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

February 16, 2022

Buy: Dr. Califf Approved by Senate.
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The United States Senate approved Dr. Robert Califf as the commissioner of the FDA. We believe a Senate-approved commissioner will empower the agency to move forward on sensitive policies including a menthol ban and a low-nicotine mandate.

The United States Senate approved Dr. Robert Califf as the next commissioner of the Food and Drug Administration (FDA). This is Dr. Califf's second term as FDA commissioner, the first during the final year of President Obama's term in 2016. We believe this is positive news for 22nd Century. In our view, a Senate-approved commissioner is necessary for the FDA to move forward on a low-nicotine mandate which is key value driver for the company.

Dr. Califf will need to replace the Director of the Center for Tobacco Products (CTP) when current director Mitch Zeller retires in April. The CTP will shepherd a low-nicotine mandate if proposed, as we expect, this year. A low-nicotine mandate was initially explored in 2017 by the FDA, shortly after Dr. Califf resigned as commissioner of the FDA, and resulted in 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 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	\$2.48		
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)	-21.9x	-16.8x	-16.9x
Stock Data			
52-Week Range	\$1.86	-	\$6.07
Shares Outstanding (mil.)			162.7
Market Capitalization (mil.)			\$404
Enterprise Value (mil.)			\$351
Debt to Capital			0%
Cash (mil.)			\$55.2
Cash/share			\$0.34
Average Three Months Trading Volume (K)			4,712
Insider Ownership			2.3%
Institutional Ownership			28.2%
Short interest (mil.)			9.0%
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.

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

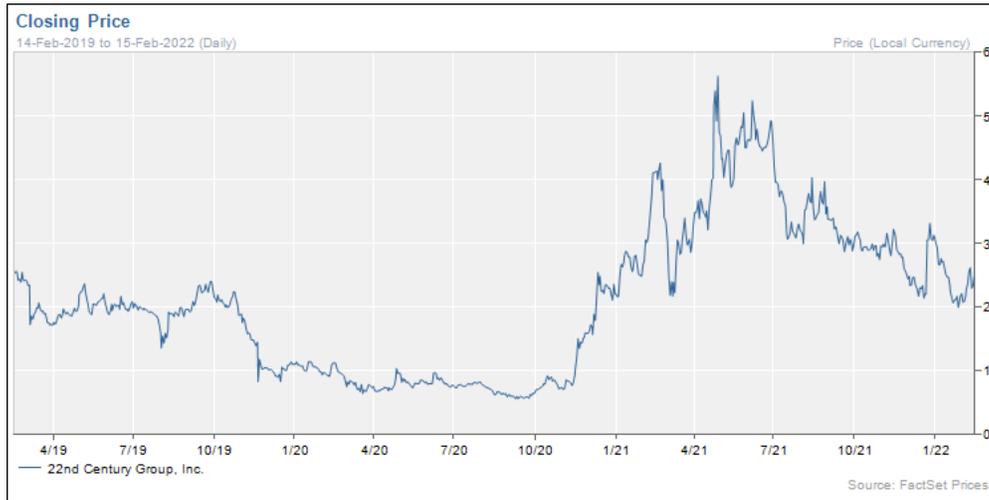
Exhibit 2. Balance Sheet and Cash Flow Statement

(\$ 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
- Update – Buy – February 16, 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.
- 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... 8-Feb-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	76%	6	19%
Market Perform (Neutral)	10	24%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	41	100%	6	15%

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