CHARDAN

Company Update
March 19, 2018
Industrial & Consumer Technology

22nd Century Group, Inc. (XXII - $2.48 - Buy)

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	03/16/18
Price	$2.48
52 Week Range	($0.89 - $4.44)
Price Target	$11.50
Market Cap (mil)	$307.87
Shares out (mil)	124.14
3-Mo Avg Vol	4,060,733
Cash per share	$0.50
Total Debt (mil)	$0.00

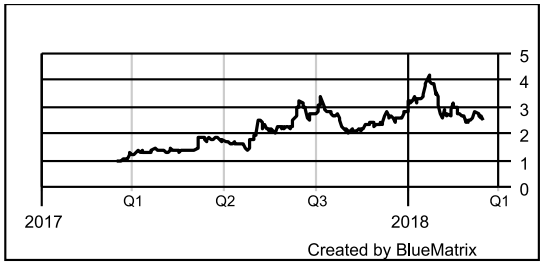
Revenues ($ millions)

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



ANPRM Published Last Friday. Bullish for XXII

The FDA's ANPRM, "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes" was published in the Federal Register on Friday the 16th. We believe this is an important milestone for 22nd Century and the details of the ANPRM are supportive of our bullish thesis on the shares particularly regarding the maximum nicotine level, the discussion of technical achievability and the length of the comment period. We reiterate our Buy recommendation and $11.50 price target.

The comment period for the ANPRM expires in 90 days from publication date, or June 14. There is wide latitude for setting the comment period and a shorter period suggests a sense of urgency for the rule-making and limits the delay tactics that are likely to be pursued by the industry. Comment periods can be extended so we wouldn't be surprised by that. Plus, following the ANPRM an NPRM could be issued and the whole process started again. We still think a 12-24 month process is likely, but given the import and complexity it could take longer.

With the ANPRM the FDA is contemplating setting a "maximum nicotine level in cigarettes so that they are minimally addictive or nonaddictive." Doing so, the FDA believes will reduce the number of current smokers and lower the number of new smokers as well. An article in the NEJM last week cited a model that 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%."

The FDA is asking for comment and information in seven categories: 1). The Scope of the standard, 2). The Maximum Nicotine Level. 3). Implementation (Single Target vs.Stepped-Down Approach) 4). Analytical Testing Method. 5). Technical Achievability. 6) Possible Countervailing Effects. 7). Other Considerations.

Scope. The FDA implies the standard should apply to a wide variety of tobacco products including combustible cigarettes, cigarette tobacco, cigars pipe tobacco and waterpipe tobacco. The FDA is concerned if the standard only covers combustible cigarettes users may switch to other forms of tobacco obviating the purpose of limiting nicotine levels. The ANPRM states, that whatever standard it adopts will apply to all products in that category as well as new products in that category.

Maximum Nicotine Level. The FDA cites a 2013 survey which estimated 0.5 milligrams per rod would minimize addictiveness. However, more

recent estimates aver a lower level is needed. The FDA seeks comment on what the maximum level should be and how it is measured (eg nicotine yield, nicotine in tobacco filler, something else). The FDA is particularly interested in levels of 0.3, 0.4, and 0.5 mg nicotine/g of tobacco filler. From the FDA's perspective, too high a level will reduce the effectiveness of the standard. From 22nd Century's perspective, too high a level would allow a greater number of alternatives to its technology. The levels being discussed, based on the current evidence, will enable the FDA to achieve its goal and from 22nd Century's vantage limits realistic options to the company's technology.

Analytical Testing Method. Per the FDA "It is critical that the results from the test method used demonstrate a high level of specificity, accuracy, and precision in measuring a range of nicotine levels across a wide variety of tobacco blends and products."

Technical Achievability. The FDA is still analyzing the technical achievability of a maximum nicotine level but indicates the standard can be achieved via a). blending and cross breeding plants b). genetic engineering c). chemical extraction d). Other agricultural practices.

Blend. The FDA cites a tobacco industry executive's testimony that the tobacco blend is the main component of the cigarette that determines the nicotine content. "The tobacco industry has used breeding and cultivation practices to develop high nicotine tobacco plants… These practices could be used to develop low nicotine plants as well." Manufacturers could replace high-nicotine plants with lower-nicotine plants, and/or use leaves lower on the plant, which have lower-nicotine levels. Given the nicotine levels the FDA is considering it is uncertain if blending alone can be used to meet the standard and if cross-breeding is used to develop plants with the required amounts of nicotine, how long that would take.

Genetic Engineering. Genetic engineering of tobacco, per the ANPRM, has been of interest to the tobacco industry for decades and VLNC have been produced since the 1970's. None of these programs have resulted in commercial products, and the ability of those prior efforts to meet the FDA's standard is unknown. Importantly, the FDA singles out 22nd Century's technology as a way to achieve the standard. Specifically, the ANPRM states, "More recently, 22nd Century, acting as vendor for RTI's contract with NIDA, has developed cigarettes, not currently commercially available, that are similar in many sensory characteristics to conventional cigarettes but with extremely low nicotine levels." 22nd Century's technology is the only genetic engineering solution mentioned by the FDA that has been used recently. All of the other genetic engineering instances mentioned are from many years ago including the 2003 Quest cigarette produced by Vector Tobacco.

Chemical Extraction. There have been multiple attempts to lower nicotine via chemical engineering, including the Next brand from Philip Morris, which used a similar process to making decaffeinated coffee. The product was unsuccessful and withdrawn from the US market. The FDA also points to water extraction, solvent extraction, and supercritical fluid extraction as potential methods to lower nicotine levels.

The tobacco industry will likely argue the time and expense of lowering nicotine levels will be significant. For instance, last year, Rolf Lutz, Director of Product Policy at Philip Morris International, estimated it would cost $10 billion to $12 billion to extract nicotine from the cigarettes it sells in the European market and genetically modifying plants to lower nicotine would take 20 years. However, the FDA has already pointed out there are genetically engineered solutions that are available today, for instance, through 22nd Century. If the FDA sticks with an aggressive standard, and adopts a relatively short implementation period, covering all product categories, we believe this is very bullish for the company as the industry admits using chemical methods to de-nic cigarettes and/or cross-breeding and their own genetic engineering capableness will be both expensive and time consuming.

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. 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.

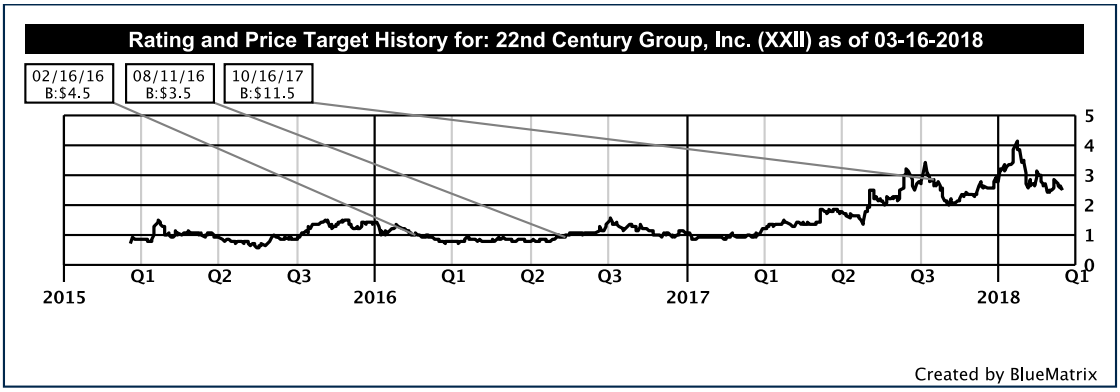
Risks to achievement of target price:

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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Chardan Capital Markets

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
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HOLD [NEUTRAL]	**24**	**24.24**	**2**	**8.33**
SELL [SELL]	**0**	**0.00**	**0**	**0.00**
NOT RATED [NR]	**6**	**6.06**	**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.

22nd Century Group, Inc. (XXII - $2.48 - Buy)
Price Target $11.50

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.

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