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

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BUY: Expect Multiple Catalysts this Year

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The New Zealand Ministry of Health has proposed multiple actions to achieve its Smokefree 2025 goal, including reducing nicotine in cigarettes to minimal levels. We view this announcement as very positive for 22nd Century.

Smokefree 2025 Action Plan: The New Zealand Ministry of Health released a Smokefree 2025 Action plan (<https://www.health.govt.nz/publication/proposals-smokefree-aotearoa-2025-action-plan>) to “reduce smoking prevalence and tobacco availability to minimal levels, essentially making Aotearoa New Zealand smokefree by 2025.” The plan includes a low-nicotine mandate.

Comments Due May 31. The closing date for public comments is May 31, 2021. The Ministry of Health will analyze the feedback and then draft an action plan, which will be considered by the Cabinet of New Zealand.

A U.S. Low-Nicotine Mandate. The FDA began an Advanced Notice of Proposed Rulemaking (ANPRM) in 2018 that would have required non-addictive nicotine levels in combustible cigarettes. A change in regulatory policy by the federal government and the resignation of the FDA commissioner could have been key factors in the initiative not moving forward, but we believe the goal is still alive and a new administration could revive the mandate in the coming quarters. In our opinion, the New Zealand proposal suggests the low-nicotine mandate can gather momentum globally.

Valuation: Our \$7 price target is the sum of the estimated values of the VLN, non-addictive nicotine and hemp franchises. 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 comprises the investment in the hemp business and its relationship with KeyGene.

Risks to Target: 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 and market share.

Current Price	\$3.41		
Price Target	\$7.00		
Estimates	F2020A	F2021E	F2022E
Revenues (\$000s)	\$ 28,111	\$ 29,000	\$ 30,000
1Q March	\$ 7,058	\$ 7,250	\$ 7,500
2Q June	\$ 6,435	\$ 7,250	\$ 7,500
3Q September	\$ 7,310	\$ 7,250	\$ 7,500
4Q December	\$ 7,308	\$ 7,250	\$ 7,500
	F2020A	F2021E	F2022E
EPS (diluted)	\$ (0.14)	\$ (0.12)	\$ (0.12)
1Q March	\$ (0.03)	\$ (0.03)	\$ (0.03)
2Q June	\$ (0.04)	\$ (0.03)	\$ (0.03)
3Q September	\$ (0.03)	\$ (0.03)	\$ (0.03)
4Q December	\$ (0.05)	\$ (0.04)	\$ (0.04)
EBITDA (\$Ms)	\$ (16.0)	\$ (16.2)	\$ (16.3)
EV/EBITDA (x)	-30.6x	-30.2x	-30.1x
Stock Data			
52-Week Range	\$0.55	-	\$4.66
Shares Outstanding (mil.)	152.4		
Market Capitalization (mil.)	\$520		
Enterprise Value (mil.)	\$490		
Debt to Capital	2%		
Book Value/Share	\$0.32		
Price/Book	10.8x		
Average Three Months Trading Volume (K)	2,738		
Insider Ownership	2.0%		
Institutional Ownership	24.7%		
Short interest (mil.)	4.9%		
Dividend / Yield	\$0.00/0.0%		



The Low-Nic Mandate

The New Zealand 2025 action plan proposes to strengthen the tobacco control system, make smoked tobacco products less available to the public by reducing the number of tobacco retailers, make smoked products less addictive by lowering nicotine levels in cigarettes, increase the price of tobacco and increase investments in media campaigns and smoking cessation services.

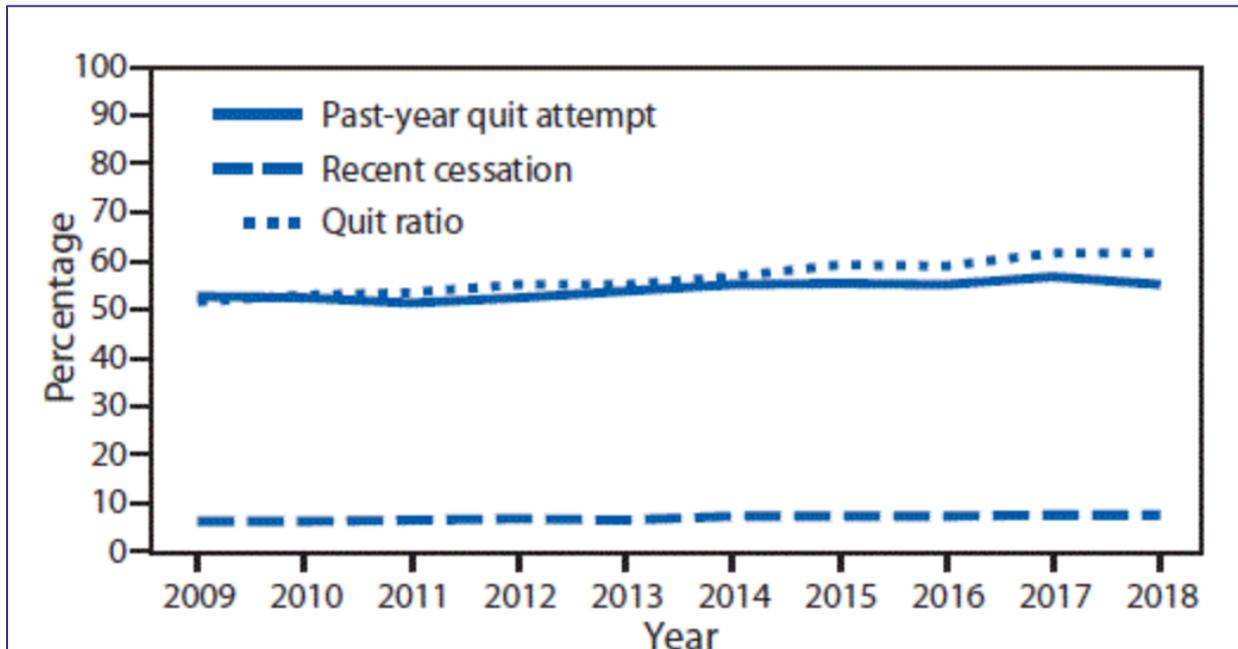
We believe there are few economic options to reducing nicotine levels in cigarettes and 22nd Century’s technology is the most cost-effective and efficient way to achieve this goal.

In our view, New Zealand’s action will not directly drive the FDA to revive its low-nicotine mandate, but it does show regulatory agencies are looking at additional ways to lower the incidence of smoking. We continue to believe the FDA will revive its proposal for a low-nicotine mandate, but probably after an FDA Commissioner is nominated by the President and then approved by the Senate.

Our valuation for 22nd Century is driven solely by the U.S. market. We have not included projections on additional markets but believe the company’s technology is suited for deployment in markets outside the U.S. The proposal by New Zealand could be the leading edge of additional actions by other regulatory agencies and this, in our opinion, is positive for 22nd Century.

Valuing VLN

According to the CDC, “based on 2019 data, about 34 million US adults smoke cigarettes,” (<https://www.cdc.gov/tobacco/about/osh/index.htm>) and about two-thirds would like to quit (Stephen Babb, MPH; Ann Malarcher, PhD; Gillian Schauer, PhD; Kat Asman, MSPH; Ahmed Jamal, MBBS, January 6, 2017, “Quitting Smoking Among Adults — United States, 2000–2015,” Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Vol. 65 / No. 52), with more than half making some attempt to quit in the past 12 months. The ratio of smokers making some quit attempt in the past year has remained fairly stable over the past ten years.



Source: CDC. Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018

The Federal Trade Commission Cigarette Report for 2018 reports 216.9 billion cigarette sticks were sold in the U.S. in 2018. At 20 cigarettes per pack and 34 million smokers, this equals daily consumption of about 0.87 packs per day. However, the impact of the very-low-nicotine-content (VLNC) cigarette is a reduction in consumption. From 22nd Century’s TPSAC Briefing Document:

independent studies of VLNC cigarettes show that daily smokers gradually reduced their cigarette consumption by as much as 50% over 20 weeks of use. (see Hatsukami, 2018; Donny, 2015). Such studies also showed that non-daily smokers reduced their cigarette consumption after extended use of VLNC cigarettes. (Shiffman, 2018).

According to the CDC, in 2010, there were 45.4 million smokers in the U.S. Over the subsequent 10 years, the number of smokers in the U.S. declined at a 2.8% compound annual rate. If that rate continues, by 2025, the number of smokers will have declined to about 29.7 million. Assuming 50% try to quit in a year, the number of smokers who are likely customers of a VLN cigarette are approximately 14.8 million smoking 0.44 packs per day or 2.4 billion packs per year. If we assume prices rise 5% annually from the current \$3/pack rate to \$3.83 per pack, that is a potential addressable revenue (before excise taxes) of \$9.1 billion.

A modest market share would result in substantial value for the company. Currently, tobacco company stocks trade around 5x forward 12-month sales estimates (Source: FactSet consensus estimates). At this multiple, and a 3% market share of the smokers who attempt to quit (about 1.5% of the total market), the value of the VLN franchise, in 2025, would be worth close to \$1.4 billion, in our estimation. We believe a take-over would be at higher multiples due to the synergies available. Still assuming a 3% market share of the smokers who attempt to quit (1.5% of the total market), the VLN franchise in 2025 would be valued at close to \$2.0 billion if instead we capitalized sales at 7x.

Potential VLN Franchise Values

Market Share of Quitters	3x sales	5x sales	7x sales
0.5%	\$ 137M	\$ 228M	\$ 319M
1.0%	\$ 274M	\$ 456M	\$ 639M
2.0%	\$ 547M	\$ 912M	\$ 1,277M
3.0%	\$ 821M	\$ 1,368M	\$ 1,916M

Source: Dawson James Securities estimates

If the company seeks a partner to achieve these market share estimates, we think that the values above should be reduced by 30% to 50% to reflect the partner's interest. The discounted per-share value of the VLN franchise based on 5x to 7x sales in 2025E, using a 20% discount rate, 3% market share estimate and a 30% interest for a potential partner, is, at the midpoint, \$3.08 per share.

Valuing a Low-Nicotine Mandate

The ANPRM has not turned into an NPRM, yet, but we believe it is still possible in the next 12 months. A new administration could be more willing to impose greater restrictions on nicotine in the pursuit of public health. We also believe the FDA is being careful in building a record to withstand the challenges a low-nicotine mandate is likely to encounter and part of that could be the approval of 22nd Century's MRTP. One of the stated objections to the mandate is it would be impossible to comply since the technology does not exist. Marketing of a VLN cigarette would obviate that argument.

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 cost to comply with a mandate has been discussed publicly. For instance, 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 is 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. Using Mr. Lutz's estimate of time and money required, we believe the opportunity for 22nd Century is large.

If the FDA mandates a non-addictive level of nicotine, we expect the company to pursue a royalty and license model for its technology in addition to marketing a VLN brand on its own. The following table is based on a successful royalty/licensing model in the U.S. There are about 10 billion packs of cigarettes sold in the U.S. annually (Altira Group 2020 10K based on 20 sticks/pack) and we estimate this will decline by 2.8% annually over the next five years. We assume a 5% market share and \$0.10 per pack royalty. The table shows per-share discounted values based on different discount rates and revenue multiples. The mean of these estimates is \$3.18 per share.

Potential Non-Addictive Nicotine Franchise Values

Per share Value: \$0.10/pack royalty; 5% share		Discount Rate	
		15%	20%
Revenue multiple	20x	\$ 3.12	\$ 2.52
	25x	\$ 3.90	\$ 3.16

Source: Dawson James Securities estimates

This is not a straight shot for the company. The big tobacco companies will likely resist a mandate, try to push it to the right as far as possible, seek out the lowest-cost solution to comply and continue developing other nicotine delivery systems like IQOS.

The timeline for a mandate is probably 3-5 years. An NPRM will probably take 12-24 months from release to rulemaking and an additional 24- to 36-month transition time.

For now, we are valuing the CBD and KeyGene opportunities at \$100 million, or \$0.67 per share.

Price Target

Our \$7 price target is the sum of the estimated values of the VLN, non-addictive nicotine and hemp franchises. 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 comprises the investment in the hemp business and the relationship with KeyGene.

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 000s, except per-share data)

	2018	2019	2020	Q1 21 E	Q2 21 E	Q3 21 E	Q4 21 E	2021 E	2022 E
Revenue	\$ 26,426	\$ 25,833	\$ 28,111	\$ 7,250	\$ 7,250	\$ 7,250	\$ 7,250	\$ 29,000	\$ 30,000
Cost Of Goods Sold	25,527	25,818	26,673	6,720	6,720	6,720	6,720	26,880	27,000
Gross Profit	899	14	1,438	530	530	530	530	2,120	3,000
R&D	14,990	8,057	4,128	1,250	1,250	1,250	1,250	5,000	5,250
G&A	7,658	12,956	14,971	3,298	3,298	3,298	5,418	15,312	16,078
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	349	349	349	349	1,396	1,396
Opex	24,918	23,581	20,621	4,897	4,897	4,897	7,017	21,708	22,724
Operating Income	\$ (24,019)	\$ (23,566)	\$ (19,183)	\$ (4,367)	\$ (4,367)	\$ (4,367)	\$ (6,487)	\$ (19,588)	\$ (19,724)
Other	14,945	(4,002)	(428)	0	0	0	0	0	0
Impairment Charge	49	0	(1,741)	0	0	0	0	0	0
Interest Income	1,069	1,066	1,751	223	307	274	240	1,044	538
Interest Expense	(11)	(56)	(72)	(18)	(18)	(18)	(18)	(72)	(72)
Pretax Income	(7,967)	(26,559)	(19,673)	(4,162)	(4,079)	(4,111)	(6,265)	(18,616)	(19,258)
Income Tax Expense	0	0	38	0	0	0	0	0	0
Net to Common	\$ (7,967)	\$ (26,559)	\$ (19,711)	\$ (4,162)	\$ (4,079)	\$ (4,111)	\$ (6,265)	\$ (18,616)	\$ (19,258)
Shares (000)	124,299	125,883	138,813	145,730	152,648	153,148	153,648	151,293	154,460
EPS	(\$0.06)	(\$0.21)	(\$0.14)	(\$0.03)	(\$0.03)	(\$0.03)	(\$0.04)	(\$0.12)	(\$0.12)
D&A	1,200	1,425	1,346	348	348	348	348	1,392	1,392
Stock Comp	3,187	3,540	1,654	492	492	492	492	1,968	2,066
Other	0	1,142	176	0	0	0	0	0	0
EBITDA	\$ (19,632)	\$ (17,459)	\$ (16,007)	\$ (3,527)	\$ (3,527)	\$ (3,527)	\$ (5,647)	\$ (16,228)	\$ (16,265)

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

Exhibit 2. Balance Sheet and Cash Flow Statement

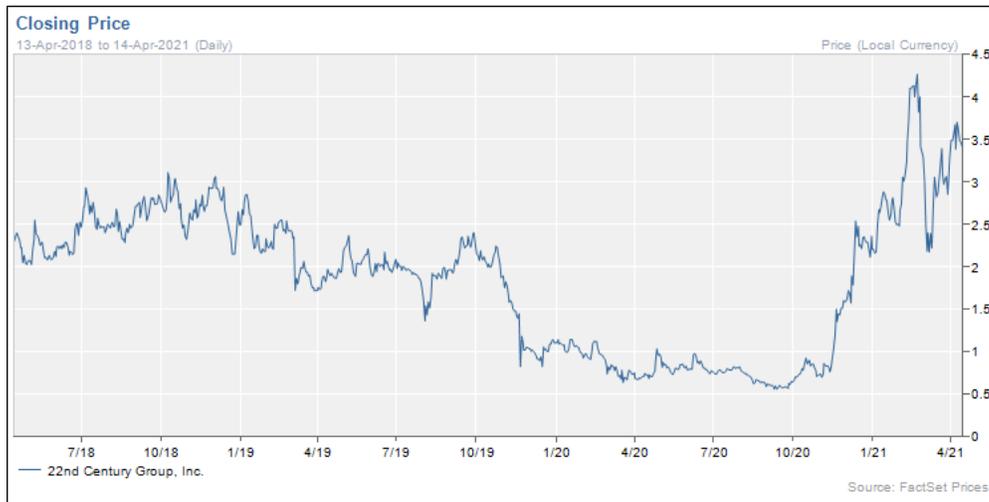
(\$ in 000s)

	2018	2019	2020	2021 E	2022 E
Cash	605	485	1,029	1,029	1,029
Short-Term Investments	55,749	38,477	21,313	17,540	1,540
A/R	871	867	2,159	2,159	2,159
Inventory	3,044	2,266	2,034	2,034	2,034
Prepaid Exp.	928	648	1,806	1,806	1,806
Total Current Assets	\$ 61,198	\$ 42,743	\$ 28,341	\$ 24,568	\$ 8,568
PP&E	3,261	3,120	2,483	1,723	963
Operating Lease	0	602	247	247	247
Patent, Trademark, other intangibles	9,752	8,494	8,211	8,179	8,147
Equity Investment	3,092	8,403	6,536	6,536	6,536
Convertible Note Receivable	0	5,589	5,876	5,876	5,876
Total Assets	\$ 77,302	\$ 68,951	\$ 51,694	\$ 47,129	\$ 30,337
Bank Loans and N/P	689	581	539	539	539
Operating Lease	0	220	247	247	247
A/P	2,575	1,998	1,116	1,116	1,116
Accrued Expenses	1,826	2,619	4,830	4,830	4,830
Accrued Severance	0	359	339	339	339
Deferred Income	83	5	272	272	272
Total Current Liabilities	\$ 5,174	\$ 5,780	\$ 7,343	\$ 7,343	\$ 7,343
Long-Term Debt	848	292	0	0	0
Operating Lease	0	382	0	0	0
Accrued Severance	0	446	241	241	241
Shareholders' Equity	71,280	62,051	44,110	39,545	22,753
Total Liabilities And Equity	\$ 77,302	\$ 68,951	\$ 51,694	\$ 47,129	\$ 30,337
	2018	2019	2020	2021 E	2022 E
Net Income	(7,967)	(26,559)	(19,711)	(18,616)	(19,258)
Depreciation & Amort.	1,200	1,425	1,345	1,392	1,392
Stock Comp	3,187	3,540	1,654	1,968	2,066
Other	(14,618)	7,249	2,722	0	0
Working Capital	354	(242)	(1,631)	0	0
Operating Cash Flow	\$ (17,844)	\$ (14,587)	\$ (15,621)	\$ (15,256)	\$ (15,799)
Acquisition of Patents and trademarks	(657)	(515)	(468)	(500)	(500)
CapEx	(449)	(527)	(54)	(100)	(100)
Other	16,251	5,595	16,991	0	0
Investing Activities	\$ 15,145	\$ 4,552	\$ 16,469	\$ (600)	\$ (600)
Debt	(800)	(700)	(354)	0	0
Equity	445	10,616	50	12,083	400
Other	0	0	0	0	0
Financing Activities	\$ (355)	\$ 9,916	\$ (304)	\$ 12,083	\$ 400
Change in Cash	(\$3,055)	(\$120)	\$ 544	(\$3,773)	(\$15,999)

 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

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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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Market Outperform (Buy)	20	69%	6	30%
Market Perform (Neutral)	9	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	6	21%

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