22nd Century Group, Inc.
Form S-1
April 11, 2011

As filed with the Securities and Exchange Commission on April 8, 2011

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.)

8201 Main Street, Suite 6
Williamsville, New York 14221
(716) 270-1523
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Joseph Pandolfino
Chief Executive Officer
22nd Century Group, Inc.
8201 Main Street, Suite 6
Williamsville, New York 14221
(716) 270-1523
(Address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

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

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the number of shares of common stock registered hereby is subject to adjustment to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of determining the amount of the registration fee, based on the average of the high and low sale prices of the common stock as reported by the OTC Bulletin Board on April 6, 2011 in accordance with Rule 457(o) under the Securities Act of 1933.

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 APRIL 8, 2011

PROSPECTUS

22nd CENTURY GROUP, INC.

5,434,446 Shares of Common Stock

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

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

Our common stock is traded on the OTC Bulletin Board under the symbol "XXII.OB". On April 6, 2011, the closing sale price of our common stock was $1.25 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 April 8, 2011

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

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PROSPECTUS SUMMARY

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

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

Our Company

Overview

We are a plant biotechnology company and a global leader in modifying the content of nicotinic alkaloids in tobacco plants through genetic engineering and plant breeding. The Company owns or exclusively controls 98 issued patents in 79 countries where at least 75% of the world's smokers reside. We believe that our proprietary technology will enable us to capture a significant share of the global market for approved smoking cessation aids and the emerging market for modified risk tobacco products.

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

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

The 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") granted the FDA authority over the regulation of all tobacco products. While it prohibits the FDA from banning cigarettes outright, it allows the

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

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

We believe that two of our cigarette products, which we refer to as BRAND A and BRAND B, will qualify as Modified Risk Cigarettes. Compared to other commercial cigarettes, the tobacco in BRAND A has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes, and BRAND B's smoke contains the lowest amount of "tar" per milligram of nicotine.

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

Smoking Cessation Aids

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

Modified Risk Cigarettes

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

RED SUN and MAGIC Cigarettes

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

Government Research Cigarettes

The National Institute on Drug Abuse ("NIDA"), a component of the National Institutes of Health ("NIH"), provides the scientific community with controlled and uncontrolled research chemicals and drug compounds in its Drug Supply Program. In 2009, NIDA included an option to develop and produce research cigarettes with ten different levels of nicotine, including a minimal (placebo) level, or Research Cigarette Option, in its request for proposals for a five (5)-year contract for Preparation and Distribution of Research and Drug Products. We have agreed, as a subcontractor

to RTI International ("RTI") in RTI's contract with NIDA for the Research Cigarette Option, to supply modified nicotine cigarettes to NIDA. In August 2010, we met with officials from NIDA, FDA, RTI, the National Cancer Institute and the Centers for Disease Control and Prevention to finalize certain aspects of the design of these research cigarettes. These research cigarettes will be distributed under the mark SPECTRUM.

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

Technology Platform and Intellectual Property

Our proprietary technology enables us to decrease or increase the level of nicotine in tobacco plants by decreasing or increasing the expression of gene(s) responsible for nicotine production in the tobacco plant using genetic engineering. For example, one of our proprietary tobacco varieties contains the lowest nicotine content of any tobacco ever commercialized, with approximately 95% less nicotine than tobacco in leading "light" cigarette brands. This proprietary tobacco grows with virtually no nicotine without adversely affecting the other leaf constituents important to a cigarette's characteristics, including taste and aroma.

Our proprietary technology is covered by 12 patent families consisting of 98 issued patents in 79 countries, and approximately 43 pending patent applications, which are either owned by or exclusively licensed to us. A "patent family" is a set of patents granted in various countries to protect a single invention. Our patent coverage in the United States, the most valuable smoking cessation market and cigarette market, consists of 14 issued patents and 6 pending applications. In China, the world's largest cigarette market, we exclusively control 5 issued patents and 3 pending patent applications. We have exclusive worldwide rights to all uses of the following genes responsible for nicotine content in tobacco plants: QPT, A622, NBB1, MPO and genes for several transcription factors. We have exclusive rights to plants with altered nicotine content produced from modifying expression of these genes and tobacco products produced from these plants. We also have the exclusive right to license and sublicense these patent rights. The patents owned by or exclusively licensed to us are issued in countries where at least 75% of the world's smokers reside.

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

Recent Developments

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

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

Prior to the closing of the Merger, we transferred all of our pre-Merger operating assets and liabilities pursuant to the terms of a split-off agreement (the "Split-Off Agreement"), to our wholly-owned subsidiary, Touchstone Split Corp., a Delaware corporation (the "Split-Off Subsidiary"). Thereafter, pursuant to the Split-Off Agreement, we transferred all

of the outstanding capital stock of the Split-Off Subsidiary to our then-sole director in exchange for $1.00, such consideration being deemed to be adequate by our pre-Merger Board of Directors (the "Board").

At the closing of the Merger, each limited liability company membership interest of 22nd Century issued and outstanding immediately prior to the closing of the Merger was exchanged for one (1) share of our common stock, and each warrant to purchase limited liability company membership interests of 22nd Century was exchanged for one warrant of like tenor and term to purchase shares of our common stock. An aggregate of 21,434,446 shares of common stock and warrants to purchase an aggregate of 8,151,980 shares of common stock were issued to the holders of Units and warrants, respectively, of 22nd Century, and immediately following the closing of the Merger an aggregate of 26,759,646 shares of common stock were issued and outstanding and an aggregate of 8,651,980 shares are common stock were reserved for issuance pursuant to the exercise of warrants to purchase shares of common stock.

In connection with the Merger, our Board was expanded to five (5) members. The sole officer and sole member of the Board prior to the closing of the Merger, David Rector, resigned as an officer and a director after the closing of the Merger. The current members of our Board are Joseph Pandolfino, Henry Sicignano III, Joseph Alexander Dunn, Ph.D., James W. Cornell and Steven Katz. Messrs. Cornell and Katz and Dr. Dunn qualify as "independent" directors under the applicable definition of the NASDAQ Global Market ("NASDAQ") listing standards, so that a majority of the Company's Board members are "independent." Although the Company's securities are not currently traded on the NASDAQ or any other exchange, which would require that the Company's Board include a majority of directors that are "independent," the Company has elected to do so anyhow as part of its corporate governance policies. Our current executive officers are Joseph Pandolfino, Chief Executive Officer, Henry Sicignano III, President and Secretary, Michael R. Moynihan, Ph.D., Vice President of Research & Development, and C. Anthony Rider, Chief Financial Officer and Treasurer. Each of Messrs. Pandolfino, Sicignano and Rider were executive officers of 22nd Century prior to the closing of the Merger.

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

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

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

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

Corporate Information

We were incorporated under the laws of the State of Nevada on September 12, 2005 under the name Touchstone Mining Limited. We changed our name to 22nd Century Group, Inc. on November 23, 2010 in anticipation of the Merger with 22nd Century. Our principal executive offices are located at 8201 Main Street, Suite 6, Williamsville, New York 14221. 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.

The Offering

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

(1) As of April 1, 2011
(2) Assumes that all other outstanding warrants and options are not exercised

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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.

Recurring losses from operations, our negative working capital of approximately $4.1 million as of December 31, 2010 (approximately $3.2 million at December 31, 2009), members' deficit of $2.1 million as of December 31, 2010 ($1.8 million at December 31, 2009) and the uncertainty of obtaining additional financing on a timely basis, raise doubt about our ability to continue as a going concern. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2010, includes an emphasis of a matter paragraph expressing substantial doubt whether we can continue as a going concern. Even in light of our receipt of the proceeds of the Private Placement Offering, we cannot guarantee our ability to continue as a going concern.

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

We experienced net losses of approximately $1.4 million during the year ended December 31, 2010 and $1.2 million and $0.74 million in the years 2009 and 2008, 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 have achieved limited revenue of product sales. We will need to spend significant capital to fulfill planned operating goals and conduct clinical studies, achieve regulatory approvals and, subject to such approvals, successfully produce products for commercialization. In addition, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company.

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

We had negative cash flow before financing activities of approximately $1,018.000, $172,000 and $762,000 in the years 2010, 2009 and 2008, respectively. We anticipate that we will continue to have negative cash flow for the foreseeable future as we will continue to incur increased expenses from seeking regulatory approvals, including clinical trials and exposure studies, sales and marketing, and general and administrative expenses, as well as to purchase inventory. Our business will also require significant amounts of working capital to support our growth. Therefore, we may need to raise additional investment capital to achieve growth, and we may not achieve sufficient revenue growth to generate positive future cash flow. An inability to generate positive cash flow for the foreseeable future or raise additional capital on reasonable terms may decrease our long-term viability.

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

We have been in existence since 1998, but our activities have been limited primarily to licensing and funding research and development activities. Our limited operating history may make it difficult to evaluate our current business and our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced

by growing companies in rapidly changing industries, including increasing expenses as we continue to grow our business. If we do not manage these risks successfully, our business will be harmed.

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

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

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

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

The net proceeds of the Private Placement Offering will not be sufficient to enable us to complete the FDA approval process for our X-22 smoking cessation product and the FDA authorization process for our Modified Risk Cigarettes.

We will require additional capital in the future beyond the net proceeds of the Private Placement Offering to complete the FDA approval process for our X-22 smoking cessation product and the FDA authorization process for our Modified Risk Cigarettes, and we may not be able to obtain additional debt or equity financing on favorable terms, if at all. If we raise additional funds through the issuance of equity securities, our stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. We also could elect to seek funds through arrangements with collaborators. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to us.

Due to market conditions and the status of our product development activities, additional funding may not be available to us on acceptable terms, or at all. Having insufficient funds may require us to delay, scale back or eliminate some or all of our clinical programs or to relinquish greater rights to potential products at an earlier stage of development or on less favorable terms than we would otherwise choose. Our failure to raise additional financing would adversely affect our ability to maintain, develop, enhance or grow our business, take advantage of future opportunities or respond to competitive pressures. If we cannot raise additional capital on acceptable terms, we may not be able to, among other things:

- continue or complete clinical trials of our X-22 smoking cessation aid;
- continue or complete 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.

Continued instability in the credit and financial market conditions may negatively impact our business, results of operations, and financial condition.

Financial markets in the United States, Canada, Europe and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be reduced and local governments and many businesses are still in serious difficulty due to the lack of consumer spending and the lack of liquidity in the credit markets. As a clinical-stage biotechnology company, we rely on third parties for several important aspects of our business, including the supply of tobacco, manufacturing and distribution of our products, development of our potential products, and conduct of our clinical trials. Such third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business. The continued instability in the credit and financial market conditions may also negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of the adverse conditions in the United States and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

We will depend on the success of our X-22 smoking cessation aid and our Modified Risk Cigarettes and we may not be able to successfully commercialize these potential products.

Our goal is to develop products whose potential for risk reduction can be substantiated and that meet adult smokers' taste expectations. We may not succeed in these efforts. If we do not succeed, but one or more of our competitors do, we may be at a competitive disadvantage. The success of our business depends in part on our ability to obtain FDA approval for our X-22 smoking cessation aid and FDA authorization under the Tobacco Control Act to market our BRAND A and BRAND B cigarettes as Modified Risk Cigarettes. We have not obtained approval to market X-22 in any jurisdiction, nor have we obtained authorization to market our BRAND A or BRAND B cigarettes as Modified Risk Cigarettes, and we cannot predict whether we will be able to obtain such approval or authorizations, or if regulators will permit the marketing of tobacco products with claims of reduced risk to consumers. Any failure to obtain such approval or authorizations would significantly undermine the commercial viability of the applicable product. If we fail to successfully commercialize these products in the United States, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, results of operations and cash flows will be adversely affected.

We will depend on third parties to manufacture our products.

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

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

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

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

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

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

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

- limitations on the indications for use for which X-22 may be marketed ;
- the establishment and demonstration in the medical community of the clinical efficacy and safety of our 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/or
- sufficient third-party coverage or reimbursement.

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

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

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

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

Cigarette companies compete primarily on the basis of product quality, brand recognition, brand loyalty, taste, innovation, packaging, service, marketing, advertising, retail shelf space and price. We are subject to highly competitive conditions in all aspects of our business and we may not be able to effectively market and sell our RED SUN and MAGIC cigarettes or other cigarettes we may introduce to the market, even if we are able to market our BRAND A and BRAND B cigarettes as Modified Risk Cigarettes. 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, Reynolds American Inc., Lorillard Inc., Commonwealth Brands, Inc., Liggett Group LLC, Vector Tobacco Inc. and Star Scientific Inc. International competitors include Philip Morris International, British American Tobacco, Japan Tobacco Inc. and regional and local tobacco companies; and, in some instances, government-owned tobacco enterprises, principally in China, Egypt, Thailand, Taiwan, Vietnam and Algeria.

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

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

- develop and market products that are less expensive or more effective than our proposed products;
- commercialize competing products before we or our partners can launch our proposed products;
- operate larger research and development programs or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

In addition, if we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages that we believe we derive from our research approach and proprietary technologies.

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

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

We may not be able to successfully recruit and retain skilled employees, particularly scientific, technical and management professionals.

We believe that our future success will depend in large part on our ability to attract and retain highly skilled technical, managerial and marketing personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to retain sufficient scientific, technical and managerial personnel or quickly recruit and attract qualified replacements could limit or delay our product development efforts, which could adversely affect the development and commercialization of our potential products and growth of our business. This competition will intensify if the smoking cessation market continues to grow and if a market for Modified Risk Cigarettes develops. We compete in the market for personnel against numerous companies, including larger, more established competitors who have significantly greater financial resources than we do and may be in a better financial position to offer higher compensation packages to attract and retain human capital. We cannot be certain that we will be successful in attracting and retaining the skilled personnel

necessary to operate our business effectively in the future.

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

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

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

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

The risk of product liability claims or product recalls, and associated adverse publicity, is inherent in the development, manufacturing, marketing and sale of cigarettes and smoking cessation products. We do not currently have product liability insurance for our products or our potential products and do not expect to be able to obtain product liability insurance at reasonable commercial rates for these products. Any product recall or lawsuit seeking significant monetary damages may have a material adverse affect 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.

We may be unable to complete or integrate acquisitions effectively, which may adversely affect our growth, profitability and results of operations.

We may pursue acquisitions as part of our business strategy. However, we cannot be certain that we will be able to identify attractive acquisition targets, obtain financing for acquisitions on satisfactory terms or successfully acquire identified targets. Additionally, we may not be successful in integrating acquired businesses into our existing operations or achieving projected synergies. Competition for acquisition opportunities in the industries in which we operate may rise, thereby increasing our costs of making acquisitions or causing us to refrain from making further acquisitions. These and other acquisition-related factors could negatively and adversely impact our growth, profitability and results of operations.

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 ("EMA"), 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. 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, EMA 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 if we are able to demonstrate reduced exposure to certain tobacco smoke toxins, the FDA may decide that allowing a reduced 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. The FDA may prevent us from selling BRAND A or BRAND B or both products in the U.S. market before the FDA makes a determination of whether to authorize us to market our BRAND A 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.

If we fail to comply with extensive regulations enforced by the FDA and other agencies, the commercialization of our potential products could be prevented, delayed or halted.

Clinical trials and the manufacturing and marketing of X-22, BRAND A and BRAND B are subject to extensive regulation by various government authorities. We have not received marketing approval for our X-22 smoking cessation aid, nor have we applied for or received FDA authorization to market BRAND A or BRAND B cigarettes as Modified Risk Cigarettes. The process of obtaining FDA and other required regulatory approvals and authorizations is lengthy and expensive, and the time required for such approvals and authorizations is uncertain. The processes are affected by such factors as:

- the severity of the disease involved;
- the quality of submissions relating to the potential product;
- the potential product's clinical efficacy and safety;
- the strength of the chemistry and manufacturing control of the process;
- the manufacturing facility's compliance;
- the availability of alternative treatments;
- the risks and benefits demonstrated in clinical trials; and
- the patent status and marketing exclusivity rights of certain innovative products.

Any regulatory approval or authorization that we receive for our potential products may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The subsequent discovery of previously unknown problems with the product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product and/or withdrawal of the product from the market.

Manufacturing, labeling, storage and distribution activities in the United States also are subject to strict regulation and licensing by the FDA. The manufacturing facilities for biopharmaceutical products and tobacco products are subject to periodic inspection by the FDA and other regulatory authorities and from time to time, these agencies may send notice of deficiencies as a result of such inspections. Our failure, or the failure of our contractors' manufacturing facilities, to continue to meet regulatory standards or to remedy any deficiencies could result in corrective action by the FDA or these other authorities, including the interruption or prevention of marketing, closure of our contractors' manufacturing facilities, and fines or penalties.

Regulatory authorities also could require post-marketing surveillance to monitor and report to the FDA potential adverse effects of our potential products. The U.S. Congress or the FDA in specific situations can modify the regulatory process. If approved, any of our potential products' subsequent failure to comply with applicable regulatory requirements could, among other things, result in warning letters, fines, suspension or revocation of regulatory

approvals, product recalls or seizures, operating restrictions, injunctions and criminal prosecutions.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our potential products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action. If we are not able to maintain regulatory compliance, we might not be permitted to market our potential products and our business could suffer.

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

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

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

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

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

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

The trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our potential products which could adversely affect our business, financial condition, results of operations and cash flows.

In addition, legislation and regulations affecting the pricing of our potential products may change in ways adverse to us before or after the FDA or other regulatory agencies approve any of our potential products for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory

agency adopts these proposals, they could materially adversely affect our business, financial condition, results of operations and cash flows.

We could be negatively impacted by the application or enforcement of federal and state fraud and abuse laws, including anti-kickback laws and other federal and state anti-referral laws.

We will need to establish a program to ensure compliance with all potentially applicable laws in connection with the development, manufacturing, marketing and sales of our potential products. For example, all product marketing efforts must be strictly scrutinized to assure that they are not associated with improper remunerations to referral sources in violation of the federal Anti-Kickback Statute and similar state statutes. Remunerations may include potential future activities for our potential products, including discounts, rebates and bundled sales, which must be appropriately structured to take advantage of statutory and regulatory "safe harbors." From time to time, we may engage physicians in consulting activities. In addition, we may decide to sponsor continuing medical education activities for physicians or other medical personnel. We also may award or sponsor study grants to physicians from time to time. All relationships with physicians, including consulting arrangements, continuing medical education and study grants, must be similarly reviewed for compliance with the Anti-Kickback Statute to assure that remuneration is not provided in return for referrals. Patient inducements may also be unlawful. Inaccurate reports of product pricing, or a failure to provide product at an appropriate price to various governmental entities, could also serve as a basis for an enforcement action under various theories.

Claims which are "tainted" by virtue of kickbacks or a violation of self-referral rules may be alleged as false claims if other elements of a violation are established. The federal False Claims Act, which includes a provision allowing whistleblowers to bring actions on behalf of the federal government and receive a portion of the recovery, applies to those who submit a false claim and those who cause a false claim to be submitted. Because our potential customers may seek payments from the federal healthcare programs for our potential products, even during the clinical trial stages, we must ensure that we take no actions which could result in the submission of false claims. For example, free product samples which are knowingly or with reckless disregard billed to the federal healthcare programs could constitute false claims. If the practice was facilitated or fostered by us, we could be liable. Similarly, inadequate accounting for or a misuse of any federal grant funds used for product research and development could be alleged as a violation of the False Claims Act or other relevant statutes.

The risk of us being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Significant delays in clinical testing could materially increase our product development costs. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence and continue a study, delays in reaching agreement on acceptable clinical study terms with prospective sites, delays in obtaining institutional review board approval to conduct a study at a prospective site and delays in recruiting patients to participate in a study.

In addition, we plan to rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to oversee the operations of these clinical trials and to perform data collection and analysis. As a result, we may face additional delays outside of our control if these parties do not perform their obligations in a timely fashion. Significant delays in testing or regulatory approvals or authorizations for any of our current or future potential products, including our X-22 smoking cessation aid or our BRAND A and BRAND B cigarettes as Modified Risk Cigarettes, could prevent or cause delays in the commercialization of such potential products, reduce potential revenues from the sale of such potential products and cause our costs to increase.

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

cease our trials.

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

The use of hazardous materials in our operations may subject us to environmental claims or liabilities.

Our research and development activities involve the use of hazardous materials. Injury or contamination from these materials may occur and we could be held liable for any damages, which could exceed our available financial resources. This liability could materially adversely affect our business, financial condition, results of operations and cash flows.

We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We may be required to incur significant costs to comply with environmental laws and regulations in the future that could materially adversely affect our business, financial condition, results of operations and cash flows.

The degree of public acceptance or perceived public acceptance of our genetically modified tobacco may affect our sales and operations.

Some opponents of genetically modified crops have actively raised public concern about the potential adverse effects these crops, and the products made from them, may have on human and animal health, other plants, and the environment. Public concern may affect the timing of, and whether we are able to obtain, government approvals. Even after approvals are granted, public concern may lead to increased regulation or legislation, which could affect our sales and profitability, and may adversely affect sales of our products, due to concerns about products derived from biotechnology. In addition, opponents of agricultural biotechnology have attacked farmers' fields and facilities used by agricultural biotechnology companies, and may launch future attacks against farmers' fields and our research, production or other facilities, which could affect our sales and our costs.

Risks Related to the Tobacco Industry

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

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

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

Significant regulatory developments will take place over the next few years in many markets, driven principally by the World Health Organization's Framework Convention on Tobacco Control ("FCTC"). The FCTC is the first international public health treaty on tobacco, and its objective is to establish a global agenda for tobacco regulation with the purpose of reducing initiation of tobacco use and encouraging cessation. In addition, the FCTC has led to increased efforts by tobacco control advocates and public health organizations to reduce the palatability and appeal of tobacco products. Partly because of some or a combination of these efforts, unit sales of tobacco products in certain markets,

principally Western Europe and Japan, have been in general decline and we expect this trend to continue. Our operating results could be significantly affected by any significant decrease in demand for cigarettes, any significant increase in the cost of complying with new regulatory requirements and requirements that lead to a commoditization of tobacco products.

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 our BRAND A and BRAND B cigarettes. Legal proceedings covering a wide range of matters related to tobacco use are pending or threatened in various U.S. and foreign jurisdictions. Various types of claims are raised in these proceedings, including product liability, consumer protection, antitrust, tax, contraband shipments, patent infringement, employment matters, claims for contribution and claims of competitors and distributors.

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

Damages claimed in some tobacco-related litigation are significant and, in certain cases range into the billions of dollars. We anticipate that new cases will continue to be filed. The FCTC encourages litigation against tobacco product manufacturers. It is possible that our results of operations, cash flows or financial position could be materially affected by an unfavorable outcome or settlement of litigation, whether or not we are a party to such litigation.

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

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

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

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

Risks Related to Intellectual Property

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

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our technologies, products and potential products. We will only be able to protect our technologies, products and potential

products from unauthorized use by third parties to the extent that valid and enforceable patents cover them, or other market exclusionary rights apply.

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

Our issued patents may be subject to challenge and possibly invalidated by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property.

In addition, others may independently develop similar or alternative products and technologies that may be outside the scope of our intellectual property. Should third parties obtain patent rights to similar products or technology, this may have an adverse effect on our business.

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

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

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

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

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

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

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management's attention from our core business strategy;

- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- a court order prohibiting us from commercializing our potential products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our potential products to market.

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

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

We own or exclusively control 98 issued patents in 79 countries. In addition, we also have approximately 43 pending patent applications. We cannot assure you these patent applications will issue, in whole or in part, as patents. Patent applications in the United States are maintained in secrecy until the patents are published or are issued. Since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we are the first creator of inventions covered by pending patent applications or the first to file patent applications on these inventions. We also cannot be certain that our pending patent applications will result in issued patents or that any of our issued patents will afford protection against a competitor. In addition, patent applications filed in foreign countries are subject to laws, rules and procedures that differ from those of the United States, and thus we cannot be certain that foreign patent applications related to U.S. patents will be issued. Furthermore, if these patent applications issue, some foreign countries provide significantly less effective patent enforcement than in the United States.

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

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

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

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

We are currently in payment default for certain patent-related costs pursuant to the terms of our exclusive worldwide license agreement with North Carolina State University ("NCSU"), dated as of March 6, 2009, (the "License Agreement"). We are required to reimburse NCSU for such patent-related costs within 30 days of being invoiced, and a portion of such reimbursements have become past due mainly as a result of (i) an interference proceeding invoked by the U.S. Patent and Trademark Office between NCSU and a former licensee of 22nd Century and (ii) an arbitration proceeding brought by 22nd Century against the same former licensee. Both of these actions involved the License Agreement. 22nd Century at its sole option decided to defend NCSU in this patent interference and pay all related expenses including legal fees. This resulted in NCSU obtaining international rights to a patent family that was incorporated into the License Agreement, thereby mutually benefiting NCSU and 22nd Century. Separately, the arbitration decision was decisively in 22nd Century's favor containing multiple awards to 22nd Century, some of which also benefited NCSU since its technology was involved in the proceeding. The arbitration award was not disputed and was fulfilled by the defendant in its entirety in 2009. We believe the results of both of these actions, the interference proceeding and arbitration proceeding, greatly benefited NCSU and 22nd Century beyond 22nd Century's cumulative net cost of these actions which was approximately $800,000. Consequently, as of March 31, 2011, the balance we owed to NCSU for these patent-related costs was approximately $740,000, after our $400,000 payment in February 2011. We have entered into negotiations with NCSU regarding the timing of payment for the balance. We have not received any termination notice from NCSU, however, NCSU may have the right to terminate the License Agreement upon 60 days prior written notice, which includes the opportunity for us to cure the payment default within this timeframe. The intellectual property licensed to us under the License Agreement is crucial to our business and, if NCSU chooses to invoke any right it may have to terminate the License Agreement and we are unable to cure the default, our business would be materially and adversely affected.

Risks Related to Ownership of Our Common Stock

The Securities issued in the Merger are "restricted securities" and, as such, may not be sold except in limited circumstances.

None of the shares of common stock or warrants issued in the Merger or the shares of common stock issuable upon exercise of such warrants, which we refer to collectively as the "Securities," have been registered under the Securities Act, or registered or qualified under any state securities laws. The Securities were sold and/or issued pursuant to exemptions contained in and under those laws. Accordingly, the Securities are "restricted securities" as defined in Rule 144 under the Securities Act and must, therefore, be held indefinitely unless registered under applicable federal and state securities laws, or an exemption from the registration requirements of those laws is available. The securities purchase agreements, warrants and certificates representing the Securities contain legends reflecting their restricted status.

Although we are required to register the shares of common stock issued to the investors in the Private Placement Offering in exchange for the 22nd Century limited liability company membership interests included in the Units purchased by such investors in the Private Placement Offering, we cannot assure that the SEC will declare the registration statement effective, thereby enabling the shares of common stock to be freely tradable. Rule 144 under the Securities Act, which permits the resale, subject to various terms and conditions, of limited amounts of restricted securities after they have been held for six months will not immediately apply to our common stock because we were at one time designated as a "shell company" under SEC regulations. Pursuant to Rule 144(i), securities issued by a current or former shell company that otherwise meet the holding period and other requirements of Rule 144 nevertheless cannot be sold in reliance on Rule 144 until one year after the date on which the issuer filed current "Form 10 information" (as defined in Rule 144(i)) with the SEC reflecting that it ceased being a shell company, and provided that at the time of a proposed sale pursuant to Rule 144, the issuer has satisfied certain reporting requirements under

the Exchange Act. Because, as a former shell company, the reporting requirements of Rule 144(i) will apply regardless of holding period, the restrictive legends on certificates for the shares of common stock issued to the investors in the Private Placement Offering in exchange for the 22nd Century limited liability company membership interests included in the Units sold in the Private Placement Offering or issued upon exercise of the warrants cannot be removed except in connection with an actual sale that is subject to an effective registration statement under, or an applicable exemption from the registration requirements of, the Securities Act.

Because the Merger was a reverse merger, we may not be able to attract the attention of major brokerage firms if we seek to raise additional capital in the future.

Additional risks may exist since the Merger was a “reverse merger.” Certain SEC rules are more restrictive when applied to reverse merger companies, such as the ability of stockholders to resell their shares of common stock pursuant to Rule 144. In addition, securities analysts of major brokerage firms may not provide coverage of our common stock following the Merger since there may be little incentive for brokerage firms to recommend the purchase of our common stock. We cannot assure you that brokerage firms will want to conduct any secondary offerings on our behalf if we seek to raise additional capital in the future.

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

As a public company, we will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We will also incur substantial expenses in connection with the preparation and filing of the registration statement and responding to SEC comments in connection with its review of the registration statement. We also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the OTC Bulletin Board or any stock exchange on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We are unable to currently estimate these costs with any degree of certainty. We also expect these new rules and regulations may make it difficult and expensive for us to obtain director and officer liability insurance. We may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage available to privately-held companies. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

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

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

The number of shares of common stock and warrants issued as a result of the Merger bears no relationship to our assets, book value or historical results of operations or any other established criterion of value on a stand alone or pro forma combined basis with 22nd Century, or the trading price of the shares of our common stock prior to the Merger, and may not bear any continuing relationship to the trading price of our common stock following the Merger.

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

- results from and any delays in any clinical trials programs;
- failure or delays in entering potential products into clinical trials;
- failure or discontinuation of any of our research programs;
- delays in establishing new strategic relationships;
- delays in the development of our potential products and commercialization of our potential products;
- market conditions in our sector and issuance of new or changed securities analysts' reports or recommendations;
- general economic conditions, including recent adverse changes in the global financial markets;
- actual and anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing or distributing our products or potential products;
- market acceptance of our products or potential products;
- third-party healthcare reimbursement policies;
- FDA or other United States or foreign regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our products or potential products;
- additions or departures of key personnel;
- third-party sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors or significant stockholders; and
- equity sales by us of our common stock or securities convertible into common stock to fund our operations.

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

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

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

We currently have outstanding 27,909,646 shares of common stock, of which 5,434,446 are included in the registration statement of which this prospectus is a part and of which 5,317,920 shares can be freely sold in the public market after the date of this prospectus. Of the 27,909,646 shares of common stock outstanding, unless they are registered for resale pursuant to the registration statement, or included in a subsequent registration statement declared effective by the SEC, 22,584,446 shares are restricted shares owned by "affiliates" and by "non-affiliates" who have held such shares for less than one year (including investors in the Private Placement Offering), which could be sold after meeting certain requirements of Rule 144 of the Securities Act. Shares of common stock held by "non-affiliates" (including investors in the Private Placement Offering) may be resold after such shares have been held for longer than

one year, without meeting such requirements. In addition, 16,074,903 of such restricted shares held by our directors, executive officers, and beneficial owners of 10% of more of our issued and outstanding common stock are subject to lock-up agreements preventing the re-sale of such shares for 18 months following the date of the closing of the Merger, except to another individual or entity that is subject to a similar lock-up agreement. These lock-up agreements do not apply to the 422,544 shares of common stock or warrants to purchase 211,272 shares of common stock issued to Clearwater Partners, LLC and Angelo Tomasello upon consummation of the Merger in exchange for the securities contained in the PPO Securities purchased by Clearwater Partners, LLC and Angelo Tomasello in the Private Placement Offering nor to any shares of common stock issued to Clearwater Partners, LLC or Angelo Tomasello upon the exercise of such warrants.

On March 31, 2011, we registered all of the shares of common stock that we may issue under the EIP, including 4,250,000 shares reserved for future issuance under such plan. On April 1, 2011, the Board granted an aggregate of 1,150,000 shares of our common stock to our officers and directors and options to purchase an aggregate of 35,000 shares of our common stock to our employees under the EIP. These shares can be freely sold in the public market upon issuance, subject to the lock-up agreements of certain recipients.

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. Accordingly, although we will undertake to register under the Securities Act the resale of the shares of common stock issued in the Merger, these shares will be highly illiquid. Because of such expected illiquidity, it will likely be difficult to re-sell shares of our common stock as desired.

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

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

We are controlled by our current officers, directors and principal stockholders.

Our directors and executive officers beneficially own approximately 33.8% of the outstanding shares of our common stock. Accordingly, our directors and executive officers will have substantial influence over, and may have the ability to control, the election of our board of directors and the outcome of issues submitted to a vote of our stockholders.

We do not expect to declare any dividends in the foreseeable future.

We have not paid cash dividends to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business, and we do not anticipate paying any cash dividends on our capital stock for the foreseeable future. In addition, the terms of any future debt facilities may preclude us from paying dividends on the common stock. As a result, capital appreciation, if any, of our common stock could be the sole source of gain for the foreseeable future.

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

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

- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock; and
- limiting the liability of, and providing indemnification to, our directors and officers

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

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

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

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

PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of April 1, 2011, except as noted below, by:

- each of our directors;
- each of our Named Executive Officers;
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- all of our directors and executive officers as a group; and
- each selling stockholder.

Beneficial ownership is determined in accordance with rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include shares of common stock issuable upon exercise of warrants that are immediately exercisable or exercisable within 60 days of April 1, 2011. Except as otherwise indicated in the footnotes to the table below, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

Percentage ownership calculations for beneficial ownership prior to this offering are based on 27,909,646 shares of common stock outstanding as of April 1, 2011. Beneficial ownership calculations for after the offering assume that the selling stockholder disposes of all shares of common stock covered by this registration statement and does not acquire or dispose of any additional shares of common stock. The selling stockholder is not, representing, however, that any of the shares covered by this registration statement will be offered for sale, and the selling stockholder reserves the right to accept or reject, in whole or in part, any proposed sale of shares.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options held by that person that are immediately exercisable or exercisable within 60 days of April 1, 2011. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*). Except as otherwise indicated in the footnotes to the table below, the address of named beneficial owners that are officers, directors or owners of 5% or more of our common stock is: c/o 22nd Century Group, Inc., 8201 Main Street, Suite 6, Williamsville, New York 14221.

Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering			Shares Offered	Shares Beneficially Owned After Offering	
	Number of Shares Held	Shares Issued Under 2010 Equity Incentive Plan ("EIP")	Percent		Number	Percent
Management & Directors						
Joseph Pandolfino (1)	6,010,396	200,000	21.16 %	75,000	6,135,396	20.90 %
Henry Sicignano, III (2)	3,634,927	700,000	15.06 %	31,626	4,303,301	14.95 %
Michael R. Moynihan, Ph.D. (3)	1,017,645	100,000	3.97 %	9,900	1,107,745	3.93 %
C. Anthony Rider (4)	243,473	75,000	1.14 %	-	318,473	1.14 %
Joseph A. Dunn, Ph.D.	-	25,000	*	-	25,000	*
James W. Cornell	-	25,000	*	-	25,000	*
Steven Katz	-	25,000	*	-	25,000	*
All directors and executive officers as a group (7 persons) (1)-(4)	10,906,441	1,150,000	39.50 %	116,526	11,939,915	39.12 %
Other 5% Owners						
Clearwater Partners, LLC (5)	5,144,279	-	17.65 %	97,544	5,046,735	17.31 %
Angelo J. Tomasello (6)	4,193,881	-	14.48 %	325,000	3,868,881	13.36 %
Centrum Bank AG (7)	1,500,000	-	5.28 %	1,000,000	500,000	1.76 %
Other Selling Stockholders						
Rodman & Renshaw LLC (8)	1,398,999	-	4.84 %	395,376	1,003,623	3.47 %
Joseph Anderson (9)						