

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): March 12, 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))

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.

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

Item 2.02 Disclosure of Results of Operations and Financial Condition

On March 12, 2020, 22nd Century Group, Inc. (the “Company”) issued an earnings release for the year ended December 31, 2019, which is attached as Exhibit 99.1. In addition, the Company posted on its website, at www.xxiiicentury.com, a letter to stockholders, which is attached as Exhibit 99.2.

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 Exhibits

[Exhibit 99.1](#) [Earnings release for the year ended December 31, 2019.](#)

[Exhibit 99.2](#) [Letter to Stockholders.](#)

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: March 13, 2020

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

22nd Century Group, Inc. Files 2019 Annual Report***Maintains Strong Balance Sheet; Momentum Continues for Modified Risk Tobacco Product and Major Milestone Achieved in Hemp/Cannabis Research***

WILLIAMSVILLE, N.Y. – March 12, 2020 – [22nd Century Group, Inc.](#) (NYSE American: XXII), a leading plant biotechnology company in reduced nicotine tobacco and hemp/cannabis plant genetics research and development, yesterday filed its Annual Report on Form 10-K for the year ended December 31, 2019. A supplemental letter from Michael Zercher, President and Chief Operating Officer to shareholders is available in the [Investor](#) section of the Company's website.

"We are pleased with the Company's overall progress, achieving major milestones in pursuit of our strategic objectives. We are bullish on what the potential authorization of our Modified Risk Tobacco Product application will represent for the company," said Mike Zercher, President and Chief Operating Officer of 22nd Century Group.

"In addition, we are making strides in the legal hemp/cannabis space. Through our partnership with KeyGene, we have assembled a high-quality genome sequence of two hemp/cannabis plant lines and established a new proprietary hemp/cannabis bioinformatics platform. These achievements are an example of the valuable and innovative early results that will enable the rapid breeding of novel hemp/cannabis plants which have exceptional cannabinoid profiles for medical and therapeutic use," Zercher added.

For the fourth quarter of 2019, our accomplishments and notable events include:

In late November, the Company entered into Warrant Exercise Agreements with all of the holders of its outstanding warrants to purchase up to 11,293,211 shares of common stock with an exercise price of \$2.15 per share whereby the Company and the exercising holders agreed that the exercising holders would exercise for cash all of their warrants at a reduced exercise price of \$1.00 per share, generating gross proceeds of approximately \$11.3 million.

In early December, the Company announced that it had conducted an initial closing of an investment in Panacea Life Sciences, Inc., ("Panacea") a vertically-integrated developer, producer and seller of legal, hemp-derived, CBD products, with extraction, distillation, testing and manufacturing operations located in Golden, Colorado. The Company's investments in Panacea from such initial closing through the ensuing twelve to eighteen-month period are expected to be approximately \$24 million, in a combination of cash and shares of the Company's common stock in exchange for Panacea-issued debt and Panacea preferred stock.

In mid-December, the FDA publicly announced that it had authorized the Company to sell in the U.S. its very low nicotine content tobacco cigarettes that were the subject of its Premarket Tobacco Product Application ("PMTA") under the brand names Moonlight[®] and Moonlight Menthol[®].

Subsequent to the end of the fourth quarter of 2019, our accomplishments and notable events include:

In mid-February, the FDA's Tobacco Products Scientific Advisory Committee ("TPSAC") conducted a public hearing regarding the Company's Modified Risk Tobacco Product Application ("MRTPA") for its very low nicotine content tobacco cigarettes for which the Company is requesting a reduced exposure marketing authorization from the FDA to market its very low nicotine content tobacco cigarettes in the U.S. under the proposed brand name of VLN[®] and with product labeling and advertising claims stating that VLN[®] has 95% less nicotine than conventional cigarettes, among other claims. This meeting was the first time that TPSAC considered an MRTP application for a modified exposure claim, and it was also TPSAC's first discussion of an application for a combustible tobacco product. The Company presented data in support of its product applications, and FDA also presented perspectives on the applications and posed questions for the committee members to discuss. Recordings of the proceedings, briefing materials for the committee and the FDA, and presentations given by different stakeholders are publicly available on [FDA's website](#). The public comment period on the Company's MRTPA remains open at this time, and the FDA continues their comprehensive evaluation of the Company's application.

In late February, the Company appointed Lisa Parks as its Vice President of Acquisitions and Mei Kuo as its Director of Communications and Investor Relations. Parks will drive the Company's strategic partnership activities focused on creating a synergistic portfolio of operating companies to commercialize the Company's proprietary hemp/cannabis plants and intellectual property in development. Kuo will serve as the primary liaison between the Company, its external stakeholders and the investment community with a focus on improving investor engagement.

In early March, the Company announced that it has completed, in just under three months, the first, high-density, hemp/cannabis genome sequencing through its partnership with KeyGene. The data has been integrated into a comprehensive bioinformatics platform developed by KeyGene for visualization and analytics of all available genomic transcriptomic and metabolomic datasets. These achievements are an example of some of the valuable, early results delivered by the exclusive, worldwide strategic research and development collaboration between the Company and KeyGene that is focused on developing proprietary, valuable and new hemp/cannabis plants with exceptional cannabinoid profiles for medical and therapeutic use.

Fourth Quarter & Full Year 2019 Financial Summary

- As of December 31, 2019, the Company's liquidity remains strong, with cash, cash equivalents, and short-term investment securities totaling approximately \$39.0 million. The company maintains working capital of \$37.0 million and has total debt of \$1.5 million.
- Net sales revenue for the fourth quarter 2019 increased to \$7.3 million. Net sales revenue for full year 2019 was \$25.8 million, a decrease of \$0.6 million, or 2.2% from full year 2018. This decrease in net revenue was primarily from sales of SPECTRUM® research cigarettes during fourth quarter 2018 in the amount of \$0.6 million that did not recur in the fourth quarter of 2019.
- Operating loss for the fourth quarter was \$5.6 million, a favorable decrease of \$0.3 million, or 4.3% from the same quarter in the prior year. The improvement was primarily due to a decrease in operating expenses of approximately \$0.5 million. For full year 2019, operating loss was \$23.6 million, an improvement of approximately \$0.5 million, or 1.9% compared to prior year.
- Net loss for the fourth quarter was \$6.2 million, representing earnings (loss) per share of (\$0.05), compared to net loss of \$8.9 million, or earnings (loss) per share of (\$0.07) for fourth quarter 2018. Net loss for full year 2019 was \$26.6 million, or (\$0.21) in earnings (loss) per share, compared to net loss of \$7.9 million or earnings (loss) per share of (\$0.06) for the year ended December 31, 2018. The increased net loss for the full year was driven primarily by a one-time gain on investment in 2018 related to the realized gain of \$14.5 million in 2018 as a result of the Company's investment in Aurora, which was not repeated in 2019, as well as impairment charges of \$1.1 million, inventory write-offs of \$1.0 million, and gross profit reduction of \$0.9 million in 2019.
- Operating cash flow for fourth quarter 2019 was (\$2.9) million compared to (\$5.3) million in fourth quarter 2018. The improvement was driven by a reduction in net loss of \$2.7 million for fourth quarter of 2019. For full year 2019 operating cash flow was (\$14.6) million, an improvement of \$3.3 million.
- For full year 2019, Adjusted EBITDA was (\$15.6) million, an improvement of \$3.7 million when compared to the prior year. Please refer to Non-GAAP Financial Measures below for a reconciliation of Adjusted EBITDA to net income (loss).

Non-GAAP Financial Measures

"Adjusted EBITDA," defined as earnings before interest, taxes, depreciation, amortization, and equity-based compensation 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.

	Year Ended December 31,		
	2019	2018	% Change
Net income (loss)	\$ (26,558,544)	\$ (7,966,911)	233%
Adjustments:			
Impairment	1,142,349	-	-
Amortization and depreciation	1,186,343	1,199,794	(1%)
Amortization of license fees	238,661	142,541	67%
Severance expense	880,838	-	-
Unrealized loss (gain) on investments	2,419,348	(284,400)	(951%)
Realized gain on the sale of investments	-	(14,492,968)	(100%)
Realized (gain) loss on short-term investment securities	(220,872)	54,451	(506%)
Litigation expense	1,890,900	-	-
Gain on the sale of machinery and equipment	(87,351)	-	-
Warrant liability (gain) loss	-	(48,711)	(100%)
Accretion of interest on note payable and accrued severance	47,775	10,939	337%
Accretion of interest on convertible note receivable	(21,978)	-	-
Equity-based employee compensation expense	3,539,745	3,187,331	11%
Inventory write-off	985,238	-	-
Interest Income	(1,066,323)	(1,069,036)	(0%)
Interest Expense	56,382	10,939	415%
Adjusted EBITDA	\$ (15,567,492)	\$ (19,256,032)	(19%)

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.

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

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. 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.

Dear Fellow Shareholders,

It has been an exciting year at 22nd Century Group as we accelerated our leadership position in plant genetics and laid a strong foundation for future success. We are leading the world in plant genetics research focused on the disruption of two large and valuable industries – the evolving area of tobacco harm reduction and the emerging, rapidly-growing, legal hemp/cannabis space.

The tobacco and cannabis industries are similar in many ways. Both are plant-based, highly regulated and consumer facing, but they also differ. Tobacco – under fire and dominated by just a few major players – is ripe for disruption. Cannabis – emerging, fast-growing, highly fragmented and undercapitalized – has yet to see real differentiation in its marketplace. We believe 22nd Century is well positioned to capitalize on these unique opportunities. By leveraging our strengths and expertise in plant genetics R&D, intellectual property, FDA regulation and consumer packaged goods, we have the ability to disrupt the global tobacco industry and position our Company for leadership in the legal hemp/cannabis industry. We have made significant progress in the past year in pursuit of this vision, which we believe will create meaningful value for shareholders and lead to positive change in the world.

Last year, we made major progress in our efforts to launch our highly disruptive very low nicotine content (VLNC) tobacco cigarettes. While our VLNC tobacco cigarettes look and smoke like conventional cigarettes, they contain 95% less nicotine than their conventional counterparts. We have spent several years and millions of dollars to develop our proprietary VLNC tobacco and related patents as well as to support and develop the enormous body of clinical science that studies the benefits of our VLNC tobacco cigarettes to adult smokers and for public health.

Our own research and that of leading independent researchers has confirmed that smokers who use our VLNC tobacco cigarettes – even smokers with no intention of quitting – reduce their nicotine exposure and dependence, smoke fewer cigarettes per day, experience reduced withdrawal symptoms, increase their number of smoke-free days and double their quit attempts – without demonstrating any compensatory behavior to obtain more nicotine.

We filed two applications with the U.S. Food and Drug Administration (FDA) in 2018 requesting authorization to introduce our reduced nicotine tobacco cigarettes to market under the brand name VLN® along with several marketing claims including “95% Less Nicotine.” We believe the substantial, independent science supporting these applications is compelling and clearly supports a product launch with a modified risk tobacco product authorization from FDA.

Last year FDA authorized the first of our applications, our Pre-Market Tobacco Product Application (PMTA) for our VLNC tobacco cigarettes, which was a major milestone in our efforts. This authorization occurred largely due to the efforts of our new regulatory science group, who have worked closely with FDA over the past year on our applications. This authorization is the first – and likely the only such authorization that will ever be – granted by FDA to any company for a combustible cigarette. In authorizing this application, FDA determined that the sale of our products is “appropriate for the protection of the public health because of, among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers.”

Our regulatory science team also successfully presented the second of our two FDA applications, which is a Modified Risk Tobacco Product Application (MRTPA), to FDA’s Tobacco Products Scientific Advisory Committee (TPSAC) earlier this year. Our presentation to TPSAC marked another important milestone in the FDA application review process, and we look forward to FDA’s upcoming decision about this second application.

Our tobacco R&D activities this year were focused on supporting not only the planned commercialization of our VLNC tobacco cigarettes but also the FDA’s proposed plan to reduce the nicotine content of all cigarettes sold in the U.S. to minimally or non-addictive levels. Our VLNC tobacco cigarettes already meet the FDA’s proposed product standard, and our ultimate success in tobacco will be enhanced by FDA implementing a rule requiring all cigarettes sold in the U.S. to have very low nicotine content. Our science and operations teams have also worked hard to refine our product design, tobacco growing practices and production processes to ensure we are able to bring the highest quality VLNC tobacco cigarettes to market. This work included activities to further develop and commercialize our proprietary, non-GMO tobacco with 95% less nicotine in both bright and burley varieties. Our R&D activities are important to the continued development of our VLNC tobacco plants and IP as well as the eventual global marketing of our VLNC tobacco cigarettes.

While we are very pleased with our tobacco-related activities, we also took important steps to accelerate our work in legal hemp/cannabis. We continued to leverage our scientific assets and the expertise of our team in plant genetics and IP to create value in the emerging area of hemp/cannabis plant genetics. We are focused on the creation of proprietary hemp/cannabis plants with proprietary, unique and valuable cannabinoid profiles and other desirable agronomic traits. Of critical importance to our hemp/cannabis R&D this year was the formation of our exclusive, global, hemp/cannabis research partnership with KeyGene, a Netherlands-based company that is a leader in plant biotechnology.

Our first year of work with KeyGene focused on the development of hemp/cannabis plant research tools and genome knowledge. In a few short months, we have created one of the world's first complete and high-quality maps of the entire hemp/cannabis plant genome. We are now completing annotations and adding genomic maps of new hemp/cannabis plant lines to create a proprietary, high-powered analytics and data visualization platform that will be key to our continued genetics discovery and plant development. KeyGene has already begun applying its proprietary knowledge of and tools for plant mutagenesis, transformation, regeneration, rapid-cycle speed breeding and metabolite quantification to our proprietary hemp/cannabis plants lines. This first year was thus an exciting start to a novel process in the world of hemp/cannabis plant genetics that is expected to yield proprietary, unique and valuable hemp/cannabis plants and IP for 22nd Century.

We also are building a portfolio of strategic partnerships in the hemp/cannabis space and took important steps to do so last year. We made our first investment in a platform company, Panacea Life Sciences, Inc. (Panacea), a vertically integrated, consumer-facing, hemp-derived CBD products company based in Golden, Colorado. Panacea has grown quickly with a wide variety of products and a strong leadership team, and we look forward to working with them to help accelerate their growth. We also added new leadership to our team to help drive our partnership activities. We believe that our strategic partnerships will position 22nd Century well to lead in the hemp/cannabis products space through the marketing of highly differentiated and legal cannabinoid products derived from our proprietary, unique and valuable hemp/cannabis plants and IP in development.

We also have exciting and compelling goals and plans for the coming year in both tobacco and hemp/cannabis.

We will continue to work toward a commercial launch of our VLNC tobacco cigarettes upon authorization of our MRTPA by the FDA. Our consumer research shows that an astounding 60% of smokers are interested in buying our VLN® cigarettes, and with over 34 million smokers in the United States and nearly 1 billion smokers worldwide, the commercial and public health opportunity for 22nd Century's VLN® product is enormous. Our regulatory team will continue its work with FDA, and our science team, research partners and tobacco growers will continue to enhance and improve our VLNC tobacco and products.

We will continue to support efforts to advance the FDA's proposed plan to reduce the nicotine content of all cigarettes sold in the U.S. to minimally or non-addictive levels. This is important, worthwhile and valuable work given the FDA's plan to save millions of lives and prevent millions more people, especially youth, from ever becoming addicted to nicotine.

We will continue to pursue our strategies to leverage our scientific, regulatory and commercial capabilities and assets in the emerging and fast-growing hemp/cannabis space. With our research partner, KeyGene, we will continue our high-density genetic mapping and metabolic profiling of hundreds of hemp/cannabis plant lines, which will enable continued genetics improvements, new gene discovery and new plant design to create proprietary, unique and valuable hemp/cannabis plants for 22nd Century.

We look forward to Panacea's continued success in the hemp CBD marketplace as they focus on driving growth of their branded products business, and we will continue exploring new strategic partnerships in our quest to become a leading plant-derived cannabinoid products company differentiated by proprietary, unique and valuable plant genetics and intellectual property.

Finally, last year we mourned the passing of our friend, colleague and Board member, Joseph A. Dunn, PhD. Joe's contributions to 22nd Century over his many years of Board service were numerous and valuable. He will be long remembered by his family and his many friends as a kind, generous, warm-hearted, and fun-loving soul.

We thank you for your continued interest in and support of 22nd Century and the important work we are doing to create value and meaningful change in the world through plant genetics.

With warm regards,

Mike Zercher
President & Chief Operating Officer
