

22nd Century Group, Inc. (XXII - \$2.81 - 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	10/12/18
Price	\$2.81
52 Week Range	(\$1.92 - \$4.44)
Price Target	\$11.50
Market Cap (mil)	\$348.83
Shares out (mil)	124.14
3-Mo Avg Vol	1,963,036
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: CTP Summarizes Scientific Case for Limiting Nicotine in Cigarettes

Last Thursday's webcast, "The Science to Inform a Tobacco Product Standard for the Level of Nicotine in Combusted Cigarettes," by Lynn Hull, Lead Pharmacologist, Division of Individual Health Science at the FDA's Center for Tobacco Products summarized the scientific evidence the FDA will use to support its upcoming rule to limit nicotine in combustible cigarettes to non-addictive levels. Since the webcast was a summary of existing science it did not break new ground in the FDA's case. In our view, the FDA is carefully building the case for its pending rule, a critical component being the science supporting the public health benefits of very low nicotine (VLN) cigarettes.

Dr. Hull summarized findings from 99 studies that have been conducted examining the impact of VLN cigarettes. These include: decreased dependence, increased quit attempts, lower addiction potential, reduced export to harmful constituents, loan of adverse effects without an increase in the number of cigarettes smoked daily. In addition, a review of social science literature indicates consumers would generally support a standard to lower nicotine levels, but an education program to correct some beliefs would need to be implemented. There are considerable public health benefits to reducing smoking in the US and the FDA regards lowering nicotine to non-addictive levels an effective way to meet this goal.

We expect the FDA to release a Notice of Proposed Rulemaking (NPRM) before year-end that, like the ANPRM, proposes a rule that limits nicotine in combustible cigarettes to non-addictive levels. After the FDA releases the NPRM, there will be a comment period, after which the FDA will evaluate the comments and issue a final rule. We believe this could happen by the end of next year, but earlier is certainly possible. There is significant support for the FDA's goals from the public health community and many have called for an early and aggressive transition to cigarettes with non-addictive nicotine levels.

An MRTP from 22nd Century for its very-low nicotine, non-addictive cigarettes is also expected before year end. A decision by the FDA could take up to 12 months. The application can have two impacts for the company. First, the application could be used by the FDA as evidence there is commercially available very low nicotine tobacco for the industry to comply with a very low nic mandate. Second, the creation of a modified risk product, capturing even a 1% market share, can be worth over \$1 billion, or \$8 per share, much more than the current share price.

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.

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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Distribution of Ratings/IB Services Chardan Capital Markets

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [BUY]	60	67.42	24	40.00
HOLD [NEUTRAL]	22	24.72	2	9.09
SELL [SELL]	0	0.00	0	0.00
NOT RATED [NR]	7	7.87	0	0.00

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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.

Neutral: Returns expected to be in line with sector average over 12 months and indicates total return between negative 10% and 10% over the next 12 months.

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.

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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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