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

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Buy: Nic Mandate Will be Major Driver of Value for XXII.

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Reports the FDA is preparing to re-introduce a rulemaking for a low-nicotine mandate could drive substantial share price appreciation in the coming months for 22nd Century. We reiterate our Buy recommendation and \$8.50 price target.

We believe the [possible introduction](#) of a notice of proposed rulemaking (NPRM) to limit the amount of nicotine to non-addictive levels in combustible cigarettes could result in substantial share price appreciation for 22nd Century in the coming months. Our \$8.50 price target assumes implementation of a low-nic mandate, introduction of the company's VLN cigarettes and growth of the company's hemp franchise. We believe news of the introduction of the low-nicotine mandate will be a major catalyst for the shares.

The FDA's introduction of a [comprehensive plan for tobacco and nicotine regulation](#) in 2017 was responsible for a 135% share price increase in XXII over the subsequent 2+ months, to a market cap of \$350 million. Reports in 2021 of FDA plans to introduce a low-nic mandate resulted in a 56% increase in XXII to a market cap of \$813 million over the course of almost two months. If the shares only achieved the \$813 million market cap reached last year, the shares would increase over 150% from current levels. The market reaction a year ago did not reflect the value of the FDA's approval of the company's MRTP application for very-low nicotine cigarettes, the current pilot in Chicagoland Circle K stores, and the pending low-nicotine mandate in New Zealand. The inclusion of these additional value drivers could result in an even stronger share price advance.

We believe it is reasonable to assume a new mandate would broadly follow the 2018 ANPRM since none of the studies supporting the efficacy of a low-nicotine mandate have been invalidated and, in our opinion, technical achievability of a mandate has been demonstrated by 22nd Century. Complying with a non-addictive low-nicotine mandate will be a challenge for the industry, and, as the current tobacco vendors admitted in their public comments on the ANPRM, 22nd Century has technology that could solve their problem.

The Director of Product Policy at Philip Morris International, Rolf Lutz, stated in 2016 it would cost \$10 billion to \$12 billion to extract nicotine from all its EU cigarettes. The company sold about 10 billion packs of cigarettes in the EU at that time, which was similar to the U.S. market currently. Mr. Lutz also indicated it could take up to 20 years to achieve lower nicotine levels with genetically modified plants. 22nd Century's technology enables a much quicker and cost-effective path to comply with this mandate and the company's introduction of a VLN cigarette demonstrates industry objections to technical feasibility is not a compelling argument.

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	\$1.62		
Price Target	\$8.50		
Estimates	F2021A	F2022E	F2023E
Revenues (\$000s)	\$ 30,948	\$ 65,555 E	\$ 96,812
1Q March	\$ 6,806	\$ 9,045 A	\$ 23,040
2Q June	\$ 8,371	\$ 13,520 E	\$ 23,761
3Q September	\$ 7,811	\$ 20,870 E	\$ 24,563
4Q December	\$ 7,960	\$ 22,120 E	\$ 25,448
	F2021A	F2022E	F2023E
EPS (diluted)	\$ (0.21)	\$ (0.17)E	\$ (0.14)
1Q March	\$ (0.03)	\$ (0.05)A	\$ (0.04)
2Q June	\$ (0.03)	\$ (0.04)E	\$ (0.03)
3Q September	\$ (0.06)	\$ (0.04)E	\$ (0.03)
4Q December	\$ (0.09)	\$ (0.04)E	\$ (0.03)
EBITDA (\$Ms)	\$ (23.2)	\$ (24.5)	\$ (21.3)
EV/EBITDA (x)	-12.4x	-11.7x	-13.5x
Stock Data			
52-Week Range	\$1.42	-	\$4.98
Shares Outstanding (mil.)	197.4		
Market Capitalization (mil.)	\$320		
Enterprise Value (mil.)	\$287		
Debt to Capital	3%		
Cash (mil.)	\$38.6		
Cash/share	\$0.20		
Average Three Months Trading Volume (K)	1,311		
Insider Ownership	3.6%		
Institutional Ownership	27.3%		
Short interest (mil.)	7.5%		
Dividend / Yield	\$0.00/0.0%		



We have adjusted our estimates to reflect the acquisition of GVB as of mid-May. Total revenue for GVB this year is expected to be \$48 million, and we have assumed a \$30 million contribution for the partial year it is owned by 22nd Century. For 2023 we have assumed a \$57 million revenue contribution from GVB. Gross margin for GVB has been running at about 44% and we have assumed this is maintained for this year and next. We have assumed the operating income contribution from GVB is modest for this year and next and believe there is room for upside as the business scales.

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>	2019	2020	2021	Q1 22 A	Q2 22 E	Q3 22 E	Q4 22 E	2022 E	2023 E
Revenue	\$ 25,833	\$ 28,111	\$ 30,948	\$ 9,045	\$ 13,520	\$ 20,870	\$ 22,120	\$ 65,555	\$ 96,812
Cost Of Goods Sold	25,818	26,673	28,879	8,585	10,440	14,360	14,920	48,305	65,313
Gross Profit	14	1,438	2,069	460	3,080	6,510	7,200	17,250	31,499
	0.1%	5.1%	6.7%	5.1%	22.8%	31.2%	32.5%	26.3%	32.5%
R&D	8,057	4,128	3,274	972	972	972	972	3,888	3,888
G&A	12,956	14,971	25,881	7,305	9,700	12,780	13,280	43,065	54,116
Impairment Charge	1,142	176	78	0	0	0	0	0	0
Depreciation & Amort.	1,425	1,346	1,248	329	329	329	329	1,316	1,316
Opex	23,581	20,621	30,481	8,606	11,001	14,081	14,581	48,269	59,320
Operating Income	\$ (23,566)	\$ (19,183)	\$ (28,412)	\$ (8,146)	\$ (7,921)	\$ (7,571)	\$ (7,381)	\$ (31,019)	\$ (27,821)
Interest and other, net	(2,992)	(490)	(4,183)	(772)	45	45	45	(637)	180
Pretax Income	(26,559)	(19,673)	(32,595)	(8,918)	(7,876)	(7,526)	(7,336)	(31,656)	(27,641)
Income Tax Expense	0	38	14	0	0	0	0	0	0
Net to Common	\$ (26,559)	\$ (19,711)	\$ (32,609)	\$ (8,918)	\$ (7,876)	\$ (7,526)	\$ (7,336)	\$ (31,656)	\$ (27,641)
Shares (000)	125,883	138,813	156,208	163,157	180,987	197,687	198,187	185,004	198,824
EPS	(\$0.21)	(\$0.14)	(\$0.21)	(\$0.05)	(\$0.04)	(\$0.04)	(\$0.04)	(\$0.17)	(\$0.14)
D&A	1,425	1,346	1,248	421	421	421	421	1,684	1,684
Stock Comp	3,540	1,654	3,983	1,213	1,213	1,213	1,213	4,852	4,852
Other	1,142	176	0	0	0	0	0	0	0
EBITDA	\$ (17,459)	\$ (16,007)	\$ (23,181)	\$ (6,512)	\$ (6,287)	\$ (5,937)	\$ (5,747)	\$ (24,483)	\$ (21,285)

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

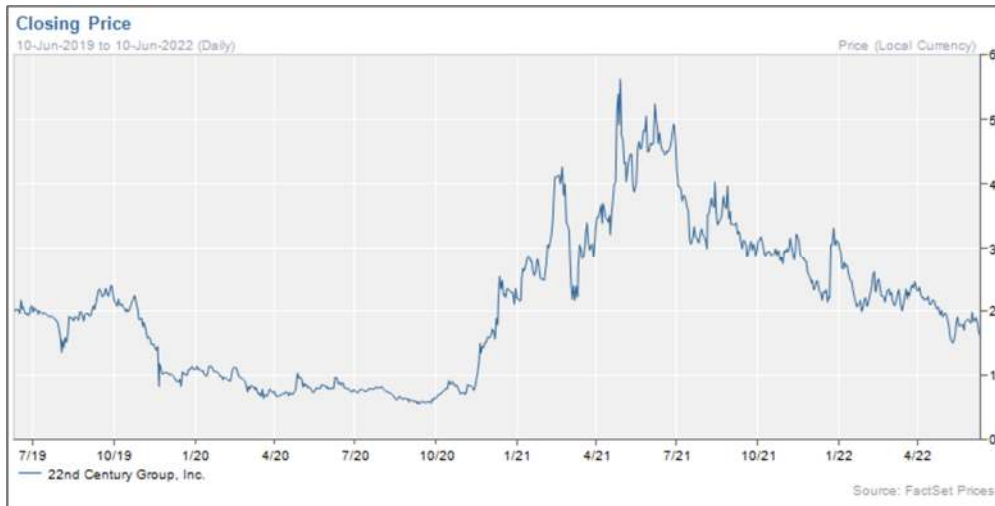
Exhibit 2. Balance Sheet and Cash Flow Statement

(\$ in 000's)	2019	2020	2021	2022 E	2023 E
Cash	485	1,029	1,336	1,584	1,584
Short-Term Investments	38,477	21,313	47,400	12,477	6,559
A/R	867	2,159	585	3,636	6,972
Inventory	2,266	2,034	2,881	5,676	6,553
Prepaid Exp.	648	1,806	2,183	1,389	1,389
Total Current Assets	\$ 42,743	\$ 28,341	\$ 54,385	\$ 24,762	\$ 23,057
PP&E	3,120	2,483	5,841	5,745	5,473
Operating Lease	602	247	1,723	1,631	1,631
Patent, Trademark, other intangibles	8,494	8,211	7,919	67,550	67,038
Equity Investment	8,403	6,536	2,345	2,211	2,211
Convertible Note Receivable	5,589	5,876	3,741	3,770	3,770
Total Assets	\$ 68,951	\$ 51,694	\$ 75,954	\$ 105,669	\$ 103,180
Bank Loans and N/P	581	539	596	0	0
Operating Lease	220	247	308	359	359
A/P	1,998	1,116	2,173	1,512	1,512
Accrued Expenses	2,619	4,830	5,014	2,632	2,632
Accrued excise taxes and fees					
Accrued Severance	359	339	217	187	187
Deferred Income	5	272	119	483	483
Total Current Liabilities	\$ 5,780	\$ 7,343	\$ 8,427	\$ 5,173	\$ 5,173
Long-Term Debt	292	0	0	4,500	4,500
Operating Lease	382	0	1,432	1,326	1,326
Accrued Severance	446	241	21	0	0
Shareholders' Equity	62,051	44,110	66,074	94,670	92,181
Total Liabilities And Equity	\$ 68,951	\$ 51,694	\$ 75,954	\$ 105,669	\$ 103,180
	2019	2020	2021	2022 E	2023 E
Net Income	(26,559)	(19,711)	(32,609)	(31,656)	(27,641)
Depreciation & Amort.	1,425	1,345	1,248	1,684	1,684
Stock Comp	3,540	1,654	3,983	4,852	4,852
Other	7,249	2,722	5,272	936	0
Working Capital	(242)	(1,631)	(733)	(7,928)	(4,213)
Operating Cash Flow	\$ (14,587)	\$ (15,621)	\$ (22,839)	\$ (32,112)	\$ (25,318)
Acquisition of Patents and trademarks	(515)	(468)	(326)	(480)	(500)
CapEx	(527)	(54)	(745)	(558)	(400)
Other	5,595	16,991	(26,658)	9,135	0
Investing Activities	\$ 4,552	\$ 16,469	\$ (27,729)	\$ 8,097	\$ (900)
Debt	(700)	(354)	49	(596)	0
Equity	10,616	50	50,826	300	20,300
Other	0	0	0	0	0
Financing Activities	\$ 9,916	\$ (304)	\$ 50,875	\$ (296)	\$ 20,300
Change in Cash	(\$120)	\$ 544	\$ 307	(\$24,311)	(\$5,918)

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
- Update – Buy – February 16, 2022 – Price Target \$8.50
- Update – Buy – February 24, 2022 – Price Target \$8.50
- Update – Buy – March 4, 2022 – Price Target \$8.50
- Update – Buy – May 2, 2022 – Price Target \$8.50
- Update – Buy – May 6, 2022 – Price Target \$8.50
- Update – Buy – May 16, 2022 – Price Target \$8.50
- Update – Buy – June 13, 2022 – Price Target \$8.50

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- 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.
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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 16-May-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	72%	4	13%
Market Perform (Neutral)	12	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	43	100%	4	9%

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