22nd Century Group, Inc.
Form 8-K
February 01, 2011

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 25, 2011

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

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

8201 Main Street, Suite 6, Williamsville, NY 14221
(Address of principal executive offices, including ZIP code)

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

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

¨ Written communications pursuant to Rule 425 under the Securities Act (17 C.F.R. §230.425)
¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 C.F.R. §230.14a-12)
¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 C.F.R. §14d-2(b))
¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 C.F.R. §13e-4(c))

Cautionary Note Regarding Forward Looking Statements

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

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

Explanatory Note

This Current Report on Form 8-K is being filed in connection with a series of transactions consummated by us that relate to the merger by us with 22nd Century Limited, LLC, and certain related actions taken by us.

This Current Report on Form 8-K responds to the following items of Form 8-K:

Item 1.01	Entry into a Material Definitive Agreement.
Item 2.01	Completion of Acquisition or Disposition of Assets.
Item 3.02	Unregistered Sales of Equity Securities.
Item 4.01	Change in Registrant's Certifying Accountants.
Item 5.01	Changes in Control of Registrant.
Item 5.02	Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.
Item 5.03	Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.
Item 5.06	Change in Shell Company Status.
Item 9.01	Financial Statements and Exhibits.

As used in this Current Report on Form 8-K and unless otherwise indicated, the terms the "Parent," "we," "us," and "our" refer to 22nd Century Group, Inc. after giving effect to our merger with 22nd Century Limited, LLC, and the related transactions described below, unless the context requires otherwise.

Item 1.01. Entry into a Material Definitive Agreement.

On January 25, 2011, 22nd Century Group, Inc., a Nevada corporation (the "Parent") entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") by and among Parent, 22nd Century Limited, LLC, a privately held Delaware limited liability company ("22nd Century"), and 22nd Century Acquisition Subsidiary, a newly formed, wholly-owned Delaware limited liability company subsidiary of Parent ("Acquisition Sub"). Upon the closing of the merger transaction contemplated under the Merger Agreement (the "Merger"), Acquisition Sub was merged with and into 22nd Century, and 22nd Century, as the surviving entity, became a wholly-owned subsidiary of Parent.

The Merger Agreement and the Merger are described in Item 2.01 below, which disclosure is incorporated herein by reference.

Prior to the transactions contemplated by the Merger Agreement with 22nd Century, there were no material relationships between Parent and 22nd Century, or any of their respective affiliates, directors or officers, or any associates of their respective officers or directors.

Item 2.01. Completion of Acquisition or Disposition of Assets.

The Merger

On January 25, 2011, Parent entered into the Merger Agreement with 22nd Century and Acquisition Sub. Upon closing of the Merger on January 25, 2011, Acquisition Sub was merged with and into 22nd Century, and 22nd Century became a wholly-owned subsidiary of Parent. Pursuant to the terms and conditions of the Merger Agreement:

- Prior to the closing of the Merger, Parent (i) obtained forgiveness of all its outstanding promissory notes in the aggregate principal amount of $162,327, (ii) cancelled the 386,389 shares of the Parent's common stock, $0.00001 par value per share (the "Common Stock"), held by Milestone Enhanced Fund Ltd. and 10,015,200 shares of Common Stock held by Nanuk Warman, (iii) entered into contractual agreements with certain shareholders of Parent pursuant to which an aggregate of 139,800 shares of Common Stock (the "Contractual Cancellations") will be cancelled as soon as practicable following the closing of the Merger (such 139,800 shares of Common Stock being deemed to be no longer issued and outstanding as of January 25, 2011) and (iv) effected a 2.782-for-one forward stock split by way of dividend and subsequent cancellation to ensure that the pre-Merger shareholders of Parent owned an aggregate of 5,325,200 shares of Common Stock immediately prior to the closing of the Merger, such 5,325,200 shares of Common Stock representing approximately 19.9% of the issued and outstanding shares of Common Stock immediately following the closing of the Merger. In addition, prior to the closing of the Merger, Parent transferred all of its pre-Merger operating assets and remaining liabilities to Touchstone Split Corp., a Delaware corporation and wholly-owned subsidiary of Parent (the "Split-Off Subsidiary") pursuant to the terms of that certain Split-Off Agreement dated as of January 25, 2011 by and between Parent, David Rector (the "Buyer"), and the Split-Off Subsidiary (the "Split-Off Agreement"). Prior to the Merger and pursuant to the terms of the Split-Off Agreement, Parent transferred and sold all of the issued and outstanding shares of capital stock of the Split-Off Subsidiary to Buyer in exchange for $1, such consideration being deemed to be adequate by Parent's board of directors;

- Prior to the closing of the Merger, Parent adopted an equity incentive plan and reserved 4,250,000 shares of Common Stock for issuance as incentive awards to officers, directors, employees and other qualified persons in the future;

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

- In conjunction with the Private Placement Offering, 22nd Century issued to Rodman & Renshaw, LLC a non-transferrable five-year warrant to purchase 394,755 Units of 22nd Century at an exercise price of $1.50 per Unit and issued to Gottbetter Capital Markets, LLC a non-transferrable five-year warrant to purchase 40,000 Units of 22nd Century at an exercise price of $1.50 per Unit;

- At the closing of Merger, Parent issued to Rodman & Renshaw, LLC a non-transferrable five-year warrant to purchase 500,000 shares of Common Stock at an exercise price of $1.50 per share in connection with the provision of financial advisory services to Parent;

- At the closing of the Merger, each Unit of 22nd Century issued and outstanding immediately prior to the closing of the Merger was exchanged for one (1) share of Common Stock, and each warrant to purchase Units of 22nd Century was exchanged for one warrant of like tenor and term to purchase shares of 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 10,220,000 shares are Common Stock were reserved for issuance pursuant to the exercise of warrants to purchase shares of Common Stock;

- Upon the closing of the Merger, the board of directors was expanded and reconstituted, as described below;

- Pursuant to the terms of the Merger Agreement, Parent assumed all of 22nd Century's obligations, including those related to 22nd Century's outstanding warrants;

- Each of Parent, 22nd Century and Acquisition Sub provided customary representations and warranties, pre-closing covenants and closing conditions in the Merger Agreement; and

- Following (i) the closing of the Merger, (ii) the closing of the Private Placement Offering for $5,434,446, (iii) Parent's cancellation of 386,389 shares Common Stock held by Milestone Enhanced Fund Ltd. and 10,015,200 shares of Common Stock held by Nanuk Warman, (iv) consummation of the Split-Off Agreement and the transactions contemplated thereby, and (v) taking into account a 2.782-for-one forward stock split by way of dividend of the shares of Common Stock that took place on November 29, 2010 (with any resulting fractional shares being rounded upward to the nearest whole share) and subsequent cancellation as well as the Contractual Cancellations, 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.

The foregoing description of the Merger Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Merger Agreement, which is filed as Exhibit 2.1 hereto and incorporated herein by reference.The Merger and related transactions were approved by the holders of a requisite number of 22nd Century Units pursuant to written consent dated as of December 15, 2010.

The shares of Common Stock issued to former holders of 22nd Century Units in connection with the Merger, and 22nd Century Units and warrants to purchase Units issued in the Private Placement Offering, were not registered under the Securities Act of 1933, as amended (the "Securities Act"), and were issued and sold in reliance upon the exemption from registration provided by Section 4(2) and Section 4(6) of the Securities Act or pursuant to Regulation D or Regulation S promulgated thereunder. These securities may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements. Certificates representing these securities contain a legend stating the same.

The 5,325,200 shares of Common Stock issued and outstanding immediately prior to the closing of the Merger constitute the entirety of Parent's "public float" eligible for resale without further registration by the holders thereof. Additional shares of Common Stock will be eligible for resale at such time as a further registration statement is filed and declared effective pursuant to the Securities Act or at such time as additional shares of Common Stock are eligible to be resold pursuant to an exemption from registration under the Securities Act.

Changes Resulting from the Merger

Parent intends to carry on 22nd Century's business as its sole line of business. Parent has relocated its executive offices to 8201 Main Street, Suite 6, Williamsville, NY 14221 and its telephone number is (716) 270-1523.

The Parent intends to adopt the fiscal year of 22nd Century, which ends December 31.

Changes to the Board of Directors and Officers

In connection with the Merger, the Parent's board of directors was expanded to five (5)members. The sole officer and sole member of the board of directors prior to the closing of the Merger, David Rector, resigned as an officer but continues to serve as a member of the board of directors of Parent. Immediately following the closing of the Merger, Joseph Pandolfino was appointed to serve as a member of Parent's board of directors. As of the date ten (10) days following the filing of a Schedule 14F-1 with the SEC after the closing of the Merger, David Rector will resign as a member of Parent's board of directors and will be replaced by an individual appointed by the pre-Merger stockholders of Parent. Each of Henry Sicignano III, Joseph Alexander Dunn, Ph.D., and James W. Cornell will also be appointed to serve as members of Parent's board of directors as of that date. Immediately following the closing of the Merger, Joseph Pandolfino was appointed as our Chief Executive Officer, Henry Sicignano III was appointed as our President and Secretary, and C. Anthony Rider was appointed as our Chief Financial Officer and Treasurer.

All directors hold office for one-year terms until the election and qualification of their successors. Officers are elected by the board of directors and serve at the discretion of the board.

Accounting Treatment

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 Parent and 22nd Century, historical operations of 22nd Century and operations of Parent beginning on the closing date of the Merger. As a result, all the historical financial information reported herein is 22nd Century's.

Tax Treatment; Smaller Reporting Company

The transfer of operating assets and liabilities to the Split-Off Subsidiary, the forgiveness of indebtedness by certain shareholders of Parent, and the Split-Off of the Split-Off Subsidiary, will result in taxable income to Parent in an amount equal to the difference between the fair market value of the assets transferred and Parent's tax basis in the assets. Any gain recognized, to the extent not offset by Parent's net operating losses carry-forwards, if any, will be subject to federal income tax at regular corporate income tax rates.

The exchange of Membership Units for Common Stock in the Merger is expected to qualify for treatment as a tax-free transfer under section 351 of the United States Internal Revenue Code ("IRC") as long as the exchange results in the members of 22nd Century Limited, LLC immediately prior to the Merger having at least 80% "control" (within the meaning of IRC §351(a)) of Parent immediately following the Merger and certain other requirements are met. If the Merger qualifies as a tax-free transfer under IRC § 351, the shares of Common Stock received in the exchange will have the same tax basis as the Membership Units for which they were exchanged. A "significant transferor" (as defined in Treas. Reg. §1.351-3(d)(1)) will be required to include certain information with his income tax return for the year of the Merger.

Parent will continue to be a "smaller reporting company," as defined in Regulation S-K under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), following the Merger.

Company Background

Parent was formed as a Nevada corporation on September 12, 2005 to engage in the acquisition, exploration and development of mineral deposits and reserves. Parent has been in a development stage since its inception and had minimal business operations prior to the Merger. Immediately prior to the closing of the Merger, the existing asset and liabilities of Parent were disposed of pursuant to the cancellation of certain indebtedness owed to shareholders of Parent, the cancellation of certain shares of Common Stock held by shareholders of Parent, and the Split-Off.

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

After the Merger with Parent, Parent succeeded to the business of 22nd Century as its sole line of business.

Company Overview

Founded in 1998, we are a plant biotechnology company and a global leader in modifying the content of nicotinic alkaloids in tobacco plants through genetic engineering and plant breeding. We own or exclusively control 97 issued patents in 79 countries where at least 75% of the world's smokers reside. We believe that our proprietary technology will enable us to capture a significant share of the global market for approved smoking cessation aids and the emerging market for modified risk tobacco products.

We plan to use a substantial portion of the proceeds of the Private Placement Offering to complete the remaining clinical trials necessary to seek approval from the U.S. Food and Drug Administration ("FDA") for X-22, our prescription smoking cessation aid. X-22 will be a prescription-only kit containing very low nicotine ("VLN") cigarettes made from our proprietary tobacco, which has 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.

We have met with the FDA regarding the remaining X-22 clinical trials and, based on the FDA's guidance, we plan to conduct a small Phase II-B trial and two larger and concurrent Phase III trials with the same protocols, all of which entail measuring the quitting efficacy of the X-22 cigarette against a typical cigarette with conventional nicotine content that is visually indistinguishable from X-22. We believe that X-22 will qualify for "Fast Track" designation by the FDA, and that we will obtain FDA approval for X-22 in the fourth quarter of 2012 at the earliest.

Independent studies, including two Phase II clinical trials, have demonstrated that VLN cigarettes made from our proprietary 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, 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.

We intend to seek FDA authorization to market BRAND A and BRAND B as Modified Risk Cigarettes. Compared to other commercial cigarettes, the tobacco in BRAND A has approximately 95% less nicotine than tobacco in cigarettes marketed as "light" cigarettes and BRAND B's smoke contains the lowest amount of tar per milligram of nicotine. We believe that BRAND A and BRAND B will 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.

The 2009 Family Smoking Prevention and Tobacco Control Act, or 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 cigarettes. 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. We believe this new regulatory environment represents a paradigm shift for the tobacco industry and will create opportunities for us in marketing BRAND A and BRAND B and in licensing our proprietary technology and tobaccos to larger competitors. 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 or reducing withdrawal symptoms. The Tobacco Control Act provides that products for 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

For the first time in history, the FDA will 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 Cigarettes and requires the FDA to issue additional guidance regarding applications that must be submitted to the FDA for approval to market these Modified Risk Cigarettes. We believe, based in part on the timelines contained in the Tobacco Control Act, that the FDA will issue such guidance in 2011 and we also believe that BRAND A and BRAND B will qualify as Modified Risk Cigarettes under these guidelines. In addition, the Tobacco Control Act allows the FDA to mandate the use of reduced risk technologies in conventional cigarettes which could create opportunities for us to license our technology and/or tobaccos.

Tar, Nicotine, and Smoking Behavior

The dependence of many smokers on tobacco is largely due to the properties of nicotine, but the adverse effects of smoking on health are mainly due to other components present in tobacco smoke, including tar and carbon monoxide. “Tar” is the common name for the (resinous) total particulate matter minus nicotine and water produced by the burning of tobacco (or other plant material) during the act of smoking. Tar and nicotine are commonly measured in milligrams per cigarette trapped on a Cambridge filter pad under standardized conditions using smoking machines. These results are referred to as “yields” or, more specifically, tar yield and nicotine yield.

Individual smokers generally seek a certain amount of nicotine per cigarette and can easily adjust how intensely each cigarette is smoked to obtain a satisfactory amount of nicotine. Smoking of low yield (“light” or “ultra light”) cigarettes compared to high yield (“full flavor”) cigarettes often results in taking more puffs per cigarette, larger puffs and/or smoking more cigarettes per day to obtain a satisfactory amount of nicotine, a phenomenon known as “compensation” or “compensatory smoking.” A report by the National Cancer Institute in 2001 stated that due to compensatory smoking, low yield cigarettes are not safer than high yield cigarettes, which is the reason that the Tobacco Control Act has banned the use of the terms “low tar,” “light” and “ultra light” in the U.S. market. Studies have shown that smokers do not compensate when smoking cigarettes made with our VLN tobacco, and that smoking VLN cigarettes actually assist smokers to smoke fewer cigarettes per day and reduce their exposure to tar and nicotine. Other studies have shown that non-commercial cigarettes with low tar-to-nicotine ratios (tar yield divided by nicotine yield from smoking

machines), such as BRAND B, result in smokers inhaling less tar and carbon monoxide (CO).

Market

Cigarettes and Smoking Cessation Aids

The U.S. cigarette market consists of approximately 44 million adult smokers who spent approximately $75 billion in 2009 on 320 billion cigarettes. The World Health Organization ("WHO") predicts that the current 1.3 billion smokers worldwide will increase to 1.7 billion smokers by the year 2025. Worldwide manufacturer sales in 2009 were 5.91 trillion cigarettes, which has been increasing at approximately 1.0% per year, resulting in annual retail sales of over $300 billion. Our products address unmet needs of smokers; for those who want to quit, an innovative smoking cessation aid, and for those who do not quit, cigarettes that can reduce the level of exposure to nicotine, tar and other chemicals in cigarettes they smoke.

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

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

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

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

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

Chantix® was introduced in the U.S. market in the fourth quarter 2006. Since 2007, Chantix® has been the best selling smoking cessation aid in the United States, with sales of $701 million in 2007, $489 million in 2008 and $386 million in 2009. In July 2009, the FDA required a "Boxed Warning," the most serious type of warning in prescription drug labeling, for both Chantix® and Zyban® based on the potential side effects of these drugs. Despite this warning, sales of Chantix® in 2009 were approximately $700 million worldwide.

Other than Chantix® and Zyban®, the only FDA-approved smoking cessation therapy in the United States is NRT. These products consist of gums, patches, nasal sprays, inhalers and lozenges. Nicotine gums and nicotine patches have been sold in the U.S. for 26 years and 18 years, respectively, and millions of smokers have already tried NRT products and failed to stop smoking due to the limited effectiveness of these products. According to Perrigo Company, a pharmaceutical company that sells NRT products, sales of NRT products in the United States have averaged approximately $500 million annually from 2007 to 2009.

Modified Risk Tobacco Products

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

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

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

Complete cessation from all tobacco and medicinal nicotine products is the ultimate goal of the public health community; however, some public health officials desire to migrate cigarette smokers en masse to medicinal nicotine (also known as NRT) or smokeless tobacco products to replace cigarettes. We believe this is unattainable in the foreseeable future for many reasons including that the smoking experience is much more complex than simply seeking nicotine. In a 2009 WHO report, statistics demonstrate that approximately 90% of global tobacco users smoke cigarettes. Worldwide cigarette sales are approximately 20 times greater than sales of smokeless tobacco products and approximately 100 times greater than sales of NRT products. Although a small segment of the smoking population is willing to use NRT or smokeless tobacco products in conjunction with cigarettes (known as dual users), a large percentage of smokers is not interested in using NRT or smokeless tobacco products exclusively.

There are newer forms of smokeless tobacco products that have been introduced in the market that are less messy to use than chewing tobacco or dry snuff (since spitting is not involved). These products include Swedish-style snus and dissolvable tobacco products such as Ariva® and Stonewall® tablets made by Star Scientific Inc., and Camel® Orbs, Camel® Strips and Camel® Sticks recently introduced by R.J. Reynolds Tobacco Company. Although use of such products may be more discreet and convenient than traditional forms of smokeless tobacco, they have the same route of delivery of nicotine as nicotine gum and nicotine lozenges, which have been available over-the-counter in the United States for 15 years and 7 years, respectively, and have not significantly replaced cigarettes.

Products

X-22 Smoking Cessation Aid

X-22 is a tobacco-based botanical medical product for use as a smoking cessation therapy. X-22 will be a prescription-only kit containing very low nicotine ("VLN") cigarettes made from our proprietary tobacco, which has 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 also believe X-22 will be more attractive to smokers than other therapies since it smokes and tastes like a typical cigarette, involves the same smoking behavior, and does not expose the smoker to any new drugs or new side effects.

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

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

We have met with the FDA regarding the remaining X-22 clinical trials and, based on the FDA's guidance, we plan to conduct a small Phase II-B trial and two larger and concurrent Phase III trials with the same protocols, all of which entail measuring the quitting efficacy of the X-22 cigarette against a typical cigarette with conventional nicotine content that is visually indistinguishable from X-22. As depicted below, we plan to complete the FDA-approval process for our X-22 smoking cessation aid and upon such approval launch X-22 in the U.S. market in the fourth quarter of 2012 at the earliest (as a prescription), and in other top smoking cessation markets thereafter.

Our Modified Risk Cigarettes

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

BRAND A Cigarettes

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

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

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

We believe these findings and future exposure studies the FDA may require will result in a Modified Risk Cigarette claim for BRAND A. We further believe smokers who desire to smoke fewer cigarettes per day while also satisfying cravings and reducing exposure to nicotine will find BRAND A beneficial. We intend that BRAND A will be available in regular and menthol; with both styles being king size (85 mm) cigarettes.

BRAND B Cigarettes

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

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

In a 2001 report, entitled Clearing the Smoke, Assessing the Science Base for Tobacco Harm Reduction, the Institute of Medicine notes that a low tar/moderate nicotine cigarette is a viable strategy for reducing the harm caused by smoking. It states: “Retaining nicotine at pleasurable or addictive levels while reducing the more toxic components of tobacco is another general strategy for harm reduction.” We believe that evaluation of BRAND B in short-term human exposure studies will confirm that exposure to smoke, including tar and carbon monoxide, is significantly reduced when smoking BRAND B as compared to smoking the leading brands of cigarettes. We believe results from these exposure studies will warrant a Modified Risk Cigarette claim for BRAND B.

Additional Tobacco Products

We expect to introduce other cigarettes into the U.S. market in the first quarter of 2011, particularly to 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 purchase these cigarettes to replace their lost sales of flavored cigarettes as well as lost sales of “light” cigarettes.

Clinical Trials with Cigarettes Containing our Very Low Nicotine (“VLN”) Tobacco

VLN cigarettes containing our proprietary tobacco have been the subject of various independent studies, including two Phase II clinical trials for smoking cessation which were not funded by us. Both of these Phase II clinical trials were “intent to treat” trials, meaning that any patients who dropped out of the trials for any reason at any time during treatment or during the follow-up periods were considered failures (still smoking and not abstinent). Dropout rates during smoking cessation trials are generally high since patients either quit smoking or resume smoking their usual brand. In either case, they may believe there is no reason to continue.

One of these two Phase II clinical trials compared the quitting efficacy of a VLN cigarette containing our proprietary tobacco versus a low nicotine cigarette and an FDA-approved nicotine lozenge (4 mg) in a total of 165 patients treated for 6 weeks (Hatsukami et al. 2010). This clinical trial was led by Dr. Dorothy Hatsukami, Director of the National Transdisciplinary Tobacco Use Research Center (TTURC) at the University of Minnesota Masonic Comprehensive Cancer Center. For reference, Dr. Hatsukami was selected in 2010 as one of the nine voting members of the 12-person Tobacco Products Scientific Advisory Committee (“TPSAC”) within the FDA’s Center for Tobacco Products created by the Tobacco Control Act. TPSAC will make recommendations and issue reports to the FDA Commissioner on tobacco regulatory matters, including but not limited to, the impact of the use of menthol in cigarettes, altering levels of nicotine in tobacco products, and applications submitted to the FDA for modified risk tobacco products.

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

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

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

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

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

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

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

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

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

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

Technology Platform

Our proprietary technology enables us to decrease or increase the level of nicotine in tobacco plants by decreasing or increasing the expression of gene(s) responsible for nicotine production in the tobacco plant using genetic engineering. The basic techniques are the same as those used in the production of genetically modified varieties of other crops, which in 2009 were planted on 330 million acres in 25 countries according to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA). This includes 85% of the corn and soybeans grown in the United States. The only components of the technology that are distinct from those in commercialized genetically modified varieties of major crops are segments of tobacco genes (DNA sequences) that are also present in all conventional tobacco plants. Genetically modified tobacco that we use in our products is produced from plants that have been deregulated by the USDA. Thus, plants may be grown and used in products in the United States without

legal restrictions or labeling requirements related to the genetic modification. Nevertheless, our proprietary genetically engineered tobacco is grown only by farmers under contracts that require segregation and prohibit transfer of material to other parties.

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

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

Intellectual Property

Our proprietary technology is covered by 12 patent families consisting of 97 issued patents in 79 countries, and approximately 44 pending patent applications, which are either owned by or exclusively licensed to us. A “patent family” is a set of patents granted in various countries to protect a single invention. Our patent coverage in the 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 (“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.

Sales and Marketing

X-22 Smoking Cessation Aid

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

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

BRAND A and BRAND B

We expect significant sales in the U.S. of Brand A and Brand B within specialty tobacco channels such as 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 purchase our BRAND A and BRAND B cigarette brands to replace their lost sales of flavored cigarettes as well as lost sales of "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 ("Research Cigarette Option") in its request for proposals for a 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 two more purchase orders for an additional 8.275 million research cigarettes over the next three months. We estimate the revenue from this contract, including other direct orders from researchers, will be approximately $700,000 in 2011 and $3 million over the next 5 years.

Healthcare Reimbursement

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

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

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

Approximately 47 million Americans were covered by state Medicaid programs in 2009. Approximately 30% of Medicaid recipients are smokers. Medicaid programs in 42 states and the District of Columbia cover at least one form of pharmacologic treatment for smoking cessation (Chantix®, Zyban® or NRT). The new healthcare legislation is expanding Medicaid coverage to all 50 states. The current retail price of the 12-week prescription of Chantix® is over $450, which should give us great latitude in pricing X-22. We expect X-22 to be price competitive with any FDA-approved smoking cessation aid, especially Chantix®, which will not only encourage governmental and private third-party payers to cover X-22, but will encourage smokers to attempt to quit with X-22 since they will not have to purchase their usual brand of cigarettes over the 6-week treatment period. This equates to approximately $239 in out-of-pocket savings to the consumer if their insurance plan covers X-22.

Manufacturing

We are in the process of entering into agreements with several cigarette manufacturing companies to manufacture X-22 for us for sale in the United States and foreign markets. We are also in the process of entering into agreements with several cigarette manufacturing companies to manufacture BRAND A and BRAND B for us for sale in the Unites States and foreign markets, subject to FDA approval to market BRAND A and BRAND B as Modified Risk Cigarettes.

Competition

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

Cigarette companies compete primarily on the basis of product quality, brand recognition, brand loyalty, taste, innovation, packaging, service, marketing, advertising, retail shelf space and price. Cigarette sales can be significantly influenced by weak economic conditions, erosion of consumer confidence, competitors' introduction of low-price products or innovative products, higher cigarette taxes, higher absolute prices and larger gaps between price categories, and product regulation that diminishes the ability to differentiate tobacco products. Domestic competitors include Philip Morris USA, Reynolds American Inc., Lorillard Inc., Commonwealth Brands, Inc., Liggett Group LCC, Vector Tobacco Inc., and Star Scientific Inc. International competitors include Philip Morris International, British

American Tobacco, Japan Tobacco Inc. and regional and local tobacco companies; and, in some instances, government-owned tobacco enterprises, principally in China, Egypt, Thailand, Taiwan, Vietnam and Algeria.

Potential Smoking Cessation Aids

Nicotine Vaccines

Nicotine vaccines are under development in clinical trials; however they have not yet achieved the efficacy of other FDA-approved smoking cessation therapies. Nicotine itself is not recognized by the body as a foreign compound since the molecule is too small. In order to stimulate the production of antibodies, nicotine must be attached to a carrier to make the vaccine work. Different vaccine development programs use different carriers. Four companies, Cytos Biotechnology AG, Celtic Pharmaceuticals Holdings, Nabi Biopharmaceuticals, L.P. and Independent Pharmaceutica AB have or have had vaccine candidates in clinical trials. Cytos exclusively licensed its nicotine vaccine candidate to Novartis in 2007 for 35 million Swiss Francs ($30 million) and up to 565 million Swiss Francs ($492 million) in milestone payments and royalties. In October 2009, it was announced that Cytos' nicotine vaccine candidate failed to show efficacy in a Phase II trial.

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

These vaccine treatments entail six to seven consecutive monthly injections. Increases in abstinence rates have been reported but only among a minority of trial subjects with the highest levels of anti-nicotine antibodies. To date, all subjects do not develop sufficient antibody levels despite receiving multiple injections. Even in those who do develop sufficient antibody levels, cravings for cigarettes are not addressed by this treatment, although the pharmacological reward of nicotine is suppressed. Expectations are that the treatment, if approved, would need to be repeated every 12 to 18 months to assist in preventing relapse. Dr. Michael C. Fiore, lead chairperson and author of the 2008 U.S. government report on clinical practice guidelines for treating tobacco use and co-principal Investigator of the Transdisciplinary Tobacco Use Research Center at the University of Wisconsin, Madison, estimated in 2009 that any approval of a nicotine vaccine may be 5 to 10 years away.

Electronic or E-cigarettes

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

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

The FDA has also been confiscating imports of e-cigarettes and has been in litigation with importers of these products. A federal appeals court ruled on December 7, 2010 that the FDA can regulate electronic cigarettes as tobacco products rather than a drug-delivery device. The FDA is appealing this decision, however, the U.S. Court of Appeals for the District of Columbia Circuit on January 2011 rejected the FDA's request to have the entire court review the December 7, 2010 decision that went against the agency. The FDA, which has always contended that e-cigarettes should be regulated as drug-delivery devices not tobacco products, now has the option of asking the U.S. Supreme Court to take up the case. An FDA spokesman said that the agency is evaluating the latest court ruling "and considering its legal and regulatory options." Many countries have already banned e-cigarettes as has the state of Oregon and other states are in the process of banning them.

Government Regulation

Smoking Cessation Aids

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

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

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

Preclinical Phase

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

Clinical Phase

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

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

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

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

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

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

institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

New Drug Application and Review

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

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

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

Fast Track Development

The Food and Drug Administration Modernization Act of 1997, or the Modernization Act, establishes a statutory program for relatively streamlined approval of "Fast Track" products, which are defined under the Modernization Act as new drugs or biologics intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Fast Track status requires an official designation by the FDA. The 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") provides that products for smoking cessation, such as X-22, be considered for "Fast Track" designation by the FDA.

We intend to submit a request to the FDA for Fast Track designation in the fourth quarter 2010 and, although there can be no assurance, we believe that our X-22 smoking cessation aid will be granted Fast Track designation by the FDA. A product that receives Fast Track designation is eligible for (i) more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, and (ii) more frequent written correspondence from the FDA about such things as the design of the proposed clinical trials. A Fast Track product is also eligible for Rolling Review, in which sections of the NDA can be submitted for review by the FDA before the entire application is completed. A Fast Track product would ordinarily meet FDA criteria for Priority Review. The FDA goal for reviewing a drug with Priority Review status is six months from the filing of the NDA.

Post-Approval Phase

Once the FDA has approved a new drug for marketing, the product becomes available for physicians to prescribe in the United States. After approval, we must comply with post-approval requirements, including ongoing compliance

with cGMP regulations, delivering periodic reports to the FDA, submitting descriptions of any adverse reactions reported, and complying with drug sampling and distribution requirements. We are required to maintain and provide updated safety and efficacy information to the FDA. We must also comply with requirements concerning advertising, product promotions, and labeling.

X-22 Clinical Trials

We have met with the FDA regarding the remaining X-22 clinical trials and, based on the FDA's guidance, we plan to conduct a small Phase II-B trial and two larger and concurrent Phase III trials with the same protocols that entail measuring the quitting efficacy of the X-22 cigarette against a typical cigarette with conventional nicotine content that is visually indistinguishable from X-22 (the "active control"). The Phase II-B optimization trial will consist of approximately 200 participants over a 6-week treatment period, and the Phase III trials will use the same protocol with larger groups of participants. In all of the remaining clinical trials, half of the participants will smoke X-22 for 6 weeks and half of the participants will smoke the active control for 6 weeks, with all participants instructed to quit on the last day of the 6-week treatment period.

Smokers who do not smoke over the four-week period immediately following the conclusion of the 6-week treatment period (weeks 7 through 10) are considered abstinent. The abstinence (quit) rates of the X-22 group and the active control group will then be compared for statistical significance. With adequate funding, we will be able to conduct our two concurrent Phase III clinical trials with the same protocols in order to expedite the FDA approval process. We have submitted our Pre-IND (PIND 103,589) to the FDA and, subject to closing this Offering, we expect to initiate our Phase II-B clinical trial in the first quarter of 2011 after we file our IND. Our IND will contain all of the information and data of our PIND 103,589 plus standard tobacco industry smoke analyses of the X-22 clinical trial cigarette and the active control. Before Phase III trials, some additional information and testing of X-22 and its tobacco are required by the FDA, some of which we already have from our former licensee's IND 69,185. All analyses that FDA requires are efficiently outsourced to Arista Laboratories which is the industry leader in tobacco and tobacco smoke analyses that we have been contracting with for years. We intend to initiate our Phase III clinical trials in the third quarter of 2011 and to file our NDA with the FDA for X-22 by the first quarter of 2011. We expect the FDA to Fast Track the approval of X-22 and that we should receive FDA approval to commence the marketing and sales of X-22 in the U.S. as early as the fourth quarter of 2012.

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

Modified Risk Cigarettes

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

For the first time in history, the FDA will evaluate cigarettes that may pose lower health risks as compared to conventional cigarettes. The Tobacco Control Act established procedures for the FDA to regulate the labeling and marketing of Modified Risk Cigarettes and requires the FDA to issue additional guidance regarding applications that must be submitted to the FDA for Modified Risk Cigarettes. We believe the FDA will issue such guidance in 2011. We also believe that BRAND A and BRAND B will qualify as Modified Risk Cigarettes. In addition, the Tobacco Control Act allows the FDA to mandate the use of reduced risk technologies in conventional cigarettes (e.g., Marlboro®) which could create opportunities for us to license our technology or tobaccos.

We have begun to supply our cigarettes to the National Transdisciplinary Tobacco Use Research Centers in the United States so they can conduct studies to obtain additional information on our products, including results from exposure studies (for BRAND A and BRAND B) and smoking clinical trials (for X-22). We expect this information will assist us, along with our own funded studies, in obtaining the necessary FDA authorizations and approvals to market BRAND A and BRAND B as Modified Risk Cigarettes and for X-22 as a prescription smoking cessation aid.

Biomass Products

We have funded extensive biomass field trials conducted by North Carolina State University (“NCSU”) and work on feedstock digestibility and bioconversion at the National Renewable Energy Lab. The results have been included in a comprehensive feasibility study relating to our nicotine-free tobacco biomass crop (Verfola) to produce a variety of bioproducts. First, protein and other plant fractions are extracted, and then biofuels and other products are produced from the remaining cellulosic residue. In 2008, we put our biomass development projects on hold so that our management could focus its attention and resources on X-22, BRAND A and BRAND B. We plan to move forward in our biomass business activities when we have sufficient resources to do so. We plan to form a separate subsidiary in the future which will be dedicated to our biomass business model.

Tobacco has a number of advantages as a starting point for development of novel bioproduct crop systems. Because tobacco is a widely cultivated crop, grown in over 100 countries throughout the world, tobacco agronomy is highly understood. For decades tobacco has been used as a model system for plant biology, and recently the tobacco genome has been mapped. Tobacco plants rapidly sprout back after each harvest and produce large amounts of leaf and total biomass. Tobacco grown for cigarettes yields about 3,000 pounds of cured leaf per acre (~20% moisture) per year from 7,500 tobacco plants. In our field trials in North Carolina, nicotine-free tobacco grown for biomass yields about 100,000 pounds of fresh weight per acre (which equals 10,000 pounds of dry weight) per year with multiple machine harvests from about 80,000 tobacco plants.

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

Rubisco is a crystalline (greater than 99 pure) pharmaceutical grade protein that is tasteless, odorless, and colorless when mixed with water. It is not perishable and can be stored for years. As a plant-based protein source, it is useful as a food additive or supplement. Rubisco includes all the essential amino acids in quantities that equal or exceed the Food and Agriculture Organization (“FAO”) Provisional Pattern and compares favorably to soybeans in essential amino acid content (measured in grams of each essential amino acid per 100 grams of protein). Rubisco has a low lysine-to-arginine (“L/A”) ratio (0.95) compared to L/A ratios in protein from animal sources (2.4 for milk protein, 1.9 for casein, and 1.4 for fish meal). A low L/A ratio is reportedly correlated with low serum cholesterol and

atherosclerotic incidence in animals. Rubisco can be added to fortify almost any food or beverage with a high quality protein without affecting the aroma or taste.

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

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

Research and Development

Most research and development (R&D) since 22nd Century's inception have been outsourced to highly qualified groups in their respective fields. Since 1998, 22nd Century has had multiple R&D agreements with North Carolina State University ("NCSU") resulting in exclusive worldwide licenses to various patented technologies. We have utilized the model of many public-sector research organizations which entails obtaining an exclusive option or license agreement to any invention arising out of the funded research. In all cases, we fund and exclusively control all patent filings as the exclusive licensee. This model of contracting with public-sector researchers has enabled 22nd Century to control R&D costs while achieving our desired results, including obtaining exclusive intellectual property rights relating to all of our funded R&D.

Other R&D partners with the same arrangement have included the National Research Counsel of Canada, Plant Biotechnology Institute in Saskatoon, Canada ("NRC") and the Nara Institute of Science and Technology in Nara, Japan ("NAIST"). Our R&D agreements with NCSU, NRC and NAIST have expired in 2009 and the majority these agreements have involved the biosynthesis of nicotine in plants. During the years ended December 31, 2009 and 2008, we incurred research and development expenses of approximately $540,000 and $654,000, respectively. In 2010, NAIST assigned all of their worldwide patents to 22nd Century which were a result of our R&D at NAIST and that were previously licensed to 22nd Century on a exclusive basis.

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

Employees

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

Description of Property

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

Legal Proceedings

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

We anticipate that we will expend significant financial and management resources to the defense of our intellectual property rights in the future if we believe that our rights have been infringed. We also anticipate that we will expend significant financial and management resources to defend against claims that our products and services infringe upon the intellectual property rights of third parties.

Risk Factors

There are numerous and varied risks, known and unknown, that may prevent the Company from achieving its goals. The risks described below are not the only ones the Company will face. If any of these risks actually occurs, our business, financial condition or results of operation may be materially adversely affected. In such case, the trading price of our Common Stock could decline and investors in our Common Stock could lose all or part of their investment.

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 $3.6 million as of September 30, 2010 ($3.2 million at December 31, 2009), members' deficit of $1.8 million as of September 30, 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, 2009 (dated June 1, 2010 and restated on October 15, 2010), includes an emphasis of a matter paragraph expressing substantial doubt whether we can continue as a going concern. Even in light 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 $1.0 million during the nine month period ended September 30, 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 from test marketing. 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 $739,000 during the nine months ended September 30, 2010 and $172,000 and $762,000 in the years 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 greatly 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 or continue to sell these products, 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.

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We will depend on third parties to manufacture our potential 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 do not currently 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 any facility utilized by third-party manufacturers which we engage 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 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 mainly depend on third parties 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 our 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 the regulatory approvals necessary for commercialization of our X-22 smoking cessation aid in the U.S., the degree of market acceptance could depend upon a number of factors, including:

- continue limited indications of regulatory approvals;
- 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 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 BRAND A and BRAND B 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 products 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 BRAND A and BRAND B cigarettes 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 potential products.

We depend upon independent tobacco producers to grow our specialty proprietary tobaccos with specific nicotine contents for our potential 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, 22nd Century Limited, LLC's 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, and 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 potential products and do not expect to be able to obtain product liability insurance at reasonable commercial rates for our potential 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 and 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, EMEA 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, European Medicines Agency ("EMEA") 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 tar exposure for smokers. Even if we are able to demonstrate reduced nicotine or tar exposure, 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 other tobacco products that we may commercialize.

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, 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 approvals or authorizations 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 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 government 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 assure 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 assure 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 our 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 our BRAND A and BRAND B cigarettes as conventional cigarettes.

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 ("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 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 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 any future investigations.

Risks Related to Intellectual Property

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

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our technologies and potential products. We will only be able to protect our technologies 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, 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 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 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 97 issued patents in 79 countries. In addition, we also have approximately 44 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.

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 pursuant to the terms of that certain License Agreement dated as of March 6, 2009 by and between us and North Carolina State University. To date, we have not received any notice of termination from North Carolina State University. We plan to use a portion of the net proceeds from the Offering to cure the payment default. The intellectual property licensed to us pursuant to the License Agreement is crucial to our business and, if North Carolina State University chooses to invoke its right 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 (collectively, 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 will 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 Membership Units 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 Membership Units 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, the registration statement we file with respect to the shares of Common Stock received by investors in the Private Placement Offering as a result of the Merger might be subject to heightened scrutiny by the SEC, and 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.

If we are unable to register in a timely manner the shares of Common Stock issued to investors in the Private Placement Offering as a result of the Merger, then the ability to resell shares of our Common Stock so issued will be delayed.

We have agreed, at our expense, to prepare a registration statement, and to cause our company to file a registration statement with the SEC within seventy-five (75) days after the effective date of the Merger. We shall use our best efforts to cause such registration statement to be declared effective by the SEC within one hundred eighty (180) calendar days of filing with the SEC (or 240 days if the SEC reviews such registration statement). The registration statement will cover the resale of the shares of Common Stock issued to investors in the Private Placement Offering in exchange for the Membership Units purchased in the Private Placement Offering. There are many reasons, including some over which we have little or no control, which could delay our filing of the registration statement beyond seventy-five (75) days after the effective date of the Merger or which could keep the registration statement from being declared effective by the SEC, including delays resulting from the SEC review process and comments raised by the SEC during that process. Accordingly, in the event that the registration statement is not filed or declared effective within these timeframes, the shares of Common Stock proposed to be covered by such registration statement will not be eligible for resale until the registration statement is effective or an exemption from registration, such as Rule 144, becomes available.

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, and if we are able to obtain such 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 the 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 another stock exchange.

Our stock price may be highly volatile and our Common Stock 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 Parent, or the trading price of the shares of Common Stock prior to the Merger, and may bear no relationship to the trading price of our Common Stock after the Merger.

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 potential products;
- market acceptance of our 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 potential products or products;
- additions or departures of key personnel;
- third-party sales of large blocks of our Common Stock;
- sales of the Common Stock by our executive officers, directors or significant stockholders; and
- equity sales by us of the Common Stock to or securities convertible into Common Stock to fund our operations.