



March 11, 2021

22nd Century Group Reports Business Highlights and Financial Results for the Fourth Quarter and Full-Year 2020

Key Business and Financial Highlights

- 22nd Century has a tremendous global commercial opportunity in the more than \$800 billion markets across the tobacco and hemp/cannabis industry.
- Securing Modified Risk Tobacco Product (MRTP) authorization for VLN[®] remains 22nd Century's number one priority. The Company is highly confident that the FDA is in the final stages of the review process related to its application.
- 22nd Century is fully prepared and eager to launch VLN[®] King and VLN[®] Menthol King within 90 days of receiving MRTP designation. MRTP designation is a catalyst for the VLN[®] brand and tobacco franchise via partnerships and licensing agreements in the U.S. and internationally.
- 22nd Century believes that recent political changes will likely be highly favorable to its business prospects from a policy priority and regulatory standpoint. The Company believes that, under the new administration, the FDA will now be re-energized in implementing its ground-breaking Comprehensive Plan for Tobacco and Nicotine Regulation, in particular the Agency's plan to cap the amount of nicotine in combustible cigarettes to a "minimally or non-addictive" level.
- The Company has now secured four out of the five key partnerships needed to maximize each component in the upstream segment of the hemp/cannabis value chain. The partnerships will enable 22nd Century to accelerate the new development of valuable, commercial hemp/cannabis lines and intellectual property to market in two years while it monetizes a portion of the Company's current portfolio of intellectual property (IP) from its previous license agreement with Anandia Laboratories. 22nd Century is also in final discussions with top-tier plant breeders that will be announced soon.
- Net sales revenue of \$7.3 million for the fourth quarter was consistent over the prior-year period and improved by 8.8% to \$28.1 million for the full-year.
- Gross profit for the fourth quarter improved by \$364 thousand and by \$1.4 million for the full-year; gross profit margin improved by 500 basis points for both periods.
- Net loss increased by \$207 thousand for the fourth quarter. For the full-year, net loss improved by \$6.8 million.
- Adjusted EBITDA was unfavorable by \$1.3 million for the fourth quarter. For the full-year Adjusted EBITDA improved by \$1.8 million.
- The Company's balance sheet is well funded with \$22.3 million at the end of full-year 2020. Additional cash of \$11.8 million received from warrants exercised in February and March 2021 will provide the Company with additional runway to fuel current operations, strategy, and growth initiatives. 22nd Century does not have any outstanding warrants following these transactions.

Note: All financials referenced in this release are in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") and comparisons in this release are to the same period in the prior year unless otherwise noted.

WILLIAMSVILLE, N.Y., March 11, 2021 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a leading plant-based, biotechnology company that is focused on tobacco harm reduction, very low nicotine content tobacco, and hemp/cannabis research, announced today that the Company filed its Annual Report on Form 10-K with the U.S. Securities and Exchange Commission. The Company will provide a business update for investors on a live audio webcast to be held today at 8:00 a.m. ET.

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 host the webcast. Interested parties are invited to participate by visiting the Events section on the Company's Investor Relations website at www.xxiicentury.com/investors/events. Following prepared remarks, the Company will host a Q&A session during which management will accept questions from industry analysts. Investors, shareholders, and members of the media will also have the opportunity to submit their questions through the interactive webcast.

"Since joining 22nd Century Group in June, we have communicated our strategic plan and go forth strategy. Our stock price has increased significantly since reporting third quarter earnings demonstrating our commitment to our shareholders," said James A. Mish, chief executive officer of 22nd Century Group. "As we look to 2021, we see tremendous commercial opportunity for our tobacco and hemp/cannabis franchises. Our focus remains on our primary mission: to reduce the harm caused by smoking. Once we secure MRTP designation, we will capitalize on our VLN[®] brand and begin to build our tobacco franchise through licensing and partnership opportunities in the U.S. and internationally. We have made significant progress in our hemp/cannabis research and look forward to monetizing a portion of our hemp/cannabis IP this year. With the majority of our hemp/cannabis operational partnerships now in place, we believe we will be able to commercialize our new disruptive, commercially valuable hemp/cannabis plants in development in two years."

Tobacco Franchise Highlights and Recent Key Events

- Over the past several months, 22nd Century has been executing on the strategic plan that it announced on its third quarter earnings call in November 2020. The Company continues to focus on its primary mission and highest, near-term priority of securing MRTP authorization for its proprietary, reduced nicotine content tobacco cigarettes, VLN[®]. The Company is maintaining its dialogue with the FDA and is highly confident that the Agency is in the final stages of the review process related to its application. In addition to its ongoing contact with the FDA, 22nd Century has been and continues working with various legal advisers, regulatory consultants, and government affairs specialists to highlight the public health importance of its MRTP application to encourage a near-term authorization of its application.
- 22nd Century is fully prepared to make VLN[®] available to adult smokers in the U.S. within 90 days of receiving MRTP authorization from the FDA and is in advanced discussions with potential partners in the independent, regional, and national retail trade. The Company anticipates a phased roll out of VLN[®] in select geographies and plans to position VLN[®] in the premium pricing segment of the cigarette market and, therefore, expects it to deliver corresponding margins. On January 11, 2021, 22nd Century announced that it will significantly expand its growing program and an increase in planting in the 2021 crop year for VLN[®] based on the Company's latest sales projections. This new planting is in addition to the Company's sizeable inventory of VLN[®] tobacco, which is earmarked for the launch and initial sales of VLN[®] cigarettes.
- The Company believes that recent political changes will likely be highly favorable to its business prospects from a policy priority and regulatory standpoint. It also believes that the new administration will likely have an impact on the timing of its MRTP application based on the Company's positive and relentless approach with the FDA through multiple channels. 22nd Century has already begun work to align with the new administration and to encourage their support.
- Additionally, the Company believes that under the new administration, the FDA will now be re-energized in implementing its ground-breaking Comprehensive Plan for Tobacco and Nicotine Regulation, in particular the Agency's plan to cap the amount of nicotine in combustible cigarettes to a "minimally or non-addictive" level. 22nd Century believes that the MRTP authorization and the launch of VLN[®] will serve as a vanguard for the FDA's proposed mandate and maintains its bullish outlook on the implementation of a nicotine cap for combustible cigarettes.
- The Company's research cigarettes, SPECTRUM[®], continue to fuel numerous independent, scientific studies to validate the enormous public health benefit identified by the FDA and others of implementing a national standard requiring all cigarettes to contain "minimally or non-addictive" levels of nicotine. On December 8, 2020, 22nd Century announced that the FDA in coordination with the National Institute on Drug Abuse (NIDA) and others, submitted an order to 22nd Century for 3.6 million variable nicotine research cigarettes. In March 2021, the Company will fulfill the order bringing the total number of research cigarettes provided for public health research to more than 31 million cigarettes.
- 22nd Century believes that its next-generation, non-GMO, plant research is the key to commercializing its reduced nicotine content tobacco and technology in international markets where non-GMO products are preferred, or GMO products are banned. It continues to make significant progress in its non-GMO tobacco research. During the fourth quarter of 2020, 22nd Century confirmed that it has successfully applied its

non-GMO technology to Bright and Burley varieties of tobacco and has developed a VLN[®] 2.0 prototype cigarette. The Company is also using its non-GMO technology to introduce reduced nicotine traits into Oriental varieties of tobacco. 22nd Century believes that decades of experience with the tobacco plant will provide it with the ability to accelerate the development of additional tobacco-based technologies for multiple applications across various end-use markets beyond reduced nicotine content tobacco products.

Hemp/Cannabis Franchise Highlights and Recent Key Events

- Since reporting third quarter earnings, 22nd Century continues to place a renewed emphasis on its hemp/cannabis strategy to target the upstream segments of the cannabinoid value chain, in particular, in the areas of plant biotechnology research, gene modification and engineering, modern plant breeding and development, and extraction. The Company believes that it can differentiate itself in the hemp/cannabis industry by building upon its core strength and expertise in plant science and in the ingredient value chain and through its operational partnerships; including the addition of its new operational partner, CannaMetrix. 22nd Century continues to shift its focus away from the already saturated U.S. consumer market of cannabidiol (CBD) and hemp-based products and has refocused its partnership with Panacea, through a non-binding agreement, to provide ingredient cultivation capabilities and extraction and purification services. The agreement will provide the Company with operational assets, including Needle Rock Farms and various extraction and distillation equipment.
- Over the past year, the Company has made tremendous progress with KeyGene in its hemp/cannabis research. In March 2020, the Company announced that it has built its proprietary bioinformatics platform and can begin monetizing a portion the vast knowledge foundation and intellectual property it has developed over the past year. 22nd Century believes that its collaborative efforts with KeyGene enable the Company to modify and improve the hemp/cannabis plant using the fastest and most cost-effective methods available. The Company continues to target and develop hemp/cannabis lines with select agronomic traits including lines with stable, ultra-high tetrahydrocannabinol (THC) levels, lines with higher levels of rare cannabinoids, and lines with ultra-low terpene levels.
- On February 10, 2021, 22nd Century Group announced that it has developed and launched a new, cutting-edge technology platform that will enable the Company and its strategic partners to quickly identify and incorporate commercially valuable traits of hemp/cannabis plants to create new, stable hemp/cannabis lines. The platform, developed in collaboration with researchers at KeyGene, incorporates a suite of proprietary molecular tools and a large library of genomic markers and gene-trait correlations. 22nd Century has already characterized millions of high-value single nucleotide polymorphisms (SNPs). By targeting these newly identified SNPs, the Company has been able to locate and isolate specific sections of genetic code from genome assemblies present in the Company's state-of-the-art hemp/cannabis bioinformatics database. This major breakthrough enables 22nd Century Group to quickly and easily identify the genes responsible for specific traits in a plant and is a powerful tool for the Company and the hemp/cannabis industry. The Company has already begun discussions to license this platform to strategic partners to help them improve their plant breeding techniques and optimize their hemp/cannabis lines.
- The Company continues to secure commercially valuable patents and intellectual property through its internal research capabilities and external research partnerships. On December 17, 2020, the Company announced that it was granted a new U.S. Patent No. 10,787,674 B2 entitled "Trichome specific promoters for the manipulation of cannabinoids and other compounds in glandular trichomes." This new intellectual property enables 22nd Century to develop and deliver new hemp/cannabis plants that are designed to produce cannabinoids more efficiently by activating the molecular promoters, "on/off switches," *specifically and only* in the plant's trichomes where the majority of cannabinoids are produced. The patent application describes eight promoters covering all of the major steps in the cannabinoid biosynthesis pathway and is related to the control of cannabinoid and terpene production. The Company believes it can monetize a portion of its existing hemp/cannabis intellectual property in 2021 and will continue to bring new, disruptive technology forward.
- On March 3, 2021, 22nd Century announced that it has secured an exclusive agreement with CannaMetrix, LLC for the use of their proprietary, human cell-based testing CannaMetrix EC50Array™ technology that will enable it to accelerate the commercialization of new, disruptive hemp/cannabis plant lines and intellectual property. CannaMetrix's proprietary CannaMetrix EC50Array™ technology serves as a high-throughput roadmap for developing new hemp/cannabis plant lines with tailor-made cannabinoid and terpenoid profiles for use in the life science, consumer product, and pharmaceutical markets. The human cell-based assay has the ability to measure and validate the potency and efficacy of cannabinoids and/or terpenoids through defined biomarkers and receptor activity, and can rapidly identify optimum plant profiles by measuring the potency and effect on the human cell system.

- 22nd Century believes that it can accelerate the development of commercially, valuable hemp/cannabis lines and related intellectual property through selective partnerships and has now secured four out of the five key partnerships needed to maximize each component in the upstream segment of the cannabinoid value chain: plant profiling (CannaMetrix), plant biotechnology (KeyGene), plant cultivation (Panacea-Needle Rock Farms), and ingredient extraction/purification (Panacea). The Company is also in final discussions with top-tier, plant breeders that will be announced soon. The new partnership with CannaMetrix combined with 22nd Century's worldwide, exclusive agreement with KeyGene, and the refocused strategy with its partnership with Panacea will enable the Company to bring new commercially valuable hemp/cannabis plant lines to market in as quickly as two years.

2021 Priorities and Areas of Focus

1. 22nd Century remains focused on securing FDA authorization for VLN[®], the only reduced nicotine content combustible cigarette in the world that will receive a MRTP designation from FDA. The Company plans to execute a commercial product launch and will seek licensing and partnership initiatives within 90 days of authorization.
2. The Company believes that an equally important first priority initiative is to support and advance the FDA's plan to require all cigarettes sold in the U.S. be made "minimally or non-addictive" by limiting their nicotine content to just 0.5 milligrams of nicotine per gram of tobacco.
3. 22nd Century continues to target the upstream segment of the cannabinoid value chain by creating proprietary, commercially valuable new plant lines and related intellectual property with stabilized genetics to harness and optimize hemp/cannabis plant potential. The Company expects to monetize a portion of its existing hemp/cannabis IP in 2021 and will continue to bring disruptive technology forward.
4. The Company will turn attention to the development of a third, plant-based franchise after securing MRTP authorization for VLN[®]. 22nd Century will leverage its plant science expertise to develop and secure valuable intellectual property and sign lucrative strategic partnerships to support the development of this franchise.
5. 22nd Century will maintain diligent financial execution, efficient operating structure, and balance sheet strength to support its growth initiatives.

Fourth Quarter and Full-Year 2020 Financial Results

- Net sales revenue for the fourth quarter of 2020 increased \$46 thousand, or 0.6% to \$7.3 million compared to the prior-year period. For full-year 2020, net sales revenue increased \$2.3 million, or 8.8% to \$28.1 million compared to the prior-year. The increase for both periods was primarily driven by higher volume and increased pricing in the Company's contract manufacturing business.
- Gross profit for the fourth quarter improved by \$364 thousand, or 161.8% to \$588 thousand compared to the prior-year period. For full-year 2020, gross profit improved by \$1.4 million, or 9,413% to \$1.4 million. The improvement in gross margin was primarily the result of higher volume, price increases, and lower labor and overhead costs driven by factory efficiencies implemented in 2020.
- Total operating expenses for the fourth quarter of 2020 increased by \$1.1 million compared to the prior-year period. For full-year 2020, operating expenses decreased by \$3.0 million compared to the prior-year. This was driven by the following:
 - Research and development expense for the fourth quarter of 2020 was favorable by \$127 thousand compared to the prior year period. For full-year 2020, research and development expense was also favorable by \$2.3 million compared to the prior year. This was primarily driven by a reduction in personnel expense, lower license and contract costs, and the absence of a one-time impairment charge taken on research tobacco leaf inventory in the prior year.
 - Research and development expense related to the MRTP application was favorable by \$205 thousand for the fourth quarter compared to the prior year period. For full-year 2020, research and development expense related to the MRTP application was favorable by \$1.6 million compared to the prior year. The favorability was primarily the result of expenses incurred in 2019 that were associated with the preparation for the Company's Tobacco Products Scientific Advisory Committee (TPSAC) hearing which occurred on February 14, 2020.
 - For the fourth quarter of 2020, sales, general and administrative expense increased by \$1.3 million

compared to the prior year period. This was driven primarily by higher insurance, consulting, and personnel expense which were partially offset by lower legal fees.

- For the full-year 2020, sales, general and administrative expense increased by \$2.0 million compared to the prior year. This was driven primarily by insurance expenses, consulting and professional services, and the addition of new members to the Company's management team, including its newly appointed Chief Executive Officer and Chief Financial Officer. The increase was partially offset by a decrease in one-time severance and equity compensation expenses that occurred in 2019, legal fees, and travel and entertainment savings as a result of the COVID-19 pandemic.
- Impairment of intangible assets for the fourth quarter of 2020 increased by \$30 thousand compared to the prior year period. For full-year 2020, impairment of intangible assets decreased by \$966 thousand compared to the prior year. The decrease year-over-year was related to an intellectual property portfolio rationalization that resulted in higher impairment in 2019.
- For the fourth quarter of 2020, operating loss was unfavorable by \$696 thousand 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 related to the MRTP application in 2019.
- For full-year 2020, operating loss improved by \$4.4 million to \$(19.2) million compared to the prior year driven by the combination of higher gross profit of \$1.4 million and lower total operating expenses of \$20.6 million. The decrease in operating expenses were primarily driven by a decrease in research and development expenses related to the MRTP application in 2019, a reduction in personnel expense, and an intellectual property portfolio rationalization that resulted in higher impairment in the prior year.
- Net loss for the fourth quarter of 2020 was \$(6.4) million, representing a net loss per share of \$(0.05) as compared to a net loss of \$(6.2) million, or a net loss per share of \$(0.05) for the fourth quarter of 2019.
- Net loss for full-year 2020 improved by \$6.8 million to \$(19.7) million, representing a net loss per share of \$(0.14) as compared to a net loss of \$(26.6) million, or a net loss per share of \$(0.21). In addition to the improvement in operating loss of \$4.4 million, other income and expense improved by \$2.5 million primary due to a \$1.9 million litigation expense and a reduction in the unrealized loss on Aurora warrants of \$2.4 million recorded in the prior year. This was partially offset in the current year by an impairment charge of \$1.7 million related to the Panacea stock warrant investment.
- Adjusted EBITDA was \$(5.4) million for the fourth quarter of 2020 compared to Adjusted EBITDA of \$(4.1) million for the fourth quarter 2019.
- Adjusted EBITDA was \$(15.6) million for full-year 2020, an improvement of \$1.8 million compared to Adjusted EBITDA of \$(17.5) million for full-year 2019.

Balance Sheet and Liquidity

- For twelve months 2020, net cash used in operating activities was approximately \$15.6 million, compared to approximately \$14.6 million for the twelve months in 2019.
- The Company's liquidity remains strong with cash, cash equivalents, and short-term investment securities totaling approximately \$22.3 million as of December 31, 2020.
- The Company does not have any plans or need to raise capital at this time. It believes the continued improvement in quarterly cash burn rate, an ongoing reduction in costs, a healthy cash position, and the addition of \$11.8 million to its balance sheet from an exercise on previously issued stock warrants should provide the Company with additional runway to execute for the foreseeable future.

Fourth Quarter Earnings Conference Call

22nd Century will host a live audio webcast today at 8:00 a.m. ET to discuss its full-year 2020 financial results and business highlights. Following prepared remarks, 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.

James A. Mish, chief executive officer of 22nd Century Group, together with Michael Zercher, chief operating officer, and John Franzino, chief financial officer, will host the webcast. Interested parties are invited to participate by visiting the Events section on the Company's Investor Relations website at www.xxiicentury.com/investors/events.

An archived replay of the webcast and the event transcript will 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 proprietary 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 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.

Below is a table containing information relating to the Company's Adjusted EBITDA for the three and twelve months ended December 31, 2020 and 2019, including a reconciliation of net (loss) income to Adjusted EBITDA for such periods.

	Quarter Ended December 31, Dollar Amounts in Thousands (\$000's)		
	2020	2019	\$ Change fav / (unfav)
Net loss	\$ (6,405)	\$ (6,198)	\$ (207)
Adjustments:			
Impairment of intangible assets	30	—	30
Impairment of Panacea investment	679	—	679
Amortization and depreciation	349	313	36
Unrealized loss (gain) on investment	(128)	1,010	(1,138)
Realized (gain) loss on short-term investment securities	(5)	(75)	70
Gain on the sale of machinery and equipment	—	—	—
Accretion of non cash interest expense	9	20	(11)
Equity-based employee compensation expense	491	1,134	(643)
Interest Income	(407)	(309)	(98)
Interest Expense	9	—	9
Adjusted EBITDA	\$ (5,378)	\$ (4,105)	\$ (1,273)

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

Year Ended
December 31,
Dollar Amounts in Thousands (\$000's)

			\$ Change
	2020	2019	fav / (unfav)
Net loss	\$ (19,711)	\$ (26,558)	\$ 6,847
Adjustments:			
Impairment of intangible assets	176	1,142	(966)
Impairment of Panacea investment	1,741	—	1,741
Amortization and depreciation	1,345	1,425	(80)
Unrealized loss (gain) on investment	434	2,419	(1,985)
Realized (gain) loss on short-term investment securities	(5)	(221)	216
Litigation Settlement	—	1,891	(1,891)
Gain on the sale of machinery and equipment	(1)	(87)	86
Accretion of non cash interest expense	43	53	(10)
Equity-based employee compensation expense	1,654	3,540	(1,886)
Executive and board search fees	430	—	430
Interest Income	(1,751)	(1,066)	(685)
Interest Expense	29	3	26
Adjusted EBITDA	\$ (15,616)	\$ (17,459)	\$ 1,843

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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Source: 22nd Century Group, Inc