

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

- Meeting Held October 14 with Senior Level Staff at FDA
- Company's Confidence in a Positive MRTP Application Outcome and Timing at Its Highest Level
- Monetizing Hemp/Cannabis Plant Lines and IP Beginning in the Fourth Quarter of 2021
- Introduced Hops as the Third Plant-Based Franchise, Expanding Total Addressable Markets to \$1.3 Trillion
- Record Year-to-Date Net Sales of \$23.0 Million, Up 11% From Year-To-Date of 2020
- Executing From a Strong Financial Position with Cash and Cash Equivalents of \$55.2 Million as of September 30, 2021
- Uplisted Common Shares to the Nasdaq Capital Market ("Nasdaq") Under the Symbol, "XXII"

**BUFFALO, N.Y., November 4, 2021 (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 plant science, today reported results for the third quarter ended September 30, 2021, and provided an update on recent business highlights. The Company will host a live audio webcast today at 10:00 a.m. ET.

"I am proud of the tremendous progress we have made during 2021 as we complete the final step to MRTP authorization of our VLN® reduced nicotine tobacco cigarettes and begin to monetize our highly disruptive hemp/cannabis plant lines and IP," said James A. Mish, chief executive officer of 22nd Century Group.

Mish added, "We are closer than ever to accomplishing our mission to reduce the harm caused by smoking. Our decision to maintain a collaborative approach with the FDA is moving our MRTP application forward. Based on our recent positive discussion with senior-level staff at FDA on October 14, our confidence in our MRTP application outcome and timing is at its highest level. We are ready to immediately scale production of our VLN® products for launch in both the U.S. and international markets, and we are eager to bring VLN® to adult smokers in the U.S. and globally to help address the overwhelming amount of death and disease caused by smoking."

### Key Financial and Business Highlights

#### Tobacco Franchise

- Securing MRTP designation for VLN® remains 22nd Century's number one priority. 22nd Century possesses the expertise to navigate the MRTP application process to a successful conclusion as evidenced by the positive and collaborative exchanges with FDA and throughout the process.
  - The Company held a successful meeting with the FDA on October 14, 2021, regarding its MRTP application.
  - Following the meeting, and in conjunction with recent Center for Tobacco Products (CTP) activity, the Company's confidence in a positive outcome for its MRTP application and timing is at its highest level to date.
  - Evidenced by the Agency's recent authorization of e-cigarettes and other nicotine products, the FDA continues to demonstrate its ongoing commitment to advance its [Comprehensive Plan for Tobacco and Nicotine Regulation](#) requiring that all cigarettes be made "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 to cap the levels of nicotine in combustible cigarettes.
  - Under these product standards, 22nd Century would have the only cigarette able to meet the reduced nicotine mandate on day one and, with the FDA's determination that the Company's reduced nicotine content cigarettes are "appropriate for the protection of health" under the PMTA pathway, the Company could have the only combustible menthol cigarette exempt from the [FDA's proposed menthol cigarette ban](#).
  - 22nd Century Group applauds the potential nomination of Dr. Robert Califf for FDA commissioner. Califf participated in an [event](#) hosted by STAT on March 12, 2021 where four former FDA commissioners urged the Biden administration to get tough on tobacco and move forward quickly with the reduced nicotine mandate and menthol ban.
- VLN® is market-ready. The Company's U.S. pilot program and manufacturing capabilities are in place to launch VLN® in the U.S. within 90 days of receiving MRTP designation. The Company plans to position VLN® in the premium pricing segment of the cigarette market and, therefore, expects it to deliver corresponding margins.
- The Company continued its international launch process for VLN®. The Company is focusing on several of the leading markets in Asia and a test market in Europe. These markets have a strong affinity for new, modified risk tobacco products and will likely require minimal interaction with regulators to launch VLN®. Sales to local partners in one or more markets are expected to begin in the first quarter of 2022. The Company also plans to establish a company branch in New Zealand.
- The Company has expanded its strategic discussions to include pharmaceutical partnership opportunities where reduced nicotine cigarettes may provide synergistic benefits to other products already marketed to address tobacco harm reduction.
- 22nd Century's growth in tobacco contract manufacturing volumes and disciplined operations continued in the third quarter and confirms readiness of the Company's operations ahead of VLN® launching:
  - In July 2021, the Company announced that it had secured a substantial new agreement with a tobacco industry partner that specializes in exporting cigarettes to countries outside the United States.
  - In October 2021, the Company secured an additional new contract manufacturing customer.
  - The Company has completed the expansion of its in-house nicotine content testing capabilities, which allows for rapid, in-house analysis of its tobacco. This initiative improves the cost per VLN® sample by more than 90% while

significantly reducing the lead time to uncover key data. Internal testing of the Company's current crop of VLN® leaf commenced in August using the newly installed testing equipment.

- The assets needed to manufacture research cigarettes and VLN® are generating profits and cash flow ahead of the MRTTP authorization.
- The Company's record VLN® tobacco growing program in the U.S. is driven by the Company's latest sales projections. The new crop and the Company's existing inventory of VLN® tobacco are earmarked for the launch and sales of VLN® cigarettes.
- 22nd Century Group has signed a partnership agreement to grow VLN® in the southern hemisphere providing the Company with year-round growing capabilities.
- 22nd Century Group continues to leverage its non-GMO technology to rapidly introduce reduced nicotine traits into virtually any variety of tobacco. The Company will begin planting its non-GMO VLN® varieties at commercial scale, including Bright and Burley varieties, in 2022.
- The Company submitted its [formal response](#) to the New Zealand Ministry of Health's Smokefree Aotearoa 2025 Action Plan. This follows the release of a new proposal by the New Zealand Ministry of Health Manatū Hauora that calls for reducing the amount of nicotine allowed in smoked tobacco products to "minimal levels."

### **Hemp/Cannabis Franchise**

- The Company expects to monetize its hemp/cannabis plant lines and IP beginning in the fourth quarter of 2021 with upfront license fees plus revenue from sale of its hemp biomass and extract from the current crop harvested at Needle Rock Farms. Next-generation, disruptive plant lines and IP are being accelerated for 2022 and 2023 revenue programs.
- During the quarter, 22nd Century Group and KeyGene reached a collaborative agreement with the [National Institute of Standards and Technology](#) (NIST) to establish the first-ever quality and measurement standards for cannabinoids, terpenes, and other compounds across the hemp/cannabis industry. Through the Company's collaboration with KeyGene, the two partners will provide diverse lines of cannabis plants containing varying levels of cannabinoid profiles and compounds. Utilizing these samples, NIST will establish quality standards for the entire hemp/cannabis industry, distinguishing higher quality products from the saturated marketplace. The collaboration is pivotal to the growth of the hemp/cannabis industry as there is a need for consistent, stable cannabinoids, terpenes, and other hemp/cannabis-derived compounds to meet the needs of the life science, medicinal, and pharmaceutical end-use markets.
- The Company is nearing agreements with Aurora relating to both plant development and licensing of shared Anandia IP for biosynthetic cannabinoids.
- 22nd Century added strategic partnerships with the world's leading alkaloid plant producer-breeders, including Extractas Bioscience, Sawatch Agriculture, and Folium Botanical for next-generation commercial hemp/cannabis plant breeding and commercial scale-up. The partnerships facilitate year-round growing capabilities at locations in both the southern and northern hemispheres.
- The Company now controls the most comprehensive and innovative upstream cannabinoid value chain in the industry, an asset critical to unlocking commercial success for large-scale cultivation and extraction as this emerging industry continues to scale with the continuing success of global legalization and commercialization efforts and the entrants of new players from adjacent industries including tobacco, pharmaceutical, and other consumer products companies.
- 22nd Century Group is in the process of applying for its USDA Organic Certification for its hemp farm, Needle Rock Farms. USDA Organic Certification will allow 22nd Century to command a premium in price and margins for its raw materials.

### **Hops Franchise**

- The Company announced entry into the global specialty hops market, its third and newest plant franchise, on August 30, 2021. Hops is a large global addressable market estimated at more than \$500 billion annually that includes well-established hops providers and consumer brands.
- 22nd Century is approximately eight months into its initial hops two-year development cycle and expects monetization of hop plant varieties and IP with upfront license fees beginning in late 2022 to mid-2023.
- 22nd Century is actively engaged in discussions with multiple significant hops grower and consumer product partners to develop specific desired traits in leading hops strains.
- The Company is securing hop plant germplasm for use in breeding, and it is advancing valuable IP on those plants.
- The Company is advancing its hop genome sequencing efforts through its partnership with KeyGene, which has been accelerated by its knowledge of genome sequencing in hemp/cannabis, which is closely related to the hop plant.
- 22nd Century is in the process of establishing a new subsidiary in the Netherlands, 22nd Century Group Europe B.V., to open new revenue opportunities in hops, as well as serve its tobacco and hemp/cannabis plant franchises through an expanded global footprint.

### **Corporate Business Highlights**

- 22nd Century began trading on Nasdaq Capital Markets on August 16, 2021. Uplisting to the Nasdaq aligns the Company with other high-achieving, innovative, and growth-oriented global science and technology companies and enhances the Company's visibility to a wide audience of institutional investors.
- 22nd Century appointed accomplished life sciences and biotechnology executive Anthony Johnson to its Board of Directors.

- New research coverage of the Company was initiated by Vivien Azer on July 23, 2021. Azer is a leading beverages, tobacco, and cannabis senior analyst at Cowen & Company, LLC.

### **2021 Third Quarter Financial Results**

- Net sales for the third quarter of 2021 were \$7.8 million, an increase of 6.9% from \$7.3 million in the prior year period. The increase was due to an increase in contract manufacturing sales.
- Gross profit for the third quarter of 2021 improved by \$87 thousand, or 24% to \$449 thousand compared to the prior year period – a seventh consecutive quarter of year-over-year improvement in gross profit. The improvement in gross margin was primarily the result of increased filtered cigar sales mix due to new customer contracts and price increases on the Company’s contract manufactured cigarettes.
- Total operating expenses for the third quarter of 2021 increased by \$3.5 million compared to the prior year period. This was driven by the following:
  - Sales, general and administrative expenses increased by \$3.6 million compared to the prior year period. This was driven primarily by higher personnel, insurance, financial and strategic consulting costs, and marketing costs. These investments deployed to support, evaluate, and prepare for future opportunities are critical as the Company moves quickly to market readiness in both tobacco and hemp/cannabis.
  - Research and development expense for the third quarter of 2021 was favorably lower by \$52 thousand compared to the prior year period. This favorability was primarily driven by a tobacco leaf inventory impairment in the prior year period which did not reoccur in the current year period, and lower personnel costs and contract costs partially offset by higher license and contract costs for field trials and patent fees. The Company’s R&D investments are expected to grow in future quarters as the Company continues to accelerate the development of new, highly-differentiated hemp/cannabis plants and expand its R&D efforts to hops.
- Operating loss for the third quarter of 2021 was \$(7.9) million, an increase of \$3.4 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 third quarter of 2021.
- Net loss in the third quarter of 2021 was \$(9.4) million, an increase of \$5.1 million compared to the prior year period primarily due to an increase in non-cash charges off-set by benefits to other income and expenses, and representing a net loss per share of \$(0.06). This compares to the third quarter of 2020 net loss of \$(4.2) million, or \$(0.03) per share.
- The Company recorded a non-cash unrealized loss of \$1.9 million related to its fair value adjustments for investment in Aurora Cannabis stock warrants and investment in Exactus common stock.

### **Balance Sheet and Liquidity**

- For the first nine months of 2021, net cash used in operating activities was \$18.2 million, compared to \$12.6 million in the prior year period.
- The Company ended the quarter with a cash position of \$55.2 million as of September 30, 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

### **Third Quarter Earnings Conference Call**

22nd Century will host a live webcast today at 10:00 a.m. ET to discuss its third quarter 2021 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 John Franzino, chief financial officer, will review the Company’s 2021 third quarter results, and 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. 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](http://xxiicentury.com), on [Twitter @ xxiicentury](https://twitter.com/xxiicentury), and on [LinkedIn](https://www.linkedin.com/company/xxiicentury).

### **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, 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.

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

	September 30, 2021	December 31, 2020
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 1,629	\$ 1,029
Short-term investment securities	53,532	21,313
Accounts receivable, net	1,179	2,159
Inventory, net	2,703	2,034
Prepaid expenses and other assets	3,131	1,806
<b>Total current assets</b>	<u>62,174</u>	<u>28,341</u>
Property, plant and equipment, net	4,754	2,483
Operating leases right-of-use assets, net	478	247
Intangible assets, net	8,036	8,211
Investments	7,300	6,536
Other assets	3,713	5,876
<b>Total assets</b>	<u>\$ 86,455</u>	<u>\$ 51,694</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Notes payable	\$ 1,782	\$ 539
Operating lease obligations	74	247
Accounts payable	1,443	1,116
Accrued expenses	3,440	4,830
Accrued severance	223	339
Deferred income	—	272
<b>Total current liabilities</b>	<u>6,962</u>	<u>7,343</u>
<b>Long-term liabilities:</b>		
Operating lease obligations	407	—
Severance obligations	72	241
<b>Total liabilities</b>	<u>7,441</u>	<u>7,584</u>
<b>Commitments and contingencies (Note 11)</b>		
<b>Shareholders' equity</b>		
10,000,000 preferred shares, \$.00001 par value		
300,000,000 common shares, \$.00001 par value		
Capital stock issued and outstanding:		
162,735,483 common shares (139,061,690 at December 31, 2020)		
Common stock value	2	1
Capital in excess of par value	243,087	189,439
Accumulated other comprehensive (loss) income	(27)	74
Accumulated deficit	(164,048)	(145,404)
<b>Total shareholders' equity</b>	<u>79,014</u>	<u>44,110</u>
<b>Total liabilities and shareholders' equity</b>	<u>\$ 86,455</u>	<u>\$ 51,694</u>

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
<b>Revenue:</b>				
Sale of products, net	\$ 7,811	\$ 7,310	\$ 22,988	\$ 20,803
<b>Cost of goods sold (exclusive of depreciation shown separately below):</b>				
Products	7,362	6,948	21,306	19,953
Gross profit (loss)	449	362	1,682	850
<b>Operating expenses:</b>				
Research and development	854	906	2,287	2,676
Research and development - MRTTP	2	4	16	158
Sales, general and administrative	6,821	3,169	17,827	9,809
Impairment of intangible assets	—	—	—	146
Depreciation	173	160	461	473
Amortization	168	163	471	524
Total operating expenses	8,018	4,402	21,062	13,786
Operating loss	(7,569)	(4,040)	(19,380)	(12,936)
<b>Other income (expense):</b>				
Unrealized gain (loss) on investments	(1,900)	(429)	(2,040)	(562)
Impairment of Panacea investment	—	—	—	(1,062)
Gain on Panacea investment conversion	—	—	2,548	—
Gain on the sale of property, plant and equipment	—	1	—	1
Interest income, net	52	270	272	1,344
Interest expense	(23)	(23)	(44)	(54)
Total other income (expense)	(1,871)	(181)	736	(333)
Loss before income taxes	(9,440)	(4,221)	(18,644)	(13,269)
Income taxes	—	—	—	38
Net loss	\$ (9,440)	\$ (4,221)	\$ (18,644)	\$ (13,307)
<b>Other comprehensive income (loss):</b>				
Unrealized gain (loss) on short-term investment securities	(28)	87	(101)	132
Other comprehensive income (loss)	(28)	87	(101)	132
<b>Comprehensive loss</b>	<b>\$ (9,468)</b>	<b>\$ (4,134)</b>	<b>\$ (18,745)</b>	<b>\$ (13,175)</b>
<b>Net loss per common share - basic and diluted</b>	<b>\$ (0.06)</b>	<b>\$ (0.03)</b>	<b>\$ (0.12)</b>	<b>\$ (0.10)</b>
<b>Weighted average common shares outstanding - basic and diluted (in thousands)</b>	<b>162,721</b>	<b>138,857</b>	<b>153,998</b>	<b>138,774</b>

Below is a table containing information relating to the Company's Adjusted EBITDA for the three months and year-to-date ended September 30, 2021 and 2020, including a reconciliation of net (loss) income to Adjusted EBITDA for such periods.

	Quarter Ended		
	September 30,		
	Dollar Amounts in Thousands (\$000's)		
	2021	2020	\$ Change fav / (unfav)
<b>Net loss</b>	<b>\$ (9,440)</b>	<b>\$ (4,221)</b>	<b>\$ (5,219)</b>
Adjustments:			
Amortization and depreciation	341	323	18
Unrealized loss (gain) on investment	1,900	429	1,471
Gain on the sale of machinery and equipment	—	(1)	1
Accretion of non cash interest expense	2	4	(2)
Equity-based employee compensation expense	1,119	306	813
Interest income, net	(52)	(270)	218
Interest expense	21	19	2
<b>Adjusted EBITDA</b>	<b>\$ (6,109)</b>	<b>\$ (3,411)</b>	<b>\$ (2,698)</b>

<sup>1</sup>Fav = 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)		
	2021	2020	\$ Change fav / (unfav)
<b>Net loss</b>	<b>\$ (18,644)</b>	<b>\$ (13,307)</b>	<b>\$ (5,337)</b>
Adjustments:			
Impairment of intangible assets	—	146	(146)
Impairment of Panacea investment	—	1,062	(1,062)
Amortization and depreciation	931	997	(66)
Unrealized loss (gain) on investment	2,040	562	1,478
Gain on the sale of machinery and equipment	—	(1)	1
Gain on Panacea investment conversion	(2,548)	—	(2,548)
Accretion of non cash interest expense	6	34	(28)
Equity-based employee compensation expense	2,871	1,162	1,709
Executive and board search fees	—	430	(430)
Interest income, net	(272)	(1,344)	1,072
Interest expense	38	20	18
<b>Adjusted EBITDA</b>	<b>\$ (15,578)</b>	<b>\$ (10,239)</b>	<b>\$ (5,339)</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.