 44 million adult smokers in the U.S. who do not attempt to quit in a given year. Compared to other commercial cigarettes, the tobacco in BRAND A has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes, and BRAND B 's smoke contains the lowest amount of tar per milligram of nicotine. 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. However, the FDA has not yet issued comprehensive guidance regarding applications that must be submitted to the FDA for Modified Risk Cigarettes, including the criteria for such authorizations. We believe the FDA will issue such guidance in 2011.

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BRAND A Cigarettes

Compared to other commercial tobacco cigarettes, BRAND A has the lowest nicotine content. The tobacco in BRAND A contains approximately 95% less nicotine than tobacco in leading “light” cigarette brands. Clinical studies 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.

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.

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

We believe these findings 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. We intend that BRAND A will be available in regular and menthol; with both styles being king size (85 mm) cigarettes.

BRAND B Cigarettes

Compared to other commercial tobacco cigarettes, BRAND B's smoke contains the lowest amount of tar per milligram of nicotine. Using a proprietary high nicotine tobacco blend in conjunction with a unique cigarette design, BRAND B allows the smoker to achieve a satisfactory amount of nicotine per cigarette while inhaling less tar and carbon monoxide. At the same time, we do not expect exposure to nicotine from BRAND B to be significantly higher than some full flavor cigarette brands. We believe smokers who desire to reduce smoke exposure but are less concerned about nicotine will find BRAND B beneficial. We intend that BRAND B will be available in regular and menthol; with both styles being king size (85 mm) cigarettes.

BRAND B has a tar yield between typical "light" and "ultra-light" cigarettes, but a nicotine yield of typical full flavor cigarettes. The graph below compares the tar-to-nicotine ratios of BRAND B and BRAND B menthol to those of the leading cigarette brands. As shown, smokers are expected to inhale much more tar for every milligram of nicotine from the leading brands than from BRAND B. For example, the smoke from BRAND B has approximately 47% less tar per milligram of nicotine compared to the smoke from Marlboro Light®.

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 tar and carbon monoxide, is significantly reduced when smoking BRAND B as compared to smoking the leading brands of cigarettes. We believe results from these exposure studies will warrant a Modified Risk Cigarette claim for BRAND B.

RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco Company, LLC (f/k/a Xodus, LLC), has introduced two super-premium priced cigarette brands, RED SUN and MAGIC, into the U.S. market in the first quarter of 2011. Both brands are available in regular and menthol and all four brand styles are king size, packaged in hinge-lid hard packs. We intend to focus our marketing efforts on tobacconists, smoke shops and tobacco outlets. The ban in 2009 by the FDA of all flavored cigarettes (with the exception of menthol) has resulted in a product void in these tobacco channels. Certain wholesalers and retailers are now seeking other specialty cigarettes to replace the banned flavored cigarettes. We believe that certain U.S. cigarette wholesalers and retailers will, among other reasons, purchase these cigarettes to replace their lost sales of flavored cigarettes as well as potential lost sales of "light" and "ultra light" cigarettes.

Clinical Trials with Cigarettes Containing our VLN Tobacco

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). This clinical trial was led by Dr. Dorothy Hatsukami, Director of the National Transdisciplinary Tobacco Use Research Center, at the University of Minnesota Masonic Comprehensive Cancer Center. For reference, Dr. Hatsukami was selected in 2010 as one of the nine voting members of the 12-person Tobacco Products Scientific Advisory Committee ("TPSAC"), within the FDA's Center for Tobacco Products created under the Tobacco Control Act. TPSAC will make recommendations and issue reports to the FDA Commissioner on tobacco regulatory matters, including but not limited to, the impact of the use of menthol in cigarettes, altering levels of nicotine in tobacco products, and applications submitted to the FDA for modified risk tobacco products.

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

	Treatments						
	Low Nicotine Cigarette 0.3 mg nicotine/cig. n = 52		FDA-Approved Nicotine Lozenge 4 mg nicotine n = 60		Very Low Nicotine Cigarette 0.05 mg nicotine/cig. n = 53		
	Number Abstinent	Percent	Number Abstinent	Percent	Number Abstinent	Percent	P-value
4-Week Continuous Abstinence - Standard Threshold in Cessation - Carbon Monoxide Verified - Post Treatment	11	21.2 %	21	35.0 %	23	43.4 %	0.0508
6-Week Point Prevalence Abstinence - Six Weeks from the End of Treatment - Carbon Monoxide Verified	12	23.1 %	22	36.7 %	25	47.2 %	0.0357

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 as shown in the chart below, rather than during the last four weeks of the treatment period. For example, according to the prescription Chantix® label, four (4)-week continuous abstinence in the Chantix® Phase III clinical trials (the 44 percent quit rate advertised by Pfizer) was measured during the last four (4) weeks of the twelve (12)-week treatment period, while patients were still taking Chantix®. In one of these Chantix® Phase III clinical trials, approximately one-third of those who had been abstinent during the last week of treatment returned to smoking within four (4) weeks after they stopped taking Chantix®, and approximately 45% returned to smoking within eight weeks after they stopped taking Chantix®.

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Patients who used the VLN cigarette containing our proprietary tobacco 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).

Additional biomarkers of smoke exposure were significantly reduced on average from baseline measurements (taken before the six (6)-week treatment period) in patients who used the VLN cigarette containing our proprietary tobacco:

		LEVEL IN PATIENTS (pmol/mg creatinine)		
BIOMARKER	DESCRIPTION	Baseline	VLN Cigarette	REDUCTION
NNAL	Metabolites of the tobacco-specific carcinogen NNK	0.92	0.2	78 %
NNN	Metabolites of the tobacco-specific carcinogen NNN	0.09	0.03	67 %
1-HOP	Metabolite of pyrene, a marker for uptake of carcinogenic polycyclic aromatic hydrocarbons	0.89	0.57	36 %
3-HPMA	Metabolite of the smoke toxicant acrolein	3320	1453	56 %
S-PMA	Metabolite of the carcinogen benzene	2.46	0.76	69 %

All differences 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). Treatment consisted of smoking three reduced-nicotine cigarette styles (Quest 1®, Quest 2® and Quest 3®) for two (2) weeks each, with nicotine yields per cigarette of 0.6 mg (a low nicotine cigarette made with a blend of regular tobacco and our proprietary VLN tobacco), 0.3 mg (an extra low nicotine cigarette made with a blend of regular tobacco and our proprietary VLN tobacco) and 0.05 mg (a VLN cigarette made with tobacco only from our proprietary VLN variety) either in combination with nicotine patch therapy (a nicotine replacement product) or placebo patches.

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

The major difference between the Vector Tobacco Phase II clinical trial and the University of Minnesota Phase II clinical trial is that VLN cigarettes in the Vector Tobacco trial were smoked by patients for only two (2) weeks and either in combination with using a nicotine patch or placebo patch. In both arms of the Vector Tobacco trial, patients smoked the VLN cigarette for two (2) weeks and continued to use nicotine patches or placebo patches for the subsequent ten (10) weeks. We believe that the effectiveness of VLN cigarettes for use in smoking cessation is higher when they are used alone (without another therapy) for a longer time period, as in the University of Minnesota trial, rather than with concurrent use of nicotine replacement therapy. We have therefore decided to have patients use VLN cigarettes alone and for six (6) weeks in our upcoming clinical trials.

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

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

A study at Dalhousie University, Halifax, Nova Scotia (Barrett 2010), compared the effects of low nicotine cigarettes and an FDA-approved nicotine inhaler on cravings and smoking behavior of smokers who did not intend to quit. In

separate laboratory sessions, each of twenty-two (22) participants used a VLN cigarette (Quest 3®), a reduced nicotine cigarette (Quest 1®, which contains approximately two-thirds conventional tobacco and one-third VLN tobacco), a nicotine inhaler (10 mg; 4 mg deliverable, Pharmacia), or a placebo inhaler (identical in appearance to the nicotine inhaler, but containing no nicotine). Cravings, withdrawal and mood descriptors were rated before and after a twenty (20)-minute treatment session during which subjects were instructed to smoke two cigarettes or to use an inhaler every 10 seconds. The reduction in the rating of intent to smoke (usual cigarette brand) after using the VLN cigarette (-10.0) was significantly greater than the reduction with the nicotine inhaler (-1.9). Use of the VLN cigarette was also associated with significantly increased satisfaction and relaxation compared to the nicotine inhaler.

Technology Platform

Our proprietary technology enables us to decrease or increase the level of nicotine 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 are the same as those used in the production of genetically modified varieties of other crops, which in 2009 were planted on 330 million acres in 25 countries according to the International Service for the Acquisition of Agri-Biotech Applications. This includes 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 tobacco that we use in our products is produced from plants that have 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 genetically-engineered tobacco is grown only by farmers under contracts that require segregation and prohibit transfer of material to other parties.

During the development of genetically modified varieties, many candidate 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 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 modified tobacco plant with the desired characteristics is obtained, each plant can produce hundreds of thousands of seeds. When each seed is germinated, the resulting tobacco plant has identical characteristics, including nicotine content, as the parent and sibling plants. Tobacco products with either low or high nicotine content are 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. The total delivered tobacco leaf from these farmers was approximately 50 percent greater in 2010 than 2009 and we plan to increase leaf production with farmers in 2011. 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 97 issued patents in 79 countries, and approximately 44 pending patent applications, which are either owned by or exclusively licensed to us. A “patent family” is a set of patents granted in various countries to protect a single invention. Our patent coverage in the U.S., the

most valuable smoking cessation market and cigarette market, consists of 14 issued patents and 6 pending applications. In China, the world's largest cigarette market, we exclusively control 5 issued patents and 3 pending patent applications. We have exclusive worldwide rights to all uses of the following genes responsible for nicotine content in tobacco plants: QPT, A622, NBB1, MPO and genes for several transcription factors. We have exclusive rights to plants with altered nicotine content produced from modifying expression of these genes and tobacco products produced from these plants. We also have the exclusive right to license and sublicense these patent rights. The patents owned by or exclusively licensed to us are issued in countries where at least 75% of the world's smokers reside.

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

Sales and Marketing

X-22 Smoking Cessation Aid

We intend to enter into arrangements in both the U.S. and international markets with pharmaceutical companies to market and sell X-22. We plan to seek marketing partners with existing pharmaceutical sales forces that already call on medical and dental offices in their geographic markets.

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

BRAND A and BRAND B

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco toxins and/or (ii) potentially pose lower health risks as compared to conventional cigarettes ("Modified Risk Cigarettes"). The Tobacco Control Act requires the FDA to issue specific regulations and guidance regarding applications that must be submitted to the FDA for the authorization to label and market Modified Risk Cigarettes. Based in part on the timelines contained in the Tobacco Control Act, we expect the FDA to issue such regulations and guidance in 2011. 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 other commercial cigarettes, the tobacco in BRAND A has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes, and BRAND B's smoke contains the lowest amount of "tar" per milligram of nicotine.

RED SUN and MAGIC Cigarettes

Our subsidiary, Goodrich Tobacco Company, intends to focus its marketing efforts for RED SUN and MAGIC on tobacconists, smoke shops and tobacco outlets. The ban in 2009 by the FDA of all flavored cigarettes (with the exception of menthol) has resulted in a product void in these tobacco channels. Certain wholesalers and retailers are now seeking other specialty cigarettes to replace the banned flavored cigarettes. We believe that certain U.S. cigarette wholesalers and retailers will, among other reasons, purchase these cigarettes to replace their lost sales of flavored cigarettes as well as potential lost sales of "light" and "ultra light" cigarettes.

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 ten different levels of nicotine, including a minimal (placebo) level, or Research Cigarette Option, in its request for proposals for a five

(5)-year contract for Preparation and Distribution of Research and Drug Products. We have agreed, as a subcontractor to RTI International ("RTI") in RTI's contract with NIDA for the Research Cigarette Option, to supply modified nicotine cigarettes to NIDA. 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 research cigarettes will be distributed under the mark SPECTRUM.

In 2010, we received our first purchase order of $152,660 for 1.15 million research cigarettes which included a design phase fee of $40,604. We expect to receive an additional purchase order for an additional 7.85 million SPECTRUM research cigarettes in 2011. We estimate the revenue from this contract, including other direct orders from researchers, will be approximately $700,000 in 2011 and $3 million over the next 5 years.

Healthcare Reimbursement

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, and managed-care arrangements, are continuing in many countries where we intend to sell our X-22 smoking cessation aid, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical products.

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

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

Approximately 47 million Americans were covered by state Medicaid programs in 2009. Approximately 30% of Medicaid recipients are smokers. Medicaid programs in 42 states and the District of Columbia cover at least one form of pharmacologic treatment for smoking cessation (Chantix®, Zyban® or NRT). The new healthcare legislation is expanding Medicaid coverage to all 50 states. The current retail price of the 12-week prescription of Chantix® is over $450, which should give us great latitude in pricing X-22. We expect X-22 to be price competitive with any FDA-approved smoking cessation aid, especially Chantix®, which will not only encourage governmental and private third-party payers to cover X-22, but will encourage smokers to attempt to quit with X-22 since they will not have to purchase their usual brand of cigarettes over the 6-week treatment period. On average, this equates to approximately $240 in out-of-pocket savings to the consumer if their insurance plan covers X-22.

Manufacturing

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

Competition

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

Cigarette companies compete primarily on the basis of product quality, brand recognition, brand loyalty, taste, innovation, packaging, service, marketing, advertising, retail shelf space and price. Cigarette sales can be significantly influenced by weak economic conditions, erosion of consumer confidence, competitors' introduction of low-price

products or innovative products, higher cigarette taxes, higher absolute prices and larger gaps between price categories, and product regulation that diminishes the ability to differentiate tobacco products. Domestic competitors include Philip Morris USA, 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, principally in China, Egypt, Thailand, Taiwan, Vietnam and Algeria.

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. Four companies, Cytos Biotechnology AG, Celtic Pharmaceuticals Holdings, Nabi Biopharmaceuticals, L.P. and Independent Pharmaceutica AB have or have had vaccine candidates in clinical trials. Cytos exclusively licensed its nicotine vaccine candidate to Novartis in 2007 for 35 million Swiss Francs ($30 million) and up to 565 million Swiss Francs ($492 million) in milestone payments and royalties. In October 2009, it was announced that Cytos' nicotine vaccine candidate failed to show efficacy in a Phase II trial.

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

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. Dr. Michael C. Fiore, lead chairperson and author of the 2008 U.S. government report on clinical practice guidelines for treating tobacco use and co-principal Investigator of the Transdisciplinary Tobacco Use Research Center at the University of Wisconsin, Madison, estimated in 2009 that any approval of a nicotine vaccine may be 5 to 10 years away.

Electronic or E-cigarettes

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

In a September 9, 2010 press release, the FDA issued warning letters to five e-cigarette distributors for various violations of the Federal Food, Drug, and Cosmetic Act, including unsubstantiated claims and poor manufacturing practices. The FDA said these e-cigarette companies are illegally marketing their products as tools to help people quit using cigarettes. The FDA believes e-cigarettes "[m]eet the definition of a combination drug-device product under the Federal Food, Drug and Cosmetic Act." In a letter to the Electronic Cigarette Association of the same date, the FDA said the agency intends to regulate electronic cigarettes and related products in a manner consistent with its mission of protecting the public health.

The FDA has also been confiscating 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 is appealing 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 entire court review the December 7, 2010 decision that went against the Agency. The FDA, which has always contended that e-cigarettes should be regulated as drug-delivery devices not tobacco products, now has the option of asking the U.S. Supreme Court to take up the case. An FDA spokesman said that the Agency is evaluating the latest court ruling "and considering its legal and regulatory options." Many countries have already banned e-cigarettes as has the state of Oregon and other states are in the process of banning them.

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.

We intend to submit a request to the FDA for Fast Track designation in the second quarter of 2011 and, although there can be no assurance, we believe that our X-22 smoking cessation aid will be granted 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.

Post-Approval Phase

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

X-22 Clinical Trials

We have met with the FDA regarding the remaining X-22 clinical trials and, based on the FDA's guidance, we 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"). The Phase II-B optimization trial will consist of approximately 200 participants over a six (6)-week treatment period, and the Phase III trials will use the same protocol with larger groups of participants. In all of the remaining clinical trials, half of the participants will 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 will then be compared for statistical significance. With adequate funding, we will be able to conduct our two concurrent Phase III clinical trials with the same protocols in order to expedite the FDA approval process. We have submitted our Pre-IND (PIND 103,589) to the FDA and, we expect to initiate our Phase II-B clinical trial in the second quarter of 2011 after we file our IND. Our IND will contain all of the information and data of our PIND 103,589 plus standard tobacco industry smoke analyses of the X-22 clinical trial cigarette and the active control. Before Phase III trials, some additional information and testing of X-22 and its tobacco are required by the FDA, some of which we already have from our former licensee's IND 69,185. All analyses that FDA requires are efficiently outsourced to Arista Laboratories which is one of the industry leaders in tobacco and tobacco smoke analyses with whom we have contracted since 2008. We intend to initiate our Phase III clinical trials in the fourth quarter of 2011 and to file our NDA with the FDA for X-22 in 2012. We expect the FDA to Fast Track the approval of X-22 and that we should receive FDA approval to commence the marketing and sales of X-22 in the U.S. as early as the fourth quarter of 2012.

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

Modified Risk Cigarettes

The Tobacco Control Act, which became law in June 2009, prohibits the FDA from banning cigarettes outright or mandating that nicotine levels be reduced to zero. However, among other things, it allows the FDA to require the reduction of nicotine or any other compound in cigarettes. In 2009, the Tobacco Control Act banned all sales in the United States of cigarettes with flavored tobacco (other than menthol). As of June 2010, all cigarette companies were required to cease using the terms "low tar," "light" and "ultra light" in describing cigarettes sold in the United States. We believe this new regulatory environment represents a paradigm shift for the tobacco industry and will create opportunities for us in marketing BRAND A and BRAND B and in licensing our proprietary technology and/or

tobaccos to larger competitors.

For the first time in history, a U.S. regulatory agency will scientifically evaluate cigarettes that may pose lower health risks as compared to conventional cigarettes. The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco toxins and/or (ii) potentially pose lower health risks as compared to conventional cigarettes ("Modified Risk Cigarettes"). The Tobacco Control Act requires the FDA to issue specific regulations and guidance regarding applications that must be submitted to the FDA for the authorization to label and market Modified Risk Cigarettes. Based in part on the timelines contained in the Tobacco Control Act, we expect the FDA to issue such regulations and guidance in 2011. We believe that BRAND A and BRAND B will qualify as Modified Risk Cigarettes. In addition, the Tobacco Control Act allows the FDA to mandate the use of reduced risk technologies in conventional tobacco products and cigarettes (e.g., Marlboro®) which could create opportunities for us to license our proprietary technology and/or our tobaccos to larger competitors.

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

Biomass Products

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. The results 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 X-22, BRAND A and BRAND B products. We plan to move forward in our biomass business activities once we have achieved success with X-22 and our Modified Risk Cigarettes. Ultimately, we plan to form a separate subsidiary which will be dedicated to our biomass business model.

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.

About 2,000 pounds (20%) of the per-acre dry weight biomass consists of extractable protein fractions. Of this protein, about 500 pounds (25%) is a protein known as Rubisco (RibUlose BISphosphate Carboxylase-Oxygenase) which is involved in photosynthesis. All green leaf plants contain Rubisco. However, it is most easily extracted from tobacco by a proven and simple two-step process. We believe that Rubisco has many valuable uses. Additional high-quality protein fractions can be extracted along with other plant fractions such as sugars, starches, cellulose and other components can be utilized directly, or for production of biofuels, including ethanol and butanol, by fermentation.

Rubisco is a crystalline (greater than 99% pure) pharmaceutical grade protein that is tasteless, odorless, and colorless when mixed with water. It is not perishable and can be stored for years. As a plant-based protein source, it is useful as a food additive or supplement. Rubisco includes all the essential amino acids in quantities that equal or exceed the Food and Agriculture Organization Provisional Pattern and compares favorably to soybeans in essential amino acid content (measured in grams of each essential amino acid per 100 grams of protein). Rubisco has a low lysine-to-arginine, or L/A, ratio (0.95) compared to L/A ratios in protein from animal sources (2.4 for milk protein, 1.9 for casein, and 1.4 for fish meal). A low L/A ratio is reportedly correlated with low serum cholesterol and atherosclerotic incidence in animals. Rubisco can be added to fortify almost any food or beverage with a high quality protein without affecting the aroma or taste.

We believe Rubisco is a superior substitute for casein, an animal-based protein source derived from milk. The U.S. currently imports about 70,000 metric tons of casein per year. The market price fluctuates like other commodities but currently is approximately $4.10 per pound. Besides human nutrition, Rubisco will also favorably compete in the following markets: personal care products, nutraceuticals, and pharmaceutical grade protein (e.g., for dialysis patients). Additional protein concentrates from Verfola will compete favorably in animal feed, in particular

aquaculture.

We believe Verfola provides significant advantages over any other green leaf crop, including conventional tobacco. If tobacco with conventional nicotine levels was utilized for biomass, for every acre grown, hundreds of pounds of toxic alkaloids would have to be extracted, stored and disposed.

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 NCSU resulting in exclusive worldwide licenses to various patented technologies. We have utilized the model offered by many public-sector research organizations which entails obtaining an exclusive option or license agreement to any invention arising out of funded research. In all cases, we fund and exclusively control all patent filings as the exclusive licensee. This model of contracting with public-sector researchers has enabled 22nd Century 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 Counsel of Canada, Plant Biotechnology Institute in Saskatoon, Canada, ("NRC"), and the Nara Institute of Science and Technology in Nara, Japan, ("NAIST"). Our R&D agreements with NCSU, NRC and NAIST have expired in 2009 and the majority of these agreements have involved the biosynthesis of nicotine in plants. During the years ended December 31, 2010 and 2009, we incurred research and development expenses of approximately $364,000 and $540,000, respectively. In 2010, NAIST assigned all of their worldwide patents to us which were a result of our R&D at NAIST and that were previously licensed to 22nd Century on an exclusive basis. We did not have any outsourced R&D projects during 2010.

Finally, other than our planned clinical trials for X-22 and exposure studies for our Modified Risk Cigarette candidates, we have no other third-party R&D commitments requiring funding in 2011. However, we do plan to carry out a minimal amount of other R&D in 2011 not to exceed $250,000 per year, including the execution of more field trials from the inventory of hundreds of seed lots that resulted from our R&D at NCSU, NRC and NAIST.

Employees

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

Item 1A. Risk Factors.

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal administrative offices are located in Williamsville, New York. We currently lease such facilities and the lease expires on October 31, 2011, subject to automatic renewal for an additional one-year term absent notice of non-renewal from either party.

Item 3. Legal Proceedings.

From time to time we may be involved in claims arising in the ordinary course of business. To our knowledge, no legal proceedings, governmental actions, investigations or claims are currently pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

Item 4. [Removed and Reserved.]

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is quoted on the OTC Bulletin Board under the symbol "XXII.OB." On November 23, 2010, we changed the name of our Company to 22nd Century Group, Inc. and on December 3, 2010 our symbol changed from "THSM.OB" to "XXII.OB." As of March 16, 2011, there were 26,759,646 shares of our common stock issued and

outstanding and 8,151,980 shares issuable upon exercise of outstanding stock options and warrants. On that date, there were approximately 42 holders of record of shares of our common stock.

Prior to the Merger, the trading market for our common stock had been extremely limited and sporadic. While the Form 10-K Information included in this Current Report on Form 8-K/A is intended to reflect the results of operations and information about 22nd Century as of and for the fiscal years ended December 31, 2010 and 2009, respectively, we are including our historical stock price of information as quoted on the OTC Bulletin Board for those periods prior to the Merger where we had not yet assumed the operating business of 22nd Century as our sole line of business.

As of March 16, 2011, the last reported sale price of our common stock on the OTC Bulletin Board was $1.39 per share. For the periods indicated, the following table sets forth the high and low bid prices per share of our common stock, as derived from quotations provided by the OTC Bulletin Board Information Center.

Quarter Ended	High Bid	Low Bid
December 30, 2010	$ 0.005	$ 0.005
September 30, 2010	$ 0.005	$ 0.005
June 30, 2010	$ 0.007	$ 0.005
March 31, 2010	$ 0.007	$ 0.005
December 31, 2009	$ 0.005	$ 0.005
September 30, 2009	$ 0.005	$ 0.005
June 30, 2009	$ 0.005	$ 0.005
March 31, 2009	$ 0.51	$ 0.005

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.

Dividend Policy

We have not previously and do not plan to declare or pay any cash dividends on our common stock. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business.

Item 6. Selected Financial Data.

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

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

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 herein. 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 Limited, LLC for the periods described herein. This discussion contains forward-looking statements. Please see “Cautionary Note Regarding Forward-Looking Statements” earlier in this Current Report on Form 8-K/A for a discussion of the uncertainties, risks and assumptions associated with these forward-looking statements. 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 in herein, as well as those discussed in the Company's Original Form 8-K in the section entitled "Risk Factors."Overview

We have operated at a loss since 2006, when we increased our research and development expenditures. Our license agreement with our former licensee was discontinued in 2007. In 2010, we realized revenue of $49,784 from our research cigarette program and in 2009 we realized sales of $27,612 from limited test marketing of our cigarettes. During 2009 and 2010 we transitioned from solely developing proprietary technology and tobacco to developing and commercializing our own products.

Our prospects depend on our ability to generate and sustain revenues from our X-22 smoking cessation aid and cigarettes made with our proprietary tobacco. Our ability to generate meaningful revenue from X-22, especially in the United States, depends on FDA approval, and our ability to generate meaningful revenue from BRAND A and BRAND B depends in large part on obtaining FDA authorization to market these brands as Modified Risk Cigarettes. Once our products are approved by the FDA we must still meet the challenges to gain consumer acceptance including successful marketing and distribution. We do not expect FDA approval of X-22 until the fourth quarter of 2012 at the earliest. We believe the FDA will issue regulations for modified risk tobacco products in 2011, and we therefore expect to submit applications in 2011 to the FDA to authorize the marketing and labeling of our proprietary cigarette products as Modified Risk Cigarettes. This process is likely to take at least one year. Until these approvals and authorizations are received, sales of our proprietary cigarette products will be limited and will only include RED SUN, MAGIC and SPECTRUM. We intend to focus our marketing efforts for RED SUN and MAGIC on tobacconists, smoke shops and tobacco outlets. Accordingly, our cash flow from product sales will be limited and, in addition to the net proceeds from the Private Placement that closed on January 25, 2011, we will need cash from equity or debt financing to continue operations.

In connection with our FDA activities we will incur substantial costs related to clinical trials and smoke exposure studies related to our modified risk product candidates. In December 2010, we entered into two contracts for our Phase II-B clinical trial and made a deposit of approximately $200,000. The financial requirement under these contracts during 2011 is approximately $650,000, not including various other expenses of our Phase II-B clinical trial.

At December 31, 2010, we had current assets of approximately $744,000 and current liabilities of approximately $4,823,000. Immediately preceding the Merger on January 25, 2011, the Company completed a private placement of equity securities resulting in approximately $3.4 million in net cash proceeds and a reduction of debt obligations that were on the balance sheet at December 31, 2010 of approximately $614,000 to members, which were exchanged for equity interests in the offering.

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

Revenue is recognized when tobacco products are shipped to customers and title passes. We also record appropriate provisions for rebates and discounts and credits for returns. These amounts are estimated based on information and historical experience. The Company received a grant as partial support for its next clinical trial for the FDA. This income will be recognized as a reduction of the cost of the clinical trial as such costs are incurred.

Impairment of Long-Lived Assets

We review the carrying value of amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be appropriate. We also assess recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. Non-amortizing intangibles (trademarks) are reviewed annually for impairment. We have not recognized any impairment losses during the two years ended December 31, 2010.

Amortization Estimates

We generally determine amortization based on the estimated useful lives of the assets and record amortization expense on a straight-line method over such lives. The remaining life of the patent is generally used to determine the estimated useful life of the related patent costs.

Valuation of our Equity Securities

We have issued Units to satisfy obligations to vendors or employees that were due in cash. These securities have been valued based on the cash value of the obligation satisfied by their issuance. We have also issued warrants in connection with the issuance of debt obligations. These warrants have been valued based on the value ascribed to the underlying Units issued in cash transactions or in settlement of cash obligations.

Income taxes

Prior to the closing of the Merger, 22nd Century was organized as a limited liability company and treated as a partnership for income tax purposes; accordingly, 22nd Century was not directly responsible for income taxes (income and loses passed through to its LLC members) and did not have to account for them. As of the closing of the Merger, our results of operations will be subject to income taxes and accounting for income taxes will likely be a critical accounting policy. In addition to accounting for taxes on our current taxable income, we will need to account for deferred tax assets and liabilities, including the evaluation of the recoverability of deferred tax assets.

Derivative Financial Instruments

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

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

Please refer to “Selected Financial Data” elsewhere herein to view the year-to-year comparison of our results of operations and selected financial data.

Revenues. In 2010, we realized revenue of $49,784 from our research cigarette program and in 2009 we realized sales of $27,612 from limited test marketing our cigarettes in customary market channels for tobacco products.

Costs of goods sold. In 2010 costs of goods sold of $27,964 consisted mainly of product design costs related to our research cigarette program. These cigarettes are sold directly to researchers and do not enter the customary market channels for tobacco products. In 2009, costs of goods sold of $20,112 included federal excise taxes assessed at the

manufacturer’s level on products sold in.

General and Administrative Expense. General and administrative expense was $590,826 in 2010, an increase of $310,117, or 110%, from $280,709 in 2009. Approximately, $167,000 of this increase was related to increased administrative payroll mainly due to adding two executive officers during 2010. In addition, approximately $92,000 of the increase in 2010 was for accounting, tax, and audit services. The balance was in various other expense categories such as supplies, printing and travel.

Research and Development Expense. Research and Development expense was $363,781 in 2010, a decrease of $176,519, or 32.6%, from $540,300 in 2009. The decrease was primarily due to a reduction compensation expense of approximately $168,000 as a result of an equity compensation award in 2009 that was nearly fully amortized to expense in that year.

Amortization Expense. Amortization expense relates solely to capitalized patent and trademark costs. Amortization expense increased 13.6% in 2010 to $164,456 from $144,792 in 2009. This increase of $19,644 is due to our investment in patents and trademarks in 2010 and 2009 of $147,912 and $227,942, respectively.

Interest Expense and Debt Expense. Interest expense and debt expense, which includes interest amortization of debt discount and debt issuance costs, increased in 2010 to $326,404 from $268,503 in 2009. This increase of $57,901 or 21.6% was mainly a result of additional borrowings and interest charges from a vendor offset by reduced amortization of debt discount.

Net Loss. We had a net loss in 2010 of $1,423,647 as compared to a net loss of $1,226,804 in 2009. The increase in the net loss of $196,843, or 16%, was mainly a result of higher total operating expenses in 2010 as compared to 2009.

Liquidity and Capital Resources

Summary of Balances and Recent Sources and Uses

As of December 31, 2010, we had negative working capital of approximately $4.1 million compared to negative working capital, of approximately $3.2 million at December 31, 2009. The increase of $0.9 million was a result of increase in current liabilities of $1.6 million offset by an increase in current assets of $0.7 million. Members' deficit increased $0.3 million from $1.8 million as of December 31, 2009 to $2.1 million as of December 31, 2010 due to our net loss for the year ended December 31, 2010 offset by an increase to contributed capital of $1.1 million.

Cash demands on operations

In 2009 and 2010, we operated at a loss and operating activities consumed more than $1,000,000 in cash during this two year period. Cash used in operating activities will increase significantly in 2011 as we reduce outstanding balances to our vendors and other debt holders. In addition we will continue to spend money maintaining and protecting our patent portfolio and for expenditures related to the FDA for our smoking cessation aid and our Modified Risk Cigarettes.

If we are unable to improve operations or raise funds during the next twelve months there would be a material adverse effect on our ability to meet our working capital needs and the risk that we would be unable to continue operations would increase.

Net Cash used in Operating Activities.

In 2010, $909,939 of cash was used in operating activities compared to $165,213 of cash used in operating activities in 2009. This increase use of cash of $744,726 was due to the increase of approximately $490,000 in the cash portion

of the net loss in 2010 as compared to 2009. The balance of the increase was a result of the net increase in working capital components related to operations.

Net Cash used in Investing Activities.

In 2010, we used $108,116 of cash from the net activity related to third party costs incurred for patents and trademarks as compared to $6,840 used in 2009 because we had to pay a greater portion of current charges in 2010 than in 2009.

Net Cash From Financing Activities.

During 2010, we generated $1,018,207 in our financing activities through the issuance of units, warrants, notes and advances from members with total proceeds of $1,275,411 offset by $120,028 in net repayments of advances from a related party, payment of private placement costs of $60,976 and repayments of debt of $76,200. During 2009, we generated net cash of approximately $159,000 from financing activities. Approximately $55,000 was generated by the issuance of notes and related warrants. We also received cash advances from our members and a related party of $105,000 and repaid $1,000 of bank demand loans.

As stated earlier we received approximated $3.4 million in net cash proceeds from a private placement that closed on January 25, 2011. Approximately $1,400,000 of the offering were used to retire debt obligations that had matured or make payments on past due amounts owed to vendors and NCSU. We have undertaken negotiations for deferred payment arrangements relating to approximately $1,300,000 owed to NCSU and two vendors. Based on our current operating plans, including X-22 clinical trials, we believe that the remaining proceeds from the January 25, 2011 private placement will be sufficient to enable the Company to complete its next clinical trial for X-22 and submit the results to the FDA. However, we expect to require additional funds to complete the FDA clinical trials and launch X-22. Before we can raise additional capital we must satisfy the registration rights granted to investors who acquired shares of our common stock in the January 25, 2011 private placement and Merger. These registration rights provide that the Company must have an effective registration statement covering the shares that are subject to these registration rights for a period of 90 days before it can sell any equity securities or securities convertible into equity securities. Our future capital requirements will depend on many factors, including the progress made in our X-22 clinical trials. As additional funds are required, we may raise such funds from time to time through public or private sales of equity or debt securities. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and its financial condition and results of operations. Additional equity financing will be dilutive to the ownership interests of holders of the Common Stock, and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

Off-Balance Sheet Arrangements

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

Item 8A. Quantitative and Qualitative Disclosures About Market Risk.

We are not exposed to market risk related to interest rates and foreign currencies.

Except for the warrants for our common stock issued in January 2011, we have not entered into any transactions using derivative financial instruments or derivative commodity instruments and believe that our exposure to market risk associated with other financial instruments (such as investments and borrowings) and interest rate risk is not material.

Item 8. Financial Statements and Supplementary Data.

The required financial statements and the notes thereto are contained in a separate section of this Form 8-K Information section beginning with the page following Item 15 (Exhibits and Financial Statement Schedules).

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

On January 27, 2011, our Board approved the dismissal of Child, Van Wagoner & Bradshaw, PLLC (“Child”) as our independent registered public accounting firm and engaged Freed Maxick & Battaglia CPAs, PC (“Freed”) as our

independent registered public accounting firm, both effective as of January 27, 2011. Freed was the independent registered public accounting firm of 22nd Century prior to the Merger and, given that the business of 22nd Century is now our sole line of business, our board of directors concluded that Freed should serve as our independent registered public accounting firm.

Child's report on our financial statements for each of the past two fiscal years ended September 30, 2010 and 2009 did not contain an adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles, except that the report was qualified as to our ability to continue as a going concern.

During the fiscal years ended September 30, 2010 and 2009 and the subsequent interim period through January 27, 2011, there were no: (i) disagreements with Child on any matter of accounting principles or practices, financial statement disclosure, or auditing scope of procedure which, if not resolved to the satisfaction of Child, would have caused Child to make reference to the matter in their report, or (ii) reportable events as defined in Item 304(a)(1)(v) of Regulation S-K.

During the fiscal years ended September 30, 2010 and 2009 and the subsequent interim period through January 27, 2011, neither 22nd Century Group, Inc. nor anyone acting on its behalf consulted Freed regarding either: (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements; or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K) or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures.

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives and the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that information required to be disclosed in the reports that we file and submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms; and (2) accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting.

This item is not applicable to us; see the following paragraph.

Management Report on Internal Control Over Financing Reporting.

This item is not applicable to us because 22nd Century, whose operating business we assumed in connection with the Merger, was not subject to applicable SEC reporting requirements related to its internal control over financial reporting as it was a private company prior to the closing of the Merger on January 25, 2011. We, as the legal acquirer in the Merger that assumed the operating business of 22nd Century, may exclude management’s report on internal control over financial reporting for the fiscal year ended December 31, 2010. Specifically, per SEC guidance, since the Merger was accounted for as a reverse acquisition and recapitalization and was consummated shortly after fiscal year-end, we are required to file an amended Form 8-K to update our financial statements for the most recent fiscal year-end. However, per SEC guidance, this filing is equivalent to the first annual report filed by us subsequent to the consummation of the Merger. Accordingly, we are not required to include management's report on internal control over financial reporting in this Current Report on Form 8-K/A, but will include such management reports on internal control over financial reporting in our subsequent annual reports filed with the SEC, commencing with our Annual Report on Form 10-K for the fiscal year ending December 31, 2011.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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

Name	Age	Position
Joseph Pandolfino	42	Chief Executive Officer and Director
Henry Sicignano, III	43	President, Secretary and Director
Michael R. Moynihan, Ph.D.	58	Vice President of R&D
C. Anthony Rider	59	Chief Financial Officer and Treasurer
Joseph Alexander Dunn, Ph.D.	57	Director
James W. Cornell	54	Director
Steven Katz	62	Director

Our directors and executive officers hold office until the earlier of their death, resignation, removal or until their successors have been duly elected and qualified. Our executive officers are appointed by our Board and serve at the discretion of the Board. There are no family relationships among our directors and executive officers. In connection with the Merger, our Board was expanded to five (5) members. The sole officer and sole member of the Board prior to the closing of the Merger, David Rector, resigned as an officer and a director after the closing of the Merger. The current members of our Board are Joseph Pandolfino, Henry Sicignano III, Joseph Alexander Dunn, Ph.D., James W. Cornell and Steven Katz. Our current executive officers are Joseph Pandolfino, Chief Executive Officer, Henry Sicignano III, President, Michael R. Moynihan, Ph.D., Vice President of R&D, and Secretary, and C. Anthony Rider, Chief Financial Officer and Treasurer. Each of Messrs. Pandolfino, Sicignano and Rider were executive officers of 22nd Century prior to the closing of the Merger.

Joseph Pandolfino, MBA, Chief Executive Officer and Director

Mr. Pandolfino has served as our Chief Executive Officer and as a director since the closing of the Merger. He founded 22nd Century 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 from its inception until April 2010 and as Chief Executive Officer of 22nd Century 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 led to our conclusion that he should serve as a director of our Company.

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

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

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

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

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

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

Joseph Alexander Dunn, Ph.D., Director

Dr. Dunn is currently Associate Dean for Research and Professor of Pharmaceutical Sciences at D'Youville College of Pharmacy in Buffalo, New York and has served in this capacity since April 1, 2010. Dr. Dunn has also served as Chief Executive Officer of the National Center for Food and Agricultural Policy in Washington, D.C. since November 1, 2009 and as Chief Executive Officer and Director of Research at OmniPharm Research International, Inc., a drug company, and affiliated entities, Therex Technologies Inc., a drug company, and Therex LLC, a drug company, each located in Buffalo, New York since January, 1994. From May 1, 2008, until January 20, 2009, Dr. Dunn served as Deputy Under Secretary and from August 1, 2006, until April 30, 2008 Dr. Dunn served as Senior Scientific Advisor at the United States Department of Agriculture, Research, Education and Economics Mission Area in Washington, D.C. From December 1, 2006, until April 30, 2008 Dr. Dunn served as Executive Director of the United States Department of Agriculture NAREEE Advisory Board. From July, 1998 until July 1, 2006, Dr. Dunn served as Research Associate Professor in the Department of Oral Biology, School of Dental Medicine, at the State University of New York at Buffalo. Since June 1, 2010, Dr. Dunn has served as a member of the Board of Directors of Brothers of Mercy, Inc., a not-for-profit nursing and rehabilitation concern. Dr. Dunn holds a B.S. Degree in Medical Chemistry and a Ph.D. Degree in Pharmacology, both from the State University of New York at Buffalo School of Pharmacy. Dr. Dunn also served as a Postdoctoral Fellow in the Department of Pharmacology at Harvard Medical School and as a Staff Fellow at the National Institutes of Health, National Cancer Institute Laboratory of Cellular Carcinogenesis and Tumor Promotion. Dr. Dunn's extensive scientific and regulatory background led to our conclusion that he should serve as a director of our Company.

James W. Cornell, MBA, Director

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

Steven Katz, Director

Mr. Katz is currently the President of Steven Katz & Associates, Inc., a management consulting firm and has served in this capacity since January 1981. From April 2000 until March 9, 2007, Mr. Katz served on the Board of Directors, and as a member of the audit and compensation committees thereof, of Biophan Technologies, a technology development company. From November 1999 until May 13, 2010, Mr. Katz served on the Board of Directors, and as a member of the audit and compensation committees thereof, of USA Technologies, a cashless transactions solutions company. From July 2004 until July 20, 2007, Mr. Katz served on the Board of Directors, and as a member of the audit and compensation committees thereof, of Natural Nano, a nanomaterials company. From February 2005 until March 1, 2010, Mr. Katz served on the Board of Directors, and as a member of the audit and compensation committees thereof, of Health Systems Solutions, a technology and services company in the health care and mobile work force industries. From November 2006 until September 13, 2008, Mr. Katz served as Chairman of the Board of Directors and President of GammaCan International Inc., an immunotherapies products company; from September 2003 until May 4, 2006, he served on the Board of Directors of Nanoscience Technologies, a company previously engaged in the commercialization of third-party intellectual property; and from October 2004 until April 26, 2006, he served on the Board of Directors of Vivid Learning Systems, a company engaged in the providing computer-based compliance training products and services. From January 2000 until October 2001, Mr. Katz also served as a member of the Board of Directors, President, and Chief Operating Officer of Senesco Technologies, Inc., a company engaged in the identification and development of proprietary gene technology with application to human, animal and plant systems. Mr. Katz holds a B.A. Degree in Accounting from the City College of New York. Mr. Katz’s extensive experience in management consulting as well as his significant services on the boards of numerous public and private companies led to our conclusion that he should serve as a director of our Company.

Code of Ethics

In 2006, we adopted a Code of Ethics that applies to all of our employees. A copy of our Code of Ethics will be provided to any person requesting same without charge. To request a copy of our Code of Ethics, please make written request to our Chief Executive Officer c/o 22nd Century Group, Inc., 8201 Main Street, Suite 6, Williamsville, NY 14221.

Stockholder Communications

As of the date of this Current Report on Form 8-K/A, we do not yet have a defined process for security holders to send communications to the Board. Security holders that wish to communicate with the Board are encouraged to contact the Company at its principal executive offices by letter or telephone.

Board Committees

Nominating Committee

At of the date of this Current Report on Form 8-K/A, the Company does not have a nominating committee. The Company intends to adopt a nominating committee in the future.

As of the date of this Current Report on Form 8-K/A, we do not have any defined policy or procedure requirements for stockholders to submit recommendations or nominations for directors. The Company does not currently have any specific or minimum criteria for the election of nominees to the Board, and does not have any specific process or procedure for evaluating such nominees. Our current Board assesses all candidates, whether submitted by management or stockholders, and makes recommendations for election or appointment.

Audit Committee

As of the date of this Current Report on Form 8-K/A, the role of audit committee is performed by the Board.

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

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

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

Compensation Committee

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers, and stockholders holding more than 10% of our outstanding common stock to file with the SEC initial reports of ownership and reports of changes in beneficial ownership of our common stock. Executive officers, directors and greater-than-10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. We not have any information to report in this regard.

Item 11. Executive Compensation.

The following table summarizes the compensation paid by us in each of the last two (2) completed fiscal years ended December 31, 2010 for our principal executive officer and the two most highly compensated executive officers who received annual compensation in excess of $100,000. These officers are referred to herein as our "Named Executive Officers."

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Joseph Pandolfino, Chief Executive Officer	2010	150,000	0	-	-	-	-	-	150,000
	2009	150,000	0	-	-	-	-	-	150,000
Henry Sicignano III, President	2010	85,000	0	-	-	-	-	-	85,000
	2009	-	-	-	-	-	-	-	0
Michael R. Moynihan, Vice President of R&D	2010	114,019	0	-	-	-	-	-	114,019
	2009	92,000	0	258,660	-	-	-	-	350,660

Outstanding Equity Awards at Fiscal Year-End

As of December 31, 2010, there were no outstanding equity awards held by our Named Executive Officers or any other executive officers of either 22nd Century or the Company.

Agreements with Executive Officers

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

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

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

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

These employment agreements were included as Exhibit 10.15, Exhibit 10.16, and Exhibit 10.17, respectively, to the Original Form 8-K and are incorporated herein by reference.

We also provide each of these individuals with health insurance and vacation benefits.

Director Compensation

We currently do not have a set compensation package for members of our Board for acting as such, but we expect to establish these arrangements in the near future.

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

Beneficial Ownership Table

The following tables set forth certain information regarding the beneficial ownership of our common stock as of March 16, 2011, by (i) each person who, to our knowledge, owns more than 5% of our common stock, (ii) each of our directors and executive officers, and (iii) all of our executive officers and directors as a group. Shares of our common stock subject to options, warrants, or other rights currently exercisable or exercisable within sixty (60) days of March 16, 2011, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person. Except as otherwise noted below, the address for each person or entity listed in the table below is c/o 22nd Century Group, Inc., 8201 Main Street, Suite 6, Williamsville, NY 14221.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned (1)	
Management and Directors:			
Joseph Pandolfino (2)	6,010,396	21.3	%
Henry Sicignano, III (3)	3,634,927	13.2	%
Michael R. Moynihan, Ph.D. (4)	1,017,645	3.8	%

C. Anthony Rider (5)	243,473	*	
Joseph Alexander Dunn, Ph.D.	0	*	
James W. Cornell	0	*	
Steven Katz	0	*	
All directors and executive officers as a group (7 persons) (2)-(5)	10,906,441	37.1	%
Other 5% Owners:			
Clearwater Partners, LLC (6)	5,144,279	18.4	%
Angelo J. Tomasello (7)	4,193,881	15.1	%
Henry Sicignano III Group, LLC (8)	3,342,760	12.1	%

* Less than 1%

(1) Based on 26,759,646 shares of common stock issued and outstanding, plus common stock subject to options, warrants, or other rights currently exercisable or exercisable within sixty (60) days of March 16, 2011, held by the beneficial owner to whom the disclosure pertains.

(2) Includes 1,441,761 shares of common stock issuable upon exercise of warrants.

(3) Consists of 222,603 shares of common stock held by Mr. Sicignano, 2,543,347 shares of common stock held by Henry Sicignano III Group, LLC, 69,564 shares of common stock issuable to Mr. Sicignano upon exercise of warrants, and 800,413 shares of common stock issuable to Henry Sicignano III Group, LLC upon exercise of warrants.

(4) Includes 243,711 shares of common stock issuable upon exercise of warrants.

(5) Includes 57,970 shares of common stock issuable upon exercise of warrants.

(6) Includes 1,238,763 shares of common stock issuable upon exercise of warrants. The address of Clearwater Partners, LLC is 34 Sunburst Circle, East Amherst, New York 14051.

(7) Includes 1,044,972 shares of common stock issuable upon exercise of warrants. The address of Mr. Tomasello is 4720 Spaulding Drive, Clarence, New York 14031.

(8) Includes 800,413 shares of common stock issuable upon exercise of warrants.

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

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

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

We have had numerous transactions with Alternative Cigarettes, Inc. (“AC”). AC is 95% owned by three holders of our common stock, including Joseph Pandolfino, our Chief Executive Officer, and Angelo Tomasello, who currently owns approximately 11.8% of our issued and outstanding common stock. We share office space and employee services with AC and AC reimburses us from time to time for the value of these activities. AC paid us $32,387 during fiscal year 2009 and $57,667 during fiscal year 2008 for these services. AC has also advanced funds to us from time to time. Since January 1, 2009, the largest net amount due from us to AC was approximately $127,000. No interest has

been accrued or paid on these amounts due to AC and there are no repayment terms between the parties.

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

In November 2008, we issued a promissory note due and payable on November 11, 2010 to Mr. Tomasello in the principal amount of $325,000, with 10% interest per annum accruing thereon, and a warrant to purchase 371,006 shares of our common stock, which have since been exercised at a price of $.0001 per share. The note is guaranteed by Virgil Properties, LLC, which is jointly owned by Messrs. Pandolfino and Tomasello. Effective December 1, 2010, the $325,000 promissory note was amended to extend the maturity date until January 10, 2011 and to increase the interest rate to 15% during this extension period. On January 25, 2011, Mr. Tomasello converted the principal amount of this promissory note into 325,000 shares of our common stock through an investment in the Private Placement Offering and Mr. Tomasello was paid cash in the amount of $79,401.06 in January 2011, which represents the accrued interest on the original $325,000 promissory note. Mr. Tomasello has also made funds available to us in the form of cash advances. The largest net amount outstanding since January 1, 2009 was approximately $166,000. No interest was accrued or paid on such advances and there were no repayment terms between the parties. In December 2009, Mr. Tomasello was issued 504,553 shares of our common stock in lieu of repayment of $135,996 of such advances, and we issued him a promissory note that was exchanged for 204,639 shares of our common stock in June 2010.

Mr. Pandolfino has made funds available to us in the form of cash advances and deferred guaranteed payments due to him by us as consideration for his services as our Chief Executive Officer. The largest net amount of such advances and deferred guaranteed payments outstanding since January 1, 2009 was approximately $137,000. No interest was accrued or paid on such advances or deferrals and there are no repayment terms between the parties. In December 2009, Mr. Pandolfino was issued 504,553 shares of our common stock in lieu of repayment of $135,996 of such advances. During the period between January 1 and October 5, 2010, we issued Mr. Pandolfino 455,331 shares of our common stock in lieu of $103,573 due and payable to him for his services. On October 5, 2010, we issued Mr. Pandolfino a promissory note, which was assigned to Mr. Sicignano, due and payable on January 31, 2011 in the principal amount of $58,873, with 15% interest per annum accruing thereon. In January 2011, we made payment in full to Mr. Sicignano on this assigned note together with all accrued interest thereon.

In September 2010, Henry Sicignano III, our President and Secretary, loaned us $35,000, which amount was due and payable in November 2010, with 15% interest per annum accruing thereon. On December 16, 2010, Mr. Sicignano agreed to extend the maturity date of this loan until January 25, 2011. On December 28, 2010 we issued a promissory note to Mr. Sicignano due and payable on January 15, 2011 in the principal amount of $100,000, with 15% interest per annum accruing thereon. From time to time, Mr. Sicignano deferred guaranteed payments due to him by us as consideration for his services as our President with the largest net amount of such deferred guaranteed payments outstanding since January 1, 2009 being $85,000. On January 28, 2011 we made payment in full to Mr. Sicignano of all deferred guaranteed payments and all principal and accrued interest on all promissory notes then outstanding. Mr. Sicignano is also the managing member of Henry Sicignano III Group, LLC (“Sicignano Group”). On October 5, 2010, Sicignano Group purchased 112,396 shares of our common stock for $30,295 and, in a simultaneous related transaction, made a loan to the Company in the principal amount of $30,295, with 15% interest per annum accruing thereon, for which we issued Sicignano Group a promissory note due and payable on January 31, 2011. On January 25, 2011, Sicignano Group converted the principal amount of this promissory and the accrued interest thereon into 31,626 shares of our common stock through an investment in the Private Placement Offering.

Michael R. Moynihan, the Vice President of Research and Development, has deferred guaranteed payments due and payable to him as consideration for his services to us. The largest net balance of such amounts outstanding since January 1, 2009 was approximately $79,000. No interest was accrued or paid on such amounts owed and there were no repayment terms between the parties. In December 2009, Dr. Moynihan was issued 74,201 shares of our common stock and 4 membership interests in our subsidiary (100 units outstanding), Goodrich Tobacco Company, LLC (f/k/a Xodus, LLC), in lieu of $54,000 of such amount due and payable to him. During the period between January 1 and October 5, 2010, we issued Dr. Moynihan 109,584 shares of our common stock in lieu of $23,538 of such amount due and payable to him for his services.

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

On March 1, 2010, we issued a four (4) year warrant to purchase 1,706,626 shares of our common stock to Clearwater, which was exercised in full on May 27, 2010, at a price per share of $0.0001. On May 27, 2010, we further issued to Clearwater an additional four (4) year warrant to purchase 1,409,821 shares of our common stock, which was immediately exercised in full at a price per share of $0.0001, and we issued to Clearwater a promissory note due and payable on January 31, 2012 in the principal amount of $45,000, with 10% interest per annum accruing thereon. These warrants and this promissory note were issued to Clearwater in lieu of repayment of $450,000 principal, and accrued interest thereon, of funds previously advanced to us by Clearwater. On October 5, 2010, Clearwater purchased 176,358 shares of our common stock for $47,535 and, in a simultaneous related transaction, made a loan to the Company in the principal amount of $47,535, with 15% interest per annum accruing thereon, for which we issued Clearwater a promissory note due and payable on January 31, 2011. On January 25, 2011, Clearwater converted the principal amount of this $47,535 promissory note and the accrued interest thereon, and the principal amount of the $45,000 promissory note and the accrued interest thereon, due and payable on January 31, 2012, into 97,544 shares of our common stock through an investment in the Private Placement Offering.

Upon the closing of the Merger, we entered into employment agreements with each of Messrs. Pandolfino and Sicignano as well as C. Anthony Rider, our Chief Financial Officer and Treasurer. These employment agreements were included as Exhibit 10.15, Exhibit 10.16, and Exhibit 10.17, respectively, to the Original Form 8-K and are incorporated herein by reference.

In February 2011, AC was paid $22,500 by 22nd Century for AC's assignment of its MAGIC trademark to 22nd Century and other minor assets.

Policies and Procedures for Related Party Transactions

We do not currently have a formal written policy or procedure for the review and approval of related party transactions. However, effective as of the date ten (10) days following the date hereof, all future related party transactions will be reviewed and approved by a disinterested majority of the members of our Board.

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

Pursuant to this policy, our Board will: (i) review the relevant facts and circumstances of each related person transaction, including if the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the extent of the related person's interest in the transaction, and (ii) take into account the conflicts of interest and corporate opportunity provisions of our code of business conduct and ethics. Management will present to our Board each proposed related person transaction, including all relevant facts and circumstances relating thereto, and will update the Board as to any material changes to any related person transaction. All related person transactions may only be consummated if our Board has approved or ratified such transactions in accordance with the guidelines set forth in the policy. Certain types of transactions have been pre-approved by our Board under the policy. These pre-approved transactions include: (i) certain compensation arrangements; (ii) transactions in the

ordinary course of business where the related person's interest arises only (a) from his or her position as a director of another entity that is party to the transaction, and/or (b) from an equity interest of less than 5% in another entity that is party to the transaction, or (c) from a limited partnership interest of less than 5%, subject to certain limitations; and (iii) transactions in the ordinary course of business where the interest of the related person arises solely from the ownership of a class of equity securities in our Company where all holders of such class of equity securities will receive the same benefit on a pro rata basis. No director may participate in the approval of a related person transaction for which he or she is a related person.

Director Independence

Messrs. Cornell and Katz as well as Dr. Dunn qualify as "independent" directors under the applicable definition of the Nasdaq Global Market ("Nasdaq") listing standards, so that a majority of the members of our Board are "independent." Although the Company's securities are not currently traded on the Nasdaq or any other exchange, which would require that our Board include a majority of directors that are "independent," we have elected to do so anyhow as part of our corporate governance policies.

Item 14. Principal Accountant and Fees.

The following table shows the fees billed to 22nd Century for the audits and other services provided by Freed Maxick & Battaglia CPAs, PC and RSM McGladrey, Inc. (an affiliate of Freed Maxick & Battaglia, CPAs, PC, its independent registered public accounting firm, for the fiscal years ended December 31, 2010 and 2009, respectively. While the Company had a different independent public registered accounting firm serving as its independent auditors prior to the Merger, the audit and other fees billed to 22nd Century are presented herein as 22nd Century's business became our sole operating business immediately following the closing of the Merger.

	2010	2009
Audit fees	$ 28,000	$ 15,011
Audit-related fees	26,301	-
Tax fees	19,344	-
All other fees	-	-
	$ 73,645	$ 15,011

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

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

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

All Other Fees - None

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

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

Of the services provided in the fiscal years ended December 31, 2010 and 2009, respectively, all fees and services were pre-approved by 22nd Century's manager, which also performed the equivalent functions of an audit committee of 22nd Century.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements

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22nd CENTURY LIMITED, LLC AND SUBSIDIARY

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