

**22nd Century Group, Inc. (XXII - \$1.06 - Buy)**

**FLASH NOTE**

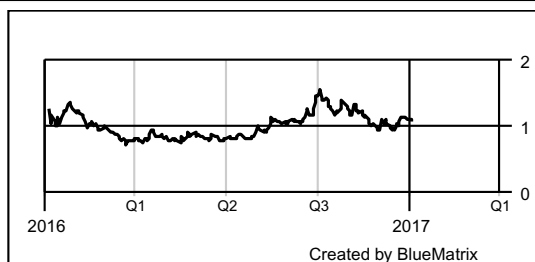
**JAMES McILREE, CFA**, Senior Research Analyst, +1-646-465-9034  
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**Sales and trading** 7 a.m. to 7 p.m. ET, (646) 465-9090

**Sales and trading** 7 p.m. to 7 a.m. ET, (646) 465-9063

Stock Data	01/04/17
52 Week Range	(\$0.71 - \$1.71)
Price Target	\$3.50
Market Cap (mil)	\$96.14
Shares out (mil)	90.70

**One year price history XXII**



For the last note available [click here](#)  
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**FDA responds to MRTP Application**

About a year ago 22nd Century filed with the FDA an application seeking a reduced exposure claim for its Brand A, very-low nicotine (VLN) cigarette. According to the company the FDA wants more information on smoking cessation and harm reduction objectives in independent clinical studies that have already occurred. In response to this and other dialog with the FDA the company is re-submitting its MRTP but bifurcating its application into a PMTA (Premarket Tobacco Product Applications) to sell the product and the MRTP which would potentially allow the reduced exposure claim. As with many government applications this is one step back and two steps forward.

We did not expect the company to receive outright approval from the FDA and expected the agency to require more information. For now, the agency is not asking for additional studies, or expensive trials from the company, and that bodes well for both the PMTA and the MRTP. Our sense is the agency is looking to build a complete record for the proceeding.

Timing on next steps is uncertain. The PMTA application can be acted on before the MRTP but is toothless for 22nd Century until the MRTP is acted upon. Nevertheless we believe it could be a necessary pre-condition for the MRTP. It is possible the MRTP takes another 12 months, but given much of the material is already in the FDA's hands, the information requested is publicly available just not part of the public record, we think a shorter time frame is more likely.

Meanwhile, the company continues to work on Phase III funding. The likelihood of 22nd Century finding a partner for a Phase III trial of the company's X-22 very-low nicotine (VLN) cigarette for smoking cessation is increased with the recent capital raise and studies demonstrating the efficacy of VLN therapy. We believe the willingness of physicians to prescribe VLN cigarettes as a smoking cessation tool has been a key concern of potential partners for the phase III study 22nd Century is pursuing and this survey will possibly alleviate some of those concerns and makes a partnership more likely. Potential partners include commercial organizations as well as non-profits whose mission includes reduced smoking programs.

We also think the company is making progress on expanding its contract manufacturing business and expect business to continue to build over the coming quarters.

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. 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.

**Valuation:**

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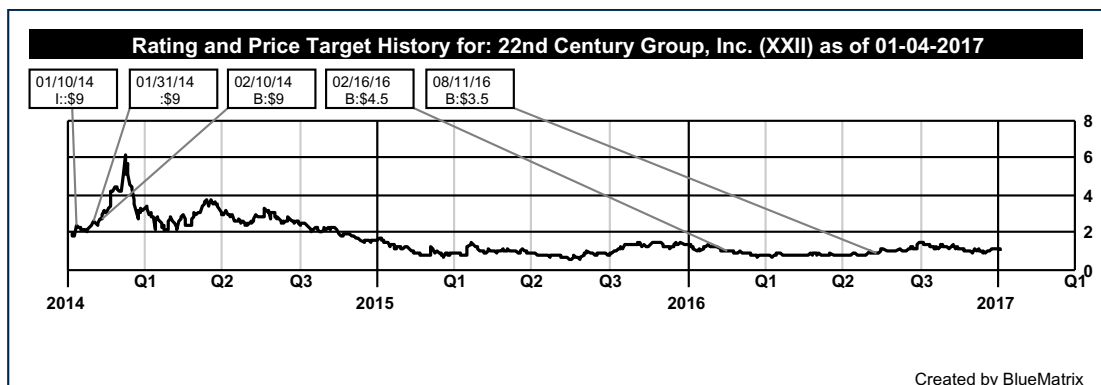
**Risks to achievement of target price:**

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.

**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.

## Important Research Disclosures



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Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
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NOT RATED [NR]	0	0.00	0	0.00

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