



May 5, 2022

22nd Century Group (Nasdaq: XXII) Reports Business Highlights and Financial Results for the First Quarter 2022

- Launched VLN[®] Pilot Program in Chicago with Circle K as First Retail Trade Partner
- Began VLN[®] Shipments to South Korea for First International Launch
- FDA's Proposed Menthol Ban Could Leave VLN[®] Menthol King as the Only Menthol Cigarette on the Market
- Achieved Breakthrough in Hemp/Cannabis Plant Transformation Technology
- First Quarter Net Sales \$9.0 million, up 33% Year-Over-Year

BUFFALO, N.Y., May 05, 2022 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (Nasdaq: [XXII](#)), a leading agricultural biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco, and improving health and wellness through modern plant science, today reported results for the first quarter ended March 31, 2022, and provided an update on recent business highlights. The Company will host a live audio webcast today at 10:00 a.m. ET.

James A. Mish, chief executive officer of 22nd Century Group, stated: "We are off to an exciting start with our VLN[®] reduced nicotine content cigarette pilot launch at more than 150 Chicagoland Circle K stores. The recently proposed menthol cigarette ban by the FDA could leave our VLN[®] Menthol King reduced nicotine cigarettes as the only menthol cigarette on the market, helping adult menthol smokers find an off-ramp from nicotine addiction. Early sales in our Chicago pilot affirm the importance of this approach, with sales of VLN[®] Menthol King already selling ahead of non-menthol in pilot stores. We fully anticipate an even more favorable regulatory environment as the FDA continues to advance the Agency's [Comprehensive Plan](#), which includes requiring all cigarettes to be 'minimally or non-addictive,' a standard our VLN[®] King and VLN[®] Menthol King cigarettes already meet.

"As part of the pilot launch, we were highlighted in a Chicago Tribune feature story and received support from the Chicago Medical Society, broadening our initial visibility as we work to put this product in front of as many adult smokers as possible. As the first and only cigarettes designed specifically to 'Help You Smoke Less,' it is increasingly clear that VLN[®] has the potential to dramatically change the tobacco marketplace by offering smokers a real choice in how or even if they consume highly addictive nicotine.

"We are particularly excited to partner with Circle K, the second largest convenience store chain in the U.S., as our lead channel partner in bringing these products to market. VLN is featured prominently in Circle K's stores where we are testing a variety of point-of-sale marketing materials and promotional programs to build awareness about VLN[®] and its unique benefits for adult smokers, 70% of whom want to quit smoking.

"As we look to expand VLN[®] marketing and distribution beyond Chicago, we have already secured regulatory clearances to sell in 9 states and have applications pending in all other U.S. states. Additionally, we are engaged in discussions with a number of national and regional channel partners who recognize the exciting potential of VLN[®] and want to offer it to their customers.

"We have also commenced our international launch efforts with the first shipment of VLN[®] to our partner in South Korea, and we continue to pursue additional partnerships and licensing of our VLN[®] tobacco and IP across multiple countries to fully realize the global potential of VLN."

Recent Key Financial and Business Highlights

Tobacco Franchise

- Commenced pilot market sales of VLN[®] King and VLN[®] Menthol King 95% reduced nicotine content

cigarettes, the first and only FDA MRTP (Modified Reduced Tobacco Product) designated combustible cigarettes.

- VLN[®] is now available at more than 150 Chicago-area Circle K retail stores in a pilot designed to optimize 22nd Century's marketing programs.
- Positioned VLN[®] in the premium pricing segment of the cigarette market, with corresponding margins expected as VLN scales.
- VLN[®] packaging and advertising prominently display FDA mandated claim "Helps You Smoke Less."
- Advanced discussions with potential channel partners to expand the regional and national sales reach of VLN[®] as the pilot program results become available.
- Ahead of its planned national VLN[®] launch, 22nd Century has secured the regulatory authorizations to sell VLN[®] in 9 states to date: Illinois, California, New York, Colorado, Texas, Florida, Minnesota, Mississippi and Rhode Island.
 - Applications pending in additional states, with responses expected by summer for most states, particularly those undertaking their annual Master Settlement Agreement (MSA) directory reviews in April.
- Completed the first shipment of VLN[®] to South Korea as part of the Company's international launch program.
 - The South Korean market is an ideal market in which to test VLN[®]'s global appeal given its strong premium pricing, high smoking rates including one in three adult men, and interest in alternative tobacco products.
 - Continuing to explore launch opportunities in additional markets in Asia and Europe with limited regulatory barriers while also leveraging VLN[®]'s MRTP authorization from FDA toward seeking approval in markets with higher regulatory barriers.
- 22nd Century Group continued its support of FDA's proposed ban on menthol as a characterizing flavor in conventional nicotine cigarettes.
 - The [FDA's proposed menthol cigarette ban](#) could leave VLN[®] Menthol King as the only combustible menthol cigarette on the market, providing a critical off-ramp to help current menthol smokers to smoke less.
 - 22nd Century also has the only FDA-authorized tobacco cigarette able to meet the stringent reduced nicotine content product standard under the FDA's [Comprehensive Plan](#) requiring that all cigarettes be made "minimally or non-addictive." The company received the MRTP designation in December 2021.
 - Completing delivery of a purchase order for 3 million additional variable nicotine research cigarettes, including menthol, for use in studies underpinning FDA's proposed menthol ban and reduced nicotine content proposals. To date, 22nd Century has manufactured 33 million proprietary, variable nicotine research cigarettes for use in independent clinical studies funded by various agencies of the U.S. federal government, including the FDA, NIH and NIDA.
- Reported record first quarter tobacco revenue of \$9.0 million, an increase of 33% year-over year, and manufacturing gross margin of approximately 5.1%.
 - Historic contract manufacturing volumes augmented by VLN[®] production for U.S. and South Korea pilot sales.
 - Signed new white-label contract manufacturing agreement expected to start production later in 2022 pending FDA authorization of our "substantial equivalence" application.
 - Expansion of the Company's existing manufacturing operations underway to increase capacity 25%.
- Contracted the largest VLN[®] tobacco planting to date to support expansion in both the U.S. and international markets.
 - Planting will include use of the Company's new southern hemisphere capabilities to facilitate year-round growing of VLN[®] tobacco.
 - The growing program for the first time includes 22nd Century's proprietary, non-GMO VLN[®] 2.0 bright and burley tobacco varieties at commercial scale.

Hemp/Cannabis Franchise

- Continued revenue from hemp/cannabis IP and plant lines, including license fees from the Anandia biosynthesis IP jointly owned with Aurora Cannabis Inc and distillate and isolate sales.
- The Company is preparing plant lines for expanded growing programs at its USDA Organic-Certified Needle Rock Farms aligned to specific buyer interest in each plant line placed into the field.
- Announced an industry-first breakthrough in hemp/cannabis plant transformation with our partner KeyGene, expanding the Company's capabilities in modifying the principal genes controlling cannabinoid

biosynthesis in the plant.

- Shipped next generation seeds to Extractas Bioscience for breeding and scale up evaluation to identify the plant lines best suited to cultivation in the Asia-Pacific region. Extractas is a world leader in the research, manufacturing, and export of botanical extracts and purified products with a specialization in hemp/cannabis.

Hops Franchise

- The Company continued to advance its entry into the \$500 billion per year global specialty hops market, its third and newest alkaloid plant franchise and closely related to hemp/cannabis.
- Expanded work under an exclusive agreement with partner KeyGene in support of proprietary hops development programs tied to specific grower needs.
- 22nd Century is focused on initial monetization of hop plant varieties and IP through upfront license fee opportunities and co-sponsored research agreements with leading global hops industry participants.

Corporate Business Highlights

- Announced that Dr. Calvin Treat will join the Company as its Chief Scientific Officer, effective May 23, 2022, further enhancing 22nd Century's deep expertise in plant-based biotechnology across all three of its plant franchises. Dr. Treat has led global plant biotechnology programs at Bayer and Monsanto, including corn, soybean, and cotton crop improvement technologies.
- Company CEO James A. Mish was appointed to 22nd Century Group's Board of Directors, enhancing the Board's depth of experience in the commercialization of science-driven consumer products as the Company prepares to launch its first reduced nicotine content tobacco products and commercially modified hemp/cannabis plant lines.
- New research coverage of the Company was initiated by Brian Wright, a leading agricultural technology analyst at Roth Capital Partners.

First Quarter 2022 Financial Results

- Net sales for the first quarter of 2022 were \$9.0 million, an increase of 33% from 2021. The increase was due to increased contract manufacturing volumes in both filtered cigar and cigarettes, including products for export markets and pricing adjustments.
- Gross profit for the first quarter was \$0.5 million, compared to \$0.6 million in the prior year first quarter. Gross margin in the first quarter was reduced by lower research cigarette sales volume compared with the prior year, and an MSA adjustment of \$0.2 million recorded in the quarter.
- Total operating expenses for the first quarter 2022 increased to \$8.6 million compared to \$5.8 million in the prior year quarter, driven by:
 - Sales, general and administrative expenses increased by \$2.5 million compared to the prior year period. This was driven primarily by higher strategic consulting, stock-based compensation, legal and insurance costs.
 - Research and development expense for the first quarter 2022 increased by \$0.3 million compared to the prior year comparable period, driven by costs associated with the Company's hemp/cannabis research programs. The Company's R&D investments are expected to grow in future quarters as the Company continues to advance and accelerate the development of new, highly-differentiated hemp/cannabis plants and expands its R&D efforts in hops.
- Operating loss for the first quarter 2022 was \$(8.1) million, compared to \$(5.2) million in the prior year period.
- Net loss was \$(8.9) million, representing a net loss per share of \$(0.05).

Balance Sheet and Liquidity

- As of March 31, 2022, the Company had \$38.6 million in cash, cash equivalents and short-term investment securities. The Company's continued initiatives to manage expenses relative to net sales revenue are intended to provide the Company with adequate capital to execute its plans for the foreseeable future.

First Quarter Earnings Conference Call

22nd Century will host a live webcast today at 10:00 a.m. ET to discuss its first quarter 2022 financial results and business highlights. During the webcast, James A. Mish, chief executive officer of 22nd Century Group, together with Michael Zercher, president and chief operating officer, and Richard Fitzgerald, chief financial officer, will provide an update on progress made in each of the Company's three franchises.

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

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

About 22nd Century Group, Inc.

22nd Century Group, Inc. (Nasdaq: [XXII](#)) is a leading agricultural biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco and improving health and wellness through plant science. With dozens of patents allowing it to control nicotine biosynthesis in the tobacco plant, the Company has developed proprietary reduced nicotine content (RNC) tobacco plants and cigarettes, which have become the cornerstone of the [FDA's Comprehensive Plan](#) to address the widespread death and disease caused by smoking. The Company received the first and only FDA MRTP authorization of a combustible cigarette in December 2021. In tobacco, hemp/cannabis, and hop plants, 22nd Century uses modern plant breeding technologies, including genetic engineering, gene-editing, and molecular breeding to deliver solutions for the life science and consumer products industries by creating new, proprietary plants with optimized alkaloid and flavonoid profiles as well as improved yields and valuable agronomic traits.

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

Learn more about VLN[®] at tryvln.com.

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 1, 2022. 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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22nd CENTURY GROUP, INC.
CONSOLIDATED BALANCE SHEETS
(\$ in thousands, except per-share data)

	March 31, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,584	\$ 1,336

Short-term investment securities	37,036	47,400
Accounts receivable, net	1,220	585
Inventory, net	3,753	2,881
Prepaid expenses and other assets	1,389	2,183
Total current assets	44,982	54,385
Property, plant and equipment, net	5,949	5,841
Operating leases right-of-use assets, net	1,631	1,723
Intangible assets, net	7,934	7,919
Investments	2,211	2,345
Other assets	3,770	3,741
Total assets	\$ 66,477	\$ 75,954

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:

Notes payable	\$ —	\$ 596
Operating lease obligations	359	308
Accounts payable	1,512	2,173
Accrued expenses	2,227	1,489
Accrued payroll	405	2,255
Accrued excise taxes and fees	2,009	1,270
Accrued severance	187	217
Deferred income	483	119
Total current liabilities	7,182	8,427

Long-term liabilities:

Operating lease obligations	1,326	1,432
Severance obligations	—	21
Total liabilities	8,508	9,880

Commitments and contingencies (Note 11)

Shareholders' equity

Preferred stock, \$.00001 par value, 10,000,000 shares authorized		
Common stock, \$.00001 par value, 300,000,000 shares authorized		
Capital stock issued and outstanding:		
164,536,566 common shares (162,872,875 at December 31, 2021)		
Common stock, par value	2	2
Capital in excess of par value	245,460	244,247
Accumulated other comprehensive loss	(562)	(162)
Accumulated deficit	(186,931)	(178,013)
Total shareholders' equity	57,969	66,074
Total liabilities and shareholders' equity	\$ 66,477	\$ 75,954

22nd CENTURY GROUP, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(\$ in thousands, except per-share data)

	Three Months Ended	
	March 31,	
	2022	2021
Revenue:		
Sale of products, net	\$ 9,045	\$ 6,806
Cost of goods sold (exclusive of depreciation shown separately below):		
Products	8,585	6,159

Gross profit	460	647
Operating expenses:		
Research and development	972	701
Sales, general and administrative	7,305	4,829
Depreciation	168	138
Amortization	161	150
Total operating expenses	<u>8,606</u>	<u>5,818</u>
Operating loss	(8,146)	(5,171)
Other income (expense):		
Unrealized gain (loss) on investments	(817)	36
Interest income, net	50	112
Interest expense	(5)	(7)
Total other income (expense)	<u>(772)</u>	<u>141</u>
Loss before income taxes	<u>(8,918)</u>	<u>(5,030)</u>
Net loss	\$ (8,918)	\$ (5,030)
Other comprehensive loss:		
Unrealized loss on short-term investment securities	(400)	(32)
Other comprehensive loss	<u>(400)</u>	<u>(32)</u>
Comprehensive loss	<u>\$ (9,318)</u>	<u>\$ (5,062)</u>
Net loss per common share - basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.03)</u>
Weighted average common shares outstanding - basic and diluted (in thousands)	163,157	144,258

Below is a table containing information relating to the Company's Adjusted EBITDA for the three months ended March 31, 2022 and 2021, including a reconciliation of net (loss) income to Adjusted EBITDA for such periods.

	Quarter Ended		
	March 31,		
	Dollar Amounts in Thousands (\$000's)		
	(UNAUDITED)		
	2022	2021	\$ Change
			fav / (unfav)
Net loss	<u>\$ (8,918)</u>	<u>\$ (5,030)</u>	<u>\$ (3,888)</u>
Adjustments:			
Unrealized loss (gain) on investment	817	(36)	853
Amortization and depreciation	329	288	41
Equity-based employee compensation expense	1,213	507	706
Interest (income)/expense, net	(45)	(105)	60
Adjusted EBITDA	<u>\$ (6,604)</u>	<u>\$ (4,376)</u>	<u>\$ (2,228)</u>

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.



Source: 22nd Century Group, Inc