

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

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Buy: VLN Launch in Q1. Low-Nic Mandate Expected this Year.

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22nd Century is preparing the imminent launch of the company's VLN product, post the FDA's approval of the company's Modified Risk Tobacco Product (MTRP) 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 the FDA to revisit a low-nicotine mandate this year, and believe this could be a significant catalyst for 22nd Century. A low-nicotine mandate was initially explored in 2017 by the FDA and resulted in significant declines in the shares of publicly-traded tobacco stocks and a significant increase in the shares of 22nd Century. We believe if the FDA issues a notice of proposed rulemaking (NPRM), to require non-addictive levels of nicotine in combustible cigarettes, shares of 22nd Century could perform better than they did five years ago when the FDA issued an advanced notice of proposed rulemaking (ANPRM).

In late July 2017 the FDA released a "[comprehensive regulatory plan to shift trajectory of tobacco-related disease, death,](#)" and announced it would issue an Advanced Notice of Proposed Rulemaking to seek input on lowering nicotine levels in cigarettes. Over the next month, the market value of the largest domestic cigarette producers, Altira, British American Tobacco, Imperial Brands and Vector Group fell 10%, or \$30 billion, while 22nd Century's market cap increased 58% or \$80 million. Over this same time period the S&P 500 fell 1.4%. By the time the FDA published its ANPRM in March of 2018, 22nd Century had increased 124%, or \$170 million in market cap versus a 7.4% decline, or \$23 billion, for the big tobacco stocks. Over that same time period the S&P 500 increased 11%.

In our view, a low-nicotine mandate would be more valuable today to 22nd Century than it was five years ago. First, the approval of the company's MTRP for a very-low nicotine cigarette and its pending introduction demonstrates there is a viable way to comply with the rule, which is critical to the rule's success. Second, we think the FDA will draw on the ANPRM and comments received in the draft of a proposed rule, shortening the time to a final rule. Also, 22nd Century's balance sheet is much larger, putting it in a strong position to negotiate license deals and/or build out the VLN product

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	\$2.06		
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)	-17.6x	-13.6x	-13.6x
Stock Data			
52-Week Range	\$1.86	-	\$6.07
Shares Outstanding (mil.)	162.7		
Market Capitalization (mil.)	\$335		
Enterprise Value (mil.)	\$282		
Debt to Capital	0%		
Cash (mil.)	\$55.2		
Cash/share	\$0.34		
Average Three Months Trading Volume (K)	854		
Insider Ownership	2.3%		
Institutional Ownership	28.5%		
Short interest (mil.)	7.7%		
Dividend / Yield	\$0.00/0.0%		



In comments to the ANPRM, tobacco companies acknowledged the existence of 22nd Century's technology but were reluctant to admit it could be used to comply with a mandate. Now with 22nd Century's pending introduction of a very low nicotine cigarette, with non-addictive levels of nicotine, this objection is ungrounded. In our view, this is one of the factors that makes the mandate more likely (the FDA can't mandate a product that the market cannot produce) and it may spur companies to license 22nd Century's technology or face market share loss as the mandate is implemented. We believe 22nd Century is the only company with cost-effective technology to grow tobacco with very-low, non-addictive levels of nicotine.

We expect regulating nicotine levels 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.

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.

We believe 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 demonstrate: 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 are 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.

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.

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.

The "Helps you smoke less" claim also opens up opportunities for the company to partner with pharmaceutical partners to investigate opportunities of providing reduced nicotine cigarettes in tandem 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.

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. We have not included international launches in our estimates or price target.

Valuation. 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

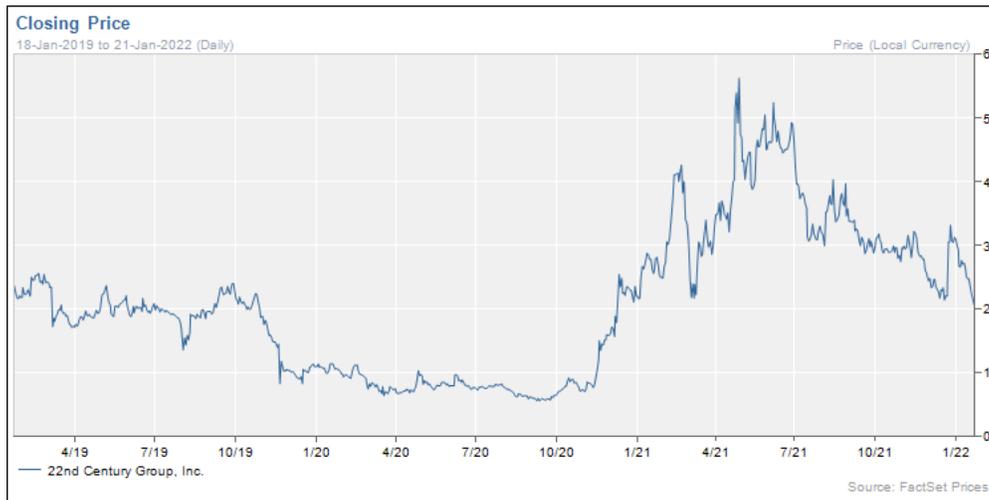
Exhibit 2. Balance Sheet and Cash Flow Statement

(\$ 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
 Update – Buy – January 24, 2022 – Price Target \$8.50

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months.
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Current as of... 10-Jan-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	27	69%	6	22%
Market Perform (Neutral)	12	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	39	100%	6	15%

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