

22nd Century Group, Inc.
Form S-1/A
September 20, 2011

As filed with the Securities and Exchange Commission on September 19, 2011

Registration No. 333-173420

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

Amendment No. 8
to
Form S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

22nd CENTURY GROUP, INC.
(Exact name of registrant as specified in its charter)

Nevada	5194	98-0468420
(State or other jurisdiction of Incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

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(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price(2)	Amount of registration fee (3)
Common stock, par value \$0.00001 per share	5,434,446	\$ 1.25	\$6,793,057.50	\$ 788.68

- (1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the number of shares of common stock registered hereby is subject to adjustment to prevent dilution resulting from stock splits, stock dividends or similar transactions.
- (2) Estimated solely for the purpose of determining the amount of the registration fee, based on the average of the high and low sale prices of the common stock as reported by the OTC Bulletin Board on April 6, 2011 in accordance with Rule 457(c) under the Securities Act of 1933.
- (3) The registration fee was previously paid on April 8, 2011.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the selling stockholders are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED SEPTEMBER 19, 2011

PROSPECTUS

22nd CENTURY GROUP, INC.

5,434,446 Shares of Common Stock

This prospectus relates to the offering by the selling stockholders of 22nd Century Group, Inc. of up to 5,434,446 shares of common stock, par value \$0.00001 per share. These shares were privately issued to the selling stockholders in connection with a private placement and merger transaction. We will not receive any proceeds from the sale of common stock by the selling stockholders.

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

Our common stock is traded on the OTC Bulletin Board under the symbol "XXII.OB". On September 15, 2011, the closing sale price of our common stock was \$0.80 per share.

Investing in our common stock involves risks. Before making any investment in our securities, you should read and carefully consider risks described in the "Risk Factors" section beginning on page 9 of this prospectus.

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

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

This date of this prospectus is September __, 2011

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

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PROSPECTUS SUMMARY

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

As used in this prospectus, unless the context otherwise requires, the “Company,” “we,” “us” and “our” refer to 22nd Century Group, Inc., a Nevada corporation, as well as its subsidiaries, 22nd Century Limited, LLC, a Delaware limited liability company, and Goodrich Tobacco Company, LLC, a Delaware limited liability company, taken as a whole, and also refer to the operations of 22nd Century Limited, LLC prior to the merger on January 25, 2011, as discussed below, which resulted in 22nd Century Limited, LLC becoming our wholly-owned subsidiary. Hereinafter, 22nd Century Limited, LLC is sometimes referred to as “22nd Century.”

Our Company

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 control 98 issued patents, of which we own 8 issued patents and we have the exclusive license to an additional 90 issued patents in an aggregate of 79 countries where at least 75% of the world’s smokers reside. Additionally, we control 45 pending patent applications, of which we own 29 and have an exclusive license to 16. In the U.S., patents that currently cover our products expire in 2019 through 2022. Also in the U.S., patent applications that we expect will cover our products would, if patents are granted in connection with such applications, expire in 2024 through 2028. However, there is no guarantee that patents will be granted in response to such patent applications and therefore cover our products. Our two worldwide exclusive licenses, one from North Carolina State University (“NCSU”) and the other from National Research Council of Canada, Plant Biotechnology Institute in Saskatoon, Canada (“NRC”), each involve multiple patent families. The exclusive rights under each of these two license agreements expire on the date on which the last patent covered by the subject license expires in the country or countries where such patents are in effect. The NCSU license relates predominately to issued patents, and the NCSU license will expire in 2022 when the last patent covered by the NCSU license will expire. The NRC license relates to only patent applications, so if such patent applications result in issued patents, then we expect the NRC license to expire in 2028, which is 20 years from the time when all such patent applications were filed together. However, in the event that none of the NRC patent applications result in issued patents, then the NRC license would expire upon our receipt of the last formal notice of rejection from the subject patent office of the domestic or foreign jurisdiction relating to the last of the NRC patent applications, which is an unknown date in the future that we cannot calculate. We believe our proprietary technology provides us with opportunities in the global market for approved smoking cessation aids and the emerging market for modified risk tobacco products, which is a term that we explain below; however, we have not yet identified any specific countries or developed any timelines or cost estimates for international expansion of our business.

Private Placement Offering

Our January 25, 2011 Private Placement Offering (as defined under the “Recent Developments” section on page 6) of 5,434,446 Units (as defined under the “Recent Developments” section), which we collectively refer to in this prospectus as “PPO Securities,” resulted in approximately \$3.4 million in net cash proceeds and a reduction of debt obligations to shareholders that were on the balance sheet at December 31, 2010 of approximately \$614,000, which were exchanged for equity interests in the Private Placement Offering. This offering involves the resale of common stock, and we have

registered that resale to satisfy registration rights related to the PPO Securities. We will not receive any proceeds from the sale of common stock under this prospectus.

The net proceeds of the Private Placement Offering will not be sufficient to enable us to complete the U.S. Food and Drug Administration ("FDA") approval process for X-22, our prescription smoking cessation aid in development, and/or the FDA authorization process for our Modified Risk Cigarettes. We will require additional capital beyond the net proceeds of the Private Placement Offering to complete these activities. We may not be able to obtain additional debt or equity financing on favorable terms, if at all. If we raise additional funds through the issuance of equity securities, our stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. We also could elect to seek funds through arrangements with collaborators. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to us. We currently project that we will need additional capital by November 2011. Our Board of Directors has authorized us to seek bridge financing of approximately \$1.5 million (net proceeds) in the form of a convertible debenture as negotiated with private accredited investors. We currently plan to seek to raise an additional \$15 million in the fourth quarter of 2011 through the sale of our common stock and/or securities convertible into common stock to fund Phase III trials for X-22 that the FDA may request, modified risk exposure studies and our general working capital requirements. We estimate the cost of completing the Phase III trials is approximately \$10 million.

We plan to use a material portion of the proceeds from the Private Placement Offering to complete a Phase II-B clinical trial which is necessary to seek approval from the FDA for X-22. We believe the cost of completing the Phase II-B trial is approximately \$1.2 million, of which we have incurred approximately one-half as of June 30, 2011. We have designated our upcoming phase II clinical trial as a "Phase II-B" clinical trial, though this is not an official FDA designation, because (i) we are looking for continued indications of clinical efficacy and safety in larger groups of patients in our clinical trial, and (ii) very low nicotine (VLN) cigarettes made from the Company's VLN tobacco have already demonstrated efficacy in previous Phase II trials, specifically the Phase II trial at the University of Minnesota which had a very similar protocol compared to our upcoming phase II clinical trial. Further research may be needed to determine the efficacy of X-22, including our review of the results of our Phase II-B trial and the results of any Phase III trial. There is no guarantee that X-22 will obtain the necessary approvals from the FDA to be marketed as a smoking cessation aid. At this time, we have not yet attempted to obtain any approval for X-22 outside of the U.S., and there is no guarantee that we will be able to obtain any approval for X-22 outside of the U.S. (for those countries that require such regulatory approvals).

Current Default Under NCSU License

We are currently in default under the terms of our exclusive worldwide license agreement with North Carolina State University (“NCSU”) for failure to timely pay certain amounts owed under the license agreement. As of June 30, 2011, the balance we owed to NCSU was approximately \$742,000. We have requested that NCSU defer payment of these amounts. Should NCSU choose instead to invoke its right to terminate this license agreement, we would have 60 days notice to cure the payment default, and if we did not cure the payment default within such 60-day period and the license terminated, our business would be materially and adversely affected. If NCSU does not agree to a deferment of the unpaid balance owing under the license agreement and we pay such balance, we may not have sufficient funds to pay in full the cost of our Phase II-B clinical trial for X-22 (as described in more detail throughout this prospectus). In addition, pursuant to the terms of our exclusive worldwide license agreement with NCSU, we are required to meet the following development and commercialization terms: (i) no later than December 31, 2010 we were required to have initiated a phase III clinical trial for a licensed product that is a smoking cessation aid; (ii) no later than December 31, 2011 we are required to have applied for FDA approval for sale of a licensed product that is a smoking cessation aid and (iii) no later than December 31, 2012, we are required to have completed our first commercial sale of licensed product that is a smoking cessation aid. We did not initiate a phase III clinical trial for a licensed product that is a smoking cessation aid by December 31, 2010 and there is no assurance that we will be able to meet the other terms. NCSU may have the right to terminate the license agreement as a result of our failure to initiate a phase III clinical trial for a licensed product that is a smoking cessation aid timely. To date, we have not received a termination notice from NCSU regarding our failure to initiate a timely phase III clinical trial. If NCSU chooses to invoke any right it may have to terminate the license agreement, our business would be materially and adversely affected.

Operations

Our revenue for the six month period ended June 30, 2011 was \$272,266 mainly from our research cigarette program. For the year ended December 31, 2010, we had revenue of \$49,784 from our research cigarette program. Our net loss for the six month period ended June 30, 2011 was \$1,754,987, or \$0.07 per diluted common share. For the year ended December 31, 2010, our net loss was \$1,423,647, or \$0.11 per diluted common share. Total assets were \$2,755,529 at June 30, 2011, compared to \$2,800,520 at December 31, 2010. Total current liabilities were \$1,793,916 at June 30, 2011, compared to \$4,823,635 at December 31, 2010. Total liabilities, including long term liabilities, were \$5,482,666 at June 30, 2011, including our warrant derivative liability of \$3,061,750, compared to \$4,889,192 at December 31, 2010, which did not include any warrant derivative liability. As of June 30, 2011, we had negative working capital of approximately \$0.5 million compared to negative working capital of approximately \$4.1 million at December 31, 2010. The improvement in our working capital position of \$3.6 million was mainly a result of proceeds from the January 25, 2011 Private Placement Offering and the transfer from accounts payable of \$487,000 (net of current portion) to notes payable as part of payment arrangements with two vendors for past due amounts we owed, offset by our net loss for the six months ended June 30, 2011. As reported in our Report on Form 8-K/A as filed with the SEC on March 23, 2011, our independent registered public accounting firm expressed substantial doubt as to whether we can continue as a going concern. Even in light of our receipt of the proceeds of the Private Placement Offering, we cannot guarantee our ability to continue as a going concern.

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. Although further research and clinical trials are needed to determine efficacy of X-22, we believe this therapy protocol has thus far 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 (other than the exposure and side effects from smoking cigarettes in general) that may occur when a person is exposed to a new drug. There is no guarantee that X-22 will obtain the necessary approvals from the FDA to be marketed as a smoking cessation aid.

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. Further research may be needed to determine the efficacy of X-22, including our review of the results of our Phase II-B trial and the results of any Phase III trial which may be requested by the FDA. As we describe further in the Technology Platform and Intellectual Property section, X-22 is a cigarette that contains our proprietary VLN tobacco. We believe X-22 will be well-positioned as a smoking cessation product by motivating and encouraging more smokers to attempt to quit smoking, although there is no assurance that these results will occur.

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 smoke toxins and/or (ii) pose lower health risks, as compared to conventional cigarettes (“Modified Risk Cigarettes”). The Tobacco Control Act requires the FDA to issue specific regulations and guidance regarding applications that must be submitted to the FDA for the authorization to label and market Modified Risk Cigarettes. The FDA has yet to release its regulations regarding modified risk tobacco products. However, based in part on the timelines contained in the Tobacco Control Act, we expect the FDA to issue such regulations and guidance within the next year.

Although we believe that two of our cigarette products, which we refer to as BRAND A and BRAND B, may qualify as Modified Risk Cigarettes, further research and exposure studies are needed for the FDA to make this determination. We believe that BRAND A and BRAND B may qualify as Modified Risk Cigarettes because, compared to commercial cigarettes, we believe 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. There is no guarantee that X-22 will obtain the necessary approvals from the FDA to be marketed as a smoking cessation aid, and there is no guarantee that Brand A or Brand B will obtain the necessary authorizations from the FDA to be classified as Modified Risk Cigarettes. We have not attempted to obtain approval of X-22 or authorization of our Modified Risk Cigarettes outside of the United States, and there is no guarantee that we will be able to gain such approval or such authorization for these products outside of the United States (for those countries that require such regulatory authorizations).

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 to be marketed for smoking cessation 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 submitted a request for Fast Track designation for X-22, and on August 18, 2011, the FDA informed us that it would not grant the designation of X-22 as a Fast Track product at this time because we did not demonstrate that X-22 shows potential to address an unmet medical need. All smoking cessation studies to date with VLN cigarettes containing our proprietary tobacco were independent studies and were not sponsored by 22nd Century under its own Investigational New Drug (“IND”). We plan to file in the fourth quarter of 2011 a subsequent Fast Track request with the FDA, which will include our Phase II-B clinical trial results that will be available in November 2011. Pursuant to FDA regulations, we believe that if our X-22 Phase II-B trial results demonstrate an advantage (over currently approved smoking cessation products) in one of the following areas: efficacy, safety or improvement in some other factor such as compliance (a patient using a product as directed) or convenience, X-22 will demonstrate potential to address an unmet medical need. However, there is no guarantee of our trial results or that the FDA will grant Fast Track designation to X-22. See “Fast Track Development” on page 54 for additional information regarding Fast Track designation by the FDA.

Modified Risk Cigarettes

We intend to seek FDA authorization to sell and 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. There is no guarantee that Brand A or Brand B will obtain the necessary authorizations from the FDA to be classified as Modified Risk Cigarettes. Further research and exposure studies are needed for the FDA to make this determination

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. Super-premium priced means brands that are priced higher than national premium brands such as Marlboro® Newport® and Camel®. 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. We believe that 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. According to Tobacco Merchants Association, flavored cigarettes (besides menthol), mainly clove cigarettes, were approximately 1% of the U.S. cigarette market (3.25 billion cigarettes equating to \$0.7 billion) before the ban on such cigarettes in June 2009, when the Tobacco Control Act became law. Since these were super-premium priced products (priced up to 60% higher than the best selling national brands), they were mainly distributed in specialty tobacco channels such as tobacconists, smoke shops and tobacco outlets, which collectively are about 10,000 stores in the U.S., a small fraction of the hundreds of thousands of stores that sell cigarettes in the U.S.

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, since as of June 2010, all cigarette companies were required to cease the use of the terms “low tar,” “light” and “ultra light.”

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-year contract for Preparation and Distribution of Research and Drug Products. We have agreed, as a subcontractor to RTI International (“RTI”) pursuant to 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 are distributed under the mark SPECTRUM.

In 2010, we received our first purchase order of \$152,660 which included a design phase fee of \$40,604. In March 2011, the Company received a revised purchase order and authorization to bill \$112,000 for manufacture planning and material procurement for 9 million cigarettes from RTI. Payment was received on May 2, 2011. The Company received an additional purchase order from RTI for approximately \$680,000 in May 2011 to ship the 9 million research cigarettes. Approximately 4 million cigarettes out of the 9 million were shipped to and received by RTI on

July 6, 2011. We believe that the revenue from the sale of SPECTRUM, plus direct orders of other cigarettes from researchers, will be approximately \$825,000 in 2011 and \$3 million over the next 5 years. As a subcontractor, we do not have a formal contractual arrangement at this time with RTI to purchase additional SPECTRUM cigarettes or with other researchers, and there is no guarantee that we will receive future orders from RTI or other researchers.

Technology Platform and Intellectual Property

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. For example, we believe that 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. We believe that, as opposed to extracting nicotine from tobacco, this proprietary tobacco grows with virtually no nicotine without adversely affecting the other leaf constituents important to a cigarette’s characteristics, including taste and aroma. Our genetic engineering processes suppress an enzyme involved in synthesis of a nicotine precursor in the roots of the tobacco plant. Roots of the tobacco plant produce nicotine which is transported to the rest of the plant. We believe levels of certain compounds in the tobacco leaf of our genetically engineered variety are not substantially different than that of conventional tobacco, except for the large reduction in nicotine and related compounds. We believe, based on analyses of a range of chemical constituents in smoke from cigarettes made from VLN tobacco, that the smoke is highly similar to smoke from conventional cigarettes, except for the large reduction in nicotine and related compounds. Furthermore, subjective ratings of our products’ smoking characteristics approximate those of conventional cigarettes. Therefore, we believe the taste and aroma characteristics are within the range of typical cigarettes.

Our proprietary technology is covered by 12 patent families consisting of 98 issued patents in 79 countries, 8 of which we own and 90 of which are exclusively licensed to us, and approximately 45 pending patent applications, of which we own 29 pending patent applications and have an exclusive license to 16 pending patent applications. A “patent family” is a set of patents granted in various countries to protect a single invention. Our patent coverage in the United States, which we believe is the most valuable smoking cessation market and cigarette market, consists of 14 issued patents and 7 pending applications. In the U.S., patents that currently cover our products expire in 2019 through 2022. Also in the U.S., patent applications that we expect will cover our products would, if patents are granted in connection with such applications, yield patents that expire in 2024 through 2028. However, there is no guarantee that patents will be granted in response to such patent applications and therefore cover our products. Our two worldwide exclusive licenses, one from North Carolina State University (“NCSU”) and the other from National Research Council of Canada, Plant Biotechnology Institute in Saskatoon, Canada (“NRC”), each involve multiple patent families. The exclusive rights under each of these two license agreements expire on the date on which the last patent covered by the subject license expires in the country or countries where such patents are in effect. The NCSU license relates predominately to issued patents, and the NCSU license will expire in 2022 when the last patent covered by the NCSU license will expire. The NRC license relates to only patent applications, so if such patent applications result in issued patents, then we expect the NRC license to expire in 2028, which is 20 years from the time when all such patent applications were filed together. However, in the event that none of the NRC patent applications result in issued patents, then the NRC license would expire upon our receipt of the last formal notice of rejection from the subject patent office of the domestic or foreign jurisdiction relating to the last of the NRC patent applications, which is an unknown date in the future that we cannot calculate. In China, which we consider the world’s largest cigarette market, we own or have the exclusive license to use 5 issued patents and 3 pending patent applications. 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 we believe approximately 75% of the world’s smokers reside. As a result of these patents, patent applications and licenses, we believe 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. Similarly, we believe 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 own various registered trademarks in the United States. We also have exclusive rights to plant variety protection, or PVP, certificates in the United States (issued by the U.S. Department of Agriculture) and Canada. A PVP certificate prevents anyone other than the owner/licensee from planting a plant variety for 20 years in the U.S. or 18 years in

Canada. The protections of PVP are independent of, and in addition to, patent protection.

While we have performed searches for third-party intellectual property rights that may affect our ability to commercialize our potential products, we have not performed searches for those third-party intellectual property rights that may raise freedom-to-operate issues, nor have we obtained legal opinions regarding the commercialization of our potential products. Therefore, there may be patents of which we are unaware that may affect our ability to commercialize our potential products.

Recent Developments

On January 25, 2011, we entered into an Agreement and Plan of Merger and Reorganization with 22nd Century Acquisition Subsidiary, our wholly-owned Delaware limited liability company subsidiary, or Acquisition Sub, and 22nd Century. On that date, Acquisition Sub merged with and into 22nd Century, and 22nd Century, as the surviving entity, became our wholly-owned subsidiary. In this prospectus, we refer to the merger and reorganization transactions consummated on January 25, 2011 as the “Merger.”

Prior to the consummation of the Merger, 22nd Century completed a private placement of units of its securities, or “Units”, with each Unit consisting of one limited liability company membership interest of 22nd Century and a five-year warrant to purchase one half of one (1/2) limited liability company membership interest of 22nd Century at an exercise price of \$1.50 per whole limited liability company membership interest of 22nd Century. We refer to the offering in this prospectus as the “Private Placement Offering.” 22nd Century also issued warrants to purchase its limited liability company membership interests to a financial advisor for financial advisory services rendered in connection with the Private Placement Offering.

Prior to the closing of the Merger, we transferred all of our pre-Merger operating assets and liabilities pursuant to the terms of a split-off agreement (the “Split-Off Agreement”), to our wholly-owned subsidiary, Touchstone Split Corp., a Delaware corporation (the “Split-Off Subsidiary”). Thereafter, pursuant to the Split-Off Agreement, we transferred all of the outstanding capital stock of the Split-Off Subsidiary to our then-sole director in exchange for \$1.00, such consideration being deemed to be adequate by our pre-Merger Board of Directors (the “Board”).

At the closing of the Merger, each limited liability company membership interest of 22nd Century issued and outstanding immediately prior to the closing of the Merger was exchanged for one share of our common stock, and each warrant to purchase limited liability company membership interests of 22nd Century was exchanged for one warrant of like tenor and term to purchase shares of our common stock. An aggregate of 21,434,446 shares of common stock and warrants to purchase an aggregate of 8,151,980 shares of common stock were issued to the holders of Units of 22nd Century, and immediately following the closing of the Merger an aggregate of 26,759,646 shares of common stock were issued and outstanding and an aggregate of 8,651,980 shares of common stock were reserved for issuance pursuant to the exercise of warrants to purchase shares of common stock.

In connection with the Merger, our Board was expanded to five 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. Messrs. Cornell and Katz and Dr. Dunn qualify as “independent” directors under the applicable definition of the NASDAQ Global Market (“NASDAQ”) listing standards, so that a majority of the Company’s Board members are “independent.” Although the Company’s securities are not currently traded on the NASDAQ or any other exchange, which would require that the Company’s Board include a majority of directors that are “independent,” the Company has elected to do so anyhow as part of its corporate governance policies. Our current executive officers are Joseph Pandolfino, Chief Executive Officer, Henry Sicignano III, President and Secretary, Michael R. Moynihan, Ph.D., Vice President of Research & Development, and C. Anthony Rider, Chief Financial Officer and Treasurer. Each of Messrs. Pandolfino, Sicignano and Rider was an executive officer of 22nd Century prior to the closing of the Merger.

Following the closing of the Merger, there were 26,759,646 shares of Common Stock issued and outstanding. Approximately 59.8% of such issued and outstanding shares were held by individuals and entities that were holders of limited liability company membership interests of 22nd Century prior to consummation of the Private Placement Offering, approximately 20.3% were held by the investors in the Private Placement Offering and approximately 19.9% were held by the pre-Merger stockholders of Parent.

On April 1, 2011, under our 2010 equity incentive plan (“EIP”), the Board granted an aggregate of 1,150,000 shares of our common stock to our officers and directors and options to purchase an aggregate of 35,000 shares of our common stock to our employees.

The Merger is being accounted for as a reverse acquisition and recapitalization of 22nd Century for financial accounting purposes whereby 22nd Century is deemed to be the acquirer for accounting and financial reporting purposes. Consequently, the assets and liabilities and the historical operations that will be reflected in the financial statements prior to the Merger will be those of 22nd Century and will be recorded at the historical cost basis of 22nd Century, and the consolidated financial statements after completion of the Merger will include the assets and liabilities of the Company and 22nd Century, historical operations of 22nd Century and operations of the Company beginning on the closing date of the Merger. As a result, all the historical financial information reported in this prospectus is the financial information of 22nd Century.

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.

Corporate Information

We were incorporated under the laws of the State of Nevada on September 12, 2005 under the name Touchstone Mining Limited. We changed our name to 22nd Century Group, Inc. on November 23, 2010 in anticipation of the Merger with 22nd Century. Our principal executive offices are located at 9530 Main Street, Clarence, New York 14031. The telephone number at our principal executive offices is (716) 270-1523. Our website address is www.xxiiicentury.com. Information contained on our website is not deemed part of this prospectus.

The Offering

Common stock currently outstanding	27,909,646 shares (1) (2)
Common stock offered by us	None
Common stock offered by the selling stockholders	5,434,446 shares
Use of Proceeds	We will not receive any proceeds from the sale of common stock offered by this prospectus.
Risk Factors	See “Risk Factors” and other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in shares of our common stock.
OTC Bulletin Board Symbol	XXII.OB

(1) As of September 15, 2011

(2) Assumes that all other outstanding warrants and options are not exercised

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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