22nd Century Group, Inc. (XXII - $2.65 - Buy)

COMPANY NOTE

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Stock Data	03/15/18
Price	$2.65
52 Week Range	($0.89 - $4.44)
Price Target	$11.50
Market Cap (mil)	$328.97
Shares out (mil)	124.14
3-Mo Avg Vol	3,951,478
Cash per share	$0.50
Total Debt (mil)	$0.00

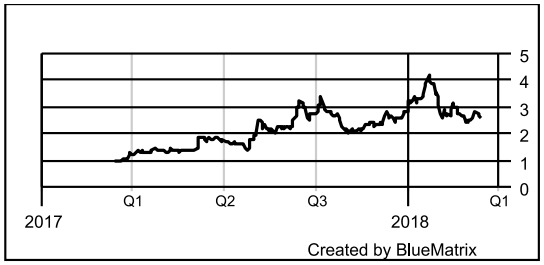
Revenues ($ millions)

Yr Dec	2017A	2018E		2019E	
	Actual	Curr	Prev	Curr	Prev
Mar	2.2	–	–	–	–
Jun	3.9	–	–	–	–
Sep	4.5	–	–	–	–
Dec	5.9	–	–	–	–
YEAR	16.6	16.0	–	16.0	–

EPS ($)

Yr Dec	2017A	2018E		2019E	
	Actual	Curr	Prev	Curr	Prev
Mar	(0.03)	–	–	–	–
Jun	(0.03)	–	–	–	–
Sep	(0.03)	–	–	–	–
Dec	(0.03)	–	–	–	–
YEAR	(0.13)	(0.11)	–	(0.11)	–

One year price history XXII



NEJM Publshes Estimates of Public Health Benefits of Minimally Addictive Cigs

Today, the New England Journal of Medicine published, "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States." This is not the results of the Hatsukami study we have been expecting but is a valuable addition to the record the FDA will consider when/if it mandates a maximum nicotine level in cigarettes to minimally addictive levels.

According to the study's authors, "The purpose of this analysis is to quantify the potential public health effects of enacting a regulation in the United States that makes cigarettes minimally addictive by setting a maximum level of nicotine in cigarettes." They arrived at their conclusions by asking eight experts to provide estimates of their anticipated effects on cigarette consumption if policy required a reduction in nicotine to minimally addictive levels.

The experts' responses had a wide distribution with the estimate of smokers who would quit in year one ranging from 4.5% to 55% and in subsequent years the range of estimates was from 4.5% to 80%. The range of estimates of the change in initiation of cigarette smoking was also wide, spanning from a 21% to 70% drop in year one to 21% to 75% in subsequent years.

The model predicted declines in smoking "from a median of 12.8% in the baseline scenario to a median of 10.8%" within a year of the policy's implementation. This equates to 5 million additional smokers who would quit within the first year of implementation and 13 million within 5 years. "By 2060, smoking prevalence drops from 7.9% in the baseline scenario to 1.4%."

Obviously there is great uncertainty with the model however, the authors conclude "a regulation to lower the nicotine content of cigarettes to minimally addictive levels in the United States would lead to a substantial reduction in tobacco related mortality, despite uncertainty about the precise magnitude of the effects on smoking behaviors." In addition, the authors assert the real world effects would probably be greater than the impacts previous studies of very low nicotine levels have shown on smoking rates because users in those studies were able to purchase higher nicotine cigarettes, something more difficult to accomplish if the FDA mandates minimally addictive levels in all cigarettes.

We still wait for publication of the FDA's Advanced Notice of Proposed Rulemaking (ANPRM) that will take the initial regulatory steps that could ultimately result in a product standard that sets a maximum nicotine level in cigarettes to non-addictive levels. This is one of three ANPRM's submitted by the FDA to the Office of Information and Regulatory Affairs, part of the

Office of Management and Budget. The other two ANPRMs deal with 1) the role of flavors in tobacco products in attracting youth to smoking and getting smokers to switch to less harmful forms of nicotine delivery and 2) the public health impacts of premium cigars. Usually the publication of the ANPRM happens soon after submission to OMB, but in unusual circumstances we have seen it take a couple of months.

A comment period follows publication of the ANPRM in the Federal Register. Sixty days is common, but often for complex and significant rules a longer period may be allowed, possibly up to 180 days. After comments are received the FDA will evaluate the comments as well as the ex parte meetings with interested parties. The ANPRM can be followed by an NPRM, or a final rule. The entire process can typically take 12-24 months, longer for the more consequential rules, such as this could be.

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.

There are some who believe the market is moving to other nicotine delivery systems, like e-cigs, which probably are less harmful than combustible cigarettes and could escape the FDA's oversight. We disagree. The research shows 90% of smokers start by age 18, 95% by 21 and 99% before they reach 26. Because of this the FDA places significant emphasis on programs and policies that reduce the incidence of smoking by the young, and we expect will be skeptical of products the offer a path for the young to become addicted.

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. 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. In Q4 positive gross margin was achieved and this should increase as volumes rise, but contract manufacturing will always be a low margin business. For now, we are estimating revenue and income for the coming years similar to 2017 levels.

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.

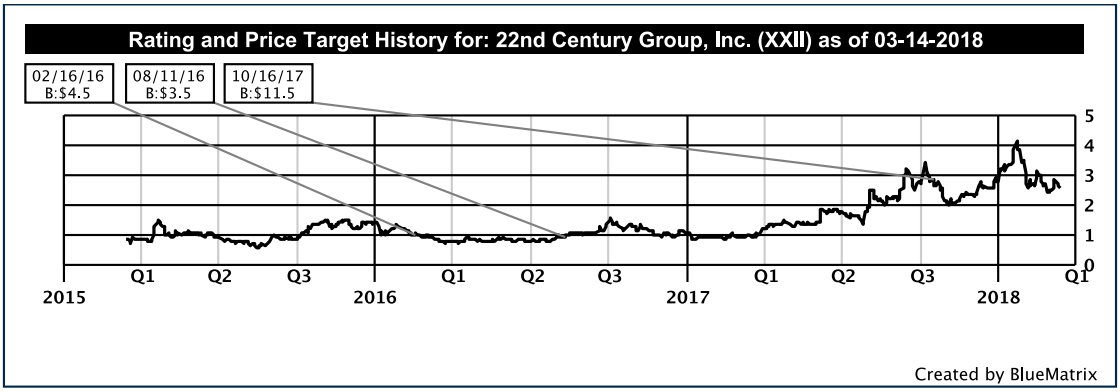
Risks to achievement of target price:

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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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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