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

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Buy: FDA Approves 22nd Century MRTP Application.

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The FDA approved 22nd Century's Modified Risk Tobacco Product (MRTP) application. The agency approved all of the company's requested claims AND requires the added claim "Helps you smoke less." We believe this will help the company attract distribution and product partners and is very bullish for the shares. We reiterate our Buy recommendation and \$7 price target.

The FDA approved 22nd Century's MRTP application allowing the company to claim on its packaging for VLN King and VLN Menthol King, the product contains "95% less nicotine," the product "Helps reduce your nicotine consumption," and 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 also believe the claim, "Helps you smoke less," will better position the company to partner with smoking cessation products, and possibly accelerate revenue growth.

We continue to believe this is the first step in the agency's goal to reduce the harm to consumers from smoking. We think it is likely the FDA will revive its low-nicotine mandate sometime in the 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.

Other catalysts are expected in the coming months. We expect a launch of VLN in the U.S. within 90 days. Validation of the company's product by well-known chains, we believe, will be perceived positively by the market. We also expect a launch of VLN in international markets, including several in Asia and a test market in Europe. Our valuation includes zero contribution from international markets, suggesting upside to our target if the company is successful in the U.S. and international markets.

Valuation: Our \$7 price target is the sum of: An estimated \$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 the company will find a partner for the VLN business, post MRTP approval, and this could take longer than estimated and/or the 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	\$2.83		
Price Target	\$7.00		
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)	-25.5x	-19.6x	-19.6x
Stock Data			
52-Week Range	\$1.86	-	\$6.07
Shares Outstanding (mil.)	162.7		
Market Capitalization (mil.)	\$461		
Enterprise Value (mil.)	\$408		
Debt to Capital	0%		
Cash (mil.)	\$55.2		
Cash/share	\$0.34		
Average Three Months Trading Volume (K)	1,041		
Insider Ownership	2.3%		
Institutional Ownership	34.8%		
Short interest (mil.)	5.0%		
Dividend / Yield	\$0.00/0.0%		



22nd Century is also in strategic discussions with potential 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.

Earlier this month, Aurora Cannabis Inc. and 22nd Century Group, Inc. 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.

Revenue from the harvest of the company's hemp crop is expected this quarter or next, depending on delivery to the customer. 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.

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. Initial sales of a hemp harvest is expected in Q4 this year and extend into Q1 of next year. VLN is being prepared for launch in several international markets and in the U.S. post MRTTP approval. We expect the license agreement with Cronos will result in revenue this quarter or next, depending on the terms of the agreement. Over the longer-term the company's discussion with potential pharma partners could be another significant source of revenue.

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, would also benefit public health by offering an alternative for smokers seeking to quit and this could weigh heavily in the FDA's decision.

22nd Century is ready to launch pilot programs within 90 days of approval of the MTRP 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 2022 and view this as quite conservative.

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. The company is

focusing on several markets in Asia, has plans to open a branch in New Zealand, and is exploring a test market in Europe. We have assumed modest revenue contributions from this endeavor, believe there is ample room for upside to our estimates and have not included this in our price target.

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 assumes the company will find a partner for the VLN business, post MRTP approval, and this could take longer than estimated and/or the 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%			
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

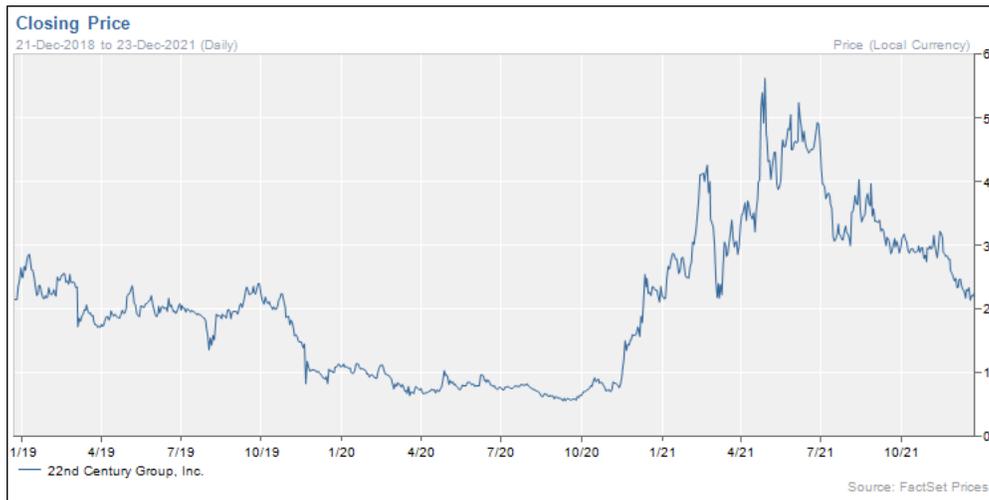
Exhibit 2. Balance Sheet and Cash Flow Statement

(\$ 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

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- 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... 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%

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