22nd Century Group, Inc.
Form S-1
February 04, 2013

As filed with the Securities and Exchange Commission on February 4, 2013

Registration No. 333-_____

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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.)*

9530 Main Street

Clarence, New York 14031

(716) 270-1523

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

Henry Sicignano III

President

22nd Century Group, Inc.

9530 Main Street

Clarence, New York 14031

(716) 270-1523

(Address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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One Independent Drive, Suite 1300

Jacksonville, Florida 32202

(904) 359-2000

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	Proposed maximum aggregate offering price	Amount of registration fee
Common stock, par value $0.00001 per share, underlying Series A-1 10% Convertible Preferred Stock, par value $0.00001 per share	10,833,332	(2) $ 0.71	(3) $ 7,691,665.72	(3) $ 1,049.14
Common stock underlying outstanding Series A Warrants	8,333,332	(4) $ 0.72	(5) $ 5,999,999.04	(5) $ 818.40
Common stock underlying outstanding Series B Warrants	4,166,668	(6) $ 0.71	(5) $ 2,958,334.28	(5) $ 403.52
Common stock underlying outstanding Series C Warrants	4,166,668	(4) $ 0.72	(5) $ 3,000,000.96	(5) $ 409.20
Total	27,500,000		$ 19,650,000.00	$ 2,680.26 (7)

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), 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) For purposes of calculating the number of shares of common stock included in this registration statement (due to potential adjustments to the conversion price and anti-dilution provisions), we have included 200% of the aggregate number of shares currently issuable (i) upon conversion of issued and outstanding shares of Series A-1 10% Convertible Preferred Stock at an initial conversion price of $0.60 per share and (ii) issuable as dividends in lieu of cash over a three (3) year period on issued and outstanding shares of Series A-1 10% Convertible Preferred

Stock (at an assumed price of $0.60 per share). The shares of common stock are being registered for resale by the selling stockholders named in this registration statement.

(3) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act based on the average of the high and low sale prices of the common stock reported on the OTC Bulletin Board on January 31, 2013, which was $0.71 per share.

(4) For purposes of calculating the number of shares of common stock included in this registration statement (due to potential adjustments to the exercise price and anti-dilution provisions), we have included 200% of the aggregate number of shares currently issuable upon exercise of warrants to purchase shares of common stock held by the selling stockholders named in this registration statement, at an initial exercise price of $0.72 per share.

(5) Represents the higher of: (i) the exercise price of the convertible security and (ii) the offering price of securities of the same class as the common stock underlying the convertible security calculated in accordance with Rule 457(c) under the Securities Act, for the purpose of calculating the registration fee pursuant to 457(g) under the Securities Act.

(6) For purposes of calculating the number of shares of common stock included in this registration statement (due to potential adjustments to the exercise price and anti-dilution provisions), we have included 200% of the aggregate number of shares currently issuable upon exercise of warrants to purchase shares of common stock held by the selling stockholders named in this registration statement, at an exercise price of $0.60 per share.

(7) The Registrant previously filed Form S-1 (333-173420) on April 8, 2011, and paid a filing fee of $788.68. The Registrant did not sell an aggregate of 4,632,534 securities pursuant to that Form S-1, and that Form S-1 was terminated on May 18, 2012. Pursuant to Rule 457(p), the Registrant hereby applies $672 of the previously paid filing fee against amounts due herewith.

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 FEBRUARY 4, 2013

PRELIMINARY PROSPECTUS

22nd CENTURY GROUP, INC.

Up to 27,500,000 Shares of Common Stock

This prospectus relates to the resale at various times by the selling stockholders indentified in this prospectus of up to 27,500,000 shares of common stock, par value $0.00001 per share, issuable (i) upon conversion of our Series A-1 Preferred Stock, (ii) as dividend payments on our Series A-1 Preferred Stock (at our option) and (iii) upon the exercise of Series A Warrants, Series B Warrants and Series C Warrants. These shares were privately issued to the selling stockholders in connection with a private placement transaction. We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Series A Warrants, Series B Warrants and Series C Warrants, if exercised for cash.

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 January 29, 2013, the closing sale price of our common stock was $0.90 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 7 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 _____, 2013

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

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Prospectus Summary

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

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

Our Company

Background

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

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

Overview

22nd Century Limited, LLC, our wholly-owned subsidiary, is a plant biotechnology company focused on tobacco harm reduction and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding. We exclusively control 107 issued patents and exclusively control an additional 38 patent applications; of these, we own 12 issued patents plus 23 patent applications and we license on an exclusive basis, 95 issued patents and 15 patent applications. Hercules Pharmaceuticals, LLC and Goodrich Tobacco Company, LLC are subsidiaries of 22nd Century Limited, LLC and are business units for our (i) smoking cessation product and (ii) premium cigarettes and modified risk tobacco products, respectively.

We are in the process of transitioning from solely developing proprietary technology and tobacco to developing and commercializing our own products. In March 2011, our subsidiary, Goodrich Tobacco Company, LLC introduced two of our products, *RED SUN* and *MAGIC* cigarettes into the U.S. market.

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

Current Financial Condition

We have operated at a loss since 2006 when we increased our research and development expenditures. We had net losses of $2.4 million, $1.3 million and $1.4 million, respectively, in the nine months ended September 30, 2012 and years ended December 31, 2011 and 2010. We realized revenue of $15,683 in the nine months ended September 30, 2012 from the sale of research cigarettes. In the year ended December 31, 2011, we realized revenue of $788,601 mainly from our research cigarette program and in 2010, we realized revenue of $49,784 from this program. As of January 22, 2013, we had cash on hand of approximately $660,000 due to the capital raises described under “Recent Developments,” which should be sufficient to fund operations for approximately 5 months.

We will need additional capital to continue operations and make payments on obligations that are and become due in 2013. Our expected capital requirements over the next 12 months without any extraordinary expenses such as exposure studies or clinical trials are approximately $1 million. We will need to raise funds through the issuance of debt or equity securities or through licensing our technology during the next twelve months in order to continue operations. Failure to raise sufficient funds would significantly increase the risk that we would be unable to continue operations. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our plans to commercialize our products, our ability to continue as a going concern and our financial condition and results of operations. Additional equity financing will be dilutive to shareholders of our common stock. To the extent that we raise additional funds through collaboration and licensing arrangements, it will be necessary in certain countries to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to us.

Corporate Information

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

Recent Developments

Private Placement of Preferred Stock and Warrants

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

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

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

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

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

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

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

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

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

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

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

Modification of Convertible Notes Due December 14, 2012

On December 14, 2011, we sold approximately $1.9 million of convertible promissory notes for an aggregate purchase price of approximately $1.7 million in a private placement. The notes were issued with an original issue discount of approximately 15% and the original maturity date of the notes was December 14, 2012 (which was extended as set forth below). The notes were initially convertible into shares of our common stock at any time prior to maturity at a per share conversion price equal to $0.75, which conversion price was subsequently adjusted pursuant to its terms to be equal to $0.7004 per share as of January 22, 2013. Upon conversion of all or a portion of the notes into common stock, the holder will receive at that time a warrant to purchase an exercise price of $1.50 per share (i) such number of shares of common stock from such warrant equal to 120% of such number of shares of common stock issuable upon conversion of the note and (ii) a pro rata portion of an increase of such warrant in the aggregate of an additional 239,890 shares of common stock that were the result of inducements granted to holders of such notes to execute lock-up agreements, which restrict the note holders from selling the underlying shares of common stock issuable upon conversions of the notes or exercising the warrants for a period from January 11, 2013 until the date which is 2 months after the effective date of this registration statement.

Between December 14, 2012 and January 2, 2013, we entered into agreements with holders of $1,675,000 of the notes. Holders of $1,330,000 of the notes agreed to extend the maturity date of the notes to April 14, 2013. Holders of $100,000 of the notes elected to convert into shares of the common stock pursuant to the terms of the notes. Holders of $215,000 of the notes elected to enter into a forbearance agreement and were subsequently paid in full. Holders of $30,000 of the notes agreed to be paid over time. On January 24, 2013, we sent out notices to the holders of the notes regarding our intent to repay the notes at the expiration of a 15-day period during which time the holders may convert to common stock and warrants to purchase common stock.

The foregoing description of the notes is only a summary and is not complete. For additional information about the terms of the notes, see the section entitled “Description of Securities” in this prospectus.

Private Placement of Common Stock and Warrants

On November 9, 2012, we sold for an aggregate purchase price of approximately $809,500 in a private placement of approximately 3,238,000 shares of our common stock and warrants with a 5-year term to purchase up to 1,619,000 shares of our common stock at an initial exercise price of $1.00 per share, which warrant exercise price was subsequently adjusted pursuant to its terms to be equal to $0.60 per share as of January 22, 2013. We used the proceeds from such private placement for licensing expenses, tobacco leaf purchases, working capital and other general corporate purposes. For additional information about these warrants, see the section entitled “Description of Securities – Warrants and Convertible Notes – Warrants issued in 2012” in this prospectus.

The Offering

Common stock currently outstanding	35,415,139 shares (1) (2)
Common stock offered by us	None.
Common stock offered by the selling stockholders	Up to 27,500,000 shares issuable (i) upon conversion of our Series A-1 Preferred Stock, (ii) as dividend payments on our Series A-1 Preferred Stock and (iii) upon the exercise of the Warrants.
Use of Proceeds	We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Warrants, if exercised for cash.
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 January 22, 2013.

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

- up to 4,166,666 shares of common stock that could be issued as a result of the conversion of the shares of Series A-1 Preferred Stock, which is subject to adjustment as described under "Description of Securities – Preferred Stock";
- up to 2,055,000 shares of common stock reserved for future issuance under the Equity Incentive Plan;
- up to 465,000 shares of common stock issuable upon exercise of outstanding stock options;
- up to 2,411,734 shares of common stock currently issuable upon the conversion of convertible notes (subject to adjustment for anti-dilution adjustments);

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up to 19,700028 shares of common stock currently issuable upon the exercise of outstanding warrants (including the Series A Warrants and Series B Warrants) (subject to adjustment for anti-dilution adjustments); and

- up to 5,142,797 shares of common stock issuable upon exercise of warrants issuable upon conversion or exercise of other instruments (including the Series C Warrants) (subject to adjustment for anti-dilution adjustments).

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Cautionary Note Regarding Forward-Looking Statements

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

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

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

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

Risk Factors

An investment in shares of our common stock is highly speculative and involves a high degree of risk. We face a variety of risks that may affect our operations or financial results and many of those risks are driven by factors that we cannot control or predict. The following discussion addresses those risks that management believes are the most significant, although there may be other risks that could arise, or may prove to be more significant than expected, that may affect our operations or financial results. Only those investors who can bear the risk of loss of their entire investment should participate in this offering. Prospective investors should carefully consider the following risk factors in evaluating an investment in our common stock.

Risks Related to Our Business and Operations

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

Recurring losses from operations, our negative working capital of approximately $3.1 million and $1.9 million as of September 30, 2012 and December 31, 2011, respectively, shareholders' deficit of $2.4 million and $1.2 million as of September 30, 2012 and December 31, 2011, respectively, and the uncertainty of obtaining additional capital on a timely basis, raise doubt about our ability to continue as a going concern. It is highly probable that any sales of equity securities will cause our stockholders to experience substantial dilution. It is also possible that such equity securities will have rights, preferences or privileges senior to those of existing stockholders. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2011 expressed substantial doubt regarding whether we can continue as a going concern. We cannot guarantee our ability to continue as a going concern.

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

We experienced net losses of approximately $2.4 million, $1.3 million and $1.4 million during the nine months ended September 30, 2012 and the years ended December 31, 2011 and 2010, respectively. We expect to continue to incur net losses and negative operating cash flows in the foreseeable future and cannot be certain that we will ever achieve profitability. Since 2007, we have received only limited licensing revenue from a former licensee and our only significant revenue has been from research cigarettes for which the market is limited. We will need to spend significant capital to fulfill planned operating goals and conduct clinical studies, achieve regulatory approvals and, subject to such approvals, successfully produce products for commercialization.

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

We had negative cash flow before financing activities of approximately $1,303,000, $4,057,000 and $1,018,000 during the nine months ended September 30, 2012 and the years ended December 31, 2011 and 2010, respectively. We anticipate that we will continue to have negative cash flow for the foreseeable future even though we have suspended clinical trials for *X-22* because we have significant liabilities that are due or that will become due in 2013 and we will continue to incur expenses for sales and marketing, and general and administrative expenses. Our business will also require significant amounts of working capital to support our growth. Therefore, we will likely need to raise additional investment capital to achieve growth, and we may not achieve sufficient revenue growth to generate positive future cash flow. An inability to generate positive cash flow for the foreseeable future or raise additional capital on reasonable terms may decrease our long-term viability.

Our ability to obtain future debt financing is limited while shares of our Series A-1 Preferred Stock is outstanding.

Our Certificate of Designations regarding our Series A-1 Preferred Stock contains restrictive covenants that limit our ability to, among other things, incur or assume additional debt or provide guarantees in respect of obligations of other persons (in each case, so long as 1,000 or more shares of our Series A-1 Preferred Stock are outstanding, and other than with respect to lease obligations and purchase money indebtedness in an amount up to $200,000 in the aggregate), or create, assume, or suffer to exist any liens (other than liens for taxes not yet due, liens contested in good faith, and liens imposed in the ordinary course of business that do not materially impair the operation of the business) without, in each instance, the prior written consent of at least 67% in stated value of the then-outstanding shares of Series A-1 Preferred Stock. A breach of these covenants would trigger the ability of the holders of the Series A-1 Preferred Stock to redeem their shares of Series A-1 Preferred Stock for cash or shares of our common stock or elect to increase the dividend payments to be made on their shares of Series A-1 Preferred Stock to 18% per annum.

Our limited operating history makes it difficult to evaluate our current business and future prospects.

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

We have no experience in managing growth. If we fail to manage our growth effectively, we may be unable to execute our business plan or address competitive challenges adequately.

We currently have six employees. Any growth in our business will place a significant strain on our managerial, administrative, operational, financial, information technology and other resources. We intend to further expand our overall business, customer base, employees and operations, which will require substantial management effort and significant additional investment in our infrastructure. We will be required to continue to improve our operational, financial and management controls and our reporting procedures and we may not be able to do so effectively. As such, we may be unable to manage our growth effectively.

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

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

We have suspended further clinical trials for FDA approval of our X-22 smoking cessation product and will not resume this process until additional capital is raised and we will need additional capital before we can complete the FDA authorization process for our Modified Risk Cigarettes.

We will require additional capital in the future before we can resume our own clinical trials for FDA approval of our *X-22* smoking cessation product and complete the FDA authorization process for our Modified Risk Cigarettes. We do not expect to undertake a capital raise for the purpose of funding further *X-22* clinical trials until the results of two independent Phase II trials are released later in 2013. If we resume our own clinical trials for our *X-22* smoking cessation product, we estimate the cost of completing a Phase II trial will be approximately $2 million and the cost of completing two Phase III trials to be approximately $12 million. We estimate that the cost of completing the FDA authorization process for each of our potential Modified Risk Cigarettes to be at least $2 million. If we raise additional funds through the issuance of equity securities for these activities, our stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. However, our ability to raise funds through debt financing is limited while any shares of our Series A-1 Preferred Stock is outstanding. We also could elect to seek funds through arrangements with collaborators or licensees. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to us.

If we choose to resume our own clinical trials for FDA approval of our *X-22* smoking cessation product and we cannot raise additional capital on acceptable terms, we may not be able to, among other things:

• complete clinical trials of our *X-22* smoking cessation aid;

• undertake the steps necessary to seek FDA authorization of our Modified Risk Cigarettes;

• develop or enhance our potential products or introduce new products;

• expand our development, sales and marketing and general and administrative activities;

• attract tobacco growers, customers or manufacturing and distribution partners;

• acquire complementary technologies, products or businesses;

• expand our operations in the United States or internationally;

• hire, train and retain employees; or

• respond to competitive pressures or unanticipated working capital requirements.

We currently are not in compliance with annual "clean-up" provisions under a revolving line of credit.

Included in current liabilities at September 30, 2012 is a demand loan under a revolving credit agreement with a balance outstanding of $174,925, which is payable to a commercial bank and guaranteed by one of our shareholders. This exact same principal amount has been outstanding for over four years on a continuous basis, notwithstanding the fact that we have not complied with annual "clean-up" provisions which require that we repay all amounts outstanding for a period of 30 consecutive days each year. There are no additional amounts available to us under this credit agreement. We have paid interest only since 2008 (currently at the bank's annual prime rate plus 0.75% or 4%) on a monthly basis according to the bank's monthly payment statements. Our plans contemplate that this balance remains outstanding while we continue to pay interest only on a monthly basis. We may incur disruptions in our operations in the event the bank were to demand repayment in full, close the revolving credit agreement, and not allow us sufficient time to locate additional capital.

We will depend on third parties to manufacture our products.

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

Manufacturers supplying our potential products must comply with FDA regulations which require, among other things, compliance with the FDA's evolving regulations on Current Good Manufacturing Practices ("cGMP(s)"), which are enforced by the FDA through its facilities inspection program. The manufacture of products at any facility will be subject to strict quality control, testing and record keeping requirements, and continuing obligations regarding the submission of safety reports and other post-market information. We cannot guarantee that our current contract manufacturers will pass FDA and/or similar inspections in foreign countries to produce the final version of our *X-22* smoking cessation aid, or that future changes to cGMP manufacturing standards will not also affect the manufactures of our other products. Therefore, we may have to build our own manufacturing facility which would require additional capital.

We will mainly depend on third parties to market, sell and distribute our products, and we currently have no commercial arrangements for the marketing, sale or distribution of our X-22 smoking cessation aid.

We expect to depend on third parties to a great extent to market, sell and distribute our products and we currently have no arrangements with third parties in place to provide such services for our *X-22* smoking cessation aid. We cannot be sure that we will be able to enter into such arrangements on acceptable terms, or at all.

If we are unable to enter into marketing, sales and distribution arrangements with third parties for our *X-22* smoking cessation aid, we would need to incur significant sales, marketing and distribution expenses in connection with the commercialization of *X-22* and any future potential products. We do not currently have a dedicated sales force, and we have no experience in the sales, marketing and distribution of pharmaceutical products. Developing a sales force is expensive and time-consuming, and we may not be able to develop this capacity. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable.

If our X-22 smoking cessation aid does not gain market acceptance among physicians, patients, third-party payers and the medical community, we may be unable to generate significant revenue.

Our *X-22* smoking cessation aid may not achieve market acceptance among physicians, patients, third-party payers and others in the medical community. If we receive FDA approval for the marketing of *X-22* as a smoking cessation aid in the U.S., the degree of market acceptance could depend upon a number of factors, including:

- limitations on the indications for use for which *X-22* may be marketed;

- the establishment and demonstration in the medical community of the clinical efficacy and safety of our potential products and their potential advantages over existing products;
- the prevalence and severity of any side effects;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

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

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

We have no experience in selling smoking cessation products. Competition in the smoking cessation aid products industry is intense, and we may not be able to successfully compete in the market. In the market for FDA-approved smoking cessation aids, our principal competitors include Pfizer Inc., GlaxoSmithKline PLC, Perrigo Company, Novartis International AG, and Niconovum AB, a subsidiary of Reynolds American Inc. The industry consists of major domestic and international companies, most of which have existing relationships in the markets which we plan to sell, as well as financial, technical, marketing, sales, manufacturing, scaling capacity, distribution and other resources and name recognition substantially greater than ours. In addition, we expect new competitors will enter the markets for our products in the future. Potential customers may choose to do business with our more established competitors, because of their perception that our competitors are more stable, are more likely to complete various projects, can scale operations more quickly, have greater manufacturing capacity, are more likely to continue as a going concern and lend greater credibility to any joint venture. If we are unable to compete successfully against manufacturers of other smoking cessation products, our business could suffer, and we could lose or be unable to obtain market share.

We face intense competition in the market for our RED SUN and MAGIC cigarettes and our BRAND A and BRAND B cigarettes, and our failure to compete effectively could have a material adverse effect on our profitability and results of operations.

Cigarette companies compete primarily on the basis of product quality, brand recognition, brand loyalty, taste, innovation, packaging, service, marketing, advertising, retail shelf space and price. We are subject to highly competitive conditions in all aspects of our business and we may not be able to effectively market and sell our *RED*

SUN and MAGIC cigarettes or other cigarettes we may introduce to the market such as our *BRAND A* and *BRAND B* cigarettes as Modified Risk Cigarettes, upon FDA authorization. The competitive environment and our competitive position can be significantly influenced by weak economic conditions, erosion of consumer confidence, competitors' introduction of low-price products or innovative products, higher cigarette taxes, higher absolute prices and larger gaps between price categories, and product regulation that diminishes the ability to differentiate tobacco products. Domestic competitors include Philip Morris USA Inc., Reynolds American Inc., Lorillard Inc., Commonwealth Brands, Inc., Liggett Group LLC, Vector Tobacco Inc. and Star Scientific Inc. International competitors include Philip Morris International Inc., British American Tobacco, JT International SA, Imperial Tobacco Group PLC and regional and local tobacco companies; and in some instances, government-owned tobacco enterprises such as the China National Tobacco Corporation.

Our competitors may develop products that are less expensive, safer or more effective, which may diminish or eliminate the commercial success of any potential product that we may commercialize.

If our competitors market products that are less expensive, safer or more effective than our potential products, or that reach the market before our potential products, we may not achieve commercial success. The market may choose to continue utilizing existing products for any number of reasons, including familiarity with or pricing of these existing products. The failure of our *X*-22 smoking cessation aid or our cigarette brands to compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition, results of operations and cash flows. Our competitors may:

• develop and market products that are less expensive or more effective than our products;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Regulatory Approvals and Insurance Reimbursement

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

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

We submitted a request for Fast Track designation for *X-22*, and on August 18, 2011, the FDA informed us that it would not grant the designation of *X-22* as a Fast Track product at this time because we did not demonstrate that *X-22* shows potential to address an unmet medical need. Except for our Phase II-B clinical trial, all smoking cessation studies with very low nicotine ("VLN") cigarettes containing our proprietary tobacco were independent studies and were not sponsored by 22nd Century Limited, LLC under its own Investigational New Drug ("IND"). We plan to reapply for Fast Track designation, but not until results of a clinical trial conducted by us demonstrates an advantage (over currently approved smoking cessation products) in one of the following areas: efficacy, safety or improvement in some other factor such as compliance (a patient using a product as directed) or convenience. There is no guarantee that the FDA will grant Fast Track designation to *X-22*. We may also not obtain Priority Review of our *X-22* New Drug Application (NDA), which would further delay FDA approval of *X-22*. The length of the FDA's review of a New Drug Application without a Priority Review designation is normally ten months from the date of filing of the New Drug Application, although it is possible in certain cases for such review time to be longer. However, the FDA's goal for reviewing a product with Priority Review status is normally six months from the date of the filing of a NDA. If we do not obtain Priority Review of our New Drug Application, we would then expect the timing of FDA approval of *X-22* to be extended several additional months. Even if *X-22* is approved by the FDA, the FDA may require the product to only be prescribed to patients who have already failed to quit smoking with another approved therapy. Further, failure to comply with applicable regulatory requirements can, among other things, result in the suspension of regulatory approval as well as possible civil and criminal sanctions.

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

sale.

The scope of review, including product testing and exposure studies, to be required by the FDA under the Tobacco Control Act in order for cigarettes such as *BRAND A* and *BRAND B* to be marketed as Modified Risk Cigarettes has not yet been fully established. We may be unsuccessful in establishing that *BRAND A* or *BRAND B* are Modified Risk Cigarettes, and we may fail to demonstrate that either *BRAND A* or *BRAND B* significantly reduces exposure to certain tobacco smoke toxins. Even upon demonstrating significant reduced exposure to certain tobacco smoke toxins, the FDA may decide that allowing a modified risk claim is not in the best interest of the public health, and the FDA may not allow us to market our *BRAND A* and/or *BRAND B* cigarettes as Modified Risk Cigarettes. Furthermore, the FDA could force us to remove from the U.S. market our other tobacco products such as RED SUN or MAGIC and even *BRAND A* and/or *BRAND B* after FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes.

In the future, we intend to distribute and sell our potential products outside of the United States, which will subject us to further regulatory risk.

In addition to seeking approval from the FDA for our *X-22* smoking cessation aid in the United States, we intend to seek governmental approvals required to market *X-22* and our other potential products in other countries. Marketing of our *X-22* smoking cessation aid is not permitted in certain countries until we have obtained required approvals or exemptions in the individual country. The regulatory review process varies from country to country, and approval by foreign governmental authorities is unpredictable, uncertain and generally expensive. Our ability to market our potential products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances. We anticipate commencing the applications required in some or all of these countries following approval by the FDA; however, we may decide to file applications in advance of the FDA approval if we determine such filings to be both time and cost effective. If we export any of our potential products or products that have not yet been cleared for commercial distribution in the United States, such products may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals could impair our ability to generate revenue from international sources.

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

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

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

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

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

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

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

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

Risks Related to the Tobacco Industry

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

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

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

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

The FDA requirement regarding graphic health warnings on cigarette packaging and in cigarette advertising in September 2012 is likely to have a negative impact on sales of our products.

In November 2010, as required by the Tobacco Control Act, the FDA issued a proposed rule to modify the required warnings that appear on cigarette packages and in cigarette advertisements. These warning were finalized on June 21, 2011 and consist of nine new textual warning statements accompanied by color graphics depicting the negative health consequences of smoking. The FDA selected nine images from the originally proposed 36 images after reviewing the relevant scientific literature, analyzing the results from an 18,000 person study and considering more than 1,700 comments from a variety of groups. The graphic health warnings will be located beneath the cellophane wrapping on cigarette packages, and will comprise the top 50 percent of the front and rear panels of cigarette packages. The graphic health warnings will occupy 20 percent of a cigarette advertisement and will be located at the top of the advertisement. Each warning is accompanied by a smoking cessation phone number, 1-800-QUIT-NOW. Although these graphic health warnings were supposed to be implemented in September 2012, a federal judge ruled that these warnings are unconstitutional. If and when these graphic health warnings are implemented, all cigarettes manufactured for sale or distribution in the United States will need to include these new graphic health warnings on their packages. Any reduction in the number of smokers will probably reduce the demand for MAGIC and RED SUN, as well as *X-22*, *BRAND A* and *BRAND B*, if and when approved/authorized by the FDA. *MAGIC*, *RED SUN*, *BRAND A* and *BRAND B* will be subject to these new packaging and advertising regulations. It is unclear at this time whether the FDA may require *X-22 and SPECTRUM* to be subject to these new packaging and advertising regulations.

We may become subject to litigation related to cigarette smoking and exposure to environmental tobacco smoke, or ETS, which could severely impair our results of operations and liquidity.

Although we are not currently subject to legal proceedings, we may become subject to litigation related to the sale of our *RED SUN* and *MAGIC* cigarettes and, upon FDA authorization, our *BRAND A* and *BRAND B* cigarettes. Legal proceedings covering a wide range of matters related to tobacco use are pending or threatened in various U.S. and foreign jurisdictions. Various types of claims are raised in these proceedings, including product liability, consumer protection, antitrust, tax, contraband shipments, patent infringement, employment matters, claims for contribution and claims of competitors and distributors.

Litigation is subject to uncertainty and it is possible that there could be adverse developments in pending cases. An unfavorable outcome or settlement of pending tobacco related litigation could encourage the commencement of additional litigation. The variability in pleadings, together with the actual experience of management in litigating claims, demonstrates that the monetary relief that may be specified in a lawsuit bears little relevance to the ultimate outcome.

Damages claimed in some tobacco-related litigation are significant and, in certain cases range into the billions of dollars. We anticipate that new cases will continue to be filed. The FCTC encourages litigation against tobacco product manufacturers. It is possible that our results of operations, cash flows or financial position could be materially affected by an unfavorable outcome or settlement of litigation.

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

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

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

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

Risks Related to Intellectual Property

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

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

market exclusionary rights apply.

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

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

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

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

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

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

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

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

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management’s attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor’s patent or other proprietary rights;
- a court order prohibiting us from commercializing our potential products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;

- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our potential products to market.

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

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

We own 12 issued patents and we have the exclusive license to an additional 95 issued patents in an aggregate of 78 countries. In addition, we own or exclusively license approximately 38 pending patent applications, of which we own 23 such patent applications and have an exclusive license to 15 such patent applications. We cannot assure you these patent applications will issue, in whole or in part, as patents. Patent applications in the United States are maintained in secrecy until the patents are published or are issued. Since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we are the first creator of inventions covered by pending patent applications or the first to file patent applications on these inventions. We also cannot be certain that our pending patent applications will result in issued patents or that any of our issued patents will afford protection against a competitor. In addition, patent applications filed in foreign countries are subject to laws, rules and procedures that differ from those of the United States, and thus we cannot be certain that foreign patent applications related to U.S. patents will be issued. Furthermore, if these patent applications issue, some foreign countries provide significantly less effective patent enforcement than in the United States.

The status of patents involves complex legal and factual questions and the breadth of claims allowed is uncertain. Accordingly, we cannot be certain that the patent applications that we file will result in patents being issued, or that our patents and any patents that may be issued to us in the near future will afford protection against competitors with similar technology. In addition, patents issued to us may be infringed upon or designed around by others and others may obtain patents that we need to license or design around, either of which would increase costs and may adversely affect our operations.

We license certain patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects could be harmed.

We license rights to third-party intellectual property that is necessary or useful for our business, and we may enter into additional licensing agreements in the future. Our success could depend in part on the ability of some of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued with respect to these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we could. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Our two worldwide exclusive licenses, one from North Carolina State University (“NCSU”) and the other from National Research Council of Canada, Plant Biotechnology Institute in Saskatoon, Canada (“NRC”), each involve multiple patent

families. The exclusive rights under the NCSU agreement expires on the date on which the last patent or registered plant variety covered by the subject license expires in the country or countries where such patents or registered plant varieties are in effect. The NCSU license relates predominately to issued patents, and the NCSU license will expire in 2023. The exclusive rights under the NRC agreement expires on the date on which the last patent or covered by the subject license expires in the country or countries where such patents are in effect. The NRC license relates predominately to patent applications, and the NRC license will expire in 2028.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not develop or be sustained, and you may not be able to resell your shares at or above the price at which you purchased them.

An active trading market for our shares may never develop or be sustained. In the absence of an active trading market for our common stock, shares of common stock may not be able to be resold at or above the purchase price of such shares. Although there can be no assurances, we expect that our common stock will continue to be quoted on the OTC Bulletin Board, an over-the-counter quotation system, on which the shares of our common stock are currently quoted. However, even if our common stock continues to be quoted on the OTC Bulletin Board, it is unlikely that an active market for our common stock will develop in the foreseeable future. It may be more difficult to dispose of shares or obtain accurate quotations as to the market value of our common stock compared to securities of companies whose shares are traded on the NASDAQ Stock Market or other stock exchanges.

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

Our common stock is currently traded on the OTC Bulletin Board, and, therefore, the trading volume is currently more limited and sporadic than if our common stock were traded on a national stock exchange such as the NASDAQ Stock Market or the NYSE. Further, the market prices for securities in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

• results from and any delays in any clinical trials programs;

• failure or delays in entering potential products into clinical trials;

• failure or discontinuation of any of our research programs;

• delays in establishing new strategic relationships;

• delays in the development of our potential products and commercialization of our potential products;

• market conditions in our sector and issuance of new or changed securities analysts' reports or recommendations;

• general economic conditions, including recent adverse changes in the global financial markets;

• actual and anticipated fluctuations in our quarterly financial and operating results;

• developments or disputes concerning our intellectual property or other proprietary rights;

• introduction of technological innovations or new commercial products by us or our competitors;

• issues in manufacturing or distributing our products or potential products;

• market acceptance of our products or potential products;

• third-party healthcare reimbursement policies;

• FDA or other United States or foreign regulatory actions affecting us or our industry;

• litigation or public concern about the safety of our products or potential products;

• additions or departures of key personnel;

• third-party sales of large blocks of our common stock;

• sales of our common stock by our executive officers, directors or significant stockholders; and

• equity sales by us of our common stock or securities convertible into common stock to fund our operations.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

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

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

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

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

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

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

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

We are controlled by our current officers and directors.

As of January 22, 2013, our directors and executive officers as a group beneficially owned approximately 38% of the shares of our common stock. Accordingly, our directors and executive officers will have substantial influence over, and may have the ability to control, the election of our board of directors and the outcome of issues submitted to a vote of our stockholders.

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

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

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

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

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

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

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

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

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

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

Principal Stockholders

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

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Class Beneficially Owned (1)	
Management & Directors			
Joseph Pandolfino (2)	7,207,296	19.4	%
Henry Sicignano III (3)	5,859,927	16.0	%
Michael R. Moynihan, Ph.D. (4)	1,457,645	4.1	%
Joseph Alexander Dunn, Ph.D.(5)	175,000	*	
James W. Cornell (6)	175,000	*	
All directors and executive officers as a group (5 persons) (2)-(6)	14,874,868	37.9	%
Other 5% Owners			
Clearwater Partners, LLC (7)	5,144,279	14.0	%
Angelo J. Tomasello (8)	4,385,214	12.0	%
Sabby Volatility Warrant Master Fund, Ltd. (9)	2,500,000	7.1	%
Sabby Heathcare Volatility Master Fund, Ltd. (10)	3,506,098	9.9	%

(1) Based on 35,415,139 shares of common stock issued and outstanding (including outstanding restricted stock), as of January 22, 2013.

(2) Includes (a) 1,831,761 shares of common stock issuable to Mr. Pandolfino upon exercise of warrants and (b) 5,375,535 shares of common stock.

(3) Consists of (a) 2,027,603 shares of common stock held by Henry Sicignano III (including 550,000 restricted shares issued as equity incentive awards under the Company's Equity Incentive Plan), (b) 2,542,347 shares of common stock held by Henry Sicignano III Group, LLC, (c) 389,564 shares of common stock issuable to Mr. Sicignano upon exercise of warrants, (d) 100,000 shares of common stock issuable to Mr. Sicignano upon exercise of stock options and (e) 800,413 shares of common stock issuable to Henry Sicignano III Group, LLC upon exercise of warrants. Mr. Sicignano is Managing Member of Henry Sicignano III Group, LLC and, accordingly, exercises voting and investment power with respect to the shares held by Henry Sicignano III Group, LLC. 450,000 of the shares issued to Mr. Sicignano under the Company's Equity Incentive Plan are time-based awards subject to vesting on April 1 of 2013, 2014 and 2015, such that 150,000 shares shall vest on April 1 of each such year. Mr. Sicignano also holds 100,000 performance based shares of restricted stock issued as equity incentive awards under the Company's Equity Incentive Plan, which are subject to forfeiture unless certain performance milestones are achieved.

(4) Includes (a) 963,934 shares of common stock, (b) 393,711 shares of common stock issuable upon exercise of warrants and (c) 100,000 shares issuable upon the exercise of stock options.

(5) Includes (a) 85,000 shares of common stock, (b) 30,000 shares of common stock issuable upon exercise of warrants and (c) 60,000 shares issuable upon the exercise of stock options.

(6) Includes (a) 85,000 shares of common stock, (b) 30,000 shares of common stock issuable upon exercise of warrants and (c) 60,000 shares issuable upon the exercise of stock options.

(7) Includes (a) 3,905,515 shares of common stock and (b) 1,238,764 shares of common stock issuable upon exercise of warrants. Richard G. Saffire, Managing Member of Clearwater Partners, LLC exercises voting and investment power with respect to shares owned by Clearwater Partners, LLC. The address of Clearwater Partners, LLC is 34 Sunburst Circle, East Amherst, New York 14051.

(8) Includes (a) 3,301,909 shares of common stock, (b) 1,044,972 shares of common stock issuable upon exercise of warrants and (c) 38,333 shares of common stock issuable upon conversion of convertible notes. The address of Angelo Tomasello is 4720 Spaulding Drive, Clarence, New York 14031.

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

(10) Consists of shares of common stock issuable upon the conversion of an aggregate of 2,000 shares of Series A-1 Preferred Stock and upon the exercise of Warrants. The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of our outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). However, the 9.99% limitation would not prevent a selling stockholder from acquiring and selling in excess of 9.99% of our common stock through a series of acquisitions and sales while never beneficially owning more than 9.99% in aggregate. Sabby Management, LLC serves as the investment manager of Sabby Healthcare Volatility Master Fund, Ltd. and, as such, Sabby Management, LLC shares voting and investment powers with respect to these shares on behalf of Sabby Healthcare Volatility Master Fund, Ltd. The address for Sabby Healthcare Volatility Master Fund, Ltd. is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. As manager of Sabby Management, LLC, Hal

Mintz also shares voting and investment power on behalf of Sabby Healthcare Volatility Master Fund, Ltd. Each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over the securities covered by this prospectus except to the extent of their pecuniary interest therein.

Selling Stockholders

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

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

This prospectus relates to the resale by the selling stockholders from time to time of up to an aggregate of 27,500,000 shares that are issuable to the selling stockholders. Pursuant to a Registration Rights Agreement between us and the selling stockholders, this prospectus covers the resale of 200% of the number of shares currently issuable (i) upon conversion of our Series A-1 Preferred Stock, (ii) as dividend payments on our Series A-1 Preferred Stock (at our option), and (iii) upon the exercise of Series A Warrants, Series B Warrants, and Series C Warrants. We agreed to register 200% of the number of shares initially issuable due to the potential adjustments to the conversion price and certain anti-dilution features that are described in the section entitled “Description of Securities.” We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Series A Warrants, Series B Warrants, and Series C Warrants, if exercised for cash.

The table below, which was prepared based on information supplied to us by the selling stockholders, sets forth information regarding the beneficial ownership of outstanding shares of our common stock owned by the selling stockholders and the shares that they may sell or otherwise dispose of from time to time under this prospectus. Each of the selling stockholders, or their respective affiliates, transferees, donees or their successors, may resell, from time to time, all, some or none of the shares of our common stock covered by this prospectus, as provided in this prospectus under the section entitled “Plan of Distribution” and in any applicable prospectus supplement. However, we do not know when, in what amount, or at what specific prices the selling stockholders may offer their shares for sale under this prospectus, if any. Each selling stockholder’s percentage of ownership in the following table is based upon 35,415,139 shares of our common stock outstanding as of January 22, 2013.

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

Selling Stockholder Name	Beneficially Owned Prior to Offering			Shares of Common Stock that may be Offered and Sold Hereby (3)		Beneficially Owned After Offering	
	Number of Shares of Common Stock (1), (2)	Percentage				Number of Shares	Percent
Sabby Volatility Warrant Master Fund, Ltd.	2,500,000	7.1	%	5,500,000	(4)	0	0
Sabby Healthcare Volatility Master Fund, Ltd.	3,506,098	9.9	%	22,000,000	(5)	0	0

(1) Includes all shares beneficially owned by the selling stockholders as of January 22, 2013.

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

(3) We have assumed (i) that each share of Series A-1 Preferred Stock is convertible into shares of common stock at a conversion price of $0.60 per share of common stock and (ii) that each Warrant is exercisable at its initial exercise price, without adjustment. We have also assumed the payment of dividends on the Series A-1 Preferred Stock is paid in shares of common stock instead of cash, which is at our option, at an assumed price of $0.60 per share for a period of three years, resulting in the issuance of 1,250,000 shares. In order to adequately cover the number of shares required due to adjustments and anti-dilution features and pursuant to a Registration Rights Agreement between us and the selling stockholders, this prospectus covers the resale of 200% of such shares.

(4) Includes 200% of (i) the 833,333 shares of common stock currently issuable upon conversion of the 500 shares of the Series A-1 Preferred Stock held by this selling stockholder, (ii) 833,333 shares of common stock currently issuable upon exercise of the Series A Warrant at $0.72 per share, (iii) 416,667 shares currently issuable upon exercise of the Series B Warrant at $0.60 per share, (iv) 416,667 shares of common stock currently issuable upon exercise of the Series C Warrant at $0.72 per share (1,666,667 in the aggregate for all three Warrants), and (v) 250,000 shares of common stock currently issuable as dividends. The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of our outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). However, the 9.99% limitation would not prevent a selling stockholder from acquiring and selling in excess of 9.99% of our common stock through a series of acquisitions and sales while never beneficially owning more than 9.99% in aggregate. Sabby Management, LLC shares voting and investment power with respect to these shares on behalf of this stockholder. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of this stockholder. Each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over the securities covered by this prospectus except to the extent of their pecuniary interest therein.

(5) Includes 200% of (i) 3,333,333 shares of common stock currently issuable upon conversion of the 2,000 shares of the Series A-1 Preferred Stock held by this selling stockholder, (ii) 3,333,333 shares of common stock currently issuable upon exercise of the Series A Warrant at $0.72 per share, (iii) 1,666,667 shares currently issuable upon exercise of the Series B Warrant at $0.60 per share, (iv) 1,666,667 shares of common stock currently issuable upon exercise of the Series C Warrant at $0.72 per share (6,666,667 in the aggregate for all three Warrants), and (v) 1,000,000 shares of common stock currently issuable as dividends. The Series A-1 Preferred Stock and the Warrants contain exercise and conversion limitations providing that a holder thereof may not convert or exercise (as the case may be) to the extent that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 9.99% of our outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). However, the 9.99% limitation would not prevent a selling stockholder from acquiring and selling in excess of 9.99% of our common stock through a series of acquisitions and sales while never beneficially owning more than 9.99% in aggregate. Sabby Management, LLC shares voting and investment power with respect to these shares on behalf of this stockholder. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of this stockholder. Each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over the securities covered by this prospectus except to the extent of their pecuniary interest therein.

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Use of Proceeds

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

Dividend Policy

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

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

Determination of Offering Price

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

Market for Common Equity and Related Stockholder Matters

Our common stock is quoted on the OTC Bulletin Board under the symbol "XXII.OB." As of January 22, 2013, there were 63 holders of record of shares of our common stock. The following table sets forth, for the quarters indicated, the high and low bid prices per share of our common stock, as derived from quotations provided by the OTC Bulletin Board Information Center.

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

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

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

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

Shares Authorized for Issuance Under Equity Compensation Plans

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

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

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

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

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

Business

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

References to the "Company," "we," us" or "our" refer to the operations of 22nd Century Group, Inc. and its direct and indirect subsidiaries for the periods described herein.

Background

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

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

Overview

22nd Century Limited, LLC, our wholly-owned subsidiary, is a plant biotechnology company focused on tobacco harm reduction and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding. The Company exclusively controls 107 issued patents and exclusively controls an additional 38 patent applications; of these, we own 12 issued patents plus 23 patent applications and we license on an exclusive basis, 95 issued patents and 15 patent applications. Hercules Pharmaceuticals LLC and Goodrich Tobacco Company, LLC are subsidiaries of 22nd Century Limited, LLC and are business units for our (i) smoking cessation product and (ii) premium cigarettes and modified risk tobacco products, respectively.

Our Investigational New Drug Application for *X-22*, a kit of very low nicotine (VLN) cigarettes, was cleared by the FDA in July 2011. Our *X-22* Phase II-B clinical trial was completed in the first quarter of 2012 and did not demonstrate a statistically significant difference in quitting between *X-22* and the active control, a cigarette containing conventional nicotine levels. In evaluating the results of this trial, we believe we may have gone too far in reducing the nicotine content of *X-22*, which was less than half the nicotine content of VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases smoking quit rates.

We continue to believe that VLN cigarettes are effective as a smoking cessation aid. However, we have suspended sponsoring further *X-22* clinical trials pending the results of two independent smoking-cessation trials (ClinicalTrials.gov Identifiers NCT01050569 and NCT01250301) utilizing a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than that used in our own sponsored Phase II-B trial. Both of these two independent clinical trials were completed in 2012. The results of these trials will be compared to our Phase II-B trial to determine which variables optimize cessation. After evaluating the results of those two independent clinical trials, we will request a meeting with the U.S. Food and Drug Administration (FDA) and may then resume our own sponsored *X-22* clinical trials.

The *X-22* therapy protocol calls for the patient to smoke our VLN cigarettes over a six-week treatment period to facilitate the goal of the patient quitting smoking by the end of the treatment period. We believe this therapy protocol has been successful in independent clinical trials because VLN cigarettes made from our proprietary tobacco satisfy smokers' cravings for cigarettes while (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine. *X-22* involves the same smoking behavior as conventional cigarettes and because patients are simply switching to VLN cigarettes for 6 weeks, *X-22* does not expose the smoker to any new drugs or new side effects.

In contrast to the results of the Company's Phase II-B trial results, independent studies have demonstrated that VLN cigarettes made whether used alone or in conjunction with nicotine replacement therapy (NRT), increased quitting. Due to the limited effectiveness and/or serious side effects of existing FDA-approved smoking cessation products, we believe that *X-22*, upon the completion of additional clinical trials that demonstrate efficacy, can capture a significant share of this market by replacing sales and market share from existing smoking cessation aids and expanding the smoking cessation market by encouraging more smokers to attempt to quit smoking.

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