CHARDAN

Company Update
November 8, 2017
Industrial & Consumer Technology

22nd Century Group, Inc. (XXII - $2.06 - 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	11/08/17
Price	$2.06
52 Week Range	($0.81 - $3.50)
Price Target	$11.50
Market Cap (mil)	$254.20
Shares out (mil)	123.40
3-Mo Avg Vol	4,199,136
Cash per share	$0.50
Total Debt (mil)	$0.31

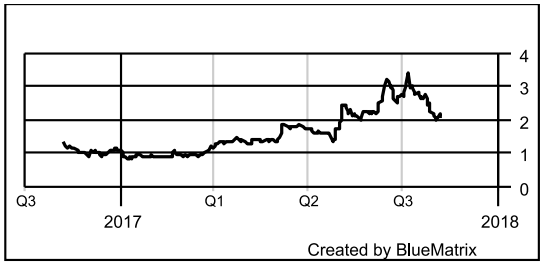
Revenues ($ millions)

Yr Dec	2016A	2017E		2018E	
	Actual	Curr	Prev	Curr	Prev
Mar	3.0	2.2A	–	–	–
Jun	2.8	3.9A	–	–	–
Sep	3.1	4.0	–	–	–
Dec	3.3	6.6	–	–	–
YEAR	12.3	16.7	–	21.5	–

EPS Basic

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)	–	(0.07)	–

One year price history XXII



Recent Stock Decline Overdone. XXII is Key to FDA's New Regulatory Regime

22nd Century shares are down ~40% from its 52-week high reached in early October and we believe at least some of that relates to the Altria analyst day held earlier this month. To some, Altria's MRTP and PMTA applications for IQOS may be construed as an alternative path for Big Tobacco to comply with still yet to be proposed rules on the FDA's new comprehensive regulatory plan that "places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts." We believe these fears are overstated particularly in light of the FDA's continued assertion that lowering nicotine levels in combustible cigarettes will be the centerpiece of its new regulatory plan. In our view, 22nd Century controls the technology that the FDA intends to utilize to reduce nicotine addiction for the two-thirds of smokers wanting to quit. This regulatory change will be a multi-year process, and there will be resistance by industry to these changes. However, we think the die is cast and significant changes are coming. With its recent $54 million capital raise 22nd Century has the resources it needs for the coming multi-year process.

Of major import for 22nd Century, the FDA is placing nicotine and addiction "at the center" of its regulatory efforts. There are about 40 million smokers in the US, over 480,000 smoking-related deaths every year and more than 16 million Americans are living with a smoking-related disease. Studies suggest about half try to quit every year and over two-thirds would like to quit. That is, 22nd Century's technology addresses the largest segment of the market and the FDA recognizes the public health benefit by implementing a regulatory regime that places nicotine and addition front and center. Also, our estimates and price target assume 22nd Century will capture some of the market for nicotine-reduced products, far below the two-thirds of the market that wants to quit. Secondary to nicotine reduction, the FDA is looking at allowing non-combustible products, which addresses the smaller segment of the market, smokers who don't want to quit. We believe there are considerable risks in gaining regulatory approval and market acceptance for these non-combustible products and placing too much faith in the timing and size of the product from a regulatory and market perspective could prove dangerous.

In July the FDA announced it would change its regulatory focus to "lowering nicotine levels in combustible cigarettes to non-addictive levels." The FDA recognizes there is a "continuum of risk" in how nicotine is and can be delivered. At the highest risk level are combustible cigarettes and at the other end medicinal nicotine products. 22nd Century's technology, which controls nicotine levels in tobacco, is currently the most cost-effective solution for tobacco makers to comply with the coming regulations of the FDA that, to reiterate, puts lowering nicotine levels in combustible cigarettes at the centerpiece of the regime.

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.

The FDA recognizes the differing levels of risk of alternative nicotine-delivery methods. It also wants to take a fresh look at non-combustible alternatives, like electronic nicotine delivery systems, or ENDS, which includes vapes, vaporizers, vape pens, and e-cigs, and heat-not-burn technology, which is at the heart of the IQOS.

Philip Morris International (PMI) has two applications pending with the FDA on IQOS. (Assuming FDA approval, Altria, via a license with PMI, would distribute and sell IQOS in the US). In March 2017 PMI submitted a pre-market tobacco application to the FDA. This was filed in August 2017, which started a clock on a scientific review that is supposed to give the FDA 180 days to act on the application. 180 days from the August 2017 application is February of next year. We believe an application of such import and complexity is unlikely to be decided within that 180 day period.

In order to approve a PMTA the FDA must be convinced that marketing the product is appropriate for the protection of the public health and that is determined partly by the likelihood existing users will stop and the likelihood non-users won't start. How this will be applied in the IQOS application for a non-combustible cigarette and how the recent change in the FDA's focus will impact the application are open questions. We would point out keeping to timelines is not a core competency of regulatory bodies and in the face of the significant changes underway it is more likely than not the PMTA determination gets pushed to the right.

PMI also submitted an MRTP (modified risk tobacco product) application in December 2016. It is seeking permission to claim switching to IQOS can reduce the risks of tobacco-related diseases, presents less risk of harm than continuing to smoke cigarettes, and reduces the body's exposure to harmful and potentially harmful chemicals. The application was filed in May 2017 and Altria hopes the FDA will host a Tobacco Products Scientific Advisory Committee on the application in May of next year. This too, we believe, is likely to get pushed to the right in light of the regulatory changes afoot at the FDA.

We believe both applications will be subject to intense review on the public health risks and benefits, particularly in light of the pending regulatory changes. Plus, the FDA has been consistently concerned over marketing to non-adults. Almost 90% of adult smokers started before they were 18 and 95% started by age 21. By the time a person is 26 years old the odds he will be a smoker is about 1%. Since IQOS is non-combustible, and arguably less harmful than a combustible cigarette, maybe the FDA will be less concerned about non-smokers taking up the product, but we seriously doubt it.

We believe the market response on how this impacts 22nd Century is over-stated. The FDA's goal is to reduce the harm from cigarettes. It is convinced lowering nicotine to non-addictive levels in combustible cigarettes is the key strategy for smokers who are looking to quit, which is about two-thirds of the market. It also knows there is a "continuum of risk" and non-combustible cigarettes are potentially safer than combustible cigarettes for consumers who want to consume nicotine. But it also probably recognizes the goal of IQOS and e-cigs is to keep the consumer addicted to nicotine and will need to be convinced harm is reduced and non-adults do not have a path to smoking before granting a PMTA or an MRTP. Whether the science currently supports those conclusions to the satisfaction of the FDA is unknown, but given the FDA is a risk-adverse organization and is changing its regulatory regime we believe timetables are likely to get pushed to the right.

An interesting aspect of the heat-not-burn market is tobacco will be used in the HeatSticks and the consumer will be demanding a certain amount of nicotine per session, similar to the amount of nicotine delivered in combustible cigarettes. We believe 22nd Century's ownership of the genes that regulate nicotine in tobacco is an important technology for this product should it be approved by the FDA.

We think a royalty and license model is the most likely path for 22nd Century, but not the only one. XXII owns a manufacturing plant in North Carolina and currently, the company 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. Receiving this approval would likely result in greater interest by potential partners in working with XXII.

We still expect 22nd Century to bifurcate the current 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 also 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. Approval on these applications can be leverage for the FDA as well in persuading industry to accept potential regulatory changes.

Our 12-month price target is $11.50 per share. The following table is based on a successful royalty/licensing model in the US. There are 12 billion packs of cigarettes sold in the US annually and the table shows potential per share value to XXII at 5%, 10% and 25% market share and per pack royalty of $0.10, $0.15, $0.20 and $0.25. The per share values presented in the table assume five-years for the FDA rulemaking to complete and industry to respond and a 20% discount rate.

XXII: Per share Value based on royalty/market share
US Market

		Market Share		
		5%	10%	25%
Royalty per pack	$ 0.10	$ 3.91	$ 7.82	$ 19.54
	$ 0.15	$ 5.86	$ 11.72	$ 29.31
	$ 0.20	$ 7.82	$ 15.63	$ 39.08
	$ 0.25	$ 9.77	$ 19.54	$ 48.85

Our price target assumes a $0.15 per pack royalty and 10% market share in 5 years, discounted at 20%. The $0.15 per pack royalty is consistent with the implicit investor estimate of the value to Big Tobacco of the regulatory change as well as the estimate articulated by Philip Morris International.

Our estimates currently assumes a five year timeline for XXII to deploy its technology. But as pointed out earlier the company is pursuing multiple paths with the FDA for reduced exposure claims and could conceivable receive authority to state its product has nicotine below addictive levels. Either of these claims could accelerate the time to market and the expected value of the technology. For instance, if instead of using a five year estimate to achieve the market share shown in the table, we use three year estimate, the $11.50 price target would increase to $17 per share.

The numbers are significantly larger if we include an estimate for regulatory changes in the rest of the world. New Zealand, Canada, the UK and Finland are all looking at changes in required nicotine levels. Investors have taken notice as on the day of the FDA announcement Philip Morris International did not decline but has fallen about 4% over the past couple of months as the potential for regulatory change has become more likely in the rest of the world.

The table below, similar to the table above, presents XXII per share value using different market share and royalty per pack estimates, but instead of using 12.1 billion packs per year sold in the US, we use the 37.8 billion packs sold per year in the US and EU.

XXII: Per share Value based on royalty/market share
US and EU Market

		Market Share		
		5%	10%	25%
Royalty per pack	$ 0.10	$ 12.32	$ 24.63	$ 61.58
	$ 0.15	$ 18.48	$ 36.95	$ 92.38
	$ 0.20	$ 24.63	$ 49.27	$ 123.17
	$ 0.25	$ 30.79	$ 61.58	$ 153.96

We maintain our Buy recommendation one 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.

22nd Century Group, Inc
Income Statement $ in 000s

	2014	2015	2016	Q1 17	Q2 17	Q3 17 E	Q4 17 E	2017 E	2018 E	2019 E
Revenue	$ 529	$ 8,522	$ 12,280	$ 2,232	$ 3,897	$ 5,087	$ 6,642	$ 17,858	$ 21,500	$ 25,651
Cost Of Goods Sold	498	9,103	12,710	2,505	4,062	4,644	6,021	17,232	19,350	17,359
Gross Profit	31	(581)	(430)	(274)	(165)	444	621	626	2,150	8,291
R&D	1,249	1,669	2,341	551	813	550	550	2,464	2,314	2,661
G&A	8,793	7,760	6,193	1,620	1,805	1,400	1,400	6,226	6,806	7,487
Pre-Mfg. Facility Costs	1,177	0	0					0	0	0
Sales & marketing	86	1,358	1,582	296	268	350	350	1,263	1,242	1,552
Depreciation & Amort.	463	676	842	229	231	193	193	845	770	847
Opex	11,768	11,463	10,958	2,696	3,117	2,493	2,493	10,799	11,132	12,547
Operating Income	$ (11,737)	$ (12,044)	$ (11,388)	$ (2,970)	$ (3,283)	$ (2,049)	$ (1,872)	$ (10,173)	$ (8,982)	$ (4,255)
Interest Expense	(7)	(22)	(21)	8	4	(2)	(2)	8	(8)	(8)
Other	(30)	889	(202)	346	0	0	0	346	0	0
Warrant Charge	(3,821)	145	30	(5)	(78)	0	0	(83)	0	0
Pretax Income	(15,595)	(11,032)	(11,581)	(2,621)	(3,356)	(2,051)	(1,874)	(9,901)	(8,990)	(4,263)
Income Tax Expense	0	0	0	0	0	0	0	0	0	(1,492)
Net before Minority Interest	(15,595)	(11,032)	(11,581)	(2,621)	(3,356)	(2,051)	(1,874)	(9,901)	(8,990)	(2,771)
Minority Interest	0	0	0					0	0	0
Net to Common	$ (15,595)	$ (11,032)	$ (11,581)	$ (2,621)	$ (3,356)	$ (2,051)	$ (1,874)	$ (9,901)	$ (8,990)	$ (2,771)
Shares	59,993	68,143	79,843	90,700	91,578	99,888	123,400	101,391	123,500	125,500
EPS	($0.26)	($0.16)	($0.15)	($0.03)	($0.04)	($0.02)	($0.02)	($0.10)	($0.07)	($0.02)

22nd Century Group, Inc
Balance Sheet and Cash Flow Statement $ in 000s

	2014	2015	2016	Q1 17	Q2 17	Q3 17 E	Q4 17 E	2017 E	2018 E
Cash	6,403	3,760	13,468	10,729	12,483	10,965	59,908	59,908	52,853
Due from relaed party and officers	46	0	0	0	0	0	0	0	0
A/R	0	51	41	2	718	482	528	528	616
Inventory	2,065	2,706	3,093	3,035	4,288	4,814	5,945	5,945	4,973
Prepaid Consulting Fees	1,979	0	0	0	0	0	0	0	0
Prepaid Exp.	214	636	196	434	551	619	764	764	639
Total Current Assets	**$ 10,707**	**$ 7,154**	**$ 16,797**	**$ 14,200**	**$ 18,040**	**$ 16,880**	**$ 67,145**	**$ 67,145**	**$ 59,082**
Patent and Trademark costs	7,078	7,364	7,390	7,439	7,444	7,383	7,321	7,321	7,076
PP&E	2,851	2,556	2,435	2,360	2,272	2,303	2,331	2,331	2,395
Equity Investment	1,318	1,223	1,020	1,366	1,366	1,366	1,366	1,366	1,366
Total Assets	**$ 21,954**	**$ 18,296**	**$ 27,642**	**$ 25,365**	**$ 29,122**	**$ 27,933**	**$ 78,163**	**$ 78,163**	**$ 69,920**
Bank Loans and N/P	495	309	308	314	321	321	321	321	321
A/P	884	1,283	1,340	1,729	2,269	2,547	3,146	3,146	2,631
Accrued Expenses	1,294	1,570	1,601	1,376	1,498	1,681	2,077	2,077	1,737
Deferred Revenue	0	0	0	0	0	0	0	0	0
Total Current Liabilities	**$ 2,673**	**$ 3,162**	**$ 3,249**	**$ 3,419**	**$ 4,087**	**$ 4,549**	**$ 5,543**	**$ 5,543**	**$ 4,689**
Long-Term Debt	605	308	0	0	0	0	0	0	0
Accrued Severance	412	200	0	0	0	0	0	0	0
Warrant Liability & Other	3,043	2,898	59	64	142	142	142	142	142
Shareholder's Equity	15,220	11,729	24,334	21,882	24,893	23,242	72,479	72,479	65,089
Total Liabilities And Equity	**$ 21,954**	**$ 18,296**	**$ 27,642**	**$ 25,365**	**$ 29,122**	**$ 27,933**	**$ 78,163**	**$ 78,163**	**$ 69,920**

	2014	2015	2016	Q1 17	Q2 17	Q3 17 E	Q4 17 E	2017 E	2018 E
Net Income	(15,595)	(11,032)	(11,581)	(2,621)	(3,356)	(2,051)	(1,874)	(9,901)	(8,990)
Depreciation & Amort.	463	774	842	205	150	155	159	668	681
Stock Comp	2,293	1,326	881	169	350	350	350	1,219	1,400
Other	6,740	2,341	241	(318)	78	0	0	(241)	0
Working Capital	(483)	(731)	(270)	(129)	(1,425)	104	(328)	(1,778)	154
Operating Cash Flow	$ (6,583)	$ (7,322)	$ (9,888)	$ (2,695)	$ (4,203)	$ (1,443)	$ (1,693)	$ (10,033)	$ (6,754)
Acquisition of Patents and trademarks	(727)	(413)	(357)	(30)	0	0	0	(30)	0
Capx	(212)	(37)	(197)	(14)	(125)	(125)	(125)	(389)	(500)
Other	(1,769)	0	0	0	0	0	0	0	0
Investing Activities	$ (2,708)	$ (451)	$ (554)	$ (44)	$ (125)	$ (125)	$ (125)	$ (419)	$ (500)
Debt	(4)	(508)	(333)	0	6	0	0	6	0
Equity	9,859	5,592	20,483	0	12,413	50	50,760	63,223	200
Other	7	46	0	0	0	0	0	0	0
Financing Activities	$ 9,863	$ 5,130	$ 20,149	$ -	$ 12,420	$ 50	$ 50,760	$ 63,230	$ 200
Change in Cash	**$ 572**	**($2,642)**	**$ 9,708**	**($2,739)**	**$ 8,092**	**($1,518)**	**$ 48,942**	**$ 52,778**	**($7,054)**

Required Research Disclosures

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Chardan Capital Markets

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [BUY]	**66**	**66.67**	**24**	**36.36**
HOLD [NEUTRAL]	**31**	**31.31**	**2**	**6.45**
SELL [SELL]	**1**	**1.01**	**0**	**0.00**
NOT RATED [NR]	**1**	**1.01**	**1**	**100.00**

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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 - $2.06 - 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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