

22nd Century Group, Inc. (XXII - \$2.24 - Buy)

Estimate Change

COMPANY NOTE

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Sales and trading 7 a.m. to 7 p.m. ET, (646) 465-9090

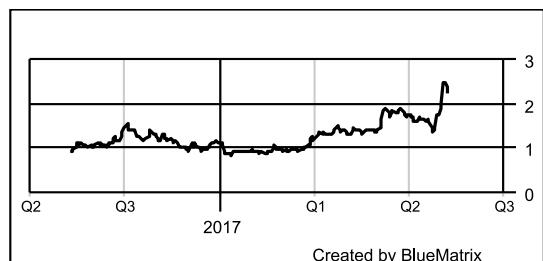
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Stock Data		08/09/17
Price		\$2.24
52 Week Range		(\$0.81 - \$2.84)
Price Target		\$3.50
Market Cap (mil)		\$203.17
Shares out (mil)		90.70
3-Mo Avg Vol		2,069,877
Cash per share		\$0.12
Total Debt (mil)		\$0.31

Revenues (\$ millions)						
Yr Dec	2016A		2017E		2018E	
	Actual	Curr	Prev	Curr	Prev	
Mar	3.0	2.2A	-	-	-	
Jun	2.8	3.9A	2.6	-	-	
Sep	3.1	4.0	6.0	-	-	
Dec	3.3	6.6	-	-	-	
YEAR	12.3	16.7	16.5	21.5	-	

EPS (\$)						
Yr Dec	2016A		2017E		2018E	
	Actual	Curr	Prev	Curr	Prev	
Mar	(0.04)	(0.03)A	-	-	-	
Jun	(0.04)	(0.03)A	-	-	-	
Sep	(0.03)	(0.02)	-	-	-	
Dec	(0.03)	(0.02)	-	-	-	
YEAR	(0.15)	(0.10)	(0.09)	(0.09)	-	

One year price history XXII



Q2 Revenues Exceed Estimate. FDA Action Drives Shares

Q2 revenue of \$3.9 million was substantially greater than our \$2.6 million estimate. Manufacturing margins remain negative with high factory start-up costs but as volumes increase we expect improved margins. The company reiterated revenue exceeding \$16 million for the year.

Operationally, improvements are afoot, yet the real driver of value for the shares is the company's ability to control nicotine levels in cigarettes, which the FDA recently endorsed as a way to reduce addiction.

The Director of Product Policy, Rolf Lutz, at Philip Morris International stated last year it would cost \$10 billion to \$12 billion to extract nicotine from all its EU cigarettes but the cost would be minimized by genetically modifying tobacco plants, which he believed would take 20 years. He was not aware of 22nd Century, since the company has the technology today. But the estimate of \$10 to \$12 billion to extract nicotine, just in the EU and just for Philip Morris, is an indication of the value of 22nd Century's technology. As a comparison, 22nd Century has a current market cap of \$228 million.

Another indication of the value is the \$21 billion drop in market cap of Altria Group, British American Tobacco, Imperial Brands and Vector Group after the FDA proposed a new regulatory plan that includes "lowering nicotine levels in combustible cigarettes to non-addictive levels."

The FDA's proposed plan is not solely targeted to lowering nicotine levels, but it certainly is a critical element to the plan. Even if lowering nicotine levels in tobacco is only 10% of what the market is worried about, that equals \$2 billion in value that could be addressed by 22nd Century's technology. All in, including warrants, 22nd Century has about 115 million shares, or about \$258 million in market cap. To state the obvious, the market estimates the potential harm to Big Tobacco of the FDA's proposed plan is \$20 billion. However, 22nd Century, which has a technology to mitigate that loss, is valued at \$250 million. Our price target of \$3.50, or a market cap of \$400 million, is a fraction of Big Tobacco's market cap loss last Friday and demonstrates, in our opinion, the significant value in the shares.

The FDA's "comprehensive regulatory plan to shift trajectory of tobacco-related disease, death," is potentially very bullish for 22nd Century. "The FDA plans to begin a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards. The agency intends to issue an Advance Notice of Proposed Rulemaking (ANPRM) to seek input on the potential public health benefits and any possible adverse effects of lowering nicotine in cigarettes." 22nd

Century's raison d'être is controlling nicotine levels in tobacco and owns the intellectual property that enables this. With the FDA exploring lower nicotine cigarettes as a way to reduce tobacco addiction, we believe this is a major boost for the company.

The FDA's regulatory plan is the start of a process that will take many months to complete but we do expect that as this process continues Big Tobacco will become interested in exploring the technology controlled by 22nd Century. How this new regulatory plan will impact the company's current work with the FDA is uncertain, but the company's work on introducing lower-nicotine cigarettes as smoking cessation tools demonstrates clearly the company is at the forefront of the FDA's strategy on tobacco regulation.

There have been multiple studies showing the efficacy of low-nicotine cigarettes as a way to reduce or quit smoking. Currently, 22nd Century is pursuing three paths with the FDA with three different products, two of which have low-nicotine levels: 1) Brand A 2) X-22 and 3) Brand B. A few months ago the company met with the FDA and based on those meetings has decided to "significantly expand" its Modified Risk Tobacco Product (MRTP) application and will request FDA approval of packaging and marketing disclosing that its Brand A Very Low Nicotine cigarettes reduce smokers' exposure to nicotine. We still expect 22nd Century to bifurcate the application into a Premarket Tobacco Product application (PMTA) and MRTP. The PMTA could advance quickly while the MRTPA would likely take 12 months to conclude.

This company has received guidance from the FDA regarding design and implementation of two parallel, Phase III clinical trials of 22nd Century's X-22 prescription-based smoking cessation product. Further work will be required to reach agreement on the construction of these trials which could begin in the first half of 2018, depending on funding.

We expect the company to also receive guidance from the FDA on an MRTP for Brand B, the company's low tar-to-nicotine product. This is a third path for commercialization in a market that has been prevented by government from innovating. However, because of the company's unique technology as well as progress on determining, in conjunction with the FDA, the efficacy of 22nd Century's products on smoking cessation and smoking behavior, it could end up offering a truly innovate product to the market.

We believe all of these paths are consistent with the FDA's proposed new regulatory path, but how the new plan will impact the timing of these is uncertain.

We expect continued momentum in revenue growth for the remainder of the year as well as progress on the multiple paths the company is pursuing to commercialize its technology that regulates nicotine in tobacco plants. Recently, the company strengthened its balance sheet with a warrant exchange that raised over \$13 million resulting in a cash runway well in to 2019. We expect a strong Q2 and even stronger 2H as it delivers on a large contract manufacturing agreement. There has also been advancements recently on 22nd Century's three-pronged approach to monetizing the company technology for the smoking cessation and traditional smoking market. In our view, this is bullish for the shares and supports our Buy recommendation and \$3.50 price target.

We value X-22/Modified risk at \$2.50 per share and the combined value of the potential BAT royalty stream and commercial products at \$1.00 per share to reflect a modest tempo in the roll-out of commercial products as well as a less steep ramp for the BAT royalties. We have not given any value for the company's 25% ownership of Anandia or its exclusive US rights to four genes required for cannabinoid production in the cannabis plant. 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.

Investment Summary:

The company's path to value creation remains the same: monetizing its extensive intellectual property which allows it to modulate the level of nicotine in tobacco plants through genetic engineering and plant breeding. There are a number of paths the company is pursuing to monetize this technology.

One of the most promising paths for 22nd Century is the pending application with the FDA for a reduced exposure designation for its Brand A, low-nicotine cigarette.

Most of the company's revenues this year have been for contract manufacturing which it is seeking to expand.

Recently, in testimony for the Crede litigation, the company stated that its patents are worth more than \$200 million, or greater than \$2.50 per share. We value X-22/Modified risk at \$2.50 per share and the combined value of the potential BAT royalty stream and commercial products at \$1.00 per share to reflect a modest tempo in the roll-out of commercial products as well as a less steep ramp for the BAT royalties. We have not given any value for the company's 25% ownership of Anandia or its exclusive US rights to four genes required for cannabinoid production in the cannabis plant. 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. The company is fully funded for almost two years.

Valuation:

We value X-22/Modified risk at \$2.50 per share and the combined value of the potential BAT royalty stream and commercial products at \$1.00 per share. We have not included a value for the company's investment in Anandia.

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.

22nd Century Group, Inc.
Actual v. Estimates

Q2 17				
	Actual	Estimates		
Revenue	\$ 3,897	\$ 2,582		50.9%
Cost Of Goods Sold	4,062	2,600		56.2%
Gross Profit	(165)	(18)		NM
R&D	813	550		47.9%
G&A	1,805	1,400		28.9%
Sales & marketing	268	350		-23.5%
Depreciation & Amort.	231	193		20.2%
Opex	3,117	2,493		25.1%
Operating Income	\$ (3,283)	\$ (2,511)		-30.8%
Interest Expense	4	(2)		
Other	0	0		
Warrant Charge	(78)	0		
Pretax Income	(3,356)	(2,513)		
Income Tax Expense	0	0		
Net before Minority Interest	(3,356)	(2,513)		
Minority Interest				
Net to Common	\$ (3,356)	\$ (2,513)		
Shares	91,578	91,000		
EPS	\$ (0.04)	\$ (0.03)		

Required Research Disclosures



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Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [BUY]	65	66.33	20	30.77
HOLD [NEUTRAL]	30	30.61	2	6.67
SELL [SELL]	2	2.04	0	0.00
NOT RATED [NR]	1	1.02	1	100.00

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RATINGS

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.

22nd Century Group, Inc. (XXII) - \$2.24 - Buy

Price Target \$3.50

VALUATION:

We value X-22/Modified risk at \$2.50 per share and the combined value of the potential BAT royalty stream and commercial products at \$1.00 per share. We have not included a value for the company's investment in Anandia.

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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