

22nd Century Group, Inc. (XXII - \$2.76 - 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	09/05/18
Price	\$2.76
52 Week Range	(\$1.92 - \$4.44)
Price Target	\$11.50
Market Cap (mil)	\$342.63
Shares out (mil)	124.14
3-Mo Avg Vol	2,012,403
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: New Study Supports Rapid Phase In of Nicotine Mandate

Publication of a study that explores the “optimal temporal approach for reducing nicotine to minimally or nonaddictive levels in all cigarettes sold in the United States” adds to a large body of evidence the FDA will use to support its forthcoming NPRM mandating non-addictive levels of nicotine in combustible cigarettes. We expect the FDA to issue an NPRM before year-end, which will be followed by a comment period, then a final rule, maybe as early as mid-year, although given the gravity and impact of the ruling later in the year should not be ruled out. We believe the pending mandate will catalyze demand for 22nd Century’s technology that controls nicotine levels in tobacco plants and enable the industry to meet the mandate. We maintain our Buy recommendation on the shares and reiterate our 12-month price target of \$11.50.

“Effect of Immediate vs Gradual Reduction in Nicotine Content of Cigarettes on Biomarkers of Smoke Exposure,” published in JAMA this week presented the results of a double-blind study of 1250 randomized participants “to determine the effects of immediate vs gradual reduction in nicotine content to very low levels and as compared with usual nicotine level cigarettes on biomarkers of toxicant exposure.” The study concluded, “Among smokers, immediate reduction of nicotine in cigarettes led to significantly greater decreases in biomarkers of smoke exposure across time compared with gradual reduction or a control group, with no significant differences between gradual reduction and control.”

The conclusions are not surprising, given the results were previewed earlier. We believe the more significant aspect of this study is it adds to the large body of evidence regarding the efficacy of very low nicotine cigarettes to result in greater success in those desiring to cease smoking and the positive impact on public health if the FDA determines to implement short phase-in period for the mandate.

There are many decisions the FDA needs to make in constructing the NPRM and in its final decision including the nicotine level and over what period the FDA will require this level to be met. From a public health perspective this study suggest a short phase in period and this would be very beneficial for 22nd Century, since it has a solution available currently to meet the mandate and there are no other options currently available.

Big tobacco has criticized the potential mandate as lacking in a scientific basis and asserts there are no economic or technical solutions available. This study add to a large body of evidence that shows the FDA’s mandate is grounded in strong scientific evidence and public health will benefit from a short phase in period. We expect Big Tobacco to argue for a long phase in period in order to defer the inevitable.

The objection regarding technical ability to meet the mandate is not persuasive since 22nd Century has supplied VLN SPECTRUM cigarettes for almost ten years; this 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.

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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Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
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NOT RATED [NR]	8	8.99	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.

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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