

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

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Buy: Recent FDA Action Bodes Well for XXII

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We believe the FDA's recent approval authorizing marketing of three new tobacco electronic nicotine delivery system (ENDS) products and the potential nomination of a new FDA commissioner who has publicly supported a low-nicotine mandate are positive signs for 22nd Century. The company is scheduled to present at the Dawson James conference this week.

We believe the FDA's authorization, last week, permitting marketing of R.J. Reynolds' Vuse Solo ENDS device bodes well for 22nd Century's MRTP application currently pending at the FDA. The FDA's [comprehensive regulatory plan](#) for tobacco and nicotine regulation, announced in 2017, 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, would also benefit public health by offering an alternative for smokers seeking to quit and this could weigh heavily in the FDA's decision.

It was [reported](#) the FDA's decision to allow some vaping devices could make it easier to impose additional regulations on the industry, including a low-nicotine mandate, that was initially explored in a [Notice of Proposed Rulemaking](#) in 2018. Approval of the company's MRTP and a re-initiation of a process for a low-nicotine mandate would be, in our view, significant catalysts for the shares.

Multiple news outlets reported President Biden is ready to nominate former FDA Commissioner Robert Califf to lead the FDA. The agency has been led by acting commissioner Janet Woodcock since January of this year and federal law requires the President to nominate a permanent commissioner by mid-November. We believe Senate approval of Mr. Califf's potential nomination could be positive for 22nd Century. In a virtual event last March, that included Mr. Califf, he endorsed a nicotine mandate. (See the discussion beginning around minute 23: [Virtual Event Four former FDA commissioners discuss the agency's future](#)).

The company is scheduled to present at the Dawson James conference this week and we expect it to address these issues, other catalysts and the company's initiatives in hemp and hops.

Valuation: Our \$7 price target is the sum of: \$3.08/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 approval of the company's MRTP application and a nicotine mandate, which could be delayed or may not be approved. Finding a partner for the VLN business could take longer than estimated and/or on different terms than assumed. 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	\$2.90		
Price Target	\$7.00		
Estimates	F2020A	F2021E	F2022E
Revenues (\$000s)	\$ 28,111	\$ 33,177 E	\$ 37,300
1Q March	\$ 7,058	\$ 6,806 A	\$ 10,000
2Q June	\$ 6,435	\$ 8,371 A	\$ 8,400
3Q September	\$ 7,310	\$ 8,000 E	\$ 8,400
4Q December	\$ 7,308	\$ 10,000 E	\$ 10,500
	F2020A	F2021E	F2022E
EPS (diluted)	\$ (0.14)	\$ (0.13)E	\$ (0.15)
1Q March	\$ (0.03)	\$ (0.03)A	\$ (0.04)
2Q June	\$ (0.04)	\$ (0.03)A	\$ (0.04)
3Q September	\$ (0.03)	\$ (0.04)E	\$ (0.04)
4Q December	\$ (0.05)	\$ (0.03)E	\$ (0.03)
EBITDA (\$Ms)	\$ (16.0)	\$ (18.1)	\$ (19.4)
EV/EBITDA (x)	-25.8x	-22.9x	-21.3x
Stock Data			
52-Week Range	\$0.68	-	\$6.07
Shares Outstanding (mil.)	162.7		
Market Capitalization (mil.)	\$472		
Enterprise Value (mil.)	\$413		
Debt to Capital	4%		
Book Value/Share	\$0.54		
Price/Book	5.4x		
Average Three Months Trading Volume (K)	4,720		
Insider Ownership	2.3%		
Institutional Ownership	35.3%		
Short interest (mil.)	5.6%		
Dividend / Yield	\$0.00/0.0%		



Senate approval for President Biden's nominations have averaged 69 days for Cabinet secretaries, 93 days for deputy secretaries and 75 days for administrators of agencies. (Source: [Biden Political Appointee Tracker](#)). A nomination by the end of October would likely put approval by year-end or early next year. However, holidays, pending legislation and unforeseen circumstances could impact the time to approval. We think a low-nicotine mandate is more likely to be proposed with a permanent commissioner, while MRTP, like the marketing orders discussed above, do not require a permanent commissioner to move forward.

We believe approval of the company's MRTP application will be a significant catalyst for the shares. The company has confidence the application will be approved soon and has announced the FDA is in the document preparation stage. There is still risk of a negative outcome, or further delays, but we continue to expect approval this year. 22nd Century is ready to launch pilot programs within 90 days of approval and a more substantial launch after evaluation of the pilot results and modification of the strategy. We have assumed meaningful domestic VLN revenue begins in Q4 22 and view this as quite conservative.

In Q4, we expect a license payment from the IP it shares with Aurora Cannabis (NASDAQ: ACB, \$7.03, Not Rated). Aurora and 22nd Century Group share the global intellectual property (IP) rights to certain patents and patent applications relating to genes in the hemp/cannabis plant required for the production of cannabinoids in the cannabis plant. The two are working closely together to enforce their IP against infringing parties and explore commercial development opportunities. Additional revenue in 2022 from this initiative appears likely.

Revenue from the harvest of the company's hemp crop is anticipated in Q4 of this year, but, depending on timing and delivery, could be pushed to the right. We have assumed revenue recognition in Q1 22. 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 Panacea 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.

International distribution of VLN in select international markets is expected to begin in Q1 of next year. This will likely occur in locations that have less strict regulatory frameworks than the U.S. but still have substantial tobacco markets. After expected approval of the MRTP application, the company intends to expand its international footprint, particularly in markets that follow the U.S. regulatory lead. We have assumed modest contributions from this endeavor and believe there is ample room for upside to our estimates.

As next steps progress, we expect additional efforts to license, in conjunction with Aurora, the legacy Anandia technology, and develop new strains of hemp utilizing the partnerships described above. Both of these initiatives are likely to generate revenue next year, in our view, but given the timing and scope, we have not included meaningful amounts in our model.

The low-nicotine mandate, in our opinion, remains a major catalyst for the shares. 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.

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.

Price Target. Our price target of \$7 comprises three components: We attribute about \$3.08/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 Panacea, 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 investment could be catalysts to more rapid development of the market and 22nd Century's monetization efforts.

Risk Analysis

The tobacco industry is highly regulated, and our price target depends on approval of the company's MRTP application and a nicotine mandate, which could be delayed or may not be approved. Our price target assumes the company will find a partner for the VLN business and this could take longer than estimated and/or the partner could demand different terms than assumed. 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

(\$ in 000's except per-share data)	2018	2019	2020	Q1 21 A	Q2 21 A	Q3 21 E	Q4 21 E	2021 E	2022 E
Revenue	\$ 26,426	\$ 25,833	\$ 28,111	\$ 6,806	\$ 8,371	\$ 8,000	\$ 10,000	\$ 33,177	\$ 37,300
Cost Of Goods Sold	25,527	25,818	26,673	6,159	7,785	7,360	7,360	28,664	32,040
Gross Profit	899	14	1,438	647	586	640	2,640	4,513	5,260
	3.4%	0.1%	5.1%						
R&D	14,990	8,057	4,128	701	746	1,000	1,000	3,447	4,000
G&A	7,658	12,956	14,971	4,829	6,177	6,177	6,177	23,360	25,638
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	303	303	1,197	1,212
Opex	24,918	23,581	20,621	5,818	7,226	7,480	7,480	28,004	30,850
Operating Income	\$ (24,019)	\$ (23,566)	\$ (19,183)	\$ (5,171)	\$ (6,640)	\$ (6,840)	\$ (4,840)	\$ (23,491)	\$ (25,590)
Other	14,945	(4,002)	(428)	36	2,372	0	0	2,408	0
Impairment Charge	49	0	(1,741)	0	0	0	0	0	0
Interest Income	1,069	1,066	1,751	112	108	312	283	815	897
Interest Expense	(11)	(56)	(72)	(7)	(14)	(14)	(14)	(49)	(56)
Pretax Income	(7,967)	(26,559)	(19,673)	(5,030)	(4,174)	(6,542)	(4,571)	(20,317)	(24,749)
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)	\$ (6,542)	\$ (4,571)	\$ (20,317)	\$ (24,749)
Shares (000)	124,299	125,883	138,813	144,258	154,811	162,710	162,985	156,191	163,798
EPS	(\$0.06)	(\$0.21)	(\$0.14)	(\$0.03)	(\$0.03)	(\$0.04)	(\$0.03)	(\$0.13)	(\$0.15)
D&A	1,200	1,425	1,346	288	302	302	302	1,194	1,208
Stock Comp	3,187	3,540	1,654	507	1,245	1,245	1,245	4,242	4,980
Other	0	1,142	176	0	0	0	0	0	0
EBITDA	\$ (19,632)	\$ (17,459)	\$ (16,007)	\$ (4,376)	\$ (5,093)	\$ (5,293)	\$ (3,293)	\$ (18,055)	\$ (19,402)

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

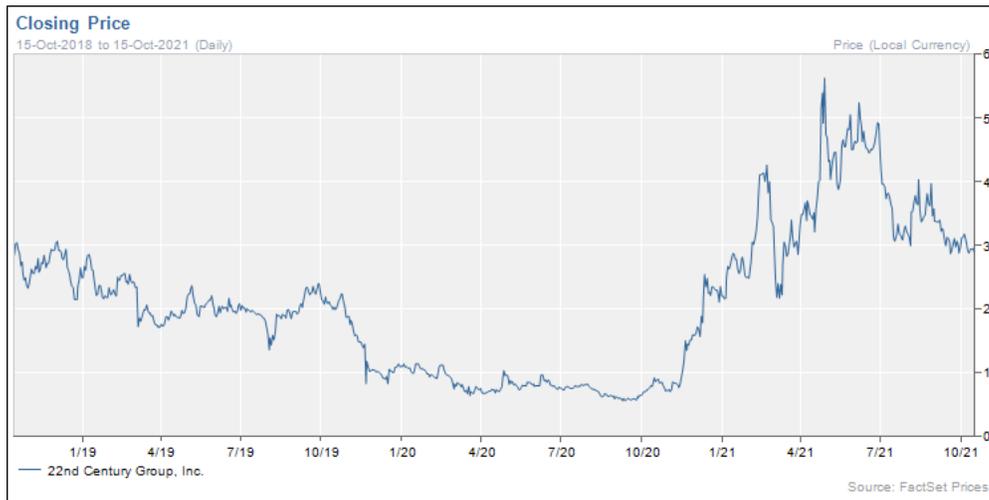
Exhibit 2. Balance Sheet and Cash Flow Statement

(\$ in 000's)	2018	2019	2020	2021 E	2022 E
Cash	605	485	1,029	2,037	2,037
Short-Term Investments	55,749	38,477	21,313	50,354	30,093
A/R	871	867	2,159	3,288	4,027
Inventory	3,044	2,266	2,034	2,823	3,283
Prepaid Exp.	928	648	1,806	3,943	3,943
Total Current Assets	\$ 61,198	\$ 42,743	\$ 28,341	\$ 62,445	\$ 43,383
PP&E	3,261	3,120	2,483	4,747	4,547
Operating Lease	0	602	247	595	595
Patent, Trademark, other intangibles	9,752	8,494	8,211	8,065	7,957
Equity Investment	3,092	8,403	6,536	9,200	9,200
Convertible Note Receivable	0	5,589	5,876	3,684	3,684
Total Assets	\$ 77,302	\$ 68,951	\$ 51,694	\$ 88,736	\$ 69,366
Bank Loans and N/P	689	581	539	2,659	2,659
Operating Lease	0	220	247	174	174
A/P	2,575	1,998	1,116	981	981
Accrued Expenses	1,826	2,619	4,830	5,072	5,072
Accrued Severance	0	359	339	212	212
Deferred Income	83	5	272	145	145
Total Current Liabilities	\$ 5,174	\$ 5,780	\$ 7,343	\$ 9,243	\$ 9,243
Long-Term Debt	848	292	0	0	0
Operating Lease	0	382	0	423	423
Accrued Severance	0	446	241	130	130
Shareholders' Equity	71,280	62,051	44,110	78,940	59,570
Total Liabilities And Equity	\$ 77,302	\$ 68,951	\$ 51,694	\$ 88,736	\$ 69,366
	2018	2019	2020	2021 E	2022 E
Net Income	(7,967)	(26,559)	(19,711)	(20,317)	(24,749)
Depreciation & Amort.	1,200	1,425	1,345	1,194	1,208
Stock Comp	3,187	3,540	1,654	4,242	4,980
Other	(14,618)	7,249	2,722	(2,340)	0
Working Capital	354	(242)	(1,631)	(4,729)	(1,200)
Operating Cash Flow	\$ (17,844)	\$ (14,587)	\$ (15,621)	\$ (21,950)	\$ (19,761)
Acquisition of Patents and trademarks	(657)	(515)	(468)	(429)	(500)
CapEx	(449)	(527)	(54)	(588)	(400)
Other	16,251	5,595	16,991	(39,100)	0
Investing Activities	\$ 15,145	\$ 4,552	\$ 16,469	\$ (40,117)	\$ (900)
Debt	(800)	(700)	(354)	2,115	0
Equity	445	10,616	50	51,030	400
Other	0	0	0	0	0
Financing Activities	\$ (355)	\$ 9,916	\$ (304)	\$ 53,145	\$ 400
Change in Cash	(\$3,055)	(\$120)	\$ 544	(\$8,922)	(\$20,261)

 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

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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.
- 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.

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Current as of 10/15/21	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	4	16%
Market Perform (Neutral)	11	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	4	11%

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