



February 24, 2021

22nd Century Group Provides Business Update Letter from CEO

Global Commercial Opportunities in Approximately +\$800 Billion Markets Across Tobacco and Hemp/Cannabis

WILLIAMSVILLE, N.Y., Feb. 24, 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, today provided a business update letter from Chief Executive Officer, James A. Mish.

Dear Fellow Shareholders,

As the Chief Executive Officer of 22nd Century Group in this important first quarter of 2021, I am proud of what our team was able to accomplish in 2020, and I look forward to sharing our financial results with you during our next quarterly earnings update in March. We are entering what I believe will be a pivotal year for 22nd Century. Since reporting third quarter earnings last November, shares of 22nd Century have appreciated 343% to \$3.82¹. Still, I believe the Company's current share price greatly undervalues the untapped potential of our business and of our extraordinary potential in very large and highly attractive markets.

Primary Mission

Top of mind for 22nd Century in the first quarter of 2021, as it is for many of our investors, is the status of our Modified Risk Tobacco Product (MRTP) application with the U.S. Food and Drug Administration (FDA) to authorize our VLN[®] reduced nicotine content (RNC) cigarettes. We are highly confident that our application is in the FDA's final review stage and upon receiving authorization, we believe 22nd Century will be the first, and likely the only, company to receive a MRTP designation for a combustible cigarette.

The Centers for Disease Control and Prevention (CDC) has [reported](#) that more than two-thirds of smokers want to quit and that more than half of all smokers report having made a quit attempt in the past year – yet fewer than one in ten smokers succeed in actually quitting each year. Cigarette smoking remains the leading cause of preventable disease and death in the United States. It is clear that adult smokers are actively seeking alternatives to addictive, combustible cigarettes.

22nd Century's VLN[®] cigarettes contain 95% less nicotine than traditional combustible cigarettes available on the market today. When told about our reduced nicotine content cigarettes, **60%** of adult smokers indicated a likelihood to use VLN[®]². With more than 34 million smokers in the United States and more than 1 billion smokers worldwide, **VLN[®] has near-term blockbuster potential**. This puts 22nd Century in a very enviable – and near standalone - position to capitalize on the global combustible market that is valued at more than \$700 billion annually. Having the only combustible cigarette with a modified exposure claim authorized by the FDA would serve as a catalyst for 22nd Century's commercial sales, as achieving even 0.25% share of the U.S. tobacco market would result in a substantial increase in revenue and market capitalization for the Company. This will be our **home run**.

The political changes now in place will likely be highly favorable to our business prospects from a policy priority and regulatory view. What's more, we believe we have made an impact on the timing of our MRTP application based on a positive and relentless approach with the FDA through multiple channels. With the Biden Administration in the White House and Democrats in control of both the Senate and House of Representatives in the 117th United States Congress, we believe that government agencies will be much more focused on improving public health in 2021. And we have already begun working to align completely with the new administration and to encourage their support.

We also believe that, under the new administration, the FDA will now be re-energized in implementing its groundbreaking [Comprehensive Plan for Tobacco and Nicotine Regulation](#), in particular the Agency's plan to cap the amount of nicotine in combustible cigarettes. At just 0.5 milligrams of nicotine per gram of tobacco, VLN[®] is the **only** combustible tobacco product today that meets the FDA's proposed product standard for nicotine levels that are "minimally or non-addictive." 22nd Century's MRTP authorization and the launch of VLN[®] will serve as a vanguard for the FDA's proposed mandate. We believe the tide is, at last, turning and have a bullish outlook on the implementation of such a mandate that will, according to public health researchers, help more than five million adult smokers quit smoking, prevent hundreds of children from becoming addicted to smoking every day, and save more than eight million American lives by the end of the century³. This is the **grand slam** that will drive our revenue and market capitalization orders of magnitude higher.

Commercial Launch Ready

As previously discussed, we are fully prepared for the commercial launch of VLN[®] King and VLN[®] Menthol King cigarettes within 90 days of receiving authorization from the FDA. The launch of VLN[®] will be paired with a compelling marketing campaign to introduce adult smokers to the world's lowest nicotine content cigarette. Based on early sales projections and to meet the expected demand from adult smokers, we have [significantly expanded the growing program for VLN[®]](#) reduced nicotine content tobacco.

Additionally, authorization in conjunction with an FDA mandate to reduce nicotine content in *all* cigarettes sold in the United States would open multiple licensing and partnership opportunities for 22nd Century's proprietary RNC tobacco intellectual property (IP) and technology, again significantly expanding our addressable market and revenue opportunities.

That is why securing the FDA authorization for VLN[®] cigarettes continues as my number one priority as CEO of 22nd Century Group. I hope that you and other social media users will make it a priority as well.

At 22nd Century, we have actively communicated with Congressional representatives to ask for their support for our MRTP application and more importantly, to move forward assertively with the FDA's proposed mandate to limit the levels of nicotine in combustibles to "minimally or non-addictive" levels. We have also expanded our public relations, public affairs, and social media efforts, to keep authorization top of mind for our friends at the FDA, other government agencies, and in the tobacco industry. Including:

- An [op-ed](#) in our hometown paper, The Buffalo News, urging the FDA to proceed with their proposed plan to limit nicotine in traditional cigarettes;
- A [news release](#) on expanding planting of VLN[®] tobacco to meet the expected demand for our VLN[®] RNC cigarettes;
- [News](#) on an order for 3.6 million of our SPECTRUM[®] Variable Nicotine Cigarettes to support U.S. Government Research;
- An [op-ed](#) penned by our Vice President of Regulatory Science, John Pritchard, that urges the FDA to accelerate the implementation of its nicotine mandate.

Cannabis: Breakthrough in Accelerating and Developing Desirable Commercial Traits

Turning attention to our hemp/cannabis side of the business, we were excited to share news about a truly incredible breakthrough earlier this month.

In collaboration with researchers from [KeyGene](#), our scientists have developed a cutting-edge molecular breeding platform that will enable 22nd Century and our strategic partners to quickly identify and accelerate the development of new varieties of hemp/cannabis plants with commercially valuable traits.

Traditional breeding methods can take ten years or longer to develop new varieties of hemp/cannabis plants that express desired traits. With 22nd Century's breakthrough molecular breeding technology, we can dramatically improve the development process time that it takes to develop new, high-value hemp/cannabis cultivars – a tremendous value to this large, emerging market. In a recent [research report](#), Prohibition Partners estimates that legal cannabis sales in North America alone reached approximately \$18.1 billion in 2020 and is projected to rise to \$39.1 billion by 2025. Additionally, the global legal hemp/cannabis market is [estimated](#) to be worth upwards of \$100 billion annually by 2024. You can read more about 22nd Century's innovation in this very attractive market, [here](#).

Since reporting third-quarter earnings, we have refocused our hemp/cannabis strategy to target the upstream segments of the cannabinoid value chain and related intellectual property in the areas of plant biotechnology

research, gene modification and engineering, modern plant breeding and development, and extraction. We are placing a renewed emphasis on developing intellectual property and high-value genetic traits by targeting and developing proprietary hemp/cannabis lines with select agronomic traits, including lines with stable, ultra-high tetrahydrocannabinol (THC) levels, lines with rare cannabinoids, and lines with ultra-low terpene levels. This is a shift away from cannabidiol (CBD) and hemp-based finished goods – a saturated market.

We believe we can establish a leadership position in the legal hemp/cannabis industry by leveraging our core strengths in plant science and intellectual property including plant engineering, gene-editing, and modern plant breeding combined with strategic, operational partnerships. We are already in advanced discussions with potential partners that will enable us to offer comprehensive commercial breeding, cultivation, and extract purification services utilizing our proprietary hemp/cannabis plants in development. We will continue to focus on and ensure the accelerated delivery of valuable, commercial plant lines, intellectual property and technology for the life science, consumer product, and pharmaceutical end-use markets. With an emphasis on science-driven differentiation 22nd Century intends to gain widespread recognition as a world leader in this legal hemp/cannabis industry.

In the coming months, we will have more news about our evolving relationships with [KeyGene](#), [Panacea](#), and other new strategic partners in the fast-growing legal hemp/cannabis space. Our collaboration with these organizations and the achievements we make together will advance our leadership position and have an enormously positive impact on our business opportunities.

Ready for the Future

As I stated at the beginning of this letter, 2021 will be a pivotal year for 22nd Century Group. The fruits of more than a decade of research and development are, at last, ripe for harvest. We are very excited about the historic milestones that 22nd Century will achieve in these, our primary areas of focus:

- Secure FDA authorization of VLN[®], the only reduced nicotine content combustible cigarette in the world that will receive a MRTP designation from FDA; execute commercial product launch and licensing and partnership initiatives within 90 days of authorization;
- Support and advance the FDA's proposed mandate to cap the nicotine content of all combustible cigarettes sold in the U.S. to just 0.5 milligrams of nicotine per gram of tobacco;
- Target the upstream segment of the cannabinoid value chain; creating proprietary, commercially valuable new plant lines and related intellectual property with stabilized genetics to harness and optimize hemp/cannabis plant potential; monetize a portion of our existing hemp/cannabis IP in 2021 and continue to bring disruptive technology forward;
- Turn attention to the Company's development of a third, plant-based franchise after securing MRTP authorization for VLN[®]; leverage 22nd Century's plant science expertise to develop and secure valuable intellectual property, and sign lucrative strategic partnerships to support the development of this franchise;
- Maintain diligent financial execution, efficient operating structure, and balance sheet strength to support 22nd Century's growth initiatives.

22nd Century's leadership team and I are ready and eager to make available VLN[®] to each and every adult smoker in the United States within 90 days of receiving authorization from the FDA.

Having refocused our hemp/cannabis strategy on intellectual property and on the upstream segments of the cannabinoid value chain, 22nd Century's relationship with KeyGene is stronger and more fruitful than ever. Throughout 2021 and beyond, we expect to reach more major research milestones with our partners at KeyGene and with other strategic partners in both hemp/cannabis and our soon-to-be-announced third franchise.

It is truly an exciting time for our company and stakeholders, and I hope that you share in our enthusiasm. Please visit our [Press Release page](#) on the 22nd Century website and follow us on [Twitter](#) and [LinkedIn](#) to learn more about our organization and continue to follow our news as it is made.

James A. Mish
Chief Executive Officer, 22nd Century Group

¹As of market close on Tuesday, February 23, 2021.

²Based on perception studies conducted by 22nd Century Group

³[Appelberg, Feirman, Salazar, et al. \(2018\)](#)

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 Annual Report on Form 10-K filed on March 11, 2020, and in its subsequently filed Quarterly Report on Form 10-Q. 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.

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Source: 22nd Century Group, Inc