

**22nd Century Group, Inc. (XXII - \$2.47 - Buy)**

**Estimate Change**

**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	08/07/18
Price	\$2.47
52 Week Range	(\$1.92 - \$4.44)
Price Target	\$11.50
Market Cap (mil)	\$306.63
Shares out (mil)	124.14
3-Mo Avg Vol	1,885,428
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	18.1	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)	(0.12)	(0.15)	(0.14)
			—		—

**One year price history XXII**



**XXII: Q2 Results. NPRM and MRTP by Year-End**

Q2 revenue was almost \$7 million, and was the second highest in the company's history. An EBITDA loss of \$5.1 million was the result of a cash burn of almost \$2.5 million per quarter for normal operating activities and \$2.6 million related to an MRTP application the company intends to file with the FDA before year end. The next two major catalysts for the company, we believe, are the issuance of an NPRM by the FDA for the mandated reduction of nicotine in combustible cigarettes and the company's MRTP application to the FDA. We expect both before year end. We reiterate our buy recommendation and \$11.50 price target.

Most of the \$6.9 million in revenue is from contract manufacturing, which has shown a steady increase over the past three years. Gross margin is now positive and will increase with volume. We have not assumed a significant change from current levels, which would result in about \$2.4 million of normal cash usage by the company. However, over the next two to three quarters 22nd Century intends to spend another \$7.5 million in order to advance its MRTP and submit to the FDA by year-end.

At the end of Q2 the company had \$53 million in cash, about five years of cash at current burn levels. The incremental spending to submit the MRTP could be offset by the sale of Anandia, which is expected to close this month resulting in stock worth \$9 million at current Aurora Cannabis prices plus warrants worth a few million more.

The comment period for the FDA's ANPRM (Advanced Notice of Proposed Rulemaking), "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes," ended with 7,700 comments filed. As expected, Big Tobacco argues the mandate is impractical, based on flawed and incomplete science and should be as weak as possible for as long as possible. 22nd Century counters many of these arguments and objections indicating it could have enough seed to supply the US market in one growing season and 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.

The FDA will evaluate the submissions and will likely publish a Notice of Proposed Rulemaking followed by another comment period and the final rulemaking, maybe late 2019/early 2020. We think the opportunity for 22nd Century is very large and the risks will likely be timing since Big Tobacco will try to delay the process and water down the mandate as much as it is able.

There is strong support for the mandate from the health care industry and in some cases urged coverage on a broad range of industry products and an aggressive schedule implemented as soon as possible. For instance 40 public health and medical organizations called for the FDA to issue a proposed rule by September this year, a final rule in March 2019 and implementation by March 2020. The letter was signed by the American Heart Association, the American Lung Association, the AMA, and many others. ([https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/2018\\_05\\_21\\_Nicotine\\_Product\\_Standard\\_Letter.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2018_05_21_Nicotine_Product_Standard_Letter.pdf)) Health care organizations are focused on the public health benefits of reducing the 480,000 premature deaths each year from smoking. The FDA estimates, "By 2060, ... almost 3 million deaths due to tobacco would be avoided (5th and 95th percentile projections range from 0.7 million to 4.3 million), rising to 8.5 million by the end of the century (5th and 95th percentile projections range from 2.2 million to 11.2 million). The reduction in premature deaths attributable to the hypothetical policy scenario would result in approximately 33 million life years gained by 2060 (5th and 95th percentile projections range from 7.8 million to 53.9 million) and over 134 million life years gained by 2100 (5th and 95th percentile projections range from 31.6 million to 183.0 million)."

22nd Century, in its comment to the FDA <https://www.regulations.gov/document?D=FDA-2017-N-6189-7550> counters many of the tobacco industry's objections and arguments against the proposed mandate. Regarding the argument there isn't a commercially available VLN product the company states, "it can produce sufficient quantities of the Company's proprietary VLN™ tobacco seed for the entire U.S. market in just one growing season." Plus it will have product available in "traditional cigarette tobaccos, including burley, Oriental, and flue-cured varieties," which goes to the concerns over taste.

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.

We continue to wait for 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.

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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**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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