



# CHARDAN

## 22nd Century Group, Inc. (XXII - \$2.77 - 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	12/10/18
Price	\$2.77
52 Week Range	(\$1.92 - \$4.44)
Price Target	\$11.50
Market Cap (mil)	\$344.59
Shares out (mil)	124.40
3-Mo Avg Vol	2,019,782
Cash (mil)	\$62.1
Total Debt (mil)	\$0.7

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	6.3A	-	-	-
Dec	5.9	-	-	-	-
YEAR	16.6	23.3	-	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)	0.04A	-	-	-
Dec	(0.03)	-	-	-	-
YEAR	(0.13)	(0.04)	-	(0.15)	-

### One year price history XXII



## XXII: PMTA, MRTP then NPRM

Last week 22nd Century filed a Premarket Tobacco Application, or PMTA, with the FDA requesting approval to commercialize a very-low nicotine combustible cigarette. In the coming weeks, possibly before year-end, the company will submit an MRTP, or Modified Risk Tobacco Product application requesting authorization to claim on packaging and in advertising that the cigarettes contain 0.5mg of nicotine per gram of tobacco. By comparison, the average American cigarette contains 19.4mg of nicotine per gram of tobacco. We believe these applications can lead to significant value creation and as importantly, be levers for the FDA to use in moving the industry towards very-low nicotine products and justifying aggressive rule changes on nicotine levels in cigarettes. An NPRM with these proposed rule changes could be issued in the near-term and provide a catalyst for 22nd Century's stock.

New cigarette products must be approved by the FDA when the product is not substantially equivalent to a tobacco product commercially marketed in the US as of February 2015. This provides a substantial barrier to entry for incumbents and prevents market participants from attracting new users and/or maintaining existing users with new products. Very few new products have received marketing orders since this authority was granted to the FDA.

Later this month, 22nd Century intends to file an MRTP with the FDA requesting authorization to state its very-low nicotine cigarette contains 0.5mg of nicotine per gram of tobacco. This would be an advantage for the company attracting consumers who recognize and want a cigarette that can be a smoking cessation tool. Numerous studies over many years have demonstrated very-low nicotine cigarettes can be effective tools to assist smokers in their quit attempts. A PMTA, followed by an MRTP would enable the company to deliver a product with significant value to the 50% of smokers in the US who have expressed a desire to quit.

We also believe this will be an important tool the FDA can use to justify and support the NPRM we expect to be issued soon. The FDA has been consistent and clear that it wants to implement a rule that would lower nicotine in combustible cigarettes to non-addictive levels. One major objection industry has made is a claim that technology is not available to accomplish this objective. Approval of 22nd Century's PMTA and MRTP would counter this objection and justify the FDA's rule change.

As the FDA moves down the path of mandating non-addictive levels of nicotine in cigarettes, 22nd Century could have a large time-to-market advantage over current providers in the market as well as demonstrate it has technology available others need to comply with the very-low nicotine mandate.

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



Created by: BlueMatrix

### Distribution of Ratings/IB Services Chardan Capital Markets

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [BUY]	63	68.48	20	31.75
HOLD [NEUTRAL]	21	22.83	0	0.00
SELL [SELL]	0	0.00	0	0.00
NOT RATED [NR]	8	8.70	0	0.00

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**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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