

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): August 6, 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 August 6, 2020, 22nd Century Group, Inc. (the “Company”) issued an earnings release for the second quarter ended June 30, 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 Exhibits

[Exhibit 99.1](#) [Earnings release for the quarter ended June 30, 2020](#)
104 Inline XBRL for the cover page of this Current Report on Form 8-K.

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.

/s/ James A. Mish

James A. Mish

Chief Executive Officer

Date: August 6, 2020

22nd Century Group Reports Financial Results and Business Highlights for the Second Quarter 2020**Key Highlights:**

- Net sales revenue increased approximately 11% to \$6.4 million
- Gross profit continues to show improvement year-over-year as a result of targeted actions to improve margins and cost structure
- Operating loss improved by approximately \$276 thousand
- Adjusted EBITDA improved 21%
- Appointed new CEO, James A. Mish and new CFO, John Franzino

WILLIAMSVILLE, N.Y., August 6, 2020 (Globe Newswire) — 22nd Century Group, Inc. (NYSE American: XXII) (“22nd Century” or “the Company”), 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, today reported results for the second quarter ended June 30, 2020.

“Despite the unprecedented challenges brought on by COVID-19, I am pleased to report net sales revenue of \$6.4 million for the second quarter of 2020, up 11% from the prior year, continued gross profit margin expansion, and improved operating loss. These results demonstrate our ability to execute on our initiatives to improve our margins and cost structure. Our financial position remains strong and we will continue to operate with strict cost controls, allocate our resources efficiently, and deploy capital where we believe it will give us the greatest return on our investments,” said James A. Mish, Chief Executive Officer of 22nd Century Group.

“With the comment period now closed on our Modified Risk Tobacco Product Application, the team is laser focused on setting the stage for a successful VLN[®] launch upon the authorization of our MRTP Application by the FDA. I am exceedingly proud of the dedication and tremendous progress the team has made so far this year and believe we are well positioned to capitalize on the many opportunities ahead,” Mish added.

Business Highlights and Notable Events:

- The Company appointed James A. Mish as its Chief Executive Officer, effective June 22, and John Franzino as its Chief Financial Officer, effective June 3. Mish has extensive global executive leadership experience leading science-driven organizations with a focus on the development, manufacturing, and commercialization of active pharmaceutical ingredients (“API”), including cannabinoids, and related consumer products. Franzino has extensive financial leadership experience in the tobacco and alcoholic beverage industries. Mish is reviewing the Company’s current strategy and objectives and is expected to provide an update in November during the Company’s third quarter earnings call.
 - The public comment period for the Company’s Modified Risk Tobacco Product (“MRTP”) Application for VLN[®] closed on May 18, 2020. The application requests a modified exposure designation from the FDA to market the Company’s proprietary reduced nicotine content tobacco cigarettes in the U.S. under the proposed brand name of VLN[®] with product labeling and advertising claims stating that VLN[®] has 95% less nicotine than conventional cigarettes, as well as other claims related to reduced nicotine exposure. The closing of the public comment period marks an important milestone in the FDA’s ongoing scientific review of the Company’s MRTP Application.
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- On April 30, 2020, the Company announced that, in collaboration with its research partner, North Carolina State University (NCSU), it had completed research field trials validating new non-GMO (genetically modified organism) methodologies for reducing nicotine in tobacco plants. The research was funded by 22nd Century and was conducted by NCSU's Department of Crop and Soil Science with project oversight provided by 22nd Century's R&D team. During the quarter, the Company also completed plantings of its non-GMO, very low nicotine content (VLNC) tobacco plant lines in multi-site, field trials to optimize the growing practices of its non-GMO, VLNC plant lines in anticipation of the commercialization of these new lines in the U.S. and internationally.
- Despite the COVID-19 pandemic, the Company was able to continue a sizeable part of its research and development program in hemp/cannabis including the sequencing of more than 250 additional plant lines. The Company continues to expand its knowledge foundation and bolster the information in its proprietary hemp/cannabis bioinformatics platform. The data will help the Company analyze and advance its understanding of the hemp/cannabis plant and enable the identification of the genes and biosynthetic pathways that are responsible for the modulation and production of various cannabinoids and terpenes in the plant. Through this work, the Company already has identified several hemp/cannabis lines that exhibit distinctive levels of key cannabinoids and the associated genetic markers that will allow the Company to create proprietary plant lines for commercial use. Additional investigation and research will be carried out to understand the mechanisms behind these distinctive traits and to identify the candidates with the greatest commercial value.

COVID-19 Update

- The Company's manufacturing facility in North Carolina remains open and operational. Despite the pandemic, the contract manufacturing business remains strong and continues to demonstrate improved gross margins.
- The Company re-opened its corporate office in Williamsville, New York, in June and its R&D laboratory in Buffalo, New York, in May. Both are operating under strict safety protocols in accordance with New York state's reopening guidelines. These protocols include physical distancing, mandatory face coverings, disinfection of surfaces, and other health and safety measures. The Company continues to encourage remote work arrangements where job duties permit.

2020 Second Quarter and Year-to-Date Financial Results

- Net sales revenue for the second quarter of 2020 was \$6.4 million, an increase of 10.7% over net sales revenue of \$5.8 million during the second quarter of 2019. Net sales revenue for the first half of 2020 was \$13.5 million, an increase of 11.4% from net sales revenue of \$12.1 million for the first half of 2019. The increase in sales for both periods was primarily driven by higher volume and pricing in our contract manufacturing business.
 - Gross profit improved by \$288 thousand in the second quarter of 2020 compared to prior year and improved \$677 thousand year-to-date compared to the first half of 2019. The improved gross margin was primarily the result of price increases and lower labor and overhead costs driven by factory efficiencies implemented over the last six months.
 - Operating loss improved by \$276 thousand in the second quarter of 2020 to (\$4.8) million, compared to an operating loss of (\$5.0) million in the prior year. The improvement was driven by higher gross profit which increased by \$288 thousand and was partially offset by higher operating expenses of \$11 thousand. Year-to-date, operating loss improved by \$1.5 million to (\$8.9) million. This improvement was driven by the combination of higher gross profit which increased by \$677 thousand and operating expenses which decreased by \$834 thousand. Operating expenses decreased as a result of lower R&D and MRTP application expenses, partially offset by an increase in SG&A expense. The majority of the decrease in R&D and MRTP expenses was driven by lower personnel and contract costs this year and a reduction in expenses related to our MRTP application. The increase in SG&A expense was driven by higher consulting and professional service fees, D&O insurance premiums, and one-time personnel expense.
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- Net loss for the second quarter of 2020 improved by \$3.0 million to (\$5.1) million, representing a net loss per share of (\$0.04) as compared to a net loss of (\$8.0) million, or a net loss per share of (\$0.06) for second quarter of 2019. In addition to the improvements in operating loss of \$276 thousand, other income and expense improved by \$2.7 million due to an unrealized gain on Aurora warrants of \$1.7 million this quarter, a legal settlement of \$1.9 million recognized last year and favorable interest income. The Company recorded an impairment charge of \$1.1 million related to its Panacea stock warrant investment, which was based on an assessment of macroeconomic indicators including, overall decline in the cannabidiol (CBD) industry, FDA regulation uncertainty, and continued disruption of the market from COVID-19. This non-cash charge partially offset the improvement in other income and expense in the quarter.
- Net loss for the first half of 2020 improved by \$1.0 million to (\$9.1) million, representing a net loss per share of (\$0.07) as compared to a net loss of (\$10.1) million, or a net loss per share of (\$0.08). An improved operating loss of \$1.5 million was offset by an increase in other income and expense of \$443 thousand. The increase in other income and expense was driven by the non-cash impairment charge related to the investment in Panacea and was offset by the interest income from Panacea this year and a legal settlement expense of \$1.9 million recognized in the prior year.
- Adjusted EBITDA was (\$3.2) million for the second quarter of 2020, an improvement of \$857 thousand, or 21% compared to Adjusted EBITDA of (\$4.1) million for the second quarter of 2019.
- Adjusted EBITDA was (\$6.5) million for the first half of 2020, an improvement of \$2.2 million, or 25% compared to Adjusted EBITDA of (\$8.7) million for the first half of 2019.

Balance Sheet and Liquidity

- For the first half of 2020, net cash used in operating activities was approximately \$11.5 million, compared to approximately \$8.7 million in the first half of 2019. Cash usage for the first half of the year included additional expenses related to professional services, executive search fees, and personnel expense, which were primarily non-recurring expenses and higher D&O insurance premiums.
- On July 21, 2020, the Company filed a Form S-3 universal shelf registration statement with the U.S. Securities and Exchange Commission (“SEC”) to raise up to \$100 million of capital. While the Company does not have any immediate plans to raise capital at this time, the new shelf registration will replace its previously expired shelf registration and should provide the Company flexibility and optionality to raise capital in order to make crucial investments, should compelling opportunities arise in the future.
- The Company’s liquidity remains strong with cash, cash equivalents, and short-term investment securities totaling approximately \$28.9 million as of June 30, 2020.

Second Quarter Earnings Conference Call

22nd Century will host an audio-only webcast today at 8:00 a.m. ET to discuss the Company’s second quarter 2020 financial results.

The live audio webcast will be accessible in the Events section on the Company's Investor Relations website at www.xxiiicentury.com/investors/events. 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 tobacco cigarettes – containing 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 valuable cannabinoid profiles and agronomic traits and to commercialize those plants through a synergistic portfolio of strategic partnerships in the hemp/cannabis industry.

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

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 the “Risk Factors” in our Annual Report on Form 10-K filed on March 11, 2020 and in our subsequently filed Quarterly Report on Form 10-Q. 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.

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.

Below is a table containing information relating to the Company's Adjusted EBTIDA for the three and six months ended June 30, 2020 and 2019, including a reconciliation of net (loss) income to Adjusted EBTIDA for such periods.

	Quarter Ended June 30,		
	Dollar Amounts in Thousands (\$000's)		
	2020	2019	% Change fav / (unfav)¹
Net loss	\$ (5,057)	\$ (8,042)	(37%)
Adjustments:			
Impairment of intangible assets	\$ 146	\$ -	-
Impairment of warrants	\$ 1,062	\$ -	-
Amortization and depreciation	\$ 346	\$ 370	(6%)
Amortization of license fees	\$ 62	\$ 60	5%
Personnel expense	\$ 306	\$ -	-
Unrealized loss (gain) on investment	\$ (312)	\$ 1,424	(122%)
Realized (gain) loss on short-term investment securities	\$ (3)	\$ (72)	(96%)
Litigation settlement	\$ -	\$ 1,891	(100%)
Accretion of non cash interest expense	\$ 19	\$ 13	42%
Accretion of interest on Panacea investment	\$ (272)	\$ -	-
Equity-based employee compensation expense	\$ 374	\$ 517	(28%)
Executive and board search fees	\$ 289	\$ -	-
Interest Income	\$ (190)	\$ (243)	(22%)
Interest Expense	\$ 19	\$ 13	42%
Adjusted EBITDA	\$ (3,213)	\$ (4,069)	21%

¹Fav = Favorable variance, which increases to Adjusted EBITDA; Unfav = unfavorable variance, which reduces Adjusted EBITDA

	YTD Ended June 30,		
	Dollar Amounts in Thousands (\$000's)		
	2020	2019	% Change fav / (unfav)¹
Net loss	\$ (9,086)	\$ (10,115)	(10%)
Adjustments:			
Impairment of intangible assets	\$ 146	\$ -	-
Impairment of warrants	\$ 1,062	\$ -	-
Amortization and depreciation	\$ 549	\$ 602	(9%)
Amortization of license fees	\$ 125	\$ 119	5%
Personnel expense	\$ 306	\$ -	-
Unrealized loss (gain) on investment	\$ 133	\$ (1,549)	(109%)
Realized (gain) loss on short-term investment securities	\$ -	\$ (56)	(100%)
Litigation settlement	\$ -	\$ 1,891	(100%)
Gain on the sale of machinery and equipment	\$ -	\$ (87)	(100%)
Accretion of non cash interest expense	\$ 13	\$ 21	(38%)
Accretion of interest on Panacea investment	\$ (306)	\$ -	-
Equity-based employee compensation expense	\$ 856	\$ 966	(11%)
Executive and board search fees	\$ 430	\$ -	-
Interest Income	\$ (768)	\$ (515)	49%
Interest Expense	\$ 31	\$ 24	31%
Adjusted EBITDA	\$ (6,510)	\$ (8,702)	25%

¹Fav = Favorable variance, which increases to Adjusted EBITDA; Unfav = unfavorable variance, which reduces Adjusted EBITDA

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