

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 7, 2020

**22nd Century Group, Inc.**  
(Exact Name of Registrant as Specified in Charter)

**Nevada**  
(State or Other Jurisdiction of Incorporation)

**001-36338**  
(Commission File Number)

**98-0468420**  
(I.R.S. Employer  
Identification No.)

**8560 Main Street, Suite 4, Williamsville, New York**  
(Address of Principal Executive Office)

**14221**  
(Zip Code)

Registrant's telephone number, including area code: **(716) 270-1523**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, \$0.00001 par value	XXII	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02**                    **Disclosure of Results of Operations and Financial Condition**

On May 7, 2020, 22nd Century Group, Inc. (the “Company”) issued an earnings release for the three months ended March 31, 2020, which is attached as Exhibit 99.1.

The information in this item shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liabilities of Section 18, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent, if any, expressly set forth by specific reference in such filing.

**Item 9.01(d)**                    **Financial Statements and Exhibit**

[Exhibit 99.1 Earnings release for the three months ended March 31, 2020.](#)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**22nd Century Group, Inc.**

Date: May 7, 2020

/s/ Michael J. Zercher  
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Michael J. Zercher  
President and Chief Operating Officer

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**22nd Century Group Reports First Quarter 2020 Financial Results**

WILLIAMSVILLE, N.Y., May 7, 2020 — 22nd Century Group, Inc. (NYSE American: XXII) (“22nd Century” or “the Company”), a leading plant biotechnology company focused on reduced nicotine tobacco and hemp/cannabis plant genetics research and development, today reported results for the first quarter ended March 31, 2020.

“We are very pleased with the solid start to 2020 with revenue increasing 12% over last year. We believe the Company is well positioned to execute on its strategies despite a challenging backdrop due to COVID-19. Our manufacturing facility has remained open and has been able to fulfill orders without any backlog. The improvements we made to our cost structure in 2019 have started to pay off in the first quarter with a 16% reduction in operating expenses compared to the same quarter last year,” said Mike Zercher, President and Chief Operating Officer of 22nd Century Group.

“Additionally, the U.S. Food and Drug Administration (“FDA”) recently announced a deadline for public comments on the Company’s Modified Risk Tobacco Product (“MRTP”) application. This moves our MRTP application one step closer to an FDA authorization decision for the Company’s proprietary, reduced nicotine content tobacco cigarettes. Bringing these products to market is an important and exciting prospect for the Company and public health,” Zercher added.

**Recent Accomplishments and Notable Events:**

- On February 14, 2020, the Company presented data to FDA’s Tobacco Products Scientific Advisory Committee (“TPSAC”) in support of our MRTP application for our reduced nicotine content tobacco cigarettes. 22nd Century’s MRTP application seeks a reduced exposure marketing authorization from the FDA to allow its reduced nicotine content cigarettes to be marketed under the brand name “VLN®,” with pack and advertising claims stating that the product contains 95% less nicotine than conventional tobacco cigarettes, as well as related claims regarding reduced nicotine exposure. This meeting was the first time that TPSAC considered an MRTP application for a modified exposure claim and was also TPSAC’s first discussion of an application for a combustible tobacco product.
  - On March 11, 2020, the Company announced in partnership with KeyGene that it has assembled, in just under three months, high-quality genome sequences of two hemp/cannabis lines and established a new, proprietary hemp/cannabis bioinformatics platform. Both are believed to be among the highest quality, hemp/cannabis reference genomes in the world. The establishment of a comprehensive bioinformatics platform is the first step in building out the Company’s hemp/cannabis knowledge foundation. Further work is underway to enhance the platform with additional plant lines. The Company has also made significant achievements in rapid cycle breeding and metabolomics with both high-CBD and oil-seed hemp/cannabis plant lines widely used in the hemp/cannabis industry.
  - On April 30, 2020, the Company announced that it and North Carolina State University (“NCSU”) have completed successful research field trials that have validated new non-GMO (genetically modified organism) methodologies for reducing nicotine in tobacco plants. As an alternative to older, genetic-engineering technologies that result in the creation of plants regulated as GMOs, the NCSU researchers used newer, non-CRISPR, non-GMO, gene editing technologies to consistently achieve reductions in nicotine levels of as much as 99%, when compared to conventional tobacco plants. This reduction in nicotine levels is believed to be caused by the inactivation of several genes believed to encode for enzymes involved in nicotine biosynthesis in the plant. 22nd Century has earlier filed a patent application with the U.S. Patent and Trademark Office to secure intellectual property rights for this non-GMO genetic approach that achieves very low nicotine content (VLNC) levels in tobacco plants using non-GMO methodologies.
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## First Quarter 2020 Financial Summary

- Net sales revenue for the first quarter of 2020 was \$7.1 million, an increase of \$0.8 million, or 12.1%, over net sales revenue of \$6.3 million during the first quarter of 2019. The increase was driven primarily by sales relating to contract manufactured cigarettes.
- Cash flows used in operations during the first quarter of 2020 was approximately \$4.7 million, flat year on year when compared to \$4.7 million for the fourth quarter of 2019. The Company's liquidity remains strong as of March 31, 2020, with cash, cash equivalents, and short-term investment securities totaling approximately \$34 million.
- For the first quarter of 2020, the Company reported an operating loss of \$4.1 million as compared to an operating loss of \$5.4 million for the first quarter of 2019, a decrease in operating loss of \$1.3 million, or 23%. The improvement was primarily due to a decrease in operating expenses of approximately \$0.9 million which was driven by primarily by efforts in expense management.
- The Company experienced a net loss for the first quarter of 2020 of \$4.0 million, representing a net loss per share of (\$0.03) as compared to a net loss of \$2.1 million, or a net loss per share of (\$0.02) for first quarter of 2019. The increased net loss for the first quarter was due primarily to a change in the fair value of warrants held by the Company in Aurora Cannabis, Inc.
- Adjusted EBITDA was negative \$3.2 million, or (\$0.02) per share, for the first quarter of 2020, as compared to a negative Adjusted EBITDA of \$4.6 million, or (\$0.04) per share, for the first quarter of 2019, a decrease in the negative Adjusted EBITDA of \$1.4 million, or 30%. The improvement year-over-year is a result of the Company returning the contract manufacturing business to a gross margin positive state and rationalizing the operating expense base.

Below is a table containing information relating to the Company's Adjusted EBITDA for the three months ended March 31, 2020 and 2019, including a reconciliation of net (loss) income to Adjusted EBITDA for such periods.

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**Quarter Ended March 31,  
Dollar Amounts in Thousands (\$000's)**

	2020	2019	% Change fav / (unfav) <sup>1</sup>
<b>Net loss</b>	\$ (4,028)	\$ (2,073)	94%
Adjustments:			
Amortization and depreciation	\$ 268	\$ 291	8%
Amortization of license fees	\$ 60	\$ 60	0%
Unrealized loss (gain) on investment	\$ 445	\$ (2,974)	(115)%
Realized gain on the sale of investments	\$ -	\$ -	-
Realized loss on short-term investment securities	\$ 3	\$ 16	81%
Gain on the sale of machinery and equipment	\$ -	\$ (87)	-
Accretion of interest on notes payable and severance	\$ 12	\$ 11	(9)%
Accretion of interest on Panacea Life Sciences investments	\$ (209)	\$ -	-
Equity-based compensation	\$ 481	\$ 449	(7)%
Executive and Board search fees	\$ 141	\$ -	-
Interest Income	\$ (403)	\$ (272)	48%
Interest Expense	\$ 12	\$ 11	(9)%
<b>Adjusted EBITDA</b>	<b>\$ (3,218)</b>	<b>\$ (4,568)</b>	<b>30%</b>

1Fav = Favorable variance, which increases to 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.

#### COVID-19 Update

In response to the COVID-19 pandemic, 22nd Century's first priority has been the health and safety of its employees. The Company implemented a work from home policy for all corporate employees on March 23, 2020, and the Company's R&D lab in Buffalo, New York has been temporarily closed to comply with the state orders. The Company's production facility in North Carolina is classified as an essential business and remains fully operational with heightened health and safety protocols in place. At this time, the Company has the ability to fulfill sales orders, while protecting the safety and well-being of its employees and complying with local, state and federal orders. The Company's executive leadership team is monitoring this rapidly evolving situation and will continue to make the best decisions for all employees and the business.

On March 30, 2020, the FDA issued a letter requesting a 120-day extension to the impending deadline for Premarket Tobacco Applications (PMTA) process, in light of the global pandemic caused by the novel virus, COVID-19. The letter cited that “as a result of the outbreak, some employees from the FDA’s Center for Tobacco Products (“CTP”) have been deployed to work for the U.S. Public Health Service, including many within one of the divisions of CTP’s Office of Science, which is responsible for reviewing premarket applications.” The FDA is part of the broad-based public health response to COVID-19; therefore, the pandemic could have the impact of delaying the timing of the FDA’s review of the Company’s MRTP application and FDA’s other tobacco control activities.

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

22nd Century will host a conference call today at 8:00 a.m. ET to discuss the Company’s first quarter 2020 financial results.

The conference call can be accessed live over the phone by dialing (877) 407-6914. A replay of the call will be available until May 21, 2020 by dialing (877) 660-6853; the passcode is 13702417.

The live audio webcast of the conference call will be accessible in the Events section on the Company's Investor Relations website [at https://www.xxiicentury.com](https://www.xxiicentury.com). An archived replay of the webcast 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. The Company’s primary mission in tobacco is to reduce the harm caused by smoking by bringing its proprietary reduced nicotine content cigarettes with 95% less nicotine than conventional cigarettes to adult smokers in the U.S. and international markets. The Company’s primary mission in hemp/cannabis is to develop proprietary hemp/cannabis plants with unique cannabinoid profiles and desirable agronomic traits and to commercialize those plants through a synergistic portfolio of strategic partnerships in the hemp/cannabis industry.

#### **Cautionary Note Regarding Forward Looking Statements**

This press release contains forward-looking statements concerning our business, operations and financial performance and condition as well as our plans, objectives and expectations for our business operations and financial performance and condition that are subject to risks and uncertainties. All statements other than statements of historical fact included in this press release are forward-looking statements. You can identify these statements by words such as “aim,” “anticipate,” “assume,” “believe,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “potential,” “positioned,” “predict,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions. These statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. All forward-looking statements are subject to risks and uncertainties and others that could cause actual results to differ materially from those contained in our forward-looking statements, please refer to “Risk Factors” in our Annual Report on Form 10-K filed on March 11, 2020 and in subsequently filed 10-Qs. We undertake 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.

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Learn more at [xxiicentury.com](http://xxiicentury.com), on Twitter [@xxiicentury](https://twitter.com/xxiicentury) and on [LinkedIn](#).

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