

22nd Century Group, Inc.
Form 10-Q
November 14, 2011

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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 2011

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period From _____ to _____

Commission File Number: 333-173420

22nd Century Group, Inc.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of incorporation or organization)

98-0468420
(I.R.S. Employer Identification No.)

9530 Main Street
Clarence, New York
(Address of principal executive offices)

14031
(Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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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.

Large Accelerated Filer

Accelerated Filer

Non-accelerated Filer

Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of October 31, 2011, there were 27,909,646 shares of common stock issued and outstanding.

22nd CENTURY GROUP, INC.

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Part I. FINANCIAL INFORMATION

Item 1. Financial Statements

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
September 30, 2011 with Comparative Figures at December 31, 2010

| | 2011 (unaudited) | 2010 |
|--|---------------------|-------------|
| ASSETS | | |
| Current assets: | | |
| Cash | \$4,375 | \$310 |
| Accounts receivable | 86,682 | - |
| Grant receivable | - | 223,540 |
| Due from related Party | 14,330 | - |
| Inventory | 833,396 | 308,662 |
| Prepaid expenses | 82,422 | 211,717 |
| Total current assets | 1,021,205 | 744,229 |
| Other assets: | | |
| Patent and trademark costs, net | 1,406,617 | 1,467,623 |
| Office Furniture and fixtures, net | 8,321 | - |
| Deferred private placement costs | - | 587,133 |
| Deposits | - | 1,535 |
| Total other assets | 1,414,938 | 2,056,291 |
| Total assets | \$2,436,143 | \$2,800,520 |
| LIABILITIES AND SHAREHOLDERS' DEFICIT | | |
| Current liabilities: | | |
| Demand bank loans | \$174,925 | \$174,925 |
| Accounts payable | 1,221,746 | 2,900,684 |
| Accrued interest payable to shareholders | 21,174 | 190,977 |
| Accrued expenses | 542,445 | 227,724 |
| Deferred grant revenue | - | 223,540 |
| Notes payable to shareholders, net of unamortized discount | 150,000 | 1,095,643 |
| Current portion of long-term debt | 524,556 | - |
| Due to related party | - | 6,942 |
| Due to officers | 31,417 | 3,200 |
| Total current liabilities | 2,666,263 | 4,823,635 |
| Long-term notes, less current portion | 227,000 | 65,557 |
| Warrant liability | 2,724,250 | - |
| Total liabilities | 5,617,513 | 4,889,192 |
| Commitments and contingencies (Note 10) | - | - |
| Shareholders' deficit | | |
| Capital stock authorized: | | |

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| | | |
|--|-------------|-------------|
| 10,000,000 preferred shares, \$.00001 par value | | |
| 300,000,000 common shares, \$.00001 par value | | |
| Capital stock issued and outstanding: | | |
| 0 preferred shares | - | - |
| 27,209,646 common shares (16,000,000 at December 31, 2010) | 273 | - |
| Capital in excess of par value | 4,711,243 | 3,598,856 |
| Accumulated deficit | (7,905,756) | (5,687,394) |
| Non-controlling interest - consolidated subsidiary | 12,870 | (134) |
| Total shareholders' deficit | (3,181,370) | (2,088,672) |
| Total liabilities and shareholders' deficit | \$2,436,143 | \$2,800,520 |

See accompanying notes

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months Ended September 30, 2011 with Comparative Figures for 2010
(unaudited)

| | 2011 | 2010 |
|--|--------------|--------------|
| Revenue | \$529,370 | \$20,302 |
| Other Income - Therapeutic Grant | 80,000 | - |
| Total revenue | 609,370 | 20,302 |
| Operating expenses: | | |
| Costs of goods sold | 130,495 | 5,302 |
| Research and development | 711,996 | 67,528 |
| General and administrative | 451,087 | 138,911 |
| Sales and marketing costs | 37,106 | - |
| Amortization and depreciation | 44,630 | 40,803 |
| | 1,375,314 | 252,544 |
| Operating loss | (765,944) | (232,242) |
| Other income (expense): | | |
| Gain warrant liability - derivative | 337,500 | - |
| Interest expense and debt expense: | | |
| Shareholders | (9,401) | (66,031) |
| Other | (12,526) | (2,611) |
| | 315,573 | (68,642) |
| Net loss | (450,371) | (300,884) |
| Net income attributable to non-controlling interest | (14,711) | - |
| Net loss attributed to common shareholders | \$(465,082) | \$(300,884) |
| Loss per common share - basic and diluted | \$(0.02) | \$(0.02) |
| Common shares used in basic earnings per share calculation | 27,209,646 | 15,322,529 |

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Nine Months Ended September 30, 2011 with Comparative Figures for 2010
(unaudited)

| | 2011 | 2010 |
|--|----------------|--------------|
| Revenue | \$801,636 | \$22,102 |
| Other Income - Therapuertic Grant | 223,540 | - |
| Total revenue | 1,025,176 | 22,102 |
| Operating expenses: | | |
| Costs of goods sold | 224,146 | 6,302 |
| Research and development | 1,509,050 | 282,971 |
| General and administrative | 1,381,480 | 383,576 |
| Sales and marketing costs | 267,810 | - |
| Amortization and depreciation | 132,432 | 121,735 |
| | 3,514,918 | 794,584 |
| Operating loss | (2,489,742) | (772,482) |
| Other income (expense): | | |
| Gain warrant liability - derivative | 337,500 | - |
| Interest expense and debt expense: | | |
| Shareholders | (28,177) | (187,431) |
| Other | (24,939) | (31,088) |
| | 284,384 | (218,519) |
| Net loss | (2,205,358) | (991,001) |
| Net (income) loss attributable to non-controlling interest | (13,004) | 4 |
| Net loss attributed to common shareholders | \$(2,218,362) | \$(990,997) |
| Loss per common share - basic and diluted | \$(0.08) | \$(0.09) |
| Common shares used in basic earnings per share calculation | 26,263,743 | 11,232,202 |

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months Ended September 30, 2011 with Comparative Figures for 2010
(unaudited)

| | 2011 | 2010 |
|--|---------------|--------------|
| Cash flows from operating activities: | | |
| Net loss | \$(2,205,358) | \$(991,001) |
| Adjustments to reconcile net loss to cash used by operating activities: | | |
| Amortization and depreciation | 132,432 | 121,735 |
| Amortization of debt issuance costs | - | 32,331 |
| Amortization of debt discount | 3,999 | 114,500 |
| Gain warrant liability - derivative | (337,500) | - |
| Equity based employee compensation expense | 327,458 | 134,808 |
| (Increase) decrease in assets: | | |
| Accounts receivable | (86,682) | (40,604) |
| Grant receivable | 223,540 | - |
| Inventory | (524,734) | (262,480) |
| Prepaid expenses | 129,294 | (23,254) |
| Deposits | 1,535 | - |
| Increase (decrease) in liabilities: | | |
| Accounts payable | (65,811) | 8,955 |
| Accrued interest payable to shareholders | (163,101) | 61,989 |
| Accrued expenses | 314,722 | 172,203 |
| Deferred revenue | (223,540) | 20,302 |
| Net cash used by operating activities | (2,473,746) | (650,516) |
| Cash flows from investing activities: | | |
| Acquisition of patents and trademarks | (570,641) | (88,382) |
| Acquisition of office furniture and fixtures | (9,106) | - |
| Net cash used by investing activities | (579,747) | (88,382) |
| Cash flows from financing activities: | | |
| Payment of deferred private placement costs | - | (58,970) |
| Payment on demand loan | - | (7,383) |
| Proceeds from issuance of notes and warrants to shareholders | 215,000 | 485,000 |
| Payments on borrowings - notes payable to shareholders | (458,275) | (4,389) |
| Proceeds from issuance of common stock | - | 411,600 |
| Net proceeds from January 25, 2011 private placement | 3,293,888 | - |
| Net payments to related party | (21,272) | (93,700) |
| Net advances from officers | 28,217 | 7,870 |
| Net cash provided by financing activities | 3,057,558 | 740,028 |
| Net increase in cash | 4,065 | 1,130 |
| Cash - beginning of period | 310 | 158 |
| Cash - end of period | \$4,375 | \$1,288 |
| Cash paid during the period for interest | \$191,524 | \$8,834 |
| Supplemental disclosure of noncash investing and financing activities: | | |
| Reduction of accounts payable not related to operating activities: | | |
| Payment of accounts payable for patent costs | \$500,000 | \$- |
| Payment of accounts payable for deferred private placement costs | 526,127 | - |
| Accounts payable converted to promissory notes | 587,000 | - |

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| | | |
|--|-------------|-----------|
| | \$1,613,127 | \$- |
| Deferred private placement costs charged to contributed capital | \$587,133 | \$- |
| Conversion of member note to common shares and warrants | \$614,070 | \$31,311 |
| Issuance of warrants as derivative liability instruments and reduction of capital in excess of par value | \$3,061,750 | \$- |
| Patent and trademark additions included in accounts payable | \$- | \$20,950 |
| Deferred private placement cost additions included in accounts payable | \$- | \$293,960 |

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF SHAREHOLDERS' DEFICIT
For the nine months ended September 30, 2011
(unaudited)

| | Common Shares Outstanding | Par value of Common Shares | Contributed Capital | Accumulated Deficit | Non-controlling Interest | Shareholders' Deficit |
|---|---------------------------------|-------------------------------------|------------------------|------------------------|-----------------------------|--------------------------|
| Balance at December 31, 2010 | 16,000,000 | \$ - | \$3,598,856 | \$ (5,687,394) | \$ (134) | \$ (2,088,672) |
| Distribution of 5,000,000 warrants for common stock, exercise price of \$3.00 per share | | | (1,550,000) | | | (1,550,000) |
| Common Shares issued in January 25, 2011 private placement | 5,434,446 | | 2,335,202 | | | 2,335,202 |
| Merger of 22nd Century Limited and 22nd Century Group | 5,325,200 | 268 | (268) | | | - |
| Stock based compensation | 450,000 | 5 | 327,453 | | | 327,458 |
| Net income (loss) | | | | (2,218,362) | 13,004 | (2,205,358) |
| Balance at September 30, 2011 | 27,209,646 | \$ 273 | \$4,711,243 | \$ (7,905,756) | \$ 12,870 | \$ (3,181,370) |

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2011

NOTE 1. - NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Introduction - These unaudited consolidated financial statements of 22nd Century Group, Inc. (“22nd Century Group”) and its direct and indirect subsidiaries (collectively with 22nd Century Group, the “Company”) incorporate and reflect the reverse acquisition of 22nd Century Limited, LLC by 22nd Century Group, Inc. as described below.

On January 25, 2011, 22nd Century Limited, LLC (“22nd Century Ltd”) completed a reverse merger transaction (the “Merger”) with 22nd Century Group, Inc. (formerly Touchstone Mining Limited). As a result, 22nd Century Ltd became a wholly owned subsidiary of 22nd Century Group which continues to operate the business of 22nd Century Ltd. In connection with the Merger, 22nd Century Group issued 21,434,446 shares of its common stock to the holders of limited liability company membership interests of 22nd Century Ltd, which share amount represented 80.1% of the outstanding shares immediately following the Merger. All references contained herein to shareholders or common shares include the historical members and limited liability company membership interests of 22nd Century Ltd because, in the Merger, limited liability company membership interests were exchanged for common shares on a one-for-one basis and from an accounting standpoint they are equivalent.

The Merger is being accounted for as a reverse acquisition and a recapitalization; 22nd Century Ltd is the acquirer for accounting purposes. Consequently, the assets and liabilities and the historical operations that are reflected in the financial statements set forth herein for periods prior to the Merger are those of 22nd Century Ltd and are recorded at the historical cost basis of 22nd Century Ltd, and the consolidated financial statements set forth herein for periods beginning on and following completion of the Merger include the assets and liabilities of 22nd Century Ltd, historical operations of 22nd Century Ltd, and operations of 22nd Century Group from the closing date of the Merger.

Upon the closing of the Merger, 22nd Century Group transferred all of its operating assets and liabilities to Touchstone Split Corp. and split-off Touchstone Split Corp. through the sale of all of the outstanding capital stock of Touchstone Split Corp. (the “Split-Off”). After the completion of the Merger and Split Off, 22nd Century Group’s consolidated financial statements include only the assets and liabilities of 22nd Century Ltd. Refer to the Current Report on Form 8-K that the Company filed with the Securities and Exchange Commission on February 1, 2011 for further information on the Merger.

Immediately prior to the Merger on January 25, 2011, 22nd Century Ltd completed a private placement offering (the “Private Placement”) of 5,434,446 securities (the “PPO Securities”) at the purchase price of \$1.00 per Unit, each such Unit consisting of one (1) limited liability company membership interest of 22nd Century Ltd and a five-year warrant to purchase one-half of one (1/2) limited liability company membership interest of 22nd Century Ltd at an exercise price of \$1.50 per whole common share. In connection with the Private Placement, 22nd Century Ltd approved a prorata distribution of 5,000,000 five-year warrants to purchase one limited liability company membership interest at an exercise price of \$3.00. Private Placement proceeds included \$614,070 from the conversion of 22nd Century Ltd indebtedness into PPO Securities and \$395,376 from the conversion of placement agent fees into PPO Securities, resulting in gross cash proceeds of \$4,425,000. Private Placement expenses incurred included cash expenses of approximately \$1,025,000 and non-cash expenses consisting of the placement agent fees of \$395,376 which were converted into PPO Securities and \$390,000 for the estimated fair value of 934,755 placement agent and advisor warrants issued to the placement agent. An additional \$167,820 of cost was incurred in the second and third quarters of 2011 in connection with registration process for the common stock issued in the Private Placement. 22nd Century Ltd/Group received net cash proceeds of approximately \$3.3 million from the Private Placement in net cash proceeds and a reduction of debt and accrued interest obligations to shareholders that were on the balance sheet at December 31, 2010 of approximately \$614,000, which was exchanged for equity interests in the offering. A portion of the

proceeds were allocated to the warrants issued, which are classified as liabilities (see Note 9).

Basis of Presentation - The accompanying unaudited statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals, considered necessary for a fair and non-misleading presentation of the financial statements have been included.

The results of operations for any interim period are not necessarily indicative of results for the full year. Operating results for the nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. The balance sheet at December 31, 2010 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

Nature of Business - 22nd Century Group is a holding company and is the sole member of 22nd Century Ltd, which is a plant biotechnology company. 22nd Century Ltd owns or exclusively licenses 99 issued patents in 79 countries predominantly related to modifying the content of nicotinic alkaloids in plants, specifically tobacco plants, through genetic engineering and plant breeding.

The overall objectives of 22nd Century Ltd are to reduce smoking-related disease by increasing smoking cessation with X-22, its botanical prescription smoking cessation aid in development and reducing the harm to smokers with 22nd Century's potential modified risk tobacco products (as defined in the Overview of Management Discussion), for smokers unwilling to quit. 22nd Century Ltd, including its subsidiary, Goodrich Tobacco Company Ltd. ("Goodrich Tobacco") is primarily involved in the following activities:

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

Principles of Consolidation - The accompanying consolidated financial statements include the accounts of 22nd Century Group, 22nd Century Ltd, and Goodrich Tobacco, a subsidiary of 22nd Century Ltd. 22nd Century Ltd owns 96% of the outstanding membership units of Goodrich Tobacco. All intercompany accounts and transactions have been eliminated.

Inventory - Inventories are valued at the lower of cost or market. Cost is determined on the first-in, first-out (FIFO) method. The Company's inventory consisted of the following categories:

| | September 30, 2011 | December 31, 2010 |
|---------------------------|-----------------------|----------------------|
| Materials, mainly tobacco | \$ 784,090 | \$ 292,480 |
| Finished goods | 49,306 | 16,182 |
| Total | \$ 833,396 | \$ 308,662 |

Intangible Assets - Intangible assets are recorded at cost and consist primarily of expenditures incurred with third parties related to the processing of patent claims and trademarks with government authorities. The Company also

capitalized costs as a result of one of its exclusively licensed patent applications being subject to an interference proceeding invoked by the U.S. Patent and Trademark Office, which favorably resulted in the Company obtaining rights to a third party's issued patent. The amounts capitalized relate to patents the Company owns or to which it has exclusive rights and its trademarks, and exclude approximately \$1.8 million recovered from a former licensee as direct reimbursements of costs incurred. These capitalized costs are amortized using the straight-line method over the remaining statutory life of the Company's primary patent family, which expires in 2019 (the assets' estimated lives). Periodic maintenance or renewal fees, which are generally due on an annual basis, are expensed as incurred. Annual minimum license fees are charged to expense in the year the licenses are effective. Total patent and trademark costs capitalized and accumulated amortization amounted to \$2,036,262 and \$629,645 as of September 30, 2011 (\$1,965,621 and \$497,998 - as of December 31, 2010). The estimated annual amortization expense for the next five years is approximately \$177,000.

Impairment of Long-Lived Assets - The Company reviews the carrying value of its amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable.

The Company assesses recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. There was no impairment loss recorded during the nine month periods ended September 30, 2011 or 2010.

Deferred Private Placement Costs - During 2010, the Company incurred costs related to the Private Placement that closed on January 25, 2011. Such costs were accumulated on the balance sheet as of December 31, 2010 and were charged against contributed capital upon closing of the offering. Deferred Private Placement costs were \$0 as of September 30, 2011 (\$587,133 – December 31, 2010).

Income Taxes - Following the Merger on January 25, 2011, 22nd Century Ltd's operations are subject to Federal and State income taxes. Accordingly, since the Merger date the Company is required to recognize deferred tax assets and liabilities for any differences in basis in assets and liabilities between tax and GAAP reporting. The corresponding asset that resulted has been fully offset by a valuation allowance. The Company incurred a net operating loss from the closing of the Merger to September 30, 2011 and, accordingly, has made no provision for current income taxes. The income tax asset arising from this net operating loss has been fully reserved because it is not probable that it will be realized before its expiration.

Prior to the Merger, 22nd Century Ltd had elected to be treated as a Partnership for federal and state income tax purposes. As a result, there was no entity level income tax for periods prior to the Merger, because all taxable income, tax deductions and tax credits were passed through to the members of 22nd Century Ltd. 22nd Century Ltd's federal and state tax returns for the years ended December 31, 2008 to December 31, 2010 are currently open to audit under statutes of limitations. There are no pending audits as of September 30, 2011.

Stock Based Compensation - The Company uses a fair-value based method to determine compensation for all arrangements under which Company employees and others receive shares, options or warrants to purchase common shares of 22nd Century Group. Stock based compensation expense is recorded over the requisite service period based on estimates of probability and time of achieving milestones and vesting. For accounting purposes, the shares will be considered issued and outstanding upon vesting.

Debt Discounts - The Company accounts for warrants issued to note holders as an inducement to provide financing for the Company in accordance with the FASB's guidance on Accounting for Convertible Debt and Convertible Debt Issued with Stock Purchase Warrants. Fair value of the warrants is determined by common share price according to recent equity transactions, since there is no vesting period and a negligible exercise price. The proceeds allocated to each warrant is recorded as a debt discount and amortized over the life of the corresponding financing as interest expense.

Unearned Grant Revenue - In 2010 22nd Century Ltd received approval of a government grant as partial support for its next clinical trial for the FDA. Costs associated with this grant are being recognized as such costs are incurred and included in research and development expense. As the costs are expensed, deferred revenue is also recognized into income. During the nine months ended September 30, 2011, the Company recognized \$223,540, which is included in other income on the statement of operations. Deferred grant revenue was \$0 as of September 30, 2011 (as compared to \$223,540 as of December 31, 2010).

Revenue Recognition - The Company recognizes revenue at the point the product is shipped to a customer and title has transferred. Revenue from the sale of the Company's products is recognized net of cash discounts, sales returns and allowances. Cigarette federal excise taxes are included in net sales and accounts receivable billed to customers, except on sales of SPECTRUM and exported cigarettes in which such taxes do not apply.

The Company was chosen to be a subcontractor for a 5-year government contract between RTI International (“RTI”) and the National Institute on Drug Abuse (“NIDA”) to supply NIDA research cigarettes which includes four development stages. Stages 1 and 2 are for product design, stage 3 is for manufacture planning and material procurement and stage 4 is for the manufacture, laboratory testing for confirmation of specifications, labeling of the product pursuant to the specifications of the Alcohol and Tobacco Tax and Trade Bureau (“TTB”) as a federal-excise tax-free product and shipping the cigarettes. The Company completed each of stages 1 to 3 and certain milestones included in stage 4 and recognized the related revenue through June 30, 2011. During the third quarter of 2011 the Company commenced shipment of cigarettes and delivered approximately 9,000,000 cigarettes and recognized the related revenue of \$510,935 when title was transferred. These government research cigarettes are distributed under the mark SPECTRUM.

Derivatives - We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair market value and then is revalued at each reporting date, with changes in fair value reported in the consolidated statement of operations. The methodology for valuing our outstanding warrants classified as derivative instruments utilizes a lattice model approach which includes probability weighted estimates of future events including volatility of our common stock. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

Research and Development - Research and development costs are expensed as incurred.

Loss Per Common Share - Basic loss per common share is computed using the weighted-average number of common shares outstanding. Diluted loss per share is computed assuming conversion of all potentially dilutive securities. Potential common shares outstanding are excluded from the computation if their effect is anti-dilutive.

Commitment and Contingency Accounting - The Company evaluates each commitment and/or contingency in accordance with the accounting standards, which state that if the item is more likely than not to become a direct liability, then the Company will record the liability in the financial statements. If not, the Company will disclose any material commitments or contingencies that may arise.

Use of Estimates - The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

NOTE 2. - LIQUIDITY AND MANAGEMENT’S PLANS

Since 2006, 22nd Century Ltd has incurred substantial operating losses as it transitioned from being only a licensor of its proprietary technology and tobaccos to commercializing its own tobacco products. At September 30, 2011, the Company had current assets of \$1,021,205 and current liabilities of \$2,666,263. On January 25, 2011, the Company completed the Private Placement of securities resulting in approximately \$3.3 million in net cash proceeds and a reduction of debt and accrued interest obligations to shareholders that were on the balance sheet at December 31, 2010 of approximately \$614,000, which were exchanged for equity interests in the Private Placement. These proceeds were sufficient to enable the Company to make substantial reductions in its outstanding current liabilities, which totaled

\$4,823,635 at December 31, 2010.

The Company will need to raise additional capital to further reduce outstanding current liabilities, pay obligations that mature or begin to mature in 2012, and complete the FDA-approval process for X-22. The Company's Board of Directors authorized management to seek approximately \$2.5 million in bridge financing on a negotiated basis in the form of convertible debentures expected to close during the fourth quarter of 2011. During the first quarter of 2012 the Company plans to raise equity capital of approximately \$10 to \$12 million. The ability to complete these 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 FDA approval process and the manufacture, distribution and sale of its products. These equity financings will be dilutive to 22nd Century Group's existing shareholders' respective ownership percentages.

Prior to FDA approval of its prescription X-22 smoking cessation aid in development and FDA authorization of its two potential modified risk cigarettes, the Company expects to generate cash from the sale of its proprietary cigarettes, RED SUN and MAGIC, through its subsidiary, Goodrich Tobacco and from sales of SPECTRUM. As of September 30, 2011 the Company had no outstanding backlog of orders for RED SUN and MAGIC.

The Company has been able to obtain debt financing from related parties. During the third quarter of 2011 the Company borrowed a total of \$215,000 from an officer-shareholder of the Company, repaid \$65,000 leaving a balance of \$150,000 at September 30, 2011.

The Company's management believes, but can offer no assurances that, the above business plans will provide sufficient cash flow to fund the Company's operations through 2012.

NOTE 3. - AMOUNTS OWED NORTH CAROLINA STATE UNIVERSITY ("NCSU")

Pursuant to the terms of an exclusive license agreement with NCSU, the Company owes NCSU approximately \$822,000 as of September 30, 2011 for patent costs and license fees (as compared to \$1,128,000 owed as of December 31, 2010). These amounts are included in accounts payable and accrued liabilities in the consolidated balance sheets. The Company was required to pay these amounts within thirty days of being invoiced and they are past due. NCSU has the right to claim interest on the balance. In February 2011, the Company, after making a \$400,000 payment to NCSU towards patent costs, proposed a deferred payment arrangement for the balance owed. If the Company and NCSU cannot reach a satisfactory agreement, NCSU may have the right to terminate the exclusive license agreement, but can only do so with a 60-day prior written notice, including the opportunity to cure within this timeframe. As of September 30, 2011, patent costs associated with the exclusive license agreement that could potentially be terminated had a carrying value of approximately \$710,000. Additionally, NCSU has not imposed interest charges on past due amounts invoiced to the Company and as such the Company has not recorded accrued interest or interest expense.

NOTE4. - DEMAND BANK LOANS

The demand loan that is among the Company's short term liabilities is payable to a commercial bank under a revolving credit agreement and is guaranteed by a shareholder of the Company. This loan had a balance of \$174,925 at September 30, 2011 and December 31, 2010, respectively. The Company is required to pay interest monthly at an annual rate of 0.75% above the prime rate, or 4.00% at September 30, 2011 and December 31, 2010. The Company is current in meeting this interest payment obligation. The terms of the demand loan includes an annual "clean-up" provision, which requires the Company to repay all principal amounts outstanding for a period of 30 consecutive days every year. The Company has not complied with this requirement; however, the bank has not demanded payment.

NOTE 5. - NOTES PAYABLE

Notes payable to shareholders consisted of the following:

| | September 30, 2011 | December 31, 2010 |
|------------------------------|-----------------------|----------------------|
| Note dated October 28, 2008 | \$ - | \$ 325,000 |
| Note dated November 11, 2008 | - | 325,000 |
| Note dated May 20, 2009 | - | 30,000 |
| Note dated January 1, 2008 | - | 100,014 |
| Note dated September 1, 2010 | - | 35,000 |
| Notes dated October 4, 2010 | - | 150,000 |

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| | | |
|--|------------|--------------|
| Note dated December 29, 2010 | - | 100,000 |
| Note payable to repurchase common shares | - | 30,629 |
| Note funded July 7, 2011 | 150,000 | - |
| | \$ 150,000 | \$ 1,095,643 |

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Note Dated October 28, 2008 - On October 28, 2008, the Company issued a note payable to a third party in the amount of \$325,000. The interest rate on the note was 10% and the outstanding principal and interest was due and payable on October 28, 2010, the maturity date.

This note matured and remained outstanding at December 31, 2010; however, in January and February 2011 this note together with the \$30,000 note dated May 20, 2009 (described below), and all the related accrued interest of \$77,300 were satisfied by: (i) conversion of \$150,000 into equity in connection with the January 25, 2010 Private Placement; (ii) a cash payment of \$142,300; and (iii) a new note dated January 25, 2011 (see Note 6) payable in the amount of \$140,000.

Note Dated November 11, 2008 - On November 11, 2008, the Company issued a note payable to a shareholder in the amount of \$325,000. The interest rate on the note was 10% and the outstanding principal and interest was due and payable on November 11, 2010, the maturity date. This note was extended as set forth below and remained outstanding at December 31, 2010.

The extended maturity date on the note was January 10, 2011 and the interest rate during the extension period was 15%. Following the maturity of this note on January 10, 2011, the principal amount of \$325,000 was converted to equity in connection with the January 25, 2011 Private Placement and the accrued interest was paid in cash.

Note Dated May 20, 2009 (unsecured) - On May 20, 2009, the Company issued a note payable in the amount of \$30,000 to the same third party that was issued the October 28, 2008 note. The interest rate on the note was 10% and the outstanding principal and interest was due and payable on May 19, 2010, the maturity date. The \$30,000 in principal and accrued interest remained outstanding as of December 31, 2010. This note was satisfied in January and February 2011 together with the October 28, 2008 note as described previously.

Note Dated January 1, 2008 (unsecured) - The Company issued a note to a member on January 1, 2008 payable in the amount of \$100,014. The interest rate on the note was 7%; the interest and principal were due on January 15, 2011, the maturity date, and were paid in cash in January 2011.

Note Dated September 1, 2010 - On September 1, 2010, the Company issued a note payable to a member in the amount of \$35,000. The interest rate on the note was 15%, and, pursuant to an extension, the interest and principal were due on January 25, 2011, the extended maturity date. The note was paid in cash in January 2011.

Notes Dated October 4, 2010 (unsecured) - The Company issued notes payable to seven members in the aggregate amount of \$150,000. The interest rate on each of these notes was 15%, and the interest and principal were due on the maturity date of January 31, 2011. These notes were satisfied in January 2011 by conversion of \$87,367 to equity in connection with the January 25, 2011 Private Placement and by payment of \$62,633 in cash.

Note Dated December 29, 2010 (unsecured) - 22nd Century Ltd issued a note payable to a member in the amount of \$100,000. The interest rate on this note was 15%, and the interest and principal were due on the maturity date of January 29, 2011. The note was paid in cash in January 2011.

Note Payable to Repurchase Common Shares (unsecured) - On December 31, 2010, the Company agreed to repurchase 51,637 common shares previously issued to a member in exchange for a \$35,019 note, which \$30,629 remained unpaid as of December 31, 2010. The interest rate on the note was 7% and the outstanding principal and interest were due and payable on September 30, 2010, the maturity date. The note remained unpaid at the maturity date; the outstanding principal balance and accrued interest were paid in cash in February 2011.

Note Funded July 7, 2011(unsecured) – The Company borrowed a total of \$215,000 from an officer-shareholder during the third quarter of 2011 and repaid \$65,000 plus interest of 12% during the quarter. This left a balance of \$150,000 at September 30, 2011 which relates to a note that was funded on July 7, 2011. The note bears interest at 12% and matures November 30, 2011.

NOTE 6. – LONG TERM NOTES PAYABLE

Long term notes payable, net of unamortized discount, consisted of the following as of the dates set forth below:

| | September 30, 2011 | December 31, 2010 |
|--|-----------------------|----------------------|
| Convertible note dated March 31, 2011 | \$ 237,000 | - |
| Note dated March 30, 2011 | 350,000 | - |
| Total long term notes | 587,000 | - |
| Notes dated September 15 and October 15, 2009, net of unamortized discount | \$ 24,556 | \$ 20,557 |
| Note dated May 27, 2010 | - | 45,000 |
| Note dated January 25, 2011 | 140,000 | - |
| Total long term notes to shareholders | 164,556 | 65,557 |
| Total long term debt | 751,556 | 65,557 |
| Less current portion | (524,556) | - |
| | \$ 227,000 | \$ 65,557 |

Convertible Note Dated March 31, 2011(unsecured) - On March 31, 2011, the Company issued a note to a vendor in the amount of \$237,000 as satisfaction of past due invoices previously recorded by the Company in accounts payable. The note bears interest at an annual rate of 9%. Principal payments together with accrued interest are due as follows: \$50,000 each January 1, 2012, May 1, 2012, August 1, 2012 and November 1, 2012; and \$37,000 January 1, 2013, the maturity date. The note is convertible into common stock of 22nd Century Group at the option of the holder after December 18, 2011. The conversion rate will be determined at the time of conversion based on the average of the closing price of the Company's common stock on the day of and day after the conversion date.

Note Dated March 30, 2011(unsecured) - 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 are due on July 1, 2012. This maturity date is automatically accelerated if the Company receives funding of \$5,000,000 or more prior to July 1, 2012.

Notes Dated September 15 and October 15, 2009 (unsecured) - On September 15, 2009 and October 15, 2009, the Company issued two notes payable to the same third party in the amounts of \$15,000 and \$10,000, respectively. In conjunction with the \$15,000 note, a warrant to purchase 185,503 common shares of 22nd Century Ltd at less than \$.0001 per unit was issued, and in conjunction with the \$10,000 note, a warrant to purchase 92,751 common shares of 22nd Century Ltd at less than \$.0001 per unit was issued. The warrants were valued at \$11,301 for the \$15,000 note and \$6,962 for the \$10,000 note, were recorded as discounts to the respective notes payable and are being amortized over the term of each note which significantly adjusts the effective interest rate. The intrinsic value of the warrants at the time of issuance was determined to be \$68,750; the debt discount recorded was based on allocating the \$25,000 in transaction proceeds proportionally between the notes and the warrants. The notes bear interest at a rate of 10% and the outstanding principal and interest is due and payable at maturity - January 31, 2012 in each case. As of September 30, 2011, the total outstanding principal and unamortized debt discounts for the two notes amounted to \$25,000 and \$444 (as compared to \$25,000 and \$4,442 at December 31, 2010), respectively. The warrants were exercised in 2010 prior to the Merger.

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Note Dated May 27, 2010 (unsecured) - On May 27, 2010, the Company issued a note for \$45,000. The note bears interest at an annual rate of 10%, which was due with the principal amount on January 31, 2012. The note was satisfied in January 2011 by conversion to equity in connection with the January 25, 2011 Private Placement.

Note Dated January 25, 2011(unsecured) - On January 25, 2011, the Company issued a note for \$140,000 to a shareholder as satisfaction of the balance due for principal and interest on matured notes that were not paid in cash or converted to common stock of 22nd Century Group and warrants to purchase shares of common stock of 22nd Century Group. The note bears interest at 12% and is due on July 1, 2013 together with accrued interest.

NOTE 7. - DUE TO RELATED PARTY

The Company has conducted numerous transactions with a related party, Alternative Cigarettes, Inc. ("AC"). AC is entirely owned by certain shareholders of the Company, including the CEO. AC shares office space and employee services with the Company. During the nine months ended September 30, 2011 the Company acquired its MAGIC trademark from AC for a purchase price of \$22,500. There were no administrative expense reimbursements from AC during each of the first nine months of 2011 and 2010. The net amount due from AC as a result of advances, repayments and expenses incurred and reimbursed amounted to \$14,330 as of September 30, 2011 (as compared with the Company owing AC \$6,942 as of December 31, 2010). No interest has been accrued or paid on amount due to AC and there are no repayment terms.

NOTE 8. - DUE TO OFFICERS

Amount due to officers is a result of advances to the Company for working capital purposes and Company expenses paid directly by the officers net of advances or reimbursements. As of September 30, 2011, the net amount due to officers was \$31,417 (as compared with \$3,200 due to officers as of December 31, 2010). No interest has been accrued or paid on any amount due to officers and there are no repayment terms.

NOTE 9. - WARRANTS FOR COMMON STOCK

Prior to December 31, 2010, 22nd Century Ltd granted warrants to purchase common shares of 22nd Century Group in connection with borrowings as an additional incentive for providing financing to the Company and as additional compensation to officers, consultants and advisors. The warrants were granted with a conversion price of less than \$.0001, and the number of warrants issued was negotiated based on the agreement at the time of the grant. These warrants had been issued for terms of two to five years. All of these warrants were exercised prior to December 31, 2010.

In connection with the January 25, 2011 Private Placement and Merger, the Company issued 8,651,978 five year warrants to purchase shares of common stock of 22nd Century Group as follows: 5,000,000 with an exercise price of \$3.00 per share, and 3,651,978 with an exercise price of \$1.50 per share. These warrants contain "down round" provisions which provide for adjustments to the exercise price if the Company issues common shares of stock of 22nd Century Group at a price that is less than the respective warrant exercise prices. This provision is a guarantee of value which requires that these warrants be classified as derivatives for accounting purposes which means they are reported as a liability and marked to market at each balance sheet date. The original amount of the warrant liability related to the 5,000,000 \$3.00 warrants was \$1,550,000 and was recorded as a reduction of equity on January 25, 2011; the original amount of the warrant liability related to the 3,651,978 \$1.50 warrants is \$1,511,750, and, because it was recorded as a liability, the portion of proceeds from the Private Placement that was recorded as contributed capital was reduced accordingly.

The Company estimated the initial value of the warrant liability at January 25, 2011 using the binomial lattice model to allocate total enterprise value to the warrants and other securities in the Company's capital structure based upon the enterprise value implied in the January 25, 2011 Private Placement. Consideration was also given to the impact of expected future capital raises and issuances of securities under the Company's 2010 Equity Investment Plan ("EIP"). Volatility was estimated based on historical observed equity volatilities and implied (forward) or expected volatilities for a sample group of guideline companies and consideration of recent market trends. The fair value of this warrant liability as of September 30, 2011 was estimated to be \$2,724,250 based on updating the factors used in the initial valuation principally the remaining exercise period and the change in the risk free interest rate. As a result a gain of \$337,500 was recorded as other income in the statement of operations during the third quarter of 2011. The following table is a roll-forward of the warrant liability from the initial valuation:

| | |
|--|-------------|
| Fair value of warrant liability as of January 25, 2011 | \$3,061,750 |
| Gain as a result of change in fair value | (337,500) |
| Fair value at September 30, 2011 | \$2,724,250 |

ASC 820 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.

- Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value.

A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The warrant liability is measured at fair value using certain estimated factors such as volatility and probability and are classified within Level 3 of the valuation hierarchy.

The following table summarizes the warrant activity since December 31, 2009:

| | Number of Warrants |
|--|--------------------|
| Warrants outstanding at December 31, 2009 | 1,688,076 |
| Warrants issued during 2010 | 3,116,447 |
| Warrants exercised during 2010 | (4,804,523) |
| Warrants outstanding at December 31, 2010 | - |
| Warrants issued during 2011 | 8,651,978 |
| Warrants exercised during 2011 | - |
| Warrants outstanding at September 30, 2011 | 8,651,978 |
| Warrants exercisable at September 30, 2011 | 8,651,978 |

On February 1, 2009, the Company granted an award for service to an executive officer of 445,207 warrants to purchase common shares, vesting over a one year service period ending February 1, 2010. The related compensation cost of \$258,662 was determined by the intrinsic value of the underlying common shares at the time of the award of \$0.58 per unit and was charged to expense on a straight line basis over the service period. The cost was fully amortized in the first quarter of 2010 with a charge of \$43,090.

NOTE 10. - COMMITMENTS

License Agreements - Under its exclusive license agreement with NCSU, the Company is required to pay minimum annual royalty payments, which are credited against running royalties on sales of licensed products. The annual minimum royalty for each of the calendar years 2010 through 2013 is \$75,000, and in 2014 the annual minimum royalty increases to \$200,000. The license agreement continues through the life of the last-to-expire patent, which is expected to be 2022. These minimum royalty payments are due each February following the end of the applicable calendar year and are reduced by any running royalties paid or payable for that year. The agreement also requires a milestone payment of \$150,000 upon FDA approval of a product that uses the NCSU licensed technology. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. These costs vary from year to year and the Company has certain rights to direct the activities that result in these costs. During the nine months ended September 30, 2011, the costs incurred related to patent costs and patent maintenance amounted to \$76,703 (as compared to \$116,010 during the nine months ended September 30, 2010).

The Company has two other exclusive license agreements which require aggregate annual license fees of approximately \$55,000, which are credited against running royalties on sales of licensed products. Each license agreement continues through the life of the last-to-expire patent.

The Company entered into a three year lease for approximately 3,800 square feet of office space in Clarence, New York which commenced September 1, 2011. Scheduled rent remaining as of September 30, 2011 is as follows:

| | |
|------------------------------------|----------|
| October 1, 2011- December 31, 2011 | \$7,875 |
| 2012 | \$32,667 |

| | |
|------|----------|
| 2013 | \$37,833 |
| 2014 | \$28,000 |

NOTE 11. - FAIR VALUE OF FINANCIAL INSTRUMENTS

The estimated fair value of cash, advances from shareholders and related party, demand bank loans and notes payable approximate the carrying value due to their short-term nature. In applying the accounting standards for fair value determination, the Company has taken into account what the Company would have to pay someone to take over its debt obligations. Considerable judgment is required in developing estimates of fair value. Therefore, the estimates presented herein are not necessarily indicative of the amounts that the Company would realize in a current market exchange and is classified within Level 3 of the valuation hierarchy.

The estimated fair value of long-term debt is summarized as follows:

| September 30, 2011 | | December 31, 2010 | |
|--------------------|-------------------------|--------------------|-------------------------|
| Carrying Amount | Estimated Fair Value | Carrying Amount | Estimated Fair Value |
| \$ 751,556 | \$ 736,000 | \$ 65,557 | \$ 63,000 |

Differences between the fair value and carrying amount of long-term debt are primarily due to instruments that provide fixed interest or contain fixed interest rate elements. Inherently, such instruments are subject to fluctuations in fair value due to subsequent movements in interest rates that are available to the Company.

NOTE 12. - EARNINGS PER COMMON SHARE

The following table sets forth the computation of basic and diluted earnings per common share for the three months ended September 30, 2011 and 2010:

| | 2011 | 2010 |
|--|---------------|---------------|
| Net loss attributed to common shareholders | \$ (465,082) | \$ (300,884) |
| Denominator for basic earnings per share-weighted average shares outstanding | 27,209,646 | 15,322,529 |
| Effect of dilutive securities: | | |
| Warrants, restricted stock and options outstanding | - | - |
| Denominator for diluted earnings per common share - weighted average shares adjusted for dilutive securities | 27,209,646 | 15,322,529 |
| Loss per common share - basic | \$ (0.02) | \$ (0.02) |
| Loss per common share- diluted | \$ (0.02) | \$ (0.02) |

The following table sets forth the computation of basic and diluted earnings per common share for the nine months ended September 30, 2011 and 2010:

| | 2011 | 2010 |
|--|-----------------|---------------|
| Net loss attributed to common shareholders | \$ (2,218,362) | \$ (990,997) |
| Denominator for basic earnings per share-weighted average shares outstanding | 26,263,743 | 11,232,202 |
| Effect of dilutive securities: | | |
| Warrants, restricted stock and options outstanding | - | - |
| Denominator for diluted earnings per common share - weighted average shares adjusted for dilutive securities | 26,263,743 | 11,232,202 |

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| | | | |
|--------------------------------|------------|------------|--|
| | | | |
| Loss per common share - basic | \$ (0.08) | \$ (0.09) | |
| Loss per common share- diluted | \$ (0.08) | \$ (0.09) | |

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Securities outstanding that were excluded from the computation because they would have been anti-dilutive are as follows:

| | 2011 | 2010 |
|------------------|-----------|-----------|
| Warrants | 8,651,978 | 4,804,523 |
| Restricted Stock | 700,000 | - |
| Options | 35,000 | - |

NOTE 13 - STOCK BASED COMPENSATION

On October 21, 2010, the Company established the 2010 Equity Incentive Plan (“EIP”) for officers, employees, directors, consultants and advisors to the Company and its affiliates, consisting of 4,250,000 shares of common stock. The EIP has a term of ten years and is administered by our Board of Directors (“Board”) or a committee to be established by our Board (the “Administrator”), to determine the various types of incentive awards that may be granted to recipients under this plan and the number of shares of common stock to underlie each such award under the EIP. The EIP also contains a provision which restricts the plan to granting awards relating to no more than 1,600,000 shares of common stock of 22nd Century Group during the first twelve months following the effective date of the Merger. On March 31, 2011, the Company filed a Form S-8 registration statement with the SEC to register all of the shares of common stock of 22nd Century Group that it may issue under the EIP. On April 1, 2011, under our EIP, the Board granted an aggregate of 1,150,000 shares of common stock of 22nd Century Group to officers and directors and incentive stock options to key employees to purchase an aggregate of 35,000 shares of 22nd Century Group’s common stock.

The number of shares of common stock of 22nd Century Group subject to the EIP, any number of shares subject to any numerical limit in the EIP, and the number of shares and terms of any incentive award will be adjusted in the event of any change in outstanding common stock of 22nd Century Group by reason of any stock dividend, spin-off, split-up, stock split, reverse stock split, recapitalization, reclassification, merger, consolidation, liquidation, business combination or exchange of shares or similar transaction.

The EIP authorizes the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, restricted stock and restricted stock units.

All awards made under the EIP may be subject to vesting and other contingencies as determined by the Administrator and will be evidenced by agreements approved by the Administrator which set forth the terms and conditions of each award.

The Company accounts for stock-based compensation under the provisions of ASC Topic 718, “Compensation — Stock Compensation.” The Company recognizes compensation cost in its financial statements for all share based payments granted, modified, or settled during the period. For awards with graded vesting, compensation cost is recognized on a straight-line basis over the related vesting period.

The Company has non-vested awards for 700,000 restricted shares outstanding; 600,000 of the outstanding restricted shares vest at the rate of 150,000 shares annually over the four-year period ending April 1, 2015 and the remaining 100,000 restricted shares vest based on achieving a performance milestone by December 31, 2013.

For the three month periods ended September 30, 2011 and 2010, the Company recorded compensation expense (included in general and administrative expense) of \$9,135 and \$0, respectively, related to stock options and \$39,844 and \$0, respectively, related to amortization of non-vested restricted stock grants. For the nine-month periods ended September 30, 2011 and 2010, the Company recorded compensation expense (included in general and administrative

expense) of \$18,270 and \$0, respectively, related to stock options and \$79,688 and \$0, respectively, related to amortization of non-vested restricted stock grants.

For the nine month periods ended September 30, 2011 and 2010, the Company recorded compensation expense \$229,500 (\$51,000 included in research and development expense and \$178,500 included in general and administrative expense) and \$0, respectively, related to stock grants for 450,000 shares which vested immediately upon award. No compensation expense was incurred by the Company during either the third quarter of 2011 or 2010.

As of September 30, 2011, unrecognized compensation expense related to non-vested restricted shares with annual vesting amounted to \$277,313 and non-vested stock options amounted to \$18,270. No expense was recorded for restricted stock grants with milestone vesting, which was valued at \$51,000.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion highlights the principal factors that have affected our financial condition and results of operations as well as our liquidity and capital resources for the periods described.

On January 25, 2011, 22nd Century Ltd completed a reverse merger transaction (the "Merger") with 22nd Century Group. 22nd Century Ltd is a wholly owned subsidiary of 22nd Century Group, which continues to operate the business of 22nd Century Ltd. All references to shareholders or common shares include the historical members and membership Units of 22nd Century Ltd because, in the Merger, such Units were exchanged for common shares on a one-for-one basis and from an accounting standpoint, they are equivalent. The Merger is being accounted for as a reverse acquisition and a recapitalization; 22nd Century Ltd is the acquirer for accounting purposes. Consequently, the assets and liabilities and the historical operations that are reflected in the financial statements prior to the Merger are those of 22nd Century Ltd and are recorded at the historical cost basis of 22nd Century Ltd, and the consolidated financial statements since completion of the Merger include the assets and liabilities of 22nd Century Ltd, historical operations of 22nd Century Ltd and operations of 22nd Century Group from the closing date of the Merger. For purposes of this Management's Discussion and Analysis of Financial Condition and Results of Operations, references to the "Company," "we," "us" or "our" refer to the operations of 22nd Century Group and its direct and indirect subsidiaries for the periods described herein.

This quarterly report contains forward-looking statements, including statements regarding our plans, goals, strategies, intentions, beliefs or current expectations. These statements are expressed in good faith and based upon a reasonable basis when made, but there can be no assurance that these expectations will be achieved or accomplished. These forward looking statements can be identified by the use of terms and phrases such as "believe," "plan," "intend," "anticipate," "target," "estimate," "expect," and the like, and/or future-tense or conditional constructions "may," "could," "should," etc. Items contemplating or making assumptions about, actual or potential future sales, market size, collaborations, and trends or operating results also constitute forward-looking statements. These forward-looking statements are only predictions, are uncertain and involve substantial known and unknown risks, uncertainties and other factors which may cause our (or our industry's) actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements.

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. Actual results may differ materially from those expressed or implied by such forward-looking statements as a result of various factors including but not limited to the risk factors set forth our prospectus filed with the SEC on September 20, 2011 and uncertainties regarding the process of obtaining Food & Drug Administration approval and authorization for our products, including time and expenses involved in seeking such approval, the Company's inability to continue as a going concern, the Company's inability to achieve or sustain profitability given a history of losses, the uncertainty of the Company's ability to generate positive cash flow, the difficulty of evaluating the Company's current business and future prospects given the Company's limited operating history, fluctuations in working capital requirements, continued instability in credit and financial market conditions, dependence on third parties to manufacture, market, sell and distribute the Company's products, dependency on market acceptance of products among physicians, patients, third-party payers and the medical community, performance of competitors in the field, retention of key personnel, and other factors.

Please see “Risk Factors” as set forth in our prospectus filed with the SEC on September 20, 2011.

Overview

We are a plant biotechnology company and a global leader in modifying the content of nicotinic alkaloids in tobacco plants through genetic engineering and plant breeding. Please see Note 1 to our consolidated financial statements for a description of our corporate history. We control 99 issued patents of which we own 9 issued patents and we have the exclusive license to an additional 90 issued patents in an aggregate of 79 countries where at least 75% of the world's smokers reside. Additionally, we control 45 pending patent applications, of which we own 29 and have an exclusive license to 16. In the U.S., patents that currently cover our products expire in 2019 through 2022. Also in the U.S., patent applications that we expect will cover our products would, if patents are granted in connection with such applications, yield patents that expire in 2024 through 2028. However, there is no guarantee that patents will be granted in response to such patent applications and therefore cover our products. Our two worldwide exclusive licenses, one from North Carolina State University ("NCSU") and the other from National Research Council of Canada, Plant Biotechnology Institute in Saskatoon, Canada ("NRC"), each involve multiple patent families. The exclusive rights under each of these two license agreements expire on the date on which the last patent covered by the subject license expires in the country or countries where such patents are in effect. The NCSU license relates predominately to issued patents, and the NCSU license will expire in 2022 when the last patent covered by the NCSU license will expire. The NRC license relates to only patent applications, so if such patent applications result in issued patents, then we expect the NRC license to expire in 2028, which is 20 years from the time when all such patent applications were filed together. We believe our proprietary technology provides us with opportunities in the global market for approved smoking cessation aids and the emerging market for modified risk tobacco products (as defined below); however, we have not yet identified any specific countries or developed any timelines or cost estimates for international expansion of our business.

We expect to complete a Phase II-B clinical trial which is necessary to seek approval from the U.S. Food and Drug Administration ("FDA") for X-22, our prescription smoking cessation aid in development. We have met with the FDA regarding the remaining clinical trials for X-22, and based on the FDA's guidance, we plan to conduct a Phase II-B trial and two larger and concurrent Phase III trials with the same protocols.

We have operated at a loss since 2006 when we increased our research and development expenditures. In the first nine months of 2011 we realized revenue of \$801,636 mainly from our research cigarette program; in 2010, we realized revenue of \$49,784 from this program and in 2009 we realized sales of \$27,612 from limited test marketing of our cigarettes. During 2009 and 2010 we transitioned from solely developing proprietary technology and tobacco to developing and commercializing our own products. In March 2011, our subsidiary, Goodrich Tobacco introduced two of our products, RED SUN and MAGIC cigarettes, into customary market channels for tobacco products.

Our prospects depend on our ability to generate and sustain revenues from sales and licensing of RED SUN and MAGIC, our X-22 smoking cessation aid, our Brand A and Brand B as potential modified risk cigarettes (as defined below) and our proprietary tobacco. Our ability to generate meaningful revenue from X-22, especially in the United States, depends on FDA approval, and our ability to generate meaningful revenue from our proprietary cigarette products depends in large part on obtaining FDA authorization to market Brand A and Brand B as modified risk cigarettes. Once X-22 is approved and Brand A and Brand B are authorized by the FDA, we must still meet the challenges of successful marketing and distribution and consumer acceptance. We do not expect FDA approval of X-22 until the first quarter of 2013 at the earliest.

FDA approval must be obtained, as has been the case for decades, before a product can be marketed for quitting smoking. The Tobacco Control Act provides that products to be marketed for smoking cessation be considered for "Fast Track" designation by the FDA. The "Fast Track" programs of the FDA are intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. We submitted a request for Fast Track designation for X-22, and on August 18, 2011, the FDA informed us that it would not grant the designation of X-22 as a Fast Track product at this time because we did not

demonstrate that X-22 shows potential to address an unmet medical need. All smoking cessation studies to date with very low nicotine (“VLN”) cigarettes containing our proprietary tobacco were independent studies and were not sponsored by 22nd Century under its own Investigational New Drug (“IND”). We plan to file in the fourth quarter of 2011 a subsequent Fast Track request with the FDA, which will include our Phase II-B clinical trial results that will be available in December 2011. Pursuant to FDA regulations, we believe that if our X-22 Phase II-B trial results demonstrate an advantage (over currently approved smoking cessation products) in one of the following areas: efficacy, safety or improvement in some other factor such as compliance (a patient using a product as directed) or convenience, X-22 will demonstrate potential to address an unmet medical need. However, there is no guarantee of our trial results or that the FDA will grant Fast Track designation to X-22. If we are not able to have X-22 designated as a Fast Track product, then we will not obtain Priority Review of our X-22 New Drug Application (NDA), which would delay FDA approval of X-22, and we would then expect FDA approval of X-22 to be approximately the third quarter of 2013.

The 2009 Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) establishes procedures for the FDA to regulate the labeling and marketing of modified risk tobacco products, which includes cigarettes that (i) reduce exposure to tobacco smoke toxins and/or (ii) pose lower health risks, as compared to conventional cigarettes (“modified risk cigarettes”). The Tobacco Control Act requires the FDA to issue specific regulations and guidance regarding applications that must be submitted to the FDA for the authorization to label and market modified risk tobacco products. Based in part on the timelines contained in the Tobacco Control Act, we expect the FDA to issue such regulations and guidance within the next year. We believe that two of our cigarette products, which we refer to as BRAND A and BRAND B, may qualify as modified risk cigarettes. Compared to other commercial cigarettes, we believe that the tobacco in BRAND A has approximately 95% less nicotine than tobacco in cigarettes previously marketed as “light” cigarettes, and BRAND B’s smoke contains the lowest amount of “tar” per milligram of nicotine.

We believe the FDA will issue regulations for modified risk tobacco products in the second quarter of 2012, and we therefore expect to submit applications in 2012 to the FDA to authorize the marketing and labeling of our proprietary cigarette products as modified risk cigarettes. This process is likely to take at least one year. Until these approvals and authorizations are received, sales of our proprietary cigarette products in the U.S. will be limited and will only include RED SUN, MAGIC and SPECTRUM. We intend to focus our marketing efforts for RED SUN and MAGIC on tobacconists, smoke shops and tobacco outlets.

Accordingly, our cash flow from product sales will be limited and, in addition to the net proceeds from the Private Placement that closed on January 25, 2011, we will need cash from equity or debt financing to continue operations. As additional funds are required, we may raise such funds from time to time through public or private sales of equity or debt securities. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and its financial condition and results of operations. Additional equity financing will be dilutive to the ownership interests of holders of the Common Stock, and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

In connection with our FDA activities we will incur substantial costs related to clinical trials for X-22 and smoke exposure studies related to our modified risk product candidates. Our total budget for the Phase II-B project is approximately \$1.5 million, and we incurred approximately \$1.1 million of that amount through September 30, 2011.

At September 30, 2011, the Company had current assets of \$1,021,205 and current liabilities of \$2,666,263. On January 25, 2011, the Company completed the Private Placement of securities resulting in approximately \$3.3 million in net cash proceeds and a reduction of debt obligations to shareholders that were on the balance sheet at December 31, 2010 of approximately \$614,000, which were exchanged for equity interests in the Private Placement. These proceeds were sufficient to enable the Company to make substantial reductions in its outstanding current liabilities, which totaled \$4,823,635 at December 31, 2010.

Three Months Ended September 30, 2011 Compared to Three Months Ended September 30, 2010

Revenue. In the three months ended September 30, 2011, we realized revenue, mainly from our research cigarette program, of \$529,370 as compared to revenue of \$20,302 in three months ended September 30, 2010. As of September 30, 2011 we had no outstanding backlog of orders for our products; however we expect about \$25,000 in sales of our research cigarettes in the fourth quarter of 2011.

Other income. In the three months ended September 30, 2011, we recognized other income of \$80,000 from the remaining portion of a therapeutic grant award we received in fourth quarter of 2010.

Costs of goods sold. In the three months ended September 30, 2011, costs of goods sold was \$130,495 or 25% of the revenue. In the three months ended September 30, 2010, costs of goods sold was \$5,302 or 26% of revenue.

Research and development expense. Research and development (R&D) expense was \$711,996 in the three months ended September 30, 2011, an increase of \$644,468, or 954%, from \$67,528 in the three months ended September 30, 2010. This increase was directly related to expenditures related to our Phase II-B clinical trials. We initiated this effort late in the fourth quarter of 2010 so there were no Phase II-B activities in the third quarter of 2010.

General and administrative expense. General and administrative expense was \$451,087 in the three months ended September 30, 2011, an increase of \$312,176, or 225%, from \$138,911 in three months ended September 30, 2010. Approximately \$100,000 of the increase was for compensation costs due to increased administrative headcount, equity based compensation and outside directors' fees. Investor relations consulting services and press release costs accounted for approximately \$74,000 of the remaining year-over-year increase with the balance caused by increases in various other expense categories such as legal, accounting and audit, and travel.

Sales and marketing costs. Sales and marketing costs were \$37,106 in the three months ended September 30, 2011; we had no costs categorized as such in the three months ended September 30, 2010. The costs in 2011 related to product testing, product and packaging, and design, product branding, trade samples, trade shows and advertising.

Amortization and depreciation expense. Amortization and depreciation expense relates almost entirely to capitalized patent and trademark costs. Amortization and depreciation expense increased 9.4% in the three months ended September 30, 2011 to \$44,630, up from \$40,803 in the three months ended September 30, 2010. This increase of \$3,827 is mainly due to our additional investment in patents and trademarks in 2010 of \$147,912 and in 2011 of \$70,641.

Gain warrant liability – derivative. In connection with the January 25, 2011 private placement we issued warrants which were accounted for as derivatives; a liability at the estimated fair value was recorded and contributed capital was reduced. The gain of \$337,500 included in the three month period ended September 30, 2011 represents the decrease in the estimated fair value of the warrants during this period.

Interest expense and debt expense. Interest expense and debt expense, which include interest amortization of debt discount and debt issuance costs, decreased in the three months ended September 30, 2011 to \$21,927, from \$68,642 in the three months ended September 30, 2010. This decrease of \$46,715 or 68% was mainly a result of reduced borrowings during the third quarter of 2011 compared to the third quarter of 2010. In January 2011, a substantial portion of our outstanding interest bearing debt was repaid or converted into shares of our common stock. This was partially offset by interest at the stated rate on long term obligations of \$587,000 which were entered into at the end of the first quarter 2011 and interest on a \$150,000 short term note funded on July 7, 2011.

Net loss. We had a net loss in the three months ended September 30, 2011 of \$450,371 as compared to a net loss of \$300,884 in the three months ended September 30, 2010. The increase in the net loss of \$149,487, or 50%, was mainly a result of higher operating expenses including clinical trial expenses, administrative compensation costs, and investor relations expenses in the three months ended September 30, 2011, as compared to the three months ended September 30, 2010, offset by increased revenue, the gain related to warrants and reduced interest and debt expense.

Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2010

Revenue. In the nine months ended September 30, 2011, we realized revenue of \$801,636, mainly from our research cigarette program, as compared to revenue of \$22,102 in nine months ended September 30, 2010. As of September 30, 2011 we had no outstanding backlog of orders for our products; however we expect about \$25,000 in sales of our research cigarettes in the fourth quarter of 2011.

Other income. In the nine months ended September 30, 2011, we recognized other income of \$223,540 from a therapeutic grant award we received in fourth quarter of 2010.

Costs of goods sold. In the nine months ended September 30, 2011, costs of goods sold related to revenues under our research cigarette program was \$224,146 or 28% of revenue. In the nine months ended September 30, 2010, costs of goods sold related to revenues under this program was \$6,302 or 29% of revenue

Research and development expense. Research and development expense was \$1,509,050 in the nine months ended September 30, 2011, an increase of \$1,226,079, or 433%, from \$282,971 in the nine months ended September 30, 2010. Approximately \$1.1 million was for expenditures related to our Phase II-B clinical trials. We initiated this effort late in the fourth quarter of 2010 so there were no Phase II-B activities in the third quarter of 2010. The balance of the increase in research and development expense in the first nine months of 2011 as compared to the first nine months of 2010 consisted of patent maintenance expenses, such as legal costs and annual filing fees related to patent renewals, employee compensation costs and travel expense.

General and administrative expense. General and administrative expense was \$1,381,480 in the nine months ended September 30, 2011, an increase of \$997,904, or 260%, from \$383,576 in nine months ended September 30, 2010. Approximately \$497,000 of the increase was for compensation costs due to increased administrative headcount, awards under our Equity Incentive Plan on April 1, 2011 and outside directors' fees. The balance of the year-over-year increase was in various other expense categories such as investor relations consulting services and press release fees (approximately \$139,000 increase), legal and SEC fees (approximately \$213,000 increase), accounting and audit fees (approximately \$77,000 increase), directors' and officers' liability insurance (approximately \$26,000 increase) and travel (approximately \$37,000 increase).

Sales and marketing costs. Sales and marketing costs were \$267,810 in the nine months ended September 30, 2011; we had no costs categorized as such in the nine months ended September 30, 2010. The costs in 2011 related to product testing, product and packaging, and design, product branding, trade samples, trade shows and advertising.

Amortization and depreciation expense. Amortization and depreciation expense relates almost entirely to capitalized patent and trademark costs. Amortization and depreciation expense increased 8.8% in the nine months ended September 30, 2011 to \$132,432, up from \$121,735 in the nine months ended September 30, 2010. This increase of \$10,697 is mainly due to our additional investment in patents and trademarks in 2010 of \$147,912 and in 2011 of \$70,641.

Gain warrant liability – derivative. In connection with the January 25, 2011 private placement we issued warrants which were accounted for as derivatives; a liability at the estimated fair value was recorded and contributed capital was reduced. The gain of \$337,500 included in the nine month period ended September 30, 2011 represents the decrease in the estimated fair value of the warrants since January 25, 2011.

Interest expense and debt expense. Interest expense and debt expense, which include interest amortization of debt discount and debt issuance costs, decreased in the nine months ended September 30, 2011 to \$53,116, from \$218,519 in the nine months ended September 30, 2010. This decrease of \$165,403 or 76% was mainly a result of reduced borrowings during the first nine months of 2011 compared to the first nine months of 2010. In January 2011, a substantial portion of our outstanding interest bearing debt was repaid or converted into shares of our common stock which was the cause of the reduced interest and debt expense. This was offset by interest on long term obligations in the amount of \$587,000 which were entered into at the end of the first quarter and \$150,000 in short term obligations borrowed early in the third quarter.

Net loss. We had a net loss in the nine months ended September 30, 2011 of \$2,205,358 as compared to a net loss of \$991,001 in the nine months ended September 30, 2010. The increase in the net loss of \$1,214,357, or 123%, was mainly a result of higher operating expenses including clinical trial expenses and increased compensation costs and other administrative expenses in the nine months ended September 30, 2011, as compared to the nine months ended September 30, 2010, offset by increased revenue, the gain related to warrants and reduced interest and debt expense.

Liquidity and Capital Resources

Summary of Balances and Recent Sources and Uses

As of September 30, 2011, we had negative working capital of approximately \$1.6 million compared to negative working capital of approximately \$4.1 million at December 31, 2010. The \$2.5 million reduction in our negative working capital position was mainly a result of the January 25, 2011 Private Placement and the transfer from accounts payable to notes payable of \$87,000 (net of current portion) as part of payment arrangements with two vendors for past due amounts we owed, offset by our net loss of approximately \$2.2 million for the nine months ended September 30, 2011.

Cash demands on operations

In 2009 and 2010, we operated at a loss and operating activities consumed more than \$1.0 million in cash during this two year period. In the nine months ended September 30, 2011 we also operated at a loss while cash used in operating activities was approximately \$2.5 million. Cash used in operating activities will continue at these levels for the balance of 2011 due to increased headcount and expenditures related to the pursuit of FDA approval of our smoking cessation aid.

If we are unable to improve operations or raise funds during the next twelve months, there would be a material adverse effect on our ability to meet our working capital needs and the risk that we would be unable to continue operations would increase. We intend and expect to require additional funds before the end of 2011 to complete the clinical trials for X-22, undertake exposure studies for our potential modified risk tobacco products, launch X-22 and pay loan and note obligations as they become due. As additional funds are required, we may raise such funds from time to time through public or private sales of equity or debt securities. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and its financial condition and results of operations. Additional equity financing will be dilutive to shareholders of our common stock, and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

Net Cash used in Operating Activities.

In the first nine months of 2011, \$2,473,746 of cash was used in operating activities compared to \$650,516 of cash used in operating activities in the first nine months of 2010. This increased use of cash of \$1,823,230 was mainly due to the increase of \$1,491,342 in the cash portion of the net loss in the first nine months 2011 as compared to the first nine months of 2010. The balance of the increase was a result of the net change in working capital components related to operations.

Net Cash used in Investing Activities.

In the first nine months of 2011, we used \$570,641 of cash related to third party costs incurred for patents and trademarks and the acquisition of office furniture and fixtures as compared to \$88,382 used in the first nine months of 2010. This increase was attributable to our payment in 2011 of approximately \$500,000 towards outstanding patent costs charges that were deferred in prior periods.

Net Cash From Financing Activities.

During the first nine months of 2011, we generated \$3,057,558 from our financing activities primarily through the issuance of shares of 22nd Century Group's common stock and warrants to purchase 22nd Century Group's common stock in the January 25, 2011 Private Placement. This resulted in net proceeds of \$3,293,888 and was offset during the this period by \$243,275 in net payments on notes to shareholders and \$21,272 in net payments to a related party. In addition the Company received net advances from its officers of \$28,217. During the first nine months of 2010, we generated net cash of \$740,028 from our financing activities; \$896,600 was generated by the issuance of common stock, notes and warrants partially offset by the payment of \$58,970 in deferred Private Placement costs, \$7,383 payment on a demand loan, a payment on a note to a shareholder of \$4,389 and \$93,700 in net payments to a related party. In addition the Company received net advances from its officers of \$7,870.

We received approximately \$3.3 million in net cash proceeds from the Private Placement that closed on January 25, 2011. We used approximately \$1,400,000 of the proceeds to retire debt obligations that had matured or make payments on past due amounts owed to vendors including \$400,000 paid to North Carolina State University

("NCSU"). As of September 30, 2011 we owe NCSU approximately \$747,000 for patent costs and \$75,000 for minimum royalties. These amounts are past due. We have requested NCSU to allow us to defer payment of the balance owed until 2012 so we can complete our Phase II-B clinical trial and raise additional equity capital. NCSU has thus far accommodated this request and we expect NCSU to continue to do so. As our licensor for 12 years, we believe NCSU has a vested interest in 22nd Century completing the FDA-approval process. Since 1998, we have funded approximately \$6 million to NCSU in royalties, patent support payments and R&D.

The Company will need to raise additional capital to further reduce outstanding current liabilities, pay obligations that mature or begin to mature in 2012, and complete the FDA-approval process for X-22. The Company's Board of Directors authorized management to seek approximately \$2.5 million in bridge financing on a negotiated basis in the form of convertible debentures expected to close during the fourth quarter of 2011. During the first quarter of 2012 the Company plans to obtain equity capital of approximately \$10 to 12 million through the public markets. The ability to complete these 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 FDA approval process and the manufacture, distribution and sale of its products. These equity financings will be dilutive to 22nd Century Group's existing shareholders' respective ownership percentages and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

Critical Accounting Policies and Estimates

Accounting principles generally accepted in the United States of America, or U.S. GAAP, require estimates and assumptions to be made that affect the reported amounts in our consolidated financial statements and accompanying notes. Some of these estimates require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations.

Revenue Recognition

We recognize revenue at the point the product is shipped to a customer and title has transferred. Revenue from the sale of our products is recognized net of cash discounts, sales returns and allowances. Cigarette federal excise taxes are included in net sales and accounts receivable billed to customers, except on sales of SPECTRUM and exported cigarettes in which such taxes do not apply.

We were chosen to be a subcontractor for a 5-year government contract between RTI International (“RTI”) and the National Institute on Drug Abuse (“NIDA”) to supply NIDA research cigarettes which includes four development stages. Stages 1 and 2 are for product design, stage 3 is for manufacture planning and material procurement and stage 4 is for the manufacture, laboratory testing for confirmation of specifications, labeling of the product pursuant to the specifications of the Alcohol and Tobacco Tax and Trade Bureau (“TTB”) as a federal-excise tax-free product and shipping the cigarettes. The Company has completed each of stages 1 to 3 and certain milestones included in stage 4 and recognized the related revenue through the second quarter of 2011. During the third quarter of 2011 the Company commenced shipment of cigarettes and delivered approximately 9,000,000 cigarettes and recognized the related revenue of \$510,935 because title was transferred. These government research cigarettes are distributed under the mark SPECTRUM.

Impairment of Long-Lived Assets

We review the carrying value of amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be appropriate. We also assess recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset’s carrying value and its fair value. Non-amortizing intangibles (trademarks) are reviewed annually for impairment. We have not recognized any impairment losses during the nine month period ended September 30, 2011 or during the two years ended December 31, 2010.

Amortization Estimates

We generally determine amortization based on the estimated useful lives of the assets and record amortization expense on a straight-line method over such lives. The remaining life of the patent is generally used to determine the estimated useful life of the related patent costs.

Valuation of our Equity Securities

We have issued shares of 22nd Century Group’s common stock to satisfy obligations to vendors or employees that were due in cash. These shares have been valued based on the cash value of the obligation satisfied by their issuance. We have also issued warrants to purchase shares of 22nd Century Group’s stock in connection with the issuance of

debt obligations. These warrants have been valued based on the value ascribed to the underlying shares issued in cash transactions or in settlement of cash obligations.

Income taxes

Prior to the closing of the Merger, 22nd Century Ltd was organized as a limited liability company and treated as a partnership for income tax purposes; accordingly, prior to the Merger, 22nd Century Ltd was not directly responsible for income taxes (income and losses passed through to its LLC members) and did not have to account for them. Since the closing of the Merger, our results of operations are subject to income taxes, and accounting for income taxes is now a critical accounting policy. In addition, we now account for deferred tax assets and liabilities, including the evaluation of the recoverability of deferred tax assets.

Derivative Financial Instruments

The warrants to purchase shares of 22nd Century Group stock that were issued in connection with the Merger are treated as derivative instruments for accounting purposes. Accordingly, upon issuance, these instruments are reported as liabilities rather than equity. We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair market value and then is revalued at each reporting date, with changes in fair value reported in the consolidated statement of operations. We use a lattice model approach which for valuing our outstanding warrants classified as derivative instruments which includes probability weighted estimates of future events including volatility of our common stock. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by Item 303(a)(4) of Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to present the information required by this item.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures:

The Company's management, with the participation of 22nd Century Group's Chief Executive Officer, and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a - 15(e) and 15(d) - 15(e) of the Securities Exchange Act of 1934) as of September 30, 2011. Based on that evaluation, 22nd Century Group's President and Chief Executive Officer, and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of September 30, 2011.

(b) Changes in Internal Control over Financial Reporting:

There were no changes in the Company's internal control over financial reporting during the third quarter of 2011 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

Neither 22nd Century Group nor any of its subsidiaries are involved in any material legal proceeding.

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Item 1A. Risk Factors

Our risk factors have not changed materially from those disclosed in our prospectus filed with the SEC on September 20, 2011.

Item 6. Exhibits

Exhibit 31.1 Section 302 Certification – Chief Executive Officer

Exhibit 31.2 Section 302 Certification – Chief Financial Officer

Exhibit 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

101 Interactive data files formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, and (iv) the Notes to the Consolidated Financial Statements.

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema Document

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF XBRL Taxonomy Extension Definition Linkbase Document

101.LAB XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized:

22nd CENTURY GROUP, INC

Date: November 14, 2011

By:/s/ Joseph Pandolfino
JOSEPH PANDOLFINO
CEO

Date: November 14, 2011

By:/s/ C. Anthony Rider
C. ANTHONY RIDER
CFO