

Member FINRA/SIPC

Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

22nd Century Group, Inc. (NASDAQ: XXII)

January 6, 2022

Buy: Global VLN Launch this Year. Raise Target to \$8.50

James McIlree, CFA
561-237-2709
jmcilree@dawsonjames.com

We are raising our price target on 22nd Century to reflect the imminent launch of the company's VLN product, post the FDA's approval of the company's Modified Risk Tobacco Product (MRTP) application. We expect a pilot in the U. S. this quarter and international launches this year, with significant revenue contribution beginning in 2023. We expect the FDA to revisit a low-nicotine mandate this year which we believe will be a major catalyst for the shares.

We expect 22nd Century's long-standing promise of a VLN launch within 90 days of receiving MRTP approval to come to fruition this quarter. The company has indicated it will launch a test program in a couple hundred retail outlets in a major metro area of the U.S. in conjunction with a national retail partner this quarter. Results from this test will drive a broader rollout with its retail partner later in the year. We expect the company's ongoing discussions with additional retail partners to result in additional retail outlets carrying VLN possibly as early as this year.

FDA approval of the MRTP will enable the company to launch the product in international markets that typically follow the FDA's lead. The company has not announced which markets it is targeting but New Zealand is likely given its recent decision to implement a low-nicotine mandate and we think Japan, Germany, Switzerland, Spain, the Netherlands and Australia are also strong possibilities.

The product launch of a very-low nicotine menthol cigarette could place 22nd Century in a unique position if the FDA follows through with its commitment to banning menthol in combustible cigarettes with addictive levels of nicotine. The [Fall 2021 unified regulatory agenda](#) suggests an NRPM (Notice of Proposed Rulemaking) will be released in April of this year. 22nd Century would be the only provider of combustible menthol cigarettes if the ban applies only to addictive combustible cigarettes, which we think is probable. In our view a menthol ban would be a key driver of adoption for 22nd Century. According to the [FTC](#), menthol cigarettes comprise 37% of total consumption in the U.S.

We think it is likely the FDA will revive its low-nicotine mandate sometime in 2022 with approval near year-end or in the first half of 2023. We believe this would be a major catalyst for the shares since 22nd Century is the only company with cost-effective technology to grow tobacco with very-low, non-addictive levels of nicotine. We expect this to be a global trend. Recently, the New Zealand Ministry of Health announced aggressive measures to reduce smoking. These measures include a proposed amendment to implement a very-low nicotine mandate. We think other governments will follow the lead set by New Zealand and the United States.

Valuation: Our \$8.50 price target is the sum of: An estimated \$4.58/share for the VLN asset, \$3.18/share for the low-nicotine mandate and \$0.74 for the hemp/cannabis franchise.

Risks to Target include, among others: Our price target assumes the company launches VLN pilots in test markets this year and this could take longer than estimated and/or its partner could demand different terms than assumed. Our price target also assumes a nicotine mandate. The nicotine mandate may take longer to decide, and the transition period could be longer than estimated. See the Risks Analysis section for additional risks.

Current Price	\$2.67		
Price Target	\$8.50		
Estimates	F2020A	F2021E	F2022E
Revenues (\$000s)	\$ 28,111	\$ 31,799 E	\$ 39,111
1Q March	\$ 7,058	\$ 6,806 A	\$ 11,811
2Q June	\$ 6,435	\$ 8,371 A	\$ 8,400
3Q September	\$ 7,310	\$ 7,811 A	\$ 8,400
4Q December	\$ 7,308	\$ 8,811 E	\$ 10,500
	F2020A	F2021E	F2022E
EPS (diluted)	\$ (0.14)	\$ (0.17)E	\$ (0.21)
1Q March	\$ (0.03)	\$ (0.03)A	\$ (0.04)
2Q June	\$ (0.04)	\$ (0.03)A	\$ (0.06)
3Q September	\$ (0.03)	\$ (0.06)A	\$ (0.06)
4Q December	\$ (0.05)	\$ (0.05)E	\$ (0.05)
EBITDA (\$Ms)	\$ (16.0)	\$ (20.8)	\$ (20.8)
EV/EBITDA (x)	-23.8x	-18.3x	-18.3x
Stock Data			
52-Week Range	\$1.86	-	\$6.07
Shares Outstanding (mil.)	162.7		
Market Capitalization (mil.)	\$434		
Enterprise Value (mil.)	\$381		
Debt to Capital	0%		
Cash (mil.)	\$55.2		
Cash/share	\$0.34		
Average Three Months Trading Volume (K)	1,118		
Insider Ownership	2.3%		
Institutional Ownership	34.8%		
Short interest (mil.)	5.1%		
Dividend / Yield	\$0.00/0.0%		



We believe approval of alternative products, including 22nd Century's VLN fits the FDA's [comprehensive regulatory plan](#) for tobacco and nicotine regulation, announced in 2017, and included "encouraging development of innovative tobacco products that may be less dangerous than cigarettes." The FDA stated the products receiving marketing authorization "[could benefit addicted adult smokers who switch to these products – either completely or with a significant reduction in cigarette consumption – by reducing their exposure to harmful chemicals.](#)" We believe 22nd Century's VLN product, will benefit public health by offering an alternative for smokers seeking to quit and this may have weighed heavily in the FDA's decision.

On December 23, 2021, the FDA approved 22nd Century's MRTP application allowing the company to claim on its packaging for VLN King and VLN Menthol King cigarettes that the product 1) contains "95% less nicotine," 2) "Helps reduce your nicotine consumption," and 3) the product "...Greatly reduces your nicotine consumption." The agency is also requiring the additional claim, "Helps you smoke less." These claims will make 22nd Century's product unique in the market. We expect the company to announce distribution agreements in the near-term with national and/or regional retail outlets.

The claim, "Helps you smoke less," will better position the company to partner with smoking cessation products, and possibly accelerate revenue growth. The claim makes explicit what the data demonstrates: the company's VLN cigarettes can be an effective tool for the large population of smokers desiring to reduce or stop smoking. This claim is a built-in marketing advantage over all other combustible products on the market, and we think makes it more attractive to potential partners with existing smoking cessation products. Since the claims made by providers is regulated by the FDA, potential competitors looking to duplicate this claim face a long, arduous and expensive path. We believe this will provide a long-lived advantage for 22nd Century. The benefits this claim brings will play out over the coming years but it makes us more confident in our market share projections and ability of the company to negotiate attractive terms with distribution partners who we expect to help carry some of the costs of bringing the product to market.

The added claim also opens up opportunities for the company to partner with pharmaceutical partners to investigate opportunities of providing reduced nicotine cigarettes with other smoking cessation products. Research has shown greater efficacy in quit attempts when VLN is used in conjunction with some smoking cessation products. This could be a significant source of value over time, and drive sales higher than our expectations both domestically and internationally.

There is also progress in the company's hemp franchise. In December of 2021, Aurora Cannabis Inc. and 22nd Century announced an agreement to license biosynthesis intellectual property to Cronos Group Inc. Cronos intends to use this IP in its R&D on the biosynthesis of cannabinoids. 22nd Century had previously predicted it would consummate an agreement like this with Aurora in Q4. We expect more of these types of deals in the future as Aurora and 22nd Century intend to seek other commercial development opportunities and enforce their IP against infringing parties.

The company has stated it will book revenue from the harvest of its first hemp crop in Q4 21, and in Q1 22. We expect the total revenue contribution to be a few million dollars, about equally divided between the two quarters. Going forward, the company will use its strategic partnerships that include CannaMetrix to develop a roadmap on plant lines, KeyGene for plant line development, breeders for trial capabilities, the company's farm for cultivation and Exactus for extraction and purification. This is a powerful, vertically integrated, unique set of capabilities in the industry and we expect the company to aggressively pursue opportunities in this space as the next year unfolds.

The company recently announced a third franchise, the specialty hops market, which leverages its expertise in plant biotechnology, regulatory navigation, and the strategic partnerships it has assembled for the hemp/cannabis franchise. The addition of another revenue source, in a market facing less regulation than tobacco, that reduces dependence on favorable regulatory rulings, is, in our view, a major positive for the company.

The company estimates the hops market opportunity at \$500 billion, which, with the \$700 billion cigarette market and \$100 billion hemp/cannabis opportunity, brings its total market opportunity to \$1.3 trillion.

The company intends to develop specialty hop varieties that may have distinctive aromas and flavors or nutraceutical and medicinal properties. The varieties may be optimized for disease resistance or to enhance yields. Initial opportunities identified include disease and pest resistance, yield increases, new flavors and nutraceutical and pharmaceutical applications such as managing anxiety, mitigating sleep disorders and stomach problems.

We expect 22nd Century to engage in unfunded research on general issues facing the industry but also to engage with customers to develop specific varieties. The company is about six months into an anticipated two-year development cycle and expects upfront license fees starting in 12 to 18 months. We believe incremental expenses will be modest and tied to development projects. Initial revenue expectations were undisclosed, but we believe they would start around \$3 to \$5 million.

One advantage of the hops market is the lower regulatory oversight relative to tobacco and hemp/cannabis. This should enable a much quicker time to market than both tobacco and hemp/cannabis. The other significant advantage for 22nd Century is its ability to leverage the infrastructure it has already built to develop varieties for the hemp/cannabis market.

Currently, revenue is primarily generated from contract manufacturing of filtered cigars and cigarettes, and we expect this to remain the case through 2022. VLN will contribute to revenue in 2022, but we expect the meaningful contribution to begin in 2023. The hemp harvest will be additive in 2021 and 2022. The license agreement with Cronos resulted in revenue in Q4 of 2021 and additional license agreements could occur in 2022.

Our new price target reflects a higher estimate of the company's VLN franchise but follows the same methodology articulated in our April 13, 2021 initiation report. Currently, tobacco company stocks trade around 5x forward 12-month sales estimates (Source: FactSet consensus estimates). At this multiple, and a 3% market share of the domestic smokers who attempt to quit (about 1.5% of the total market), the value of the VLN franchise, in five years, would be worth close to \$1.4 billion, in our estimation. We believe a take-over would be at higher multiples due to the synergies available. Still, assuming a 3% market share of the domestic smokers who attempt to quit (1.5% of the total domestic market), the VLN franchise in five years would be valued at close to \$2.0 billion if instead we capitalized sales at 7x.

Potential Domestic VLN Franchise Values

Market Share of Quitters	3x sales	5x sales	7x sales
0.5%	\$ 137M	\$ 228M	\$ 319M
1.0%	\$ 274M	\$ 456M	\$ 639M
2.0%	\$ 547M	\$ 912M	\$ 1,277M
3.0%	\$ 821M	\$ 1,368M	\$ 1,916M

Source: Dawson James Securities estimates

We assume the company will partner to achieve these market share estimates and have reduced the values in the table by 30% to reflect the partner's interest. We have also included an estimate for the value of the international markets, that is 25% of the domestic market. The discounted per-share value of the VLN franchise based on 5x to 7x sales in five years, using a 20% discount rate, 3% market share estimate and a 30% interest for a potential partner, is, at the midpoint, \$4.58 per share.

Price Target. Our price target of \$8.50 comprises three components: We attribute about \$4.58/share for the VLN asset. The non-addictive nicotine mandate is valued at \$3.18 per share. The remainder of the price target, or \$0.74 per share, equals about \$112 million and encompasses the company's investment in Exactus, the Anandia licenses and the potential from its relationship with KeyGene. We have assumed a long gestation period for the hemp/cannabis business because it is in the early stages. However, the Aurora announcement and the restructuring of the Panacea/Exactus investment could be catalysts to more rapid development of the market and 22nd Century's monetization efforts.

Risk Analysis

Our price target assumes the company launches VLN pilots in test markets this year, and this could take longer than estimated and/or its launch partner could demand different terms than assumed. Our price target also assumes a nicotine mandate. The nicotine mandate may take longer to decide, and the transition period could be longer than estimated. There will likely be other paths attempted by the industry to comply or the industry may opt to focus on other nicotine delivery systems as regulation of the combustible cigarette market increases. This could affect our assumptions on the royalty rate as well as market share.

Exhibit 1. Income Statement

<i>(\$ in 000's except per-share data)</i>	2018	2019	2020	Q1 21 A	Q2 21 A	Q3 21 A	Q4 21 E	2021 E	2022 E
Revenue	\$ 26,426	\$ 25,833	\$ 28,111	\$ 6,806	\$ 8,371	\$ 7,811	\$ 8,811	\$ 31,799	\$ 39,111
Cost Of Goods Sold	25,527	25,818	26,673	6,159	7,785	7,362	7,362	28,668	32,048
Gross Profit	899	14	1,438	647	586	449	1,449	3,131	7,063
	3.4%	0.1%	5.1%	9.5%	7.0%	5.7%	16%	10%	18%
R&D	14,990	8,057	4,128	701	746	856	1,000	3,303	4,000
G&A	7,658	12,956	14,971	4,829	6,177	6,821	6,821	24,648	28,311
Impairment Charge	0	1,142	176	0	0	0	0	0	0
Sales & marketing	927	0	0	0	0	0	0	0	0
Depreciation & Amort.	1,342	1,425	1,346	288	303	341	341	1,273	1,364
Opex	24,918	23,581	20,621	5,818	7,226	8,018	8,162	29,224	33,675
Operating Income	\$ (24,019)	\$ (23,566)	\$ (19,183)	\$ (5,171)	\$ (6,640)	\$ (7,569)	\$ (6,713)	\$ (26,093)	\$ (26,612)
Other	14,945	(4,002)	(428)	36	2,372	(1,900)	(1,900)	(1,392)	(7,600)
Impairment Charge	49	0	(1,741)	0	0	0	0	0	0
Interest Income	1,069	1,066	1,751	112	108	52	276	548	711
Interest Expense	(11)	(56)	(72)	(7)	(14)	(23)	(23)	(67)	(92)
Pretax Income	(7,967)	(26,559)	(19,673)	(5,030)	(4,174)	(9,440)	(8,360)	(27,004)	(33,593)
Income Tax Expense	0	0	38	0	0	0	0	0	0
Net to Common	\$ (7,967)	\$ (26,559)	\$ (19,711)	\$ (5,030)	\$ (4,174)	\$ (9,440)	\$ (8,360)	\$ (27,004)	\$ (33,593)
Shares (000)	124,299	125,883	138,813	144,258	154,811	162,721	162,742	156,133	163,311
EPS	(\$0.06)	(\$0.21)	(\$0.14)	(\$0.03)	(\$0.03)	(\$0.06)	(\$0.05)	(\$0.17)	(\$0.21)
D&A	1,200	1,425	1,346	288	302	342	342	1,274	1,368
Stock Comp	3,187	3,540	1,654	507	1,245	1,119	1,119	3,990	4,476
Other	0	1,142	176	0	0	0	0	0	0
EBITDA	\$ (19,632)	\$ (17,459)	\$ (16,007)	\$ (4,376)	\$ (5,093)	\$ (6,108)	\$ (5,252)	\$ (20,829)	\$ (20,768)

Source: 22nd Century Group, Inc. and Dawson James Securities estimates

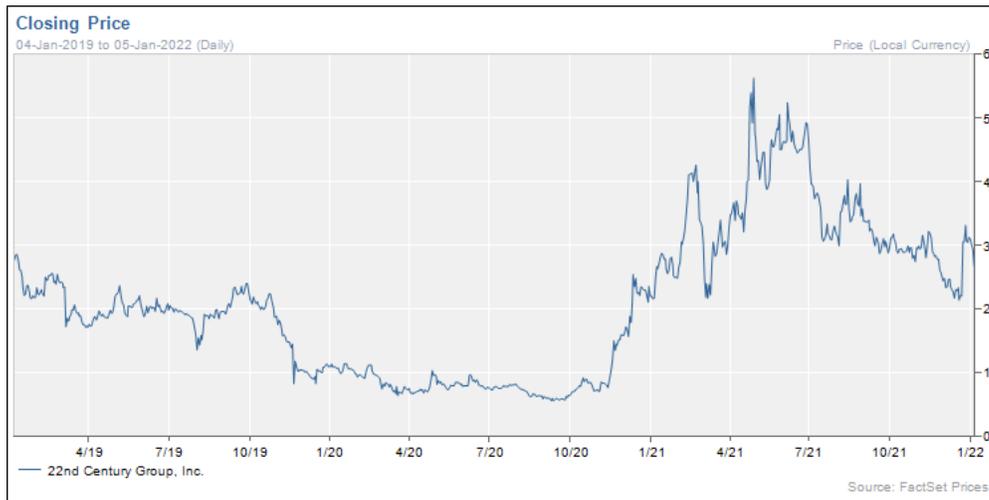
Exhibit 2. Balance Sheet and Cash Flow Statement

(\$ in 000's)	2018	2019	2020	2021 E	2022 E
Cash	605	485	1,029	1,629	1,629
Short-Term Investments	55,749	38,477	21,313	44,669	14,829
A/R	871	867	2,159	2,897	4,027
Inventory	3,044	2,266	2,034	2,824	3,284
Prepaid Exp.	928	648	1,806	3,131	3,131
Total Current Assets	\$ 61,198	\$ 42,743	\$ 28,341	\$ 55,150	\$ 26,900
PP&E	3,261	3,120	2,483	4,681	4,389
Operating Lease	0	602	247	478	478
Patent, Trademark, other intangibles	9,752	8,494	8,211	7,992	7,816
Equity Investment	3,092	8,403	6,536	7,300	7,300
Convertible Note Receivable	0	5,589	5,876	3,713	3,713
Total Assets	\$ 77,302	\$ 68,951	\$ 51,694	\$ 79,314	\$ 50,596
Bank Loans and N/P	689	581	539	1,782	1,782
Operating Lease	0	220	247	74	74
A/P	2,575	1,998	1,116	1,443	1,443
Accrued Expenses	1,826	2,619	4,830	3,440	3,440
Accrued Severance	0	359	339	223	223
Deferred Income	83	5	272	0	0
Total Current Liabilities	\$ 5,174	\$ 5,780	\$ 7,343	\$ 6,962	\$ 6,962
Long-Term Debt	848	292	0	0	0
Operating Lease	0	382	0	407	407
Accrued Severance	0	446	241	72	72
Shareholders' Equity	71,280	62,051	44,110	71,873	43,155
Total Liabilities And Equity	\$ 77,302	\$ 68,951	\$ 51,694	\$ 79,314	\$ 50,596
	2018	2019	2020	2021 E	2022 E
Net Income	(7,967)	(26,559)	(19,711)	(27,004)	(33,593)
Depreciation & Amort.	1,200	1,425	1,345	1,274	1,368
Stock Comp	3,187	3,540	1,654	3,990	4,476
Other	(14,618)	7,249	2,722	(281)	0
Working Capital	354	(242)	(1,631)	(4,924)	(1,591)
Operating Cash Flow	\$ (17,844)	\$ (14,587)	\$ (15,621)	\$ (26,945)	\$ (29,340)
Acquisition of Patents and trademarks	(657)	(515)	(468)	(364)	(500)
CapEx	(449)	(527)	(54)	(570)	(400)
Other	16,251	5,595	16,991	(32,498)	0
Investing Activities	\$ 15,145	\$ 4,552	\$ 16,469	\$ (33,432)	\$ (900)
Debt	(800)	(700)	(354)	1,236	0
Equity	445	10,616	50	50,878	400
Other	0	0	0	0	0
Financing Activities	\$ (355)	\$ 9,916	\$ (304)	\$ 52,114	\$ 400
Change in Cash	(\$3,055)	(\$120)	\$ 544	(\$8,263)	(\$29,840)

 Source: 22nd Century Group, Inc. and Dawson James Securities estimates

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

- Initiated – Buy – April 13, 2021 – Price Target \$7.00
- Update – Buy – April 15, 2021 – Price Target \$7.00
- Update – Buy – April 19, 2021 – Price Target \$7.00
- Update – Buy – May 7, 2021 – Price Target \$7.00
- Update – Buy – June 1, 2021 – Price Target \$7.00
- Update – Buy – June 11, 2021 – Price Target \$7.00
- Update – Buy – July 2, 2021 – Price Target \$7.00
- Update – Buy – July 23, 2021 – Price Target \$7.00
- Update – Buy – August 6, 2021 – Price Target \$7.00
- Update – Buy – August 31, 2021 – Price Target \$7.00
- Update – Buy – October 18, 2021 – Price Target \$7.00
- Update – Buy – November 5, 2021 – Price Target \$7.00
- Update – Buy – November 22, 2021 – Price Target \$7.00
- Update – Buy – December 9, 2021 – Price Target \$7.00
- Update – Buy – December 23, 2021 – Price Target \$7.00
- Price Target Change – Buy – January 6, 2022 – Price Target changed from \$7.00 to \$8.50

Dawson James Securities, Inc. (the "Firm") is a member of the Financial Industry Regulatory Authority ("FINRA") and the Securities Investor Protection Corporation ("SIPC").

The Firm does not make a market in the securities of the subject company(s). The Firm has not engaged in investment banking relationships with the subject company in the prior twelve months, as a manager or co-manager of a public offering and has not received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has received other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director, or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of November 30, 2021, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts, or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Information about valuation methods and risks can be found in the "Valuation" and "Risk Analysis" sections of this report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

Ratings Definitions:

- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months.
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months.
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of... 20-Dec-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	68%	5	19%
Market Perform (Neutral)	12	32%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	38	100%	5	13%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.