22nd Century Group, Inc. (XXII - $2.44 - Buy)

COMPANY NOTE

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Stock Data	07/18/18
Price	$2.44
52 Week Range	($1.33 - $4.44)
Price Target	$11.50
Market Cap (mil)	$302.90
Shares out (mil)	124.14
3-Mo Avg Vol	1,880,344
Cash per share	$0.48
Total Debt (mil)	$0.00

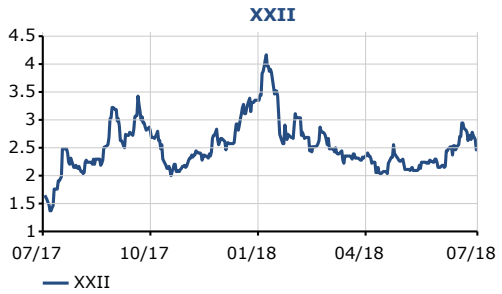
Revenues ($ millions)

Yr Dec	2017A	2018E		2019E	
	Actual	Curr	Prev	Curr	Prev
Mar	2.2	6.1A	–	–	–
Jun	3.9	–	–	–	–
Sep	4.5	–	–	–	–
Dec	5.9	–	–	–	–
YEAR	16.6	18.1	–	20.0	–

EPS ($)

Yr Dec	2017A	2018E		2019E	
	Actual	Curr	Prev	Curr	Prev
Mar	(0.03)	0.01A	–	–	–
Jun	(0.03)	–	–	–	–
Sep	(0.03)	–	–	–	–
Dec	(0.03)	–	–	–	–
YEAR	(0.13)	(0.12)	–	(0.14)	–
			–		–

One year price history XXII



FDA ANPRM Comment Period Ends

The comment period for the FDA's ANPRM (Advanced Notice of Proposed Rulemaking), "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes," has closed with almost 7,700 comments filed. As expected, Big Tobacco argues the mandate is impractical, based on flawed and incomplete science and should be as weak as possible for as long as possible. 22nd Century counters many of these arguments and objections indicating it could have enough seed to supply the US market in one growing season and 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 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.

The health care industry expressed strong support for the FDA's proposal and in many cases urged coverage on a broad range of industry products and an aggressive schedule implemented as soon as possible. We have pointed out the open letter from 40 public health and medical organizations calling 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. Organizations submitting comments in support of the mandate includes the AMA, the American Academy of Pediatrics, the American College of Cardiology, the American Society of Addiction Medicine, the American Association for Cancer Research, the American College of Physicians, the California Department of Public Health, the National Association of Pediatric Nurse Practitioners, the NYC Department of Health, the Oncology Nursing Society, Public Health Advocacy Institute and the Rutgers School of Public Health. These commenters focused mostly 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)."

Opponents of the plan include civil libertarians, some law enforcement, farmers, retailers and cigarette manufacturers. Law enforcement in particular is concerned about the impact a mandate would have on incentivizing the growth of a black market in cigarettes. Farmers and retailers, expressed, among other things, concern over the economic impact the mandate will have on their businesses. We believe it is important for the FDA to present the costs the mandate will impose, as well as the benefits, particularly in light of Judge Brett Kavanaugh's dissenting opinion in White Stallion Energy v. EPA that costs are critical to consider in new regulations. The Supreme Court is taking a more skeptical stance on regulatory over-reach with Justices Thomas, Gorsuch and Kavanaugh, if confirmed, leading the charge. We believe the FDA will need to continue building a strong case that will hold up against the highly likely litigation it will face.

Comments from Altria, ITG Brands, Philip Morris International, RAI Services and Universal were similar in their objections and the aggregated argument goes like this: 1) This is a *de facto* ban, and thus not allowed by The Family Smoking Prevention and Tobacco Control Act 2) The incidence of smoking is declining, so accelerating the process isn't necessary and/or not worth the costs imposed on consumers and industry 3) The existing research on smoking cessation and non-addictive nicotine levels is flawed, and incomplete, and much more study is required to determine the appropriate level, if there is such a thing 4) a standard shouldn't apply uniformly across all products since consumers of cigarettes, e-cigs, cigars and pipes all have different smoking behaviors 5) Lowering nicotine to non-addictive levels is not possible, or not possible at reasonable costs or not possible for decades. 6) even if it were possible the resulting product taste would be not acceptable to consumers 7) consumers would compensate by smoking more in order to get the desired nicotine 8) the black market would grow and provide even more dangerous products full of dangerous chemicals and metals endangering consumers even more than now 9) organized crime would benefit and law enforcement resources would be strained 10) instead the FDA should focus on encouraging ENDS (electronic nicotine delivery systems) which are safer and impose far less costs.

Both RAI and 22nd Century presented addendum to their comments listing the numerous studies undertaken and underway on VLN cigarettes. The number of studies and results suggest a solid body of evidence for the FDA's proposed mandate. The tobacco industry can and will attempt to throw doubt on these studies for various reasons but will probably be unsuccessful in challenging the broad conclusion that VLN cigarettes are a valuable tool in smoking cessation.

In their comments, RAI, Altria, and ITG Brands addressed 22nd Century and its technology. RAI questions whether 22nd Century's VLN tobacco is "replicable over time and on a commercial basis." and 22nd Century's patents on nicotine synthesis pathway genes could "impede the ability of the industry to take full advantage of genetic engineering to develop low-nicotine tobacco." Altria states there is no evidence VLN tobacco from 22nd Century "would be sensorially acceptable to consumers" or could be produced in commercial quantities. ITG Brands points to the failure of previous introductions of VLN products from Philip Morris, Vector and 22nd Century's Spanish product launch, Magic Zero (22nd Century points to the change in EU laws disallowing the company from stating the product's nicotine level as the reason for the product lack of commercial success) as evidence of consumer aversion to the product and hypothesizes the black market would benefit and result in increased consumer harm if the mandate is implemented.

22nd Century, in its comment to the FDA counters many of the tobacco industry's objections and arguments against the proposed mandate. Regarding the argument there isn't a commercially available VLN product the company states, "it can produce sufficient quantities of the Company's proprietary VLN™ tobacco seed for the entire U.S. market in just one growing season." Plus it will have product available in "traditional cigarette tobaccos, including burley, Oriental, and flue-cured varieties," which goes to the concerns over taste.

The company also revealed its plans to resubmit to the FDA, "an MRTP application before the end of 2018 for the Company's VLNC tobacco cigarettes, which will contain a target nicotine content level of 0.5 +/- 0.2 mg/g (dry weight) of tobacco." The submission will be supported by three clinical studies currently underway and the numerous independent clinical studies using 22nd Century's VLN. The company hopes to receive FDA authorization for VLN cigarettes with modified exposure statements regarding nicotine levels. This would be a significant accomplishment and threat to Big Tobacco's strategy of weakening the mandate as much as possible and delaying its implementation as long as possible.

At the end of Q1 the company had $59 million in cash and the sale of Anandia brings its effective cash balance to $75 million or more, more than 25% of the company's current market cap. Uses for the company's cash include submitting an MRTP application by year end, growing very low-nicotine (VLN) tobacco for testing and commercial sales and developing international opportunities for its VLN tobacco. In the short-term we expect the company's investment rate to increase from the average $3 million per quarter in 2017.

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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HOLD [NEUTRAL]	19	21.84	2	10.53
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NOT RATED [NR]	5	5.75	0	0.00

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Sell: Returns expected to be materially below sector average over 12 months and indicates total price decline of at least 10% over the next 12 months.

22nd Century Group, Inc. (XXII - $2.44 - Buy)
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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