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

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Buy: Q3 Results. Reiterate Buy and \$7 Target.

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Q3 revenue was modestly lower than our estimate and increased expenses resulted in an EBITDA loss slightly more than we projected. Our focus remains the MRTTP pending at the FDA, a potential low-nicotine mandate, and revenue from the company's hemp franchise beginning this year and growing next year. We expect multiple catalysts over the coming months and reiterate our Buy recommendation and \$7 price target.

Q3 revenue of \$7.8 million was a bit shy of our \$8 million estimate and higher than forecast expenses resulted in an EBITDA loss of \$6.1 million versus our estimate of a \$5.3 million loss. Cash at quarter end was \$55 million and the company had an additional \$7.3 million in equity of Panacea Life Sciences, providing ample liquidity for the next two years.

We believe FDA approval of the company's MRTTP application for its very-low nicotine (VLN) cigarettes is the most likely significant catalyst for the shares. The company's recent discussions with the agency gives it increased confidence of approval. Timing is still uncertain, however recent approval authorizing marketing of [three new tobacco electronic nicotine delivery system](#) (ENDS) products from R.J. Reynolds and [four new oral tobacco products](#) from U.S. Smokeless Tobacco Company LLC, and the potential nomination of a new FDA commissioner who has publicly supported a very-low-nicotine mandate are positive signs for 22nd Century. We believe an MRTTP approval is likely before year-end.

The company expects to launch VLN in the US within 90 days of MRTTP approval and international launch preparation for VLN continues for several markets in Asia and a test market in Europe. We believe these are additional catalysts for the shares.

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. The company is in the initial stages of discussion, but this could be a significant source of value over time.

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 MRTTP 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				\$2.94
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)	-26.6x	-20.4x	-20.5x	
Stock Data				
52-Week Range	\$0.75	-	\$6.07	
Shares Outstanding (mil.)				162.7
Market Capitalization (mil.)				\$478
Enterprise Value (mil.)				\$426
Debt to Capital				3%
Book Value/Share				\$0.49
Price/Book				6.1x
Average Three Months Trading Volume (K)				964
Insider Ownership				2.3%
Institutional Ownership				35.4%
Short interest (mil.)				5.2%
Dividend / Yield				\$0.00/0.0%



Q3 Results
22nd Century Q3 21 Actual v Estimates
 (\$ in 000's, except per share data)

Q3 21	Actual	Estimates	
Revenue	\$ 7,811	\$ 8,000	-2.4%
Cost Of Goods Sold	7,362	7,360	0.0%
Gross Profit	449	640	-29.8%
	5.7%	8.0%	
R&D	856	1,000	-14.4%
G&A	6,821	6,177	10.4%
Depreciation & Amort.	341	303	12.5%
Opex	8,018	7,480	7.2%
Operating Income	\$ (7,569)	\$ (6,840)	-10.7%
Other	(1,900)	0	
Warrant Charge	0	0	
Interest Income	52	312	
Interest Expense	(23)	(14)	
Pretax Income	(9,440)	(6,542)	
Income Tax Expense	0	0	
Net to Common	\$ (9,440)	\$ (6,542)	
Shares (000)	162,721	162,710	
EPS	\$ (0.06)	\$ (0.04)	
D&A	342	302	
Stock Comp	1,119	1,245	
EBITDA	(6,108)	(5,293)	

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

Revenue is primarily generated from contract manufacturing of filtered cigars and cigarettes, and we expect this to remain the case through 2022. However, beginning this quarter revenue from multiple new revenue streams are expected to begin. Initial sales of a hemp harvest will begin 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 MRTP approval. License revenue on the IP the company shares with Aurora Cannabis is expected to begin this year. 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, 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 22 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 contributions from this endeavor and believe there is ample room for upside to our estimates.

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.

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. 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.

In Q4, we also expect a license payment from the IP it shares with Aurora Cannabis. 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.

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

<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

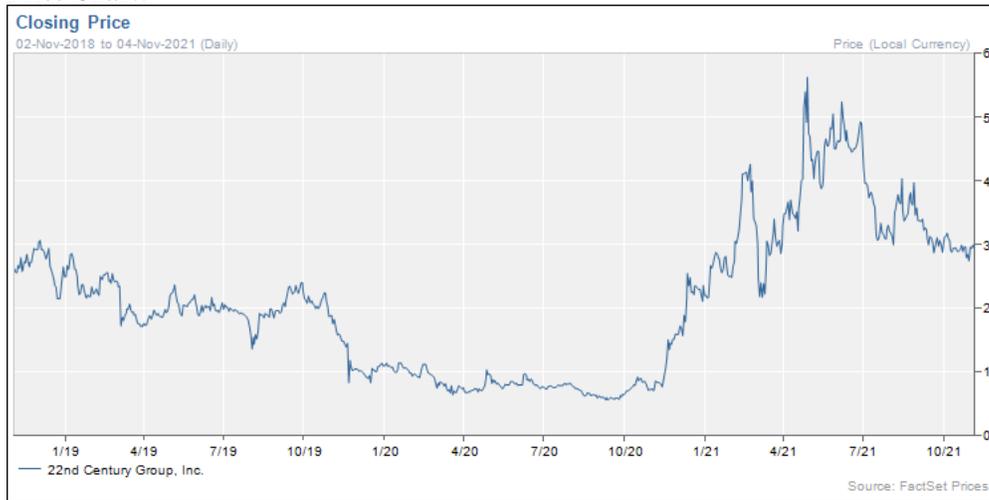
Exhibit 2. Balance Sheet and Cash Flow Statement

(\$ 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

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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.

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 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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