

22nd Century Group, Inc. (XXII - \$2.21 - Buy)

Estimate Change

COMPANY NOTE

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

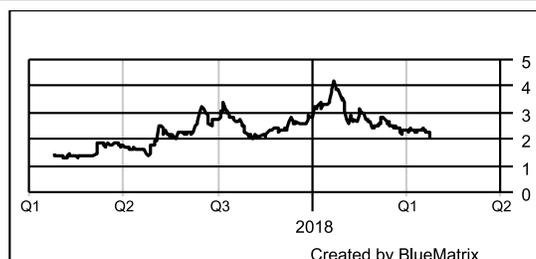
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Stock Data	05/04/18
Price	\$2.21
52 Week Range	(\$1.24 - \$4.44)
Price Target	\$11.50
Market Cap (mil)	\$274.35
Shares out (mil)	124.14
3-Mo Avg Vol	2,203,008
Cash per share	\$0.48
Total Debt (mil)	\$0.00

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	16.0	20.0	16.0

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)	(0.11)	(0.14)	(0.11)

One year price history XXII



Q1 Far Ahead of Expectations

Q1 revenue was far above our expectations and an unrealized \$6 million gain on the company's investment in Anandia resulted in net income of \$1.4 million or \$0.01 per share.

In parallel with the FDA's ANPRM "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes," 22nd Century is preparing an MRTP (Modified Risk Tobacco Products) application for its Brand A Very Low Nicotine (VLN) cigarettes with the FDA. This cost an additional \$1.3 million in Q1 and will require an additional \$8 million over the next 6 to 12 months for 3 limited clinical trials, perception studies, legal guidance, product testing, and consulting expertise.

The MRTP can be an important step in monetizing the company's technology. An MRTP will indicate to the FDA non-addictive, VLN cigarettes are possible, and could be used by the FDA to rebut potential objections by Big Tobacco that technology is not available or available at a reasonable cost. Alternatively, if the ANPRM is dragged out, a successful MRTP could position 22nd Century as the only product with a modified risk label.

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.

The comment period for the ANPRM is scheduled to expire on June 14. It wouldn't be surprising if the comment period were extended, and we are assuming it ends Q3. After reviewing comments the FDA can go straight to a final rule, or start an NPRM with the same process of a comment period followed by a review and final rule making. We think this process could complete around the beginning of 2020 and could be followed by a phase in period.

In this scenario the FDA's final rule, could occur at the same time as a decision on the MRTP. A successful application could give 22nd Century an exclusive VLN product on the market while the FDA's mandate goes into effect.

We expect the tobacco industry to attempt to push the process as far to the right as possible. We also think it will try to delay implementation, argue for a gradual reduction in nicotine levels and claim the standard is not technically achievable and/or too expensive to meet. Political risk is also present. Pushing the process to the right will allow elections to have an

impact on the Federal Government's leadership and on the composition of FDA's leadership and priorities.

Another pending catalyst for the shares is 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.

It is important for regulatory agencies to build a case that overcomes the inevitable objections by industry participants, public policy advocates, the general public and Congress. The Hatsukami study joins a large body of evidence very-low nicotine cigarettes can reduce the harm from cigarettes and lead to greater rates of smoking cessation.

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.

The company's quarterly burn is between \$3 and \$3.5 million, before the additional expenses for the MRTP. This can change as the process with the FDA progresses. There may be increased costs in hiring personnel and working with the FDA and third-parties in making known 22nd Century's capabilities in the market. Additionally, we believe the company will need to protect and advance its technology which could result in higher R&D and G&A. To date, most of the company's revenues have been generated by contract manufacturing, and the company intends to continue growing this business.

Cash will be critical. The FDA process could be long and expensive depending on additional studies that may be required to build the record as well as personnel to make 22nd Century's technology known by the relevant constituents to the FDA's nicotine limiting initiative.

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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			Count	Percent
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NOT RATED [NR]	5	5.05	0	0.00

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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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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

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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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