

22nd Century Group, Inc. (XXII - \$2.28 - Buy)

COMPANY NOTE

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Sales and trading 7 a.m. to 7 p.m. ET, (646) 465-9090
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Stock Data	08/20/18
Price	\$2.28
52 Week Range	(\$1.92 - \$4.44)
Price Target	\$11.50
Market Cap (mil)	\$283.04
Shares out (mil)	124.14
3-Mo Avg Vol	1,888,196
Cash per share	\$0.48
Total Debt (mil)	\$0.00

Revenues (\$ millions)					
Yr Dec	2017A	2018E		2019E	
	Actual	Curr	Prev	Curr	Prev
Mar	2.2	6.1A	–	–	–
Jun	3.9	6.9A	–	–	–
Sep	4.5	–	–	–	–
Dec	5.9	–	–	–	–
YEAR	16.6	21.0	–	20.0	–

EPS (\$)					
Yr Dec	2017A	2018E		2019E	
	Actual	Curr	Prev	Curr	Prev
Mar	(0.03)	0.01A	–	–	–
Jun	(0.03)	(0.05)A	–	–	–
Sep	(0.03)	–	–	–	–
Dec	(0.03)	–	–	–	–
YEAR	(0.13)	(0.14)	–	(0.15)	–

One year price history XXII



XXII: Receives Order for 3.6M SPECTRUM Cigarettes

The NIDA (National Institute on Drug Abuse), the FDA, and public health researchers have ordered, through RTI International, 3.6 million SPECTRUM very low nicotine cigarettes from 22nd Century. Upon completion of this order the company will have delivered almost 28 million SPECTRUM cigarettes to the FDA for research purposes since 2011. The company estimates agencies of the United States federal government have invested more than \$100 million in independent clinical studies using its SPECTRUM research cigarettes. The next two major catalysts for the company, we believe, are the issuance of an NPRM by the FDA for the mandated reduction of nicotine in combustible cigarettes and the company's MRTP application to the FDA. We expect both before year end. We reiterate our buy recommendation and \$11.50 price target.

One objection raised to the mandate is availability of very low nicotine (VLN) tobacco. However, 22nd Century's supply of VLN SPECTRUM cigarettes for almost ten years strongly suggests there is readily available product to meet the FDA's mandate. 22nd Century states it could have enough seed to supply the US market in one growing season. In addition, in order to prove the viability of its technology is submitting a Modified Risk Tobacco Product (MRTP) application for a VLN (Very Low Nicotine) cigarette before year end.

The FDA will evaluate the submissions to its ANPRM and will likely publish a Notice of Proposed Rulemaking followed by another comment period and the final rulemaking, maybe late 2019/early 2020. We think the opportunity for 22nd Century is very large and the risks will likely be timing since Big Tobacco will try to delay the process and water down the mandate as much as it is able.

There is strong support for the mandate from the health care industry and in some cases urged coverage on a broad range of industry products and an aggressive schedule implemented as soon as possible. For instance 40 public health and medical organizations called for the FDA to issue a proposed rule by September this year, a final rule in March 2019 and implementation by March 2020. The letter was signed by the American Heart Association, the American Lung Association, the AMA, and many others. (https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2018_05_21_Nicotine_Product_Standard_Letter.pdf) Health care organizations are focused on the public health benefits of reducing the 480,000 premature deaths each year from smoking. The FDA estimates, "By 2060, ... almost 3 million deaths due to tobacco would be avoided (5th and 95th percentile projections range from 0.7 million to 4.3 million), rising to 8.5 million by the end of the century (5th and 95th percentile projections range from 2.2 million to 11.2 million). The reduction

in premature deaths attributable to the hypothetical policy scenario would result in approximately 33 million life years gained by 2060 (5th and 95th percentile projections range from 7.8 million to 53.9 million) and over 134 million life years gained by 2100 (5th and 95th percentile projections range from 31.6 million to 183.0 million).”

We believe there is more the company can do to strengthen its position in the market including licensing agreements for its technology, producing other tobacco plant varieties, international VLN opportunities, increasing its contract manufacturing business and growing additional crops of VLN tobacco.

We continue to wait for the publication of results from a study led by Dr. Dorothy Hatsukami of a 1,250 patient, 20-week study evaluating smoking cessation strategies on three cohorts of smokers using 22nd Century’s SPECTRUM cigarettes. One group used Very Low Nicotine (VLN) cigarettes, another group gradually reduced their nicotine content and a third group used cigarettes with normal nicotine content. Preliminary results showed use of VLN cigarettes immediately is the “most likely to lead to less harm,” and has a “greater likelihood of more rapid smoking cessation.” Since this is the focus of the FDA’s regulatory process, the publication of this study will bolster the FDA’s desire to set maximum nicotine standards in cigarettes.

Regulatory changes in the US will likely be a precursor to changes in other jurisdictions. 22nd Century indicates Canada, New Zealand, Finland and the UK are investigating nicotine reduction strategies. Our price target only includes an assumption of changes in the US.

We maintain our Buy recommendation on 22nd Century and reiterate our 12-month price target of \$11.50. We believe 22nd Century’s patents, covering nicotine regulation in tobacco plants, is a solution to the FDA’s pending regulation of nicotine levels in combustible cigarettes. We believe XXII has the opportunity to license its technology to Big Tobacco at a fraction of the cost they are currently contemplating it will take to comply with potential FDA regulations and this could result in a royalties or licensing stream far surpassing today’s market cap. While our price target is based on changes in the US market we expect other countries to follow the FDA’s lead, opening up additional markets for XXII and higher expected value for the shares.

Valuation:

Our twelve-month price target of \$11.50 is based on the company garnering royalty revenue for its technology on 10% of the US market share in the next five years, discounted at a 20% annual rate.

Risks to achievement of target price:

Risks to achieving our price target include delays in the FDA process, ability to find partners for X-22, challenges in attracting contract manufacturing and selling product overseas and possibility of requiring additional capital.

Company description:

22nd Century owns or exclusively controls over 200 issued patents, 50 pending patent applications. The company’s proprietary technology enables the control of nicotine levels in tobacco plants by controlling the genes responsible for nicotine production in tobacco plants.

Required Research Disclosures

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RATINGS

Buy: Expected to materially outperform sector average over 12 months and indicates total return of at least 10% over the next 12 months.

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Price Target \$11.50

VALUATION:

RISKS TO ACHIEVEMENT OF TARGET PRICE:

Risks to achieving our price target include delays in the FDA process, ability to find partners for X-22, challenges in attracting contract manufacturing and selling product overseas and possibility of requiring additional capital.

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