



CHARDAN

Company Update

July 21, 2019

Industrial & Consumer Technology

22nd Century Group, Inc. (XXII - \$1.93 - Buy)

COMPANY NOTE

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Sales and trading 7 a.m. to 7 p.m. ET, (646) 465-9090

Sales and trading 7 p.m. to 7 a.m. ET, (646) 465-9063

Stock Data	07/19/19
Price	\$1.93
52 Week Range	(\$1.58 - \$3.29)
Price Target	\$11.50
Market Cap (mil)	\$240.56
Shares out (mil)	124.64
3-Mo Avg Vol	1,202,682
Cash (mil)	\$51.9
Total Debt (mil)	\$1.5

Revenues (\$ millions)					
Yr Dec	2018A	2019E		2020E	
	Actual	Curr	Prev	Curr	Prev
YEAR	26.4	21.3	-	21.3	-

EPS (\$)					
Yr Dec	2018A	2019E		2020E	
	Actual	Curr	Prev	Curr	Prev
YEAR	(0.06)	(0.15)	-	(0.18)	-
			-		-

One year price history XXII



XXII (Buy, PT\$11.50). MRTP Moves to Scientific Review

On Friday the 19th, the FDA filed for substantive scientific review of 22nd Century's Modified Risk Tobacco Product (MRTP) Applications for VLN King and VLN Menthol King combusted, filtered cigarettes. In addition to the review, a comment period on the company's application and a TPSAC (Tobacco Products Scientific Advisory Committee) will need to occur before a final determination on the application is made by the FDA, probably early next year.

An MRTP application can seek a "Risk Modification Order" after demonstrating the product will significantly reduce harm and the risk to users or an "Exposure Modification Order" if a filer can present evidence that it is reasonably likely to be demonstrated in future studies that morbidity and mortality can be substantially reduced by reductions of a substance in a product. 22nd Century's VLN (very low nicotine) cigarette has 95% less nicotine compared to all other cigarettes in the U.S. marketplace and it is requesting an Exposure Modification Order that authorizes three claims: 1) VLN has "95% less nicotine," 2) VLN "Helps reduce your nicotine consumption" and 3) VLN "... greatly reduces your nicotine consumption." The company is not seeking a risk modification order.

This application will be open to public comment, probably for 180 days after it is posted in the Federal Register and a meeting of the Tobacco Products Scientific Advisory Committee (TPSAC) will be scheduled in the next 6 to 9 months. TPSAC reviews and evaluates scientific issues, and provides advice, and recommendations to the FDA. The FDA is not required to follow TPSAC's recommendations. With the public comment period and TPSAC review this would put the FDA's decision on 22nd Century's application into Spring of next year.

We believe this MRTP can be an effective tool for the FDA when it issues an NPRM (Notice of Proposed Rulemaking) that builds on the ANPRM issued in March of 2018 that requested comment on limiting nicotine in combustible cigarettes to non-addictive levels. The FDA is required to consider technical achievability of its orders and 22nd Century, with this MRTP application, is demonstrating that technical achievability. We believe issuance of the NPRM was delayed by the resignation of commissioner Scott Gottlieb earlier this year. An NPRM could be issued before a new commissioner is nominated and approved, but we think it is much more likely to occur after a new commissioner is installed.

As the FDA moves down the path of mandating non-addictive levels of nicotine in cigarettes, 22nd Century could have a time-to-market advantage over current providers in the market and/or a unique tool for the industry to be in compliance. This advantage is somewhat mitigated by the financial strength of the tobacco industry and FDA approval of a reduced risk order for iQOS. Both of these gives the tobacco industry time to comply and a path to reduced dependence on combustible cigarettes.

With \$52 million in cash, 22nd Century has the resources to wait for a reasonable transition period to a non-addictive nicotine world, but the longer a decision takes and the longer the transition period is, the worse it is for 22nd Century.

Another path for the company is utilizing its expertise in ancillary markets. The company is investing in the hemp market. XXII recently entered into a collaboration and research agreement with Natural Good Medicines (NGM) that calls on NGM to process hemp and cannabis plant lines owned by NGM. 22nd Century has certain exclusive rights to NGM's plant lines. Also, 22nd Century entered into a worldwide R&D agreement with KeyGene, that will focus on developing hemp and cannabis plants with specific medical and therapeutic profiles. KeyGene is an AgBiotech company that specializes in crop improvement using molecular breeding. KeyGene believes this is the fastest and most cost-effective path to market for specialized crops.

In exchange for \$6 million over the initial five year term, KeyGene will work exclusively with 22nd Century on the Cannabis Sativa L. plant and will work specifically to create a genetic database, develop improved varieties, create a molecular genetic map of the cannabis plant genome, analyze the genomic sequences of multiple species of hemp/cannabis plants and initiate generation of plant lines with distinctive profiles. This is still early days for 22nd Century and the hemp market but it could generate considerable value as the hemp market grows.

The company has \$52 million in cash, or almost 4 years of cash at the company's current burn rate. However, investments in the hemp market will lower the company's cash balances modestly and we think a substantial cash balance is necessary in order to combat the likely delaying tactics of the tobacco industry when rule changes are implemented by the FDA

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



Created by: BlueMatrix

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			Count	Percent
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NOT RATED [NR]	0	0.00	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) - \$1.93 - Buy

Price Target \$11.50

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RISKS TO ACHIEVEMENT OF TARGET PRICE:

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