

22nd Century Group Reports Financial Results and Business Highlights for the Third Quarter 2020

Key Highlights:

- 22nd Century remains focused on its primary mission of *reducing the harm caused by smoking*. To this end, in recent weeks the Company has intensified its proactive efforts to secure a Modified Risk Tobacco Product (MRTP) authorization from the U.S. Food and Drug Administration (FDA) for VLN[®]. **With 95% less nicotine than leading brands - or any other cigarette in the U.S. - VLN[®] will make 22nd Century the first, and only company in the world to achieve a MRTP designation for a combustible cigarette.**
- The Company has plans in place to commercialize VLN[®] in the U.S. 90 days after receiving MRTP authorization. These plans include a rollout through large, well-recognized retail chains in the U.S. and a marketing campaign to introduce adult smokers to the world's lowest nicotine content cigarette.
- 22nd Century was recently granted a new, highly valuable U.S. patent which provides the Company with precise genetic control over nicotine levels in virtually any variety of the tobacco plant. The breakthrough technology will enable the Company to rapidly introduce very low nicotine traits into all varieties of tobacco currently used in the production of cigarettes and other tobacco products.
- The Company has refocused its hemp/cannabis strategy to prioritize the upstream value chain segments of plant/seed biotechnology, breeding, cultivation, and purification of disruptive, proprietary plant lines over cannabidiol (CBD) and hemp-based consumer products in the U.S.
- Net sales revenue increased approximately 13.1% from the third quarter of 2019 to \$7.3 million.
- Year-to-date, gross profit improved by \$1.1 million year-over-year and continues to show improvement as a result of increased contract manufacturing operation (CMO) sales volume and pricing as well as targeted actions to improve production costs.
- Quarter-to-date, total operating expenses improved by \$3.2 million and operating loss improved by \$3.6 million over the prior-year quarter.
- Net loss improved by \$6.0 million over the same quarter in the prior year.
- The Company's financial position remains strong with cash, cash equivalents, and short-term investment securities totaling approximately \$26.8 million at the end of the third quarter 2020.
- Adjusted EBITDA improved by 26.4% compared to the third quarter of 2019.

WILLIAMSVILLE, N.Y., November 5, 2020 (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 2020 Third Quarter Report on Form 10-Q 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, 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.xxiiicentury.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.

"In my first few months as CEO of 22nd Century, I met with scientists, public health officials, national cigarette retailers, farmers, and 22nd Century shareholders. What I heard, from each of these groups, is that 22nd Century's VLN[®] cigarettes have the potential to disrupt and redefine the entire tobacco industry and, in doing so, prevent millions of our nation's youth from becoming addicted to the only legal consumer product that, when used as intended, will kill half of all long-term users," said James A. Mish, chief executive officer of 22nd Century Group. "Understanding these facts has helped me to truly appreciate the Company's primary mission of reducing the harm caused by smoking and to reaffirm the Company's strategic priorities."

After conducting a comprehensive review of 22nd Century's existing business, extensive intellectual property portfolio, and the regulatory climate in which the Company operates, management has identified near-term milestones and medium/long-term opportunities:

1. Securing a MRTP authorization from the FDA for VLN[®] remains the Company's number one priority. Separately, but at the same time, 22nd Century has made product launch plans that include a national roll-out with large, well-recognized retail chains in the U.S. and a marketing campaign that has been designed to introduce adult smokers to the world's lowest nicotine content cigarette. Commercial product launch and licensing discussion with potential strategic partners in the U.S. and globally will commence within 90 days of MRTP authorization.
2. An equally important first priority initiative is supporting and advancing the FDA's plan to require that 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 (a level already achieved by 22nd Century's proprietary VLN[®] cigarettes). When the FDA mandate ultimately goes into effect, 22nd Century plans to make the Company's proprietary reduced nicotine content tobacco and related intellectual property available to every cigarette manufacturer in the U.S.
3. 22nd Century's near- and medium-term commercial prospects have never been brighter. Since reporting second quarter earnings, the Company has refocused its hemp/cannabis strategy to target the upstream segments of the value chain such as plant biotechnology research, gene modification and engineering, and modern plant breeding. This renewed emphasis on intellectual property and high-value genetic traits is a shift away from CBD and hemp-based consumer products in the already saturated U.S. market. Accordingly, 22nd Century will concentrate its hemp/cannabis efforts on initiatives related to the Company's current (and exclusive) KeyGene collaboration and on the existing worldwide license agreement with Anandia Laboratories.
4. 22nd Century has also identified a third plant-based franchise that has similarities in its genome to the hemp/cannabis plant. The Company plans to turn attention to this franchise after execution of its tobacco and hemp/cannabis strategies. 22nd Century is in the process of securing valuable and necessary intellectual property and pursuing strategic partnerships to support the development of this franchise. The Company will provide additional information as the competitive situation allows.
5. Additionally, 22nd Century's operating results for the third quarter were strong, driven by year-over-year revenue growth and continued gross margin improvement. The Company's balance sheet is healthy and has excellent prospects to establish strategic partnerships upon its MRTP authorization. 22nd Century is fully prepared to launch its historic VLN[®] product.

Business Highlights and Key Events

- On September 17, 2020, 22nd Century announced the appointment of Michael Koganov, Sc.D., Ph.D., to its Board of Directors. Dr. Koganov will serve as Chair of the Company's Scientific Advisory Board and as a member of the Board of Director's Finance Committee. Recognized as a leading expert in the development of plant-derived, natural products and solutions for pharmaceutical, consumer packaged goods, and life science companies, Dr. Koganov brings a valuable scientific perspective to 22nd Century's business and research and development strategies.
- On October 14, 2020, the Company announced that it was granted U.S. Patent No. 10,669,552 entitled "Up-regulation of auxin response factor NbTF7 to decrease nicotine in a plant." This crucial patent covers methods of manipulating plant metabolism and alkaloid levels by controlling transcription factor NbTF7, which regulates the nicotine alkaloid biosynthetic pathway. This breakthrough technology provides the Company with a rapid pathway to introduce very low nicotine traits into virtually any variety of tobacco, including bright, burley, oriental, and cigar tobacco varieties. This achievement further demonstrates that the FDA's Comprehensive Plan for Tobacco and Nicotine Regulation to limit the nicotine content for all cigarettes sold in the U.S. is technically feasible and at the same time definitively disproves the "Big Tobacco" claim that such low nicotine levels cannot be achieved in all tobacco varieties.
- On October 19, 2020, the Company announced its participation in the Food and Drug Law Institute's Tobacco and Nicotine Products Regulation and Policy Conference. John Pritchard, 22nd Century's vice president of regulatory science, presented as a member of the conference's "Nicotine and Harm Reduction" panel on Thursday, October 22. During the conference, 22nd Century expressed strong support for the FDA's landmark 2017 Comprehensive Plan for Tobacco and Nicotine Regulation, in particular the FDA's plan to require all cigarettes sold in the U.S. to be made "minimally or non-addictive" by limiting their nicotine content to just 0.5 milligrams of nicotine per gram of tobacco, a level already achieved by 22nd Century's proprietary VLN[®] cigarettes. The Company gained significant exposure with the 300 participants attending the conference, including members of the FDA's Center for Tobacco Products (CTP), advocates of public health and regulation, and key members of the media. 22nd Century continues to advocate for common-sense tobacco and nicotine regulation and urges public health officials to unite against the tragic toll of cigarette addiction.

- Since reporting second quarter earnings in August, the Company has finalized its strategic plans, set near-term milestones, and identified exciting medium and long-term opportunities. 22nd Century's primary mission and highest, near-term priority is on reducing the harm caused by smoking. The Company will achieve its mission by bringing to market its proprietary, reduced nicotine content tobacco cigarettes – containing 95% less nicotine than conventional cigarettes – under the brand name VLN[®] upon the FDA's authorization of its MRTP application. The Company continues to maintain its dialogue with the FDA, and believes 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 is also working with various legal counsel, advisors, and government affairs specialists to highlight the public health importance of its MRTP application to encourage a near-term authorization of its application.

With more than 34 million smokers in the U.S. and more than 1 billion worldwide, the FDA's authorization of the VLN[®] MRTP application will serve as a catalyst for 22nd Century's commercial sales. The Company believes that achieving just one-quarter of one percent (0.25%) market share of the U.S. cigarette market, could result in revenues that may over time, based on the disruptive nature of VLN[®], drive the Company's market capitalization more than 10 times higher. In addition, the Company believes the FDA's authorization of 22nd Century's MRTP with modified exposure claims would open multiple licensing opportunities for 22nd Century's proprietary reduced nicotine content tobacco in the U.S. and globally.

- The Company will make VLN[®] available to adult smokers in the U.S. through its planned distribution in pharmacies, convenience stores, and other tobacco retail outlets within 90 days of receiving MRTP authorization from the FDA. 22nd Century has received extremely positive feedback on its reduced nicotine content cigarettes from many potential partners in the independent, regional, and national retail trade, and the Company is in the process of finalizing its distribution plans and agreements. The Company is also in the final stages of completing its marketing plans for VLN[®] and currently anticipates a phased roll out in select geographies within 90 days of MRTP authorization. 22nd Century plans to position VLN[®] in the premium pricing segment of the cigarette market and expects it to deliver corresponding margins. The Company's consumer market research indicates that 60% of adult smokers have an interest in using VLN[®]. Discussions with potential tobacco retailers have indicated strong support from trade channel partners.
- 22nd Century has also made considerable progress in the development of its non-GMO (genetically modified organisms) technology and has successfully applied the next generation methodology of reducing nicotine levels in tobacco plants to several varieties of tobacco. The non-GMO technology has shown to consistently achieve reductions in nicotine levels by as much as 99% compared to conventional tobacco. The Company believes that non-GMO technology is key to commercializing global opportunities where non-GMO products are preferred by consumers or where GMO products are banned. The Company will begin to execute on commercial opportunities overseas once it secures MRTP authorization from the FDA, as the Agency is viewed as the gold standard in public health. The Company has already harvested non-GMO crops from field trials conducted earlier this year and is already developing a non-GMO very low nicotine content cigarette prototype.
- The Company's genesis in hemp/cannabis research was established in 2014 through a worldwide license agreement with Anandia Laboratories. The Company maintains its exclusive sublicense in the U.S. and co-exclusive sublicense in the remainder of the world, excluding Canada, for 23 patent and patent applications relating to the hemp/cannabis plant. The licenses for these valuable patents survive Aurora Cannabis's acquisition of Anandia. The Company believes that it can accelerate its research in hemp/cannabis through selective partnerships.

Through its partnership with KeyGene, the Company has recently completed building its proprietary bioinformatics platform. Armed with this encyclopedia of information on the hemp/cannabis genome, 22nd Century looks now to begin monetizing the vast knowledge foundation and intellectual property it has developed over the past year. The Company believes that its collaborative efforts with KeyGene enables the Company to modify and improve the hemp/cannabis plant using the fastest and most cost-effective methods available. 22nd Century 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.

- 22nd Century has refocused 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 intends to build upon its core strengths in the plant science and ingredient value chain and seek to form operational partnerships that will enable it to offer comprehensive commercial breeding, cultivation, and extract purification services utilizing its proprietary hemp/cannabis plants in development. With the progress that 22nd Century has made over the past year in its partnership with Panacea, the Company will focus on and ensure the accelerated delivery of valuable, commercial plant lines and technology, and intellectual property for the life science, consumer product, and pharmaceutical markets over finished consumer goods.
- 22nd Century has also identified a third plant-based franchise that has similarities in its genome to the hemp/cannabis plant. The Company plans to turn attention to this franchise after execution of its tobacco and hemp/cannabis strategies. 22nd Century is in the process of securing valuable intellectual property and pursuing strategic partnerships to support the development of this franchise and will provide additional information over the coming months as the competitive situation allows.

2020 Third Quarter and Year-to-Date Financial Results

- Net sales revenue for the third quarter of 2020 was \$7.3 million, an increase of 13.1% over net sales revenue of \$6.5 million during the third quarter of 2019. Net sales revenue year-to-date was \$20.8 million, an increase of 12.0% from net sales revenue of \$18.6 million for the first nine months of 2019. The increase in sales for both periods was primarily driven by higher volume and pricing in its contract manufacturing business.
- Gross profit improved by \$383 thousand in the third quarter of 2020 compared to prior year and improved \$1.1 million year-to-date compared to the first nine months of 2019. The improved gross margin was primarily the result of higher volume, price increases, and lower labor and overhead costs driven by factory efficiencies implemented over the last nine months.
- Total operating expenses improved by \$3.2 million for the third quarter and improved by \$4.0 million year-to-date, driven by the following:
 - Research and development expenses decreased by \$1.0 million quarter-to-date and \$2.2 million year-to-date. 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 expenses related to the MRTP application was favorable in the third quarter by \$65 thousand and \$1.4 million year-to-date. The expenses in the prior year were primarily related to preparation for the Company's Tobacco Products Scientific Advisory Committee (TPSAC) hearing which occurred on February 14, 2020.
 - Sales, general and administrative expense was favorable by \$890 thousand in the third quarter. The favorability was driven primarily by lower one-time severance expenses and decreased equity compensation that occurred in the third quarter of 2019 as a result of management changes.
 - Sales, general and administrative expense was \$690 thousand higher year-to-date compared to the first nine months of 2019. This was driven primarily by an increase in expenses related to consulting and professional services and personnel and insurance costs and was partially offset primarily by lower equity compensation and a decrease in one-time severance expense.
 - Impairment of intangible assets decreased by \$1.1 million in the third quarter and by \$997 thousand year-to-date. The decrease year-over year was related to an intellectual property portfolio rationalization that resulted in higher impairment in the prior year.
- Operating loss improved by \$3.6 million in the third quarter of 2020 to (\$4.0) million. The improvement in the quarter was driven by higher gross profit which increased by \$384 thousand and lower total operating expenses of \$3.2 million, primarily driven by the aforementioned impairment of intangible assets recorded in the prior year, lower sales, general and administrative expenses, and lower research and development spend.
- Operating loss year-to-date improved by \$5.1 million to (\$12.9) million driven by the combination of higher gross profit which increased by \$1.1 million and a \$4.0 million reduction in operating expenses. The decrease in operating expenses were primarily driven by a decrease in research and development expenses and the aforementioned impairment of intangible assets recorded in the prior year.
- Net loss for the third quarter of 2020 improved by \$6.0 million to (\$4.2) million, representing a net loss per share of (\$0.03) as compared to a net loss of (\$10.3) million, or a net loss per share of (\$0.08) for third quarter of 2019. In addition to the improvement in operating loss of \$3.6 million, other income and expense improved by \$2.5 million primarily due to a reduction in the unrealized loss on Aurora warrants of (\$3.0) million in the quarter.
- Net loss for the first nine months of 2020 improved by \$7.1 million to (\$13.3) million, representing a net loss per share of (\$0.10) as compared to a net loss of (\$20.4) million, or a net loss per share of (\$0.16). In addition to the improvement in operating loss of \$5.1 million, other income and expense improved by \$2.0 million primary due to a \$1.9 million litigation expense recorded in the prior year. This was partially offset in the current year by an impairment charge of \$1.1 million related to the Panacea stock warrant investment.
- Adjusted EBITDA was (\$3.4) million for the third quarter of 2020, an improvement of \$1.2 million, or 26.4% compared to Adjusted EBITDA of (\$4.6) million for the third quarter of 2019.
- Adjusted EBITDA was (\$10.2) million for the first nine months of 2020, an improvement of \$3.1 million, or 23.3% compared to Adjusted EBITDA of (\$13.4) million for the first nine months of 2019.

Balance Sheet and Liquidity

- For the first nine months of 2020, net cash used in operating activities was approximately \$12.6 million, compared to approximately \$11.7 million in the first nine months of 2019.

- The Company’s liquidity remains strong with cash, cash equivalents, and short-term investment securities totaling approximately \$26.8 million as of September 30, 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, and a healthy cash position should provide the Company with ample ability to execute for the foreseeable future.

Third Quarter Earnings Conference Call

22nd Century will host a live audio webcast today at 8:00 a.m. ET to discuss its third quarter 2020 financial results. 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.

The live audio webcast, interactive Q&A, and investor presentation will be accessible in the Events section on the Company’s Investor Relations website at www.xxiiicentury.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 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 xxiiicentury.com, on Twitter @_xxiiicentury 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, 2020 and in its subsequently filed Quarterly Report on Form 10-Q. 22nd Century undertakes no obligation to publicly update or revise any forward-looking statement as a result of new information, future events, or otherwise, except as otherwise required by law.

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 nine months ended September 31, 2020 and 2019, including a reconciliation of net (loss) income to Adjusted EBITDA for such periods.

	Quarter Ended September 30,		
	Dollar Amounts in Thousands (\$000's)		
	2020	2019	\$ Change fav / (unfav)
Net loss	\$ (4,221)	\$ (10,245)	\$ 6,024
Adjustments:			
Impairment of intangible assets	—	1,142	(1,142)
Amortization and depreciation	323	390	(67)
Unrealized loss (gain) on investment	429	2,959	(2,530)
Realized (gain) loss on short-term investment securities	—	(90)	90
Gain on the sale of machinery and equipment	(1)	—	(1)
Accretion of non-cash interest expense	4	12	(8)
Equity-based employee compensation expense	306	1,440	(1,134)
Interest Income	(270)	(242)	(28)
Interest Expense	19	—	19
Adjusted EBITDA	\$ (3,412)	\$ (4,634)	\$ 1,222

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

	Year-to-date Ended September 30,		
	Dollar Amounts in Thousands (\$000's)		
	2020	2019	\$ Change fav / (unfav)
Net loss	\$ (13,307)	\$ (20,360)	\$ 7,053
Adjustments:			
Impairment of intangible assets	146	1,142	(996)
Impairment of Panacea warrant	1,062	—	1,062
Amortization and depreciation	997	1,111	(114)
Unrealized loss (gain) on investment	562	1,410	(848)
Realized (gain) loss on short-term investment securities	—	(146)	146
Litigation Settlement	—	1,891	(1,891)
Gain on the sale of machinery and equipment	(1)	(87)	86
Accretion of non-cash interest expense	34	33	1
Equity-based employee compensation expense	1,162	2,406	(1,244)
Executive and board search fees	430	—	430
Interest Income	(1,344)	(757)	(587)
Interest Expense	19	3	16
Adjusted EBITDA	\$ (10,240)	\$ (13,354)	\$ 3,114

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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