

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

### Key Business and Financial Highlights

- 22nd Century is advancing commercial opportunities across \$1.3 trillion global addressable markets in tobacco, hemp/cannabis, and a third plant-based franchise.
- The significant increase in the Company's share price since reporting fourth quarter 2020 results in March 2021 is a testament 22nd Century's commitment to its shareholders.
- The Company believes it will be added to the Russell 2000<sup>®</sup>, Russell 3000<sup>®</sup>, and Russell Global Indexes as part of the FTSE Russell (Russell) annual reconstitution of its U.S. and global equity indexes effective June 25, 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.
- Securing Modified Risk Tobacco Product (MRTP) authorization for VLN<sup>®</sup> remains 22nd Century's number one priority. The Company continues to have high confidence that its MRTP application is in the final stages of review with the FDA. There are no outstanding requests for information from the FDA.
- 22nd Century is fully prepared for the commercial launch of its VLN<sup>®</sup> King and VLN<sup>®</sup> Menthol King products within 90 days of securing the MRTP designation, including marketing campaigns to generate brand and proposition awareness.
- With the White House and Democrats in control of both the Senate and the House of Representatives, the Company believes there will be a continued high focus on improving public health moving forward. The Biden Administration is already demonstrating its willingness to prioritize critical tobacco control initiatives. The FDA's recent commitment to eliminate the use of menthol in highly addictive cigarettes demonstrates the Agency's willingness to use its regulatory authority to aggressively address cigarette addiction and youth smoking initiation with a menthol product standard that will save lives and pave the way for a reduced nicotine product standard. 22nd Century believes that VLN<sup>®</sup> Menthol King cigarettes will remain on the market after a menthol rule is implemented to help menthol smokers reduce their consumption and quit highly addictive menthol cigarettes while mitigating risks of illicit markets and product adulteration.
- 22nd Century believes that the FDA is actively considering a product standard that would require all cigarettes be made "minimally or non-addictive", a level already achieved by VLN<sup>®</sup>. The Company believes this paradigm shift will favorably influence the timing of its MRTP application and the enactment of a nicotine cap. 22nd Century is willing to license its reduced nicotine tobacco technology to every cigarette manufacturer to comply with the proposed mandate.
- In April, the New Zealand Ministry of Health Manatū Hauora advanced a new proposal that calls for reducing the amount of nicotine allowed in smoked tobacco products to "minimal levels." When enacted, the proposal will help existing adult smokers to reduce their consumption or switch to alternative products and would protect young people from cigarette addiction. New Zealand's proposal may encourage additional countries to pursue reduced nicotine mandate strategies. 22nd Century is actively engaged and will support New Zealand's public health mission and commercial opportunities.
- Favorable federal legislation of cannabis appears increasingly likely as 36 states have legalized the medical use of marijuana, and 16 states so far have approved the recreational use of marijuana. 22nd Century believes that legalization will likely increase competition and increase the need for highly differentiated products grown at commercial scale. The growing demand for cannabis products will increasingly drive the industry to address a key challenge fundamental to agronomics – growers will require stable, consistent, and predictable plant genetics to scale commercial production to meet forecasted demand. 22nd Century is uniquely positioned to address this market-wide need as the "Monsanto of Cannabis" through its ability to accelerate the modification of cannabis plants to the highest levels of quality, stability, and scale. The Company believes that the ability to closely control the traits and consistency of hemp/cannabis plants is directly correlated to command of premium price and margins in the market, a critical component to financial success.
- On May 4, 2021, 22nd Century announced an agreement to extend and expand its successful plant research partnership agreement with KeyGene, a global leader in plant research involving high-value genetic traits and increased crop yields. The new partnership 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 non-combustible, alternative tobacco plant applications, such as protein production, and 22nd Century's third plant franchise, plus it establishes a new governance structure and working model to accelerate development timelines across all three crop/trait programs.
- On March 3, 2021, the Company announced an exclusive agreement with CannaMetrix, LLC for the use of their proprietary, human cell-based testing to enable accelerated commercialization of new, disruptive hemp/cannabis plant lines and intellectual property. CannaMetrix's proprietary CannaMetrix EC50Array<sup>™</sup> 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 technology 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.

- Net sales revenue for the first quarter of 2021 was \$6.8 million, comparable to the first quarter of 2020 at \$7.1 million.
- Gross profit for the first quarter of 2021 improved by \$360 thousand year-over-year to \$647 thousand; gross profit margin improved by 540 basis points. Gross profit margin improved year-over-year for the fifth consecutive quarter, demonstrating the Company's ability to execute on the objectives and strategies set for the business.
- Net loss for the first quarter of 2021 was \$5.0 million compared to \$4.0 million in the same quarter last year. The change in net loss was driven by investment in anticipation of 22nd Century's expected MRTP designation of VLN®.
- Adjusted EBITDA for the first quarter of 2021 was a \$4.4 million loss compared to a \$3.2 million loss for the first quarter of 2020, an increase of \$1.1 million.
- The Company's financial position is strong with cash, cash equivalents, and short-term investment securities totaling \$30.9 million at the end of the first quarter of 2021, a \$8.6 million improvement from \$22.3 on March 31, 2020. 22nd Century announced on March 12, 2021 that it received total net proceeds of \$11.8 million from the completion of the cash exercise of warrants during February and March of 2021. The Company has no further warrants outstanding.

*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.*

**BUFFALO, N.Y., May 6, 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, announced today that the Company filed its 2021 First 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 10:00 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](http://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.

"Our 2021 is off to an exciting start as we anticipate achieving multiple key milestones that will dramatically expand our commercial opportunities in both our tobacco and hemp/cannabis franchises," said James A. Mish, chief executive officer of 22nd Century Group. "I remain highly confident in our MRTP authorization. We continue to steadily increase our advocacy activities at both the federal and state levels to achieve MRTP authorization, in support of this critical public health issue. In addition to our primary VLN® launch strategy to go to market within 90 days of authorization, we remain willing to license our technology to every cigarette manufacturer to help them join us in our efforts to reduce the harm caused by smoking and to protect future generations from ever becoming addicted to cigarettes. Our technology and capabilities make the FDA's reduced nicotine mandate feasible. According to the Centers for Disease Control and Prevention (CDC), 80% of U.S. adult cigarette smokers favor requiring cigarette makers to reduce nicotine levels in cigarettes, so they are less addictive."

"The first quarter also saw a continued strong cadence of moves by both state and federal government bodies advancing marijuana legalization, including positive changes in policy on both the medical and recreational use cases," Mish continued. "22nd Century has established a strong position in the upstream hemp/cannabis market through our focus on plant genetics and IP critical to the successful commercialization of consumer products at the scale the market will ultimately demand. In doing so, we have positioned ourselves to provide valuable, tailored plant lines similar to a 'boutique Monsanto' focused on high-value markets, including tobacco, hemp/cannabis, and our third franchise."

### **Tobacco Franchise Highlights and Recent Key Events**

- The Company continues to focus on its primary mission and highest, near-term priority of securing MRTP designation of its proprietary, reduced nicotine content tobacco cigarettes, VLN®. The designation will allow 22nd Century to communicate key features of VLN® products, including the headline claim of "95% less nicotine." The Company continues to steadily increase its advocacy activities and engage in conversations at the highest levels of the Administration, Congress, and the FDA about VLN®, and every indication is that its MRTP application is in the final stages of review with the FDA. In addition to its ongoing contact with the Agency, 22nd Century has been and continues to work 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 launch sales of VLN<sup>®</sup> within 90 days of receiving MRTP designation and is in advanced discussions with potential independent, regional, and national distribution and retail partners. The Company plans to position VLN<sup>®</sup> in the premium pricing segment of the cigarette market and, therefore, expects it to deliver corresponding margins.
- 22nd Century's expected MRTP designation will serve as a catalyst for licensing and partnership opportunities in the U.S. and internationally. The Company will grow VLN<sup>®</sup> tobacco and anticipates a phased roll-out of VLN<sup>®</sup> in select geographies to learn how to optimize investments to scale VLN<sup>®</sup>.
- The Company is fully prepared to manufacture enough VLN<sup>®</sup> to secure its market position. 22nd Century owns and operates a fully credentialed 62,000 square foot facility in North Carolina. The Company's capacity is currently approximately 1% of the U.S. cigarette market volume. With minimal investment, the Company can triple that capacity to 3%.
- On January 11, 2021, 22nd Century announced that it will significantly expand its growing program and increase its planting in the 2021 crop year for VLN<sup>®</sup> based on the Company's latest sales projections. This new planting is in addition to the Company's sizeable inventory of VLN<sup>®</sup> tobacco, which is earmarked for the launch and initial sales of VLN<sup>®</sup> cigarettes.
- On May 5, 2021, 22nd Century announced it is internalizing its nicotine content testing capabilities to increase the Company's ability to rapidly conduct high-precision analysis of its VLN<sup>®</sup> cigarettes and other nicotine products that it produces. 22nd Century is making the investment now to be well-positioned for when its MRTP application is authorized. The Company estimates that its cost per VLN<sup>®</sup> sample will decrease by more than 90% and the lead time for key data will take less than a day compared to using a third-party testing service that can take weeks.
- The Company continues to advance its VLN<sup>®</sup> 2.0 program so that it can expand its business prospects internationally with its reduced nicotine, non-GMO tobacco technology. Non-GMO products are critical for success in international markets where non-GMO products are preferred, or GMO products are banned.
- On April 26, 2021, 22nd Century announced the fulfillment of an order of 3.6 million of its variable nicotine content research cigarettes, SPECTRUM<sup>®</sup>, for independent clinical research funded largely by the FDA and other federal health agencies. The FDA's proposed plan to cap the amount of nicotine in combustible cigarettes to "minimally or non-addictive" is a level already achieved in the Company's VLN<sup>®</sup> cigarettes.
- The Company believes that recent proclamations of the new Biden Administration support critical public health initiatives, including the confirmation of Xavier Becerra in March 2021 as the new Secretary of Health and Human Services, a long-term proponent of a reduced nicotine cap for cigarettes.
- Four former FDA Commissioners voiced their support for the Agency's plan to cap the amount of nicotine in combustible cigarettes to a "minimally or non-addictive" level. The mandate is projected to help 5 million smokers quit, during a panel in March 2021 about the future of the FDA.
- New Zealand recently advanced a reduced nicotine proposal, one of the bellwether countries for key global markets and tobacco regulations. On April 15, 2021, 22nd Century announced that the Company stands fully prepared to help New Zealand reach its goal to be a smoke-free nation by 2025. The Company's VLN<sup>®</sup> cigarettes contain just 0.5 milligrams of nicotine per gram of tobacco, 95% less nicotine than conventional cigarette brands, which is in line with the New Zealand proposal. The Company initially engaged with public health researchers in New Zealand in 2016, when the country announced its goal of becoming smoke-free, leading the New Zealand Medical Journal to publish a letter recommending 22nd Century's reduced nicotine content cigarettes as an "important smoking reduction tool."

### **Hemp/Cannabis Franchise Highlights and Recent Key Events**

- The Company believes the Biden Administration will be more open to updating hemp and marijuana regulations at the federal level. Senate Majority Leader Schumer has made a proclamation to federally legalize marijuana. With 36 states having legalized marijuana, and the recent House of Representatives passage of the SAFE ACT addressing the removal of banking limitation on cannabis companies, federal legalization seems increasingly likely. Legalization will increase the number of consumers and competition, which will increase the need for highly differentiated products grown at scale – exactly where 22nd Century is focused.
- 22nd Century is making great strides and believes that it can accelerate the development of commercially, valuable hemp/cannabis lines and related intellectual property targeted on the upstream segments of the cannabinoid value chain in the areas of alkaloid profiling/mapping, genetic engineering and gene editing, breeding and cultivation, and ingredient extraction and purification. The Company's technology and solutions will have broad-based appeal for a wide range of end use markets, including but not limited to the life science, consumer product and pharmaceutical industries, and will transform the global cannabis market.
- The Company has secured a number of the key partnerships needed to maximize its work in the upstream segments of the cannabinoid value chain, and vertically integrate its hemp/cannabis capabilities. The combination of its core strengths in plant science and its network of key partnerships will enable the Company to drive differentiation and value by delivering new,

disruptive plant lines and IP in two years while leveraging its current library of lines and IP, including revenue from a portion of 22nd Century's hemp/cannabis IP later this year.

- On March 3, 2021, 22nd Century announced it had secured an exclusive agreement with CannaMetrix, LLC for the use of their proprietary, human cell-based testing CannaMetrix EC50Array™ technology that will enable the Company to accelerate the commercialization of new, disruptive hemp/cannabis plant lines and intellectual property.
- On February 10, 2021, 22nd Century 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 incorporates a suite of proprietary molecular tools and a large library of genomic markers and gene-trait correlations. The platform was developed in collaboration with researchers at KeyGene, a global leader in plant research involving high-value genetic traits and increased crop yields.

## 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 expected to receive a MRTP designation from FDA. The Company is fully prepared to execute a commercial product launch and will seek licensing and partnership initiatives within 90 days of MRTP designation.
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 within two years 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 the second half of 2021, then additional plant lines coming through in the pipeline 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. The Company believes the third franchise is a faster route to commercialization because it is not as regulated relative to its first two franchises.
5. 22nd Century will maintain diligent financial execution, efficient operating structure, and balance sheet strength to support its growth initiatives.

## 2021 First Quarter Financial Results

- Net sales revenue for the first quarter of 2021 was \$6.8 million and comparable to the first quarter of 2020 at \$7.1 million. The decrease was primarily driven by lower sales volume in the early part of the quarter, partially offset by an increase in volume in March driven by the sale of SPECTRUM® cigarettes in the Company's contract manufacturing business. Higher cigarette prices in the first quarter of 2021 supported net sales revenue growth.
- Gross profit for the first quarter of 2021 improved by \$360 thousand, or 125% to \$647 thousand compared to the prior-year period. The improvement in gross margin was primarily the result of higher margin on SPECTRUM® cigarette sales partially offset by overall lower volume.
- Total operating expenses for the first quarter of 2021 increased by \$1.4 million compared to the prior-year period. This was driven by the following:
  - Research and development expense for the first quarter of 2021 was favorable by \$259 thousand compared to the prior year period. This favorability was primarily driven by \$137 thousand lower MRTP application costs, lower personnel, license, and contract costs partially offset by higher costs of patents and legal fees.
  - Research and development expense related to the MRTP application was favorable by \$137 thousand compared to the prior year primarily the result of expenses incurred in 2020 that were associated with the preparation for the Company's Tobacco Products Scientific Advisory Committee (TPSAC) hearing, which occurred on February 14, 2020.
- Sales, general and administrative expense increased by \$1.7 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 and Chief Financial Officer, higher personnel, insurance, and consulting as the Company prepares for an expected MRTP designation of VLN®. 22nd Century deployed incremental SG&A spending to support, evaluate, and prepare for future opportunities. The increase was partially offset by lower legal fees.

- Operating loss for the first quarter of 2021 was \$(5.2) million, an increase of \$1.0 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 first quarter of 2021.
- Net loss in the first quarter of 2021 was \$(5.0) million, an increase of \$1.0 million compared to the prior year period, representing a net loss per share of \$(0.03). This compares to the first quarter of 2020 net loss of \$(4.0) million, or \$(0.03) per share.
- Adjusted EBITDA was \$(4.4) million for the first quarter of 2021 compared to Adjusted EBITDA of \$(3.2) million for the first quarter of 2020.

### **Balance Sheet and Liquidity**

- For the first quarter of 2021, net cash used in operating activities was \$3.9 million, a \$751,000 improvement compared to \$4.7 million for the first quarter of 2020.
- The Company's liquidity remains strong with cash, cash equivalents, and short-term investment securities totaling approximately \$30.9 million as of March 31, 2021, a 39% higher than \$22.3 million as of March 31, 2020.
- The Company does not have any plans or need to raise capital at this time. It believes the healthy cash position of \$30.9 million as of March 31, 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.

### **First Quarter Earnings Conference Call**

22nd Century will host a live audio webcast today at 10:00 a.m. ET to discuss its first quarter 2021 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.xxiiicentury.com/investors/events](http://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](http://xxiiicentury.com), on Twitter @[\\_xxiiicentury](https://twitter.com/_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 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 months ended March 31, 2021 and 2020, including a reconciliation of net (loss) income to Adjusted EBITDA for such periods.

	Quarter Ended March 31,		
	Dollar Amounts in Thousands (\$000's)		
	2021	2020	\$ Change fav / (unfav)
<b>Net loss</b>	<b>\$ (5,030)</b>	<b>\$ (4,028)</b>	<b>\$ (1,002)</b>
Adjustments:			
Amortization and depreciation	288	328	(40)
Unrealized loss (gain) on investment	(36)	445	(481)
Realized (gain) loss on short-term investment securities	—	3	(3)
Accretion of non cash interest expense	6	12	(6)
Equity-based employee compensation expense	507	481	26
Executive and board search fees	—	141	(141)
Interest income, net	(112)	(612)	500
Interest expense	1	—	1
<b>Adjusted EBITDA</b>	<b>\$ (4,376)</b>	<b>\$ (3,230)</b>	<b>\$ (1,146)</b>

<sup>1</sup>Fav = 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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