

22nd Century Group Reports Business Highlights and Financial Results for the Second Quarter 2021

- Initiated International Launch Process For VLN[®], First Sales Planned by First Quarter 2022
- First Revenue From Hemp/Cannabis Franchise to Commence in Second Half of 2021
- Third Plant-Based Franchise to be Introduced on August 30, 2021
- Uplisting Common Shares to the Nasdaq Capital Market (“Nasdaq”) and Will Continue to Trade Under Current Symbol, “XXII”
- Record Second Quarter Net Sales of \$8.4 Million, Up Greater Than 30% From the Second Quarter of 2020
- Executing From a Strong Financial Position with Cash and Cash Equivalents of \$62.3 Million as of June 30, 2021.

BUFFALO, N.Y., August 5, 2021 (Globe Newswire) — 22nd Century Group, Inc. (NYSE American: [XXII](#)), a leading plant-based biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco, and hemp/cannabis research, today reported results for the second quarter ended June 30, 2021, and provided an update on recent business highlights. The Company will provide an additional business update for investors on a live audio webcast to be held today at 10:00 a.m. ET.

“We remain highly confident in a positive outcome for our Modified Risk Tobacco Product (MRTP) application, and based on continued engagement and very recent feedback from the FDA, we believe that our application has completed the scientific review process and is in the documentation process,” said James A. Mish, chief executive officer of 22nd Century Group. “I recognize that the delay by the FDA in authorizing our VLN[®] product is incredibly frustrating for all of us. Our application will be the first and likely the only MRTP for a combustible cigarette that the FDA will ever authorize, which means this is a complex process for the Agency that they want to be sure to get right. Our reduced nicotine content (RNC) cigarettes have been used in clinical studies that are estimated to have cost over \$100 million funded by several U.S. federal government agencies, including the FDA. The benefits of our RNC cigarettes have been well documented and the FDA has already confirmed that they are appropriate for the protection of public health in our positive PMTA designation. We possess the expertise to have progressed this far and have the know-how to cross the finish line using all of our available tools, partners, and advocates to balance leverage and collaboration with the FDA to continue advancing the process forward to a successful conclusion.”

Mish added, “Our record second quarter and first half net sales were a result of the investments to scale-up our tobacco contract manufacturing capabilities and confirms our ability to generate new business and operate at scale ahead of VLN[®] launches in the U.S. and internationally.”

Mish concluded, “In our hemp/cannabis franchise, we have secured all key partnerships needed to maximize and support what we believe is the most comprehensive and innovative upstream cannabinoid value chain in the industry, enabling the rapid development of new disruptive plant lines and genetics critical to unlocking commercial success for large-scale cultivation and extraction across this emerging industry. Along with new lines currently growing at our farm in Colorado, we also have plant lines and IP completing the initial two-year development cycle. We look forward to the monetization of these lines and our current hemp/cannabis portfolio with our first revenue from our hemp/cannabis franchise expected to commence in the second half of 2021, while we continue the rapid development of next generation, disruptive plant lines for our 2022 and 2023 revenue programs.”

Key Business and Financial Highlights

Tobacco Franchise

- Securing MRTP designation for VLN[®] is 22nd Century’s number one priority. The Company remains highly confident in a positive outcome with the FDA. There continues to be no outstanding requests for information from the FDA, and based on the most recent interactions with the Agency, the Company believes that its MRTP application has completed the scientific review process and is now in the documentation process, the final stage before FDA announces its decision. The Company is in regular contact with officials at the highest levels of the Agency and continues to highlight the public health importance of the Company’s MRTP application to encourage a positive outcome. 22nd Century possesses the expertise to navigate the MRTP application process to a successful conclusion with a balance of leverage and collaboration with the FDA.
- VLN[®] is market ready. The Company’s U.S. pilot program and manufacturing capabilities are in place to launch VLN[®] in the U.S. within 90 days of receiving MRTP designation. The Company’s leadership has successfully launched several tobacco and other plant-based consumer products, provides critical insight into the importance of a well-planned market entry and solid supply chain. The Company plans to position VLN[®] in the premium pricing segment of the cigarette market and, therefore, expects it to deliver corresponding margins.
- 22nd Century’s growth in tobacco contract manufacturing volumes and disciplined operations continued in the second quarter and confirms the readiness of the Company’s operations ahead of VLN[®] launching:

- Higher volume of cigarette production with precise standards and higher gross profit margin.
- The assets needed to manufacture research cigarettes and VLN[®] are paying for themselves, as well as capital investments in added manufacturing capacity and efficiency, ahead of MRTP authorization.
- The Company has completed an expansion of testing capabilities, which allows for rapid, in-house analysis of its tobacco. This will reduce the testing cost per VLN[®] sample by approximately 90%, while also significantly reducing the lead time to uncover key data. Internal testing of the Company's 2021 crop of VLN[®] is scheduled to begin at the facility in August 2021, using the newly installed testing equipment.
- The Company has significantly expanded its VLN[®] tobacco growing program based on the Company's latest sales projections. Plans have been initiated with experienced growers in the southern hemisphere that will allow the Company to grow and harvest its VLN[®] tobacco year-round. These new plantings are in addition to the Company's sizeable inventory of VLN[®] tobacco, which is earmarked for the launch and sales of VLN[®] cigarettes.
- The Company has initiated the launch process for VLN[®] in several countries where adult smokers have a strong affinity for new, reduced risk tobacco products and where the Company believes regulations will allow it to go to market with MRTP-type claims and minimal interaction with regulators. The Company plans to launch VLN[®] outside the U.S. by first quarter 2022.

Hemp/Cannabis Franchise

- The Company expects to monetize its hemp/cannabis plant lines and IP beginning in the second half of 2021 with upfront license fees plus revenue from the current crop. Next generation, disruptive plant lines are being accelerated for 2022 and 2023 revenue programs.
- 22nd Century announced an agreement to extend and expand its successful plant research partnership with KeyGene, a global leader in plant research involving high-value genetic traits and increased crop yields. The new agreement extends the length of the collaboration the Company has with KeyGene to develop new, disruptive hemp/cannabis plants and intellectual property for the life science, medicinal, and pharmaceutical end-use markets. It also expands the partnership to include research and development activity for alternative tobacco plant applications, such as protein production, as well as 22nd Century's third plant franchise.
- The Company has secured partnerships with highly specialized expert alkaloid-based plant breeders to support commercial scale-up and cultivation of disruptive plant lines far faster and beyond the capabilities of independent competitors or in-house breeding in consumer product companies. The newest addition is the world's leading alkaloid plant breeder, Extractas Bioscience located in the southern hemisphere providing the Company with year-round growing capabilities.
- The Company now controls the most comprehensive and innovative upstream cannabinoid value chain in the industry, an asset critical to unlocking commercial success for large-scale cultivation and extraction as this emerging industry continues to scale with the continuing success of global legalization and commercialization efforts and the entrants of new players from adjacent industries including tobacco, pharmaceutical, and other consumer products companies. Components of 22nd Century's proprietary value chain include: plant profiling tailored to the needs of customers (CannaMetrix), genetics to deliver differentiated traits to maximize yield of a specific cannabinoid or deliver a certain taste or fragrance profile (KeyGene), and commercial-scale plant breeding and cultivation of disruptive plant lines as well as year-round ingredient extraction/purification (Extractas Bioscience, Sawatch Agriculture, Folium Botanical, Aurora Cannabis, Needle Rock Farms, and Panacea).

Third Plant-Based Franchise

- 22nd Century Group will introduce its third franchise on August 30, 2021. The Company intends to outline its market opportunity, in a high-growth global market estimated at more than \$500 billion annually, and articulate its strong competitive advantages in the industry. The Company will also summarize its global plan for the route to market and commercialization in this market, which is not as highly regulated as its first two franchises.

Corporate Business Highlights

- The Company will uplist its common shares to the Nasdaq Capital Market ("Nasdaq") on Monday, August 16, 2021, and will continue to trade under its current symbol, "XXII." While remaining dedicated to its primary mission to reduce the harm caused by smoking, uplisting to the Nasdaq also aligns 22nd Century with other high-achieving, innovative, and growth-oriented global science and technology companies. The Company believes that joining the Nasdaq will enhance its visibility to a wide audience of institutional investors and increase our exposure to hemp/cannabis investors at this important time of industry progression toward mass production.
- New research coverage of the Company was initiated by Vivien Azer, a leading beverages, tobacco, and cannabis senior analyst at Cowen & Company, LLC.

- 22nd Century was added to the Russell 2000[®], Russell 3000[®], and Russell Global Indexes at the conclusion of the Russell U.S. Indexes annual reconstitution, effective at the opening of the U.S. equity markets on June 28, 2021. The Russell U.S. Indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies.

2021 Second Quarter Financial Results

- Net sales for the second quarter of 2021 were a record \$8.4 million, an increase of greater than 30% from \$6.4 million in the prior year period. The increase was primarily due to the combination of higher volume and additional price increases in the Company's contract manufacturing business. This demonstrates the Company's ability to generate new business in the tobacco category and produce growing volumes of cigarettes, confirming the Company's readiness to launch VLN[®].
- Gross profit for the second quarter of 2021 improved by \$385 thousand, or 192% to \$586 thousand compared to the prior year period – a sixth consecutive quarter of year-over-year improvement in gross profit. The improvement in gross margin was primarily the result of higher volume, price increases, cost containment measures, and factory efficiencies in 2020 and 2021 that are delivering lower labor and overhead costs relative to volume.
- Total operating expenses for the second quarter of 2021 increased by \$2.3 million compared to the prior year period. This was driven by the following:
 - Sales, general and administrative expenses increased by \$2.7 million compared to the prior year period. This was driven primarily by the addition of new members to the Company's management team, including its newly appointed Chief Executive Officer, Chief Financial Officer, and General Counsel, as well as higher personnel, insurance, financial and strategic consulting costs, and marketing costs. These investments deployed to support, evaluate, and prepare for future opportunities are critical as the Company moves quickly to market readiness in both tobacco and hemp/cannabis.
 - Research and development expense for the second quarter of 2021 was favorably lower by \$215 thousand compared to the prior year period. This favorability was primarily driven by lower personnel and contract costs partially offset by higher costs for tobacco field trials and patent fees. The Company's R&D investments are expected to grow in future quarters as the Company continues to accelerate the development of new, highly-differentiated hemp/cannabis plants and expand its R&D efforts to its third, plant-based franchise.
- Operating loss for the second quarter of 2021 was \$(6.6) million, an increase of \$1.9 million compared to the prior year period. This was primarily driven by an increase in SG&A and was partially offset by higher gross profit and lower research and development spend in the second quarter of 2021.
- Net loss in the second quarter of 2021 was \$(4.2) million, a favorable decrease of \$883 thousand compared to the prior year period primarily due to favorable year-over-year comparison of non-cash charges off-set by benefits to other income and expenses, and representing a net loss per share of \$(0.03). This compares to the second quarter of 2020 net loss of \$(5.1) million, or \$(0.04) per share.

Balance Sheet and Liquidity

- Gross proceeds of \$40.0 million of growth capital secured in second quarter 2021 will be used to accelerate the Company's revenue profile:
 - Fuel VLN[®] U.S. launch readiness and international market launches
 - Accelerate hemp/cannabis commercialization of disruptive plant lines and intellectual property
 - Launch third plant-based franchise
- For the first half of 2021, net cash used in operating activities was \$12.3 million, compared to \$11.5 million in the prior year period.
- The Company ended the quarter with a cash position of \$62.3 million as of June 30, 2021, and the Company's continued initiatives to manage expenses relative to net sales revenue should provide the Company with additional runway to execute for the foreseeable future.

Second Quarter Earnings Conference Call

22nd Century will host a live webcast today at 10:00 a.m. ET to discuss its second quarter 2021 financial results and business highlights. During the webcast, James A. Mish, chief executive officer of 22nd Century Group, together with Michael Zercher, president and chief operating officer, and John Franzino, chief financial officer, will review the Company's 2021 second quarter results, growth opportunities, and innovative strategic plans and future initiatives in the more than \$1.3 trillion global addressable markets.

Following prepared remarks, including an accompanying slide presentation, the Company will host a Q&A session, during which management will accept questions from interested analysts. Investors, shareholders, and members of the media will also have the opportunity to pose questions to management by submitting questions through the interactive webcast during the event.

The live and archived webcast, interactive Q&A, and slide presentation will be accessible on the Events web page in the Company's Investor Relations section of the website, at www.xxiicentury.com/investors/events. An archived replay of the webcast and the event transcript will also be available shortly after the live event has concluded.

About 22nd Century Group, Inc.

22nd Century Group, Inc. (NYSE American: [XXII](#)) is a leading plant biotechnology company focused on technologies that alter the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering, gene-editing, and modern plant breeding. 22nd Century's primary mission in tobacco is to reduce the harm caused by smoking through the Company's reduced nicotine content tobacco cigarettes – containing 95% less nicotine than conventional cigarettes. The Company's primary mission in hemp/cannabis is to develop and commercialize proprietary hemp/cannabis plants with valuable cannabinoid profiles and desirable agronomic traits.

Learn more at xxiicentury.com, on Twitter [@_xxiicentury](#), and on [LinkedIn](#).

Cautionary Note Regarding Forward-Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. Forward-looking statements typically contain terms such as “anticipate,” “believe,” “consider,” “continue,” “could,” “estimate,” “expect,” “explore,” “foresee,” “goal,” “guidance,” “intend,” “likely,” “may,” “plan,” “potential,” “predict,” “preliminary,” “probable,” “project,” “promising,” “seek,” “should,” “will,” “would,” and similar expressions. Actual results might differ materially from those explicit or implicit in forward-looking statements. Important factors that could cause actual results to differ materially are set forth in “Risk Factors” in the Company's Annual Report on Form 10-K filed on March 11, 2021. All information provided in this release is as of the date hereof, and the Company assumes no obligation to and does not intend to update these forward-looking statements, except as required by law.

This press release shall not constitute an offer to sell or the solicitation of any offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Below is a table containing information relating to the Company's Adjusted EBITDA for the three months ended June 30, 2021 and 2020, including a reconciliation of net (loss) income to Adjusted EBITDA for such periods.

	Quarter Ended June 30,		
	Dollar Amounts in Thousands (\$000's)		
	2021	2020	\$ Change fav / (unfav)
Net loss	\$ (4,174)	\$ (5,057)	\$ 883
Adjustments:			
Impairment of intangible assets	—	146	(146)
Impairment of Panacea investment	—	1,062	(1,062)
Amortization and depreciation	302	347	(45)
Unrealized loss (gain) on investment	176	(312)	488
Realized (gain) loss on short-term investment securities	—	(3)	3
Gain on Panacea investment conversion	(2,548)	—	(2,548)
Accretion of non cash interest expense	6	19	(13)
Equity-based employee compensation expense	1,245	376	869
Executive and board search fees	—	289	(289)
Interest income, net	(108)	(462)	354
Interest expense	8	—	8
Adjusted EBITDA	\$ (5,093)	\$ (3,595)	\$ (1,498)

¹Fav = Favorable variance, which increases Adjusted EBITDA; Unfav = unfavorable variance, which reduces Adjusted EBITDA

	Year-to-date Ended June 30,		
	Dollar Amounts in Thousands (\$000's)		
	2021	2020	\$ Change fav / (unfav)
Net loss	\$ (9,204)	\$ (9,086)	\$ (118)
Adjustments:			
Impairment of intangible assets	—	146	(146)
Impairment of Panacea investment	—	1,062	(1,062)
Amortization and depreciation	591	674	(83)
Unrealized loss (gain) on investment	140	133	7
Gain on Panacea investment conversion	(2,548)	—	(2,548)
Accretion of non cash interest expense	13	31	(18)
Equity-based employee compensation expense	1,751	856	895
Executive and board search fees	—	430	(430)
Interest income, net	(220)	(1,074)	854
Interest expense	8	—	8
Adjusted EBITDA	\$ (9,469)	\$ (6,828)	\$ (2,641)

¹Fav = Favorable variance, which increases Adjusted EBITDA; Unfav = unfavorable variance, which reduces Adjusted EBITDA

Adjusted EBITDA, which the Company defines as earnings before interest, taxes, depreciation and amortization, as adjusted by the Company for certain non-cash and non-operating expenses, as well as certain one-time expenses, is a financial measure not prepared in accordance with generally accepted accounting principles ("GAAP"). In order to calculate Adjusted EBITDA, the Company adjusts the net (loss) income for certain non-cash and non-operating income and expense items listed in the table above in order to measure the Company's operating performance. The Company believes that Adjusted EBITDA is an important measure that supplements discussions and analysis of its operations and enhances an understanding of its operating performance. While management considers Adjusted EBITDA to be important, it should be considered in addition to, but not as a substitute for or superior to, other measures of financial performance prepared in accordance with GAAP, such as operating loss, net (loss) income and cash flows from operations. Adjusted EBITDA is susceptible to varying calculations and the Company's measurement of Adjusted EBITDA may not be comparable to those of other companies.

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