22nd Century Group, Inc.
Form S-1/A
March 21, 2013

As filed with the Securities and Exchange Commission on March 21, 2013

Registration No. 333-186449

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1 to

Form S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

22nd CENTURY GROUP, INC.

(Exact name of registrant as specified in its charter)

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

9530 Main Street

Clarence, New York 14031

(716) 270-1523

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

Henry Sicignano III

President

22nd Century Group, Inc.

9530 Main Street

Clarence, New York 14031

(716) 270-1523

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

Copies to:

Michael B. Kirwan, Esq.

Thomas L. James, Esq.

Foley & Lardner LLP

One Independent Drive, Suite 1300

Jacksonville, Florida 32202

(904) 359-2000

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be Registered (1)	Proposed maximum offering price per share		Proposed maximum aggregate offering price	Amount of registration fee	
Common stock, par value $0.00001 per share, underlying Series A-1 10% Convertible Preferred Stock, par value $0.00001 per share	4,166,666	$ 0.71	(2)	$ 2,958,332.86	$ 1,049.14	
Common stock underlying outstanding Series B Warrants	2,083,334	$ 0.71	(3)	$ 1,479,167.14	$ 403.52	
Total	6,250,000			$ 4,437,500.00	$ 1,452.66	(4)

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

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

(3) Represents the higher of: (i) the exercise price of the convertible security and (ii) the offering price of securities of the same class as the common stock underlying the convertible security calculated in accordance with Rule 457(c)

under the Securities Act, for the purpose of calculating the registration fee pursuant to 457(g) under the Securities Act.

(4) The registration fee was previously paid on February 4, 2013.

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

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

SUBJECT TO COMPLETION, DATED MARCH 21, 2013

PRELIMINARY PROSPECTUS

22nd CENTURY GROUP, INC.

Up to 6,250,000 Shares of Common Stock

This prospectus relates to the resale at various times by the selling stockholders identified in this prospectus of up to 6,250,000 shares of common stock, par value $0.00001 per share, issuable (i) upon conversion of our Series A-1 Preferred Stock and (ii) upon the exercise of Series B Warrants. These shares were privately issued to the selling stockholders in connection with a private placement transaction. We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Series B Warrants, if exercised.

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

Our common stock is traded on the OTC Bulletin Board under the symbol "XXII.OB". On March 15, 2013, the closing sale price of our common stock was $0.99 per share.

Investing in our common stock involves risks. Before making any investment in our securities, you should read and carefully consider risks described in the "Risk Factors" section beginning on page 11 of this prospectus.

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

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

This date of this prospectus is _____, 2013

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

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Prospectus Summary

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

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

Our Company

Background

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

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

Overview

22nd Century Limited, LLC ("22nd Century Ltd"), our wholly-owned subsidiary, is a plant biotechnology company focused on tobacco harm reduction and smoking cessation products produced from modifying the nicotine content in tobacco plants through genetic engineering and plant breeding. The Company exclusively controls 107 issued patents and exclusively controls an additional 39 patent applications; of these, we own 12 issued patents plus 22 patent applications and we license on an exclusive basis, 95 issued patents and 17 patent applications. Hercules Pharmaceuticals LLC ("Hercules Pharmaceuticals") and Goodrich Tobacco Company, LLC ("Goodrich Tobacco") are wholly-owned subsidiaries of 22nd Century Ltd. Hercules Pharmaceuticals is focused on *X-22,* a prescription smoking cessation aid currently in development. Goodrich Tobacco is focused on commercial tobacco products and potential modified risk cigarettes.

The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 expresses substantial doubt regarding whether we can continue as a going concern and we cannot guarantee our ability to continue as a going concern. **As of March 1, 2013, we had cash on hand of approximately $410,000 due to the capital raises described under "Recent Developments," which should be sufficient to fund operations for approximately 4 months**.

The Company is primarily involved in the following activities:

- The international licensing of 22nd Century Ltd's technology, proprietary tobaccos, trademarks and brands;
- The development of its *X-22* prescription smoking cessation aid in development;
- The development of its modified risk tobacco products;
- The pursuit of necessary regulatory approvals and clearances at the U.S. Food and Drug Administration (the "FDA") to market *X-22* as a prescription smoking cessation aid and *BRAND A and BRAND B* as Modified Risk Cigarettes in the U.S.;
- The manufacture, marketing and distribution of *RED SUN* and *MAGIC* proprietary cigarettes; and
- The production of *SPECTRUM* research cigarettes for the National Institute on Drug Abuse ("NIDA").

Licensing

The Company has been in discussions with various parties in the tobacco and pharmaceutical industries for licensing its technology and products since the first quarter of 2012. Management is exploring licensing arrangements on a country-by-country basis in the U.S., Europe and Asia. The Company expects to close at least one licensing agreement for its technology and products before the end of the third quarter of 2013.

X-22

The *X-22* therapy protocol utilized in the Company's sponsored Phase II-B clinical trial calls for the patient to smoke our very low nicotine ("VLN") cigarettes over a six-week treatment period to facilitate the goal of the patient quitting smoking by the end of the treatment period. We believe this therapy protocol has been successful in independent clinical trials because VLN cigarettes made from our proprietary tobacco satisfy smokers' cravings for cigarettes while (i) greatly reducing nicotine exposure and nicotine dependence and (ii) extinguishing the association between the act of smoking and the rapid delivery of nicotine. *X-22* involves the same smoking behavior as conventional cigarettes and because patients are simply switching to VLN cigarettes for 6 weeks, *X-22* does not expose the smoker to any new drugs or new side effects. Our Investigational New Drug Application for *X-22*, a kit of VLN cigarettes, was cleared by the FDA in July 2011. Our *X-22* Phase II-B clinical trial was completed in the first quarter of 2012 and did not demonstrate a statistically significant difference in quitting between *X-22* and the active control, a cigarette containing conventional nicotine levels. However, the median number of *X-22* cigarettes smoked during the trial was significantly reduced compared to patients' baseline of usual brand of cigarettes. In evaluating the results of this trial, we believe we may have reduced the nicotine content of *X-22* by too great a percentage, to a level less than half the nicotine content of VLN cigarettes used in various independent smoking-cessation clinical trials that have demonstrated that use of VLN cigarettes increases quit rates.

In contrast to the results of the Company's Phase II-B trial results, independent studies have demonstrated that VLN cigarettes, whether used alone or in conjunction with nicotine replacement therapy (NRT), increase quitting rates. Due to the limited effectiveness and/or serious side effects of existing FDA-approved smoking cessation products, we believe that if additional clinical trials demonstrate increased smoking cessation rates, *X-22* can capture a share of this market by replacing sales and market share from existing smoking cessation aids and expanding the smoking cessation market by encouraging more smokers to attempt to quit smoking. We are currently in the process of identifying potential joint venture partners to fund the remaining *X-22* clinical trials. We estimate the cost of completing the remaining *X-22* clinical trials to be approximately $14 million and the marketing expenses to bring *X-22* to market in the U.S. are estimated to be approximately $5 million. There is no guarantee that we will (i) obtain the funds necessary to complete additional clinical trials, (ii) identify potential joint venture partners to fund the remaining *X-22* clinical trials, (iii) obtain FDA approval, or (iv) capture significant share of the smoking cessation market upon FDA approval.

We continue to believe that our VLN cigarettes are effective as a smoking cessation aid. However, we have suspended sponsoring further *X-22* clinical trials pending a complete analysis of results of two independent smoking-cessation trials that were completed in 2012 (ClinicalTrials.gov Identifiers NCT01050569 and NCT01250301), which utilized a different version of our VLN cigarette with a nicotine content similar to those used in previous successful smoking-cessation trials and higher than that used in our own sponsored Phase II-B trial. A portion of the results of these two trials has been disclosed at the annual meeting of the Society for Research on Nicotine and Tobacco ("SRNT") held in Boston on March 13 to 16, 2013.

Regarding the NCT01050569 clinical trial, results only in terms of gender differences in abstinence rates were disclosed at the SRNT annual meeting. Dorothy Hatsukami, PhD, was principal investigator of the study. Within the female population at the end of treatment (week 12), the group assigned our VLN cigarette had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned a 21mg nicotine patch. Within the male population at the end of treatment (week 12), the group assigned a 21mg nicotine patch had the highest continuous abstinence rate; the group assigned concurrent use of our VLN cigarette with a 21mg nicotine patch had the next highest continuous abstinence rate followed by the group assigned our VLN cigarette.

Regarding the NCT01250301 clinical trial, certain results were disclosed in a presentation at the SRNT annual meeting given by Hayden McRobbie, Ph.D. of Queen Mary University of London, Wolfson Institute of Preventative Medicine, who was the principal investigator of the study. Pfizer Inc. was also a collaborator of the study. This clinical trial evaluated whether the use of our VLN cigarette in combination with Chantix® or in combination with nicotine replacement therapy ("NRT") increases abstinence rates over the use of Chantix® or the use of NRT. The study included one hundred smokers who were prescribed varenicline (trademarked Chantix, or Champix outside the U.S.) and one hundred smokers who were prescribed NRT. Half the smokers of each of these groups were randomly selected to also use our VLN cigarettes for the first 2 weeks of treatment. All smokers received 9 weekly behavioral support sessions throughout the 12-week study period. The group that used our VLN cigarettes had a 70% quit rate one week after stopping VLN cigarette use compared to a 53% quit rate of the group not using VLN cigarettes after week 1 (p=0.02). The group that used our VLN cigarettes had a 64% four-week continuous abstinence rate during weeks 3 to 6 compared to a 50% four-week continuous abstinence rate during weeks 1 to 4 (p=0.06). Quit rates at 12 weeks post treatment were not reported in the presentation.

The full set of results of these 2 independent clinical trials are expected to be published in peer reviewed journals and will be compared to results of other independent clinical trials of our VLN cigarettes and results of our Phase II-B trial to determine which variables optimize cessation. One preliminary hypothesis, in conjunction with results of various other studies of our VLN cigarettes, is that having two types of prescription VLN cigarettes available may be advantageous for increased smoking cessation in the general population; one having a higher nicotine content than the other. Upon identifying a suitable joint venture partner to fund further *X-22* clinical trials, we will then request a meeting with the U.S. Food and Drug Administration ("FDA"), and thereafter we may resume our own sponsored *X-22* clinical trials.

Potential Modified Risk Cigarettes and the Tobacco Control Act

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

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco toxins and (ii) are reasonably likely to pose lower health risks as compared to conventional cigarettes ("Modified Risk Cigarettes"). The Tobacco Control Act requires the FDA to issue specific regulations or guidance regarding applications that must be submitted to the FDA for the authorization to label and market Modified Risk Cigarettes. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance.* We believe that two types of our cigarettes in development which we

refer to as *BRAND A* and *BRAND B*, may qualify as Modified Risk Cigarettes. Compared to commercial cigarettes, the tobacco in *BRAND A* has approximately 95% less nicotine than tobacco in cigarettes previously marketed as "light" cigarettes, and *BRAND B*'s smoke contains an extraordinary low amount of "tar" per milligram of nicotine.

Goodrich Tobacco intends to seek FDA authorization to market *BRAND A* and *BRAND B* as Modified Risk Cigarettes and expect to file applications with the FDA in 2013, the exact timing will depend on the timing of obtaining additional capital. After filing our modified risk applications with the FDA, we will need significant additional capital to complete the FDA authorization process for our Modified Risk Cigarettes. The exact amount of capital is currently unknown since it is uncertain how many exposure studies the FDA will require for *BRAND A* and *BRAND B*. However, we estimate that the cost of completing the FDA authorization process for each of our potential Modified Risk Cigarettes to be at least $2 million. We believe that *BRAND A* and *BRAND B* will achieve market share in the global cigarette market among smokers who will not quit but are interested in reducing the harmful effects of smoking. There is no guarantee that we will (i) obtain additional capital to complete the FDA authorization process for our potential Modified Risk Cigarettes, (ii) obtain FDA authorization to market *BRAND A or BRAND B* as Modified Risk Cigarettes, or (iii) achieve significant market with FDA authorization to market our products as Modified Risk Cigarettes.

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

Smoking Cessation Aids

FDA approval must be obtained, as has been the case for decades, before a product can be marketed for quitting smoking. The Tobacco Control Act provides that products for quitting smoking or smoking cessation, such as *X-22*, be considered for "Fast Track" designation by the FDA. The "Fast Track" programs of the FDA are intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Although *X-22* has failed previously to qualify for "Fast Track," we believe that upon completion of a company-sponsored clinical trial demonstrating efficacy, *X-22* will qualify for "Fast Track" designation by the FDA. However, there is no guarantee that the FDA will grant "Fast Track" designation to *X-22*. See "Business – Government Regulation – Fast Track Development."

Modified Risk Cigarettes

We believe this new regulatory environment represents a paradigm shift for the tobacco industry. Besides the fact that the Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, the Tobacco Control Act allows the FDA to mandate the use of reduced-risk technologies across all conventional tobacco products or cigarettes. We believe the Tobacco Control Act may create opportunities for us to license our proprietary technology and/or tobaccos to larger competitors.

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 full flavor cigarettes, which is the reason that the Tobacco Control Act has banned the use of the terms "low tar," "light" and "ultra light" in the U.S. market. Studies have shown, however, that smokers generally do not compensate when smoking cigarettes made with our VLN tobacco, and that smoking VLN

cigarettes, such as *BRAND A,* actually assist smokers to smoke fewer cigarettes per day and reduce their exposure to "tar" and nicotine. Other studies have demonstrated that compensatory smoking (e.g., more and/or larger puffs per cigarette) of low-tar research cigarettes, similar to *BRAND B (*though *BRAND B* was not used in such studies), is greatly curtailed resulting in smokers inhaling less "tar" and carbon monoxide. Additional studies will be necessary to establish whether *BRAND B* cigarettes achieve similar results.

RED SUN and MAGIC Cigarettes

Goodrich Tobacco has thus far had its cigarette brands contract manufactured by a non-participating manufacturer to the "Master Settlement Agreement" or "MSA," a settlement among 46 states and the tobacco industry administered by the National Association of Attorneys General ("NAAG"). Our subsidiary, Goodrich Tobacco, introduced in a limited capacity two super-premium priced cigarette brands, *RED SUN* and *MAGIC*, into the U.S. market in the first quarter 2011. There have been *de minimis* sales of these brands in 2011 and 2012 since we have intentionally have not expanded marketing and distribution of these brands to facilitate Goodrich Tobacco becoming a participating manufacturer of the MSA. The more *RED SUN* and *MAGIC* sold while these brands are produced by a non-participating manufacturer, the greater the settlement costs Goodrich Tobacco likely has to pay to become a participating manufacturer of the MSA. On January 23, 2013, Goodrich Tobacco applied to the Alcohol and Tobacco Tax Trade Bureau ("TTB") for a federal permit to manufacture its own tobacco products. Being a federally licensed tobacco product manufacturer is a primary requirement of becoming a participating manufacturer of the MSA. On February 26, 2013, Goodrich Tobacco applied to the NAAG to become a participating manufacturer to the MSA. Both of these measures, if approved by the TTB and NAAG, will greatly facilitate the sales and distribution potential of *RED SUN* and *MAGIC*. Goodrich Tobacco expects its cigarette factory startup costs to be approximately $250,000 and plans to lease a portion of the machinery required. The costs associated with the MSA settlement are expected to be less than $40,000. The expected marketing costs for *RED SUN* and *MAGIC* in 2013 are $100,000.

SPECTRUM Government Research Cigarettes

As a subcontractor to RTI International ("RTI") in RTI's contract with The National Institute on Drug Abuse for the Research Cigarette Option, we supply modified nicotine (from very low to high) cigarettes to NIDA. These research cigarettes are distributed under the mark *SPECTRUM*.

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

Current Financial Condition

We have operated at a loss since 2006 when we increased our research and development expenditures. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 expresses substantial doubt regarding whether we can continue as a going concern and we cannot guarantee our ability to continue as a going concern. We had net losses of $6.7 million, $1.3 million and $1.4 million, respectively, in the years ended December 31, 2012, 2011 and 2010. We realized revenue of $18,775 in the year ended December 31, 2012 mainly from the sale of research cigarettes. In the year ended December 31, 2011, we realized revenue of $788,601 mainly from the sale of research cigarettes and in 2010, we realized revenue of $49,784. **As of March 1, 2013, we had cash on hand of approximately $410,000 due to the capital raises described under "Recent Developments," which should be sufficient to fund operations for approximately 4 months.**

Subsequent to December 31, 2012, the Company realized net proceeds of approximately $2.125 million through the sale of preferred shares. Convertible Notes with a carrying value at December 31, 2012 of approximately $1.41 million were converted into common stock and warrants. While these steps significantly improved the Company's financial position, we will need additional capital or one or more licensing arrangements for our technology and products in order to meet cash requirements to fund operations and meet our obligations during 2013. Excluding contract growing of our proprietary tobacco with farmers and extraordinary expenses such as clinical trials and factory setup costs, our monthly cash expenditures are approximately $100,000. In the event the Company does not enter into an out-licensing agreement with a third party in 2013, approximately $1.6 million of additional capital is required through 2013, which includes paying approximately $1 million of obligations that will become due in 2013. The Company expects its cigarette factory start up costs to require an additional $250,000 of capital. It plans to lease a portion of the machinery required. The Company's R&D expenditures in 2013 are expected to be approximately $200,000. Upon the required funding, we expect to carry out exposure studies for our Modified Risk cigarette candidates and will carry out additional clinical trials for *X-22* if Hercules Pharmaceuticals, our subsidiary, identifies a joint venture partner willing to fund these trials.

The ability to complete additional equity or debt financings on acceptable terms will depend on a number of factors, including the general performance of the capital markets, the Company's progress in the manufacture, distribution and sale of its products, licensing of its technology, products and tobacco, and results of independent smoking cessation clinical trials utilizing the Company's products. In addition, our ability to complete additional debt and equity financings is limited by covenants related to our Series A-1 Preferred Stock. However, we can issue securities pursuant to strategic transactions approved by a majority of our disinterested directors, provided that any such issuance shall only be to an entity which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with our business which provides us additional benefits in addition to the investment of funds. See "Risk Factors - Our ability to obtain future debt financing is limited while shares of our Series A-1 Preferred Stock are outstanding" on page 12 of this prospectus. Failure to license the Company's technology, products and tobacco or to raise sufficient capital would significantly increase the risk that we would be unable to continue operations. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technology, tobacco or products or grant licenses on terms that are not favorable to us. There can be no assurance that the Company will be able to raise sufficient financing or obtain a significant licensing contract.

Corporate Information

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

Recent Developments

Private Placement of Preferred Stock and Warrants

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

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

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

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

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

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

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

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

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

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

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

Modification and Conversion of Convertible Notes Due December 14, 2012

On December 14, 2011, we sold approximately $1.9 million of convertible promissory notes for an aggregate purchase price of approximately $1.7 million in a private placement (the "Convertible Notes"). The notes were issued with an original issue discount of approximately 15% and the original maturity date of the notes was December 14, 2012 (which was extended as set forth below). Upon conversion of all or a portion of the Convertible Notes into common stock, the holder would receive at that time a warrant to purchase at an exercise price of $1.50 per share; such number of shares of common stock from such warrant equal to 120% of such number of shares of common stock issuable upon conversion of the note. All of the Convertible Notes issued on December 14, 2011 have been either converted or paid off in full subsequent to December 31, 2012. At December 31, 2012 notes with a total face and carrying value of $1,805,500 remained outstanding; of this amount $1,523,750 were extended, by agreement with the note holders, to April 14, 2013 at 15% interest per annum. The notes were initially convertible into shares of our common stock at any time prior to maturity at a per share conversion price equal to $0.75. From January 1, 2013 to February 6, 2013, $1,408,750 of the notes (together with accrued interest), with an adjusted conversion price of $0.7004 were converted into 2,035,720 shares of common stock and five-year warrants to purchase 2,662,769 shares of common stock at $1.50 per share; the Company discharged the remaining note principal of $396,750 by payment in

cash of $339,250 and issuing a new note of $57,500 maturing in August 2013. A $247,250 note held by an executive officer and another note of $30,000 were discharged through payments in cash. Subsequent to this repayment, the Company issued a promissory note to the executive officer in the amount of $150,000, with 15% interest per annum and maturing on July 1, 2013. A third note of $115,000 plus interest was discharged through a payment of $58,340 in conjunction with a new note being issued for the same amount. In connection with the issuance of preferred shares in January 2013, the note holders entered into a lock-up agreement with the Company which limits their ability to sell any of the shares received as a result of the conversion of the notes and received additional warrants (five year term at $1.50 exercise price) to purchase 239,900 shares of common stock.

Between December 14, 2012 and January 2, 2013, we entered into agreements with holders of $1,805,500 of the notes that remained outstanding. Holders of $1,408,750 of the notes agreed to extend the maturity date of the notes to April 14, 2013. Holders of $115,000 of the notes elected to convert into shares of the common stock pursuant to the terms of the notes. Holders of $247,250 of the notes elected to enter into a forbearance agreement and were subsequently paid in full. Holders of $34,500 of the notes agreed to be paid over time. On January 24, 2013, we sent out notices to the holders of the notes regarding our intent to repay the notes at the expiration of a 15-day period during which time the holders may convert to common stock and warrants to purchase common stock. From January 1, 2013 through February 6, 2013, the remaining notes were converted into common stock and warrants.

Certain Arrangements

On March 30, 2011, the Company issued a note to a vendor in the amount of $350,000 as satisfaction of past due invoices previously recorded by the Company in accounts payable. The note bears interest at an annual rate of 4%. Principal and accrued interest, which were due on July 1, 2012 have not been paid as of December 31, 2012. The outstanding principal on this note was $350,000 as of December 31, 2012 and 2011. In January 2013 the Company repaid

$175,000 of note principal and all accrued interest; the balance of $175,000 was replaced by a new note which is unsecured, bears interest at 5% and matures July 1, 2014 or sooner if the Company receives license revenue or financing of at least $1,500,000 prior to maturity.

As of March 15, 2013, the Company was in full compliance with the NCSU license agreement. Since December 31, 2012 the Company paid NCSU $400,000 and issued a note dated February 1, 2013 for $474,893; the note is unsecured, bears interest at 5% and matures the earlier of October 1, 2013 or the closing of an in-licensing agreement with up front proceeds of at least $1.5 million. NCSU also agreed to not to invoke any rights to terminate the Company’s

license agreement for nonpayment or nonperformance until October 1, 2013.

The Offering	
Common stock currently outstanding	38,259,365 shares (1) (2)
Common stock offered by us	None.
Common stock offered by the selling stockholders	Up to 6,250,000 shares issuable (i) upon conversion of our Series A-1 Preferred Stock and (ii) upon the exercise of the Series B Warrants.
Use of Proceeds	We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will receive funds from the exercise of the Series B Warrants, if exercised.
Risk Factors	See "Risk Factors" and other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in shares of our common stock.
OTC Bulletin Board Symbol	XXII.OB

(1) As of March 15, 2013.

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

- up to 4,166,666 shares of common stock that could be issued as a result of the conversion of the shares of Series A-1 Preferred Stock, which is subject to adjustment as described under "Description of Securities – Preferred Stock";
- up to 950,000 shares of common stock reserved for future issuance under the Equity Incentive Plan;
- up to 680,000 shares of common stock issuable upon exercise of outstanding stock options;
- up to 371,000 shares of common stock currently issuable upon the conversion of convertible notes (subject to adjustment for anti-dilution adjustments);
- up to 22,343,082 shares of common stock currently issuable upon the exercise of outstanding warrants (including the Series A Warrants and Series B Warrants) (subject to adjustment for anti-dilution adjustments); and
- up to 2,454,334 shares of common stock issuable upon exercise of warrants issuable upon conversion or exercise of other instruments (including the Series C Warrants) (subject to adjustment for anti-dilution adjustments).

Cautionary Note Regarding Forward-Looking Statements

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

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

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

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

Risk Factors

An investment in shares of our common stock is highly speculative and involves a high degree of risk. We face a variety of risks that may affect our operations or financial results and many of those risks are driven by factors that we cannot control or predict. The following discussion addresses all risks that management believes are material that may affect our operations or financial results. Only those investors who can bear the risk of loss of their entire investment should participate in this offering. Prospective investors should carefully consider the following risk factors in evaluating an investment in our common stock.

Risks Related to Our Business and Operations

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

Recurring losses from operations, our negative working capital of approximately $3.3 million and $1.9 million as of December 31, 2012 and 2011, respectively, shareholders' deficit of $6.1 million and $1.2 million as of December 31, 2012 and 2011, respectively, and the uncertainty of obtaining additional capital on a timely basis, raise doubt about our ability to continue as a going concern. It is highly probable that any sales of equity securities will cause our stockholders to experience substantial dilution. It is also possible that such equity securities will have rights, preferences or privileges senior to those of existing stockholders. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 expresses substantial doubt regarding whether we can continue as a going concern. We cannot guarantee our ability to continue as a going concern.

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

We experienced net losses, including adjustment of our warrant liability, of approximately $6.7 million, $1.3 million and $1.4 million during the years ended December 31, 2012, 2011 and 2010, respectively. We expect to continue to incur net losses and negative operating cash flows in the foreseeable future and cannot be certain that we will ever achieve profitability. Since 2007, we have received only limited licensing revenue from a former licensee and our only significant revenue has been from research cigarettes for which the market is limited. We will need to spend significant capital to fulfill planned operating goals and conduct clinical studies, achieve regulatory approvals and, subject to such approvals, successfully produce products for commercialization. Excluding contract growing of our proprietary tobacco with farmers and extraordinary expenses such as clinical trials and factory setup costs, our monthly cash expenditures are approximately $100,000. In the event the Company does not enter into an out-licensing agreement with a third party in 2013, approximately $1.6 million of additional cash is required through 2013, which

includes paying approximately $1 million of obligations that will become due in 2013. There can be no assurance that the Company will be able to raise sufficient financing or obtain a licensing agreement.

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

We had negative cash flow before financing activities of approximately $1,927,000, $4,057,000 and $1,018,000 during the years ended December 31, 2012, 2011 and 2010, respectively. We anticipate that we will continue to have negative cash flow for the foreseeable future even though we have suspended clinical trials for *X-22* because we have significant liabilities that are due or that will become due in 2013 and we will continue to incur expenses for sales and marketing, and general and administrative expenses. Our business will also require significant amounts of working capital to support our growth. Therefore, we will likely need to raise additional investment capital to achieve growth, and we may not achieve sufficient revenue growth to generate positive future cash flow. An inability to generate positive cash flow for the foreseeable future or raise additional capital on reasonable terms may decrease our long-term viability.

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

Our Certificate of Designations regarding our Series A-1 Preferred Stock contains restrictive covenants that limit our ability to, among other things, incur or assume additional debt or provide guarantees in respect of obligations of other persons (in each case, so long as 1,000 or more shares of our Series A-1 Preferred Stock are outstanding, and other than with respect to lease obligations and purchase money indebtedness in an amount up to $200,000 in the aggregate), or create, assume, or suffer to exist any liens (other than liens for taxes not yet due, liens contested in good faith, and liens imposed in the ordinary course of business that do not materially impair the operation of the business) without, in each instance, the prior written consent of at least 67% in stated value of the then-outstanding shares of Series A-1 Preferred Stock. A breach of these covenants would trigger the ability of the holders of the Series A-1 Preferred Stock to redeem their shares of Series A-1 Preferred Stock for cash or shares of our common stock or elect to increase the dividend payments to be made on their shares of Series A-1 Preferred Stock to 18% per annum. However, our Certificate of Designations regarding our Series A-1 Preferred Stock allows us to issue securities without restrictions pursuant to strategic transactions approved by a majority of our disinterested directors, provided that any such issuance shall only be to an entity which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with our business which provides us additional benefits in addition to the investment of funds.

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

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

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

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

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

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

We have suspended further clinical trials for FDA approval of our X-22 smoking cessation aid and we will need additional capital before we can complete the FDA authorization process for our Modified Risk Cigarettes.

We have suspended further clinical trials for FDA approval of our *X-22* smoking cessation aid until we identify a suitable joint venture partner willing to fund further *X-22* clinical trials. At that time we may resume our own sponsored *X-22* clinical trials. There is no guarantee that we will identify a joint venture partner willing to fund further *X-22* clinical trials. We estimate the cost of completing a Phase II trial will be approximately $2 million and the cost of completing two Phase III trials to be approximately $12 million. We will require additional capital in the future before we can complete the FDA authorization process for our Modified Risk Cigarettes. We estimate that the cost of completing the FDA authorization process for each of our two potential Modified Risk Cigarettes to be at least $2 million. If we raise additional funds through the issuance of equity securities for the FDA authorization process for our Modified Risk Cigarettes, our stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. However, our ability to raise funds through debt financing is limited while any shares of our Series A-1 Preferred Stock is outstanding. We also could elect to seek funds through arrangements with collaborators or licensees. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to us.

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

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

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

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

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

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

• acquire complementary technologies, products or businesses;

• expand our operations in the United States or internationally;

• hire, train and retain employees; or

• respond to competitive pressures or unanticipated working capital requirements.

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

Included in current liabilities at December 31, 2012 is a demand loan under a revolving credit agreement with a balance outstanding of $174,925, which is payable to a commercial bank and guaranteed by one of our shareholders. This exact same principal amount has been outstanding for over four years on a continuous basis, notwithstanding the fact that we have not complied with annual "clean-up" provisions which require that we repay all amounts outstanding for a period of 30 consecutive days each year. There are no additional amounts available to us under this credit agreement. We have paid interest only since 2008 (currently at the bank's annual prime rate plus 0.75% or 4%) on a monthly basis according to the bank's monthly payment statements. Our plans contemplate that this balance remains outstanding while we continue to pay interest only on a monthly basis. We may incur disruptions in our operations in the event the bank were to demand repayment in full, close the revolving credit agreement, and not allow us sufficient time to locate additional capital.

We will depend on third parties to manufacture our products.

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

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

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

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

If we are unable to enter into marketing, sales and distribution arrangements with third parties for our *X-22* smoking cessation aid, we would need to incur significant sales, marketing and distribution expenses in connection with the commercialization of *X-22* and any future potential products. We do not currently have a dedicated sales force, and we have no experience in the sales, marketing and distribution of pharmaceutical products. Developing a sales force is expensive and time-consuming, and we may no