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22nd Century Group, Inc. (NYSE AM: XXII)

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Buy: Multiple Catalysts on the Horizon

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Q2 revenue was better than expected and we believe there are multiple catalysts on the horizon, including the FDA's approval of the company's MRTP application, announcement of a third franchise on August 30th, monetization of the legacy Anandia IP, revenue from the Colorado farm crop, and VLN launches in international markets. In the coming quarters, we also expect further license revenues, proceeds from additional crop harvests and a low-nicotine mandate.

Q2 revenue was \$8.4 million, a 23% Q/Q and 30% Y/Y increase. Gross margin was 7%, down from Q1's 9.5% but more than double the year-ago level. We have modeled the Q2 rate of contract manufacturing revenue and margin will continue for the coming quarters.

We believe the FDA's approval of 22nd Century's MRTP application will be a significant catalyst for the shares. The company expressed confidence the application will be approved soon and indicated the FDA is in the document preparation stage. There is still risk of a negative outcome, or further delays, but we continue to expect approval this year. 22nd Century is ready to launch pilot programs within 90 days of approval and a more substantial launch after evaluation of the pilot results and modification of the strategy. We have assumed meaningful domestic VLN revenue begins in Q4 22 and view this as quite conservative.

A third franchise will be announced on August 30th. The company expects to leverage its expertise in plant biotechnology, regulatory navigation, and the strategic partnerships it has assembled for the hemp/cannabis franchise. The addition of another revenue source, in a market facing less regulation than tobacco, that reduces dependence on favorable regulatory rulings, is, in our view, a major positive for the company.

In Q4, we expect a license payment from the IP it shares with Aurora Cannabis (NASDAQ: ACB, \$7.35, Not Rated). Aurora and 22nd Century Group share the global intellectual property (IP) rights to certain patents and patent applications relating to genes in the hemp/cannabis plant required for the production of cannabinoids in the cannabis plant. The two are working closely together to enforce their IP against infringing parties and explore commercial development opportunities. Additional revenue in 2022 from this initiative is likely.

(Continued on page 2.)

Valuation: Our \$7 price target is the sum of: \$3.08/share for the VLN asset, \$3.18/share for the low-nicotine mandate and \$0.74 for the hemp/cannabis franchise.

Risks to Target: Our price target assumes approval of the company's MRTP application and a nicotine mandate, which could be delayed or may not be approved. Finding a partner for the VLN business could take longer than estimated and/or on different terms than assumed. The nicotine mandate may take longer to decide, and the transition period could be longer than estimated. There is no guarantee the industry will use 22nd Century's solution and it may opt to focus on other nicotine delivery systems as regulation of the combustible cigarette market increases. This could affect our assumptions on the royalty rate and market share.

Current Price	\$3.52		
Price Target	\$7.00		
Estimates	F2020A	F2021E	F2022E
Revenues (\$000s)	\$ 28,111	\$ 33,177 E	\$ 37,300
1Q March	\$ 7,058	\$ 6,806 A	\$ 10,000
2Q June	\$ 6,435	\$ 8,371 A	\$ 8,400
3Q September	\$ 7,310	\$ 8,000 E	\$ 8,400
4Q December	\$ 7,308	\$ 10,000 E	\$ 10,500
	F2020A	F2021E	F2022E
EPS (diluted)	\$ (0.14)	\$ (0.13)E	\$ (0.15)
1Q March	\$ (0.03)	\$ (0.03)A	\$ (0.04)
2Q June	\$ (0.04)	\$ (0.03)A	\$ (0.04)
3Q September	\$ (0.03)	\$ (0.04)E	\$ (0.04)
4Q December	\$ (0.05)	\$ (0.03)E	\$ (0.03)
EBITDA (\$Ms)	\$ (16.0)	\$ (18.1)	\$ (19.4)
EV/EBITDA (x)	-32.1x	-28.4x	-26.4x
Stock Data			
52-Week Range	\$0.55	-	\$6.07
Shares Outstanding (mil.)	162.6		
Market Capitalization (mil.)	\$572		
Enterprise Value (mil.)	\$513		
Debt to Capital	4%		
Book Value/Share	\$0.54		
Price/Book	6.6x		
Average Three Months Trading Volume (K)	4,065		
Insider Ownership	2.4%		
Institutional Ownership	28.2%		
Short interest (mil.)	7.7%		
Dividend / Yield	\$0.00/0.0%		



Revenue from the harvest of the company's hemp crop is anticipated in Q4 of this year, but, depending on timing and delivery, could be pushed to the right. We have assumed revenue recognition in Q1 22. Going forward, the company will use its strategic partnerships that include CannaMetrix to develop a roadmap on plant lines, KeyGene for plant line development, breeders for trial capabilities, the company's farm for cultivation and Panacea for extraction and purification. This is a powerful, vertically integrated, unique set of capabilities in the industry and we expect the company to aggressively pursue opportunities in this space as the next year unfolds.

International distribution of VLN in select international markets is expected to begin in Q1 of next year. This will likely occur in locations that have less strict regulatory frameworks than the U.S. but still have substantial tobacco markets. After approval of the MRTP application, the company intends to expand its international footprint, particularly in markets that follow the U.S. regulatory lead. We have assumed modest contributions from this endeavor and there is ample room for upside to our estimates.

As next steps progress, we expect additional efforts to license, in conjunction with Aurora, the legacy Anandia technology, and develop new strains of hemp utilizing the partnerships described above. Both of these initiatives are likely to generate revenue next year, in our view, but given the timing and scope, we have not included meaningful amounts in our model.

The low-nicotine mandate, in our opinion, remains a major catalyst for the shares. We believe it is reasonable to assume a new mandate would broadly follow the 2018 ANPRM since none of the studies supporting the efficacy of a low-nicotine mandate have been invalidated and, in our opinion, technical achievability of a mandate has been demonstrated by 22nd Century.

The [ANPRM](#) was published in March 2018 and the comment period closed in July 2018. An argument can be made that a similar comment period would be allowed if a Notice of Proposed Rulemaking (NPRM) were issued, but since a lot of the ground has already been covered in the ANPRM, it is also reasonable to believe that there would be a shorter comment period. "[A Guide to the Rulemaking Process](#)" has been published in the Federal Register and it indicates comment periods generally range from 30 to 60 days, but more complex rules can have comment periods of 180 days or more. Our guess is a rule of this import would require a three- to four-month comment period, similar to the 2018 ANPRM.

After that, there isn't a required time mentioned in "A Guide to the Rulemaking Process" for a federal agency to consider the comments and issue a final rule, if a final rule is to be issued at all. Based on our knowledge of a variety of federal agencies, a normal period to consider the comments and issue a final rule can be three to six months. The more complex the rule, or the more impactful, the longer this period will likely be.

The ANPRM asked about transition times if a mandate were issued, and this could be critical for 22nd Century. In our view, a shorter transition period would be more positive for the company since it would allow less time for alternatives to be explored, developed, and deployed by competitors.

We believe 22nd Century's technology remains the most efficient, economical way to comply with a low-nic mandate. The FDA's ANPRM included a discussion on the "Technical Achievability" of a maximum nicotine level in combustible cigarettes and asserted the standard can be achieved via some combination of a). blending and cross breeding plants, b). genetic engineering, c). chemical extraction, and d). other agricultural practices.

Blend. In the ANPRM, the FDA cited 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 was considering, we are uncertain if blending alone can be used to meet the standard and how long it would take to develop plants with the required amounts of nicotine.

Genetic Engineering. Genetic engineering of tobacco, per the ANPRM, has been of interest to the tobacco industry for decades and VLNC (very-low-nicotine-content) cigarettes have been produced since the 1970s. 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 singled out 22nd Century's technology as a way to achieve the standard. Specifically, the ANPRM stated, "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 U.S. market (see: [https://en.wikipedia.org/wiki/Next_\(cigarette\)](https://en.wikipedia.org/wiki/Next_(cigarette))). 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, [in 2017, 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. If the FDA adopts an aggressive standard, and a relatively short implementation period, covering all product categories, we believe this is very bullish for 22nd Century, as industry participants admit that using chemical methods to de-nic cigarettes and/or cross-breeding and their own genetic engineering capableness will be both expensive and time-consuming.

Q2 Results

Revenue was better than expected, but gross margin was lower than anticipated and operating expenses were higher. The company is building up sales, marketing and R&D infrastructure in anticipation of launching multiple revenue initiatives in the coming quarters.

Q2 21			
<i>\$ in 000's, except per-share data</i>	Actual	Estimates	
Revenue	\$ 8,371	\$ 7,000	19.6%
Cost Of Goods Sold	7,785	6,159	26.4%
Gross Profit	586	841	-30.3%
R&D	746	701	6.4%
G&A	6,177	4,829	27.9%
Depreciation & Amort.	303	288	5.2%
Opex	7,226	5,818	24.2%
Operating Income	\$ (6,640)	\$ (4,977)	-33.4%
Other	2,372	36	
Warrant Charge	0	0	
Interest Income	108	309	
Interest Expense	(14)	(7)	
Pretax Income	(4,174)	(4,639)	
Income Tax Expense	0	0	
Net to Common	\$ (4,174)	\$ (4,639)	
Shares (000)	154,811	157,421	
EPS	\$ (0.03)	\$ (0.03)	
D&A	302	288	
Stock Comp	1,245	507	
EBITDA	(5,093)	(4,182)	

Source: 22nd Century Group, Inc. and Dawson James Securities estimates

Outlook

We have increased our revenue estimates for this year and next based on Q2 results and the numerous revenue vectors we described above. We believe our outlook is conservative and there are opportunities to substantially exceed our estimates.

	2021E		2022E	
	Old	New	Old	New
Revenue (\$M)	\$ 29.8	\$ 33.2	\$ 32.0	\$ 37.3
EPS	\$ (0.11)	\$ (0.13)	\$ (0.10)	\$ (0.15)
EBITDA (\$M)	\$ (15.5)	\$ (18.1)	\$ (15.7)	\$ (19.4)

Source: Dawson James Securities estimates

Our price target of \$7 comprises three components: We attribute about \$3.08/share for the VLN asset. The non-addictive nicotine mandate is valued at \$3.18 per share. The remainder of the price target, or \$0.74 per share, equals about \$112 million and encompasses the company's investment in Panacea, the Anandia licenses and the potential from its relationship with KeyGene. We have assumed a long gestation period for the hemp/cannabis business because it is in the early stages. However, the Aurora announcement and the restructuring of the Panacea investment could be catalysts to more rapid development of the market and 22nd Century's monetization efforts.

Price Target. Our \$7 price target is the sum of the estimated values of the VLN, non-addictive nicotine and hemp franchises. We attribute about \$3.08/share for the VLN asset. The non-addictive nicotine mandate is valued at \$3.18 per share. The remainder of the price target comprises the investment in the hemp business and the relationship with KeyGene.

Risk Analysis

The tobacco industry is highly regulated, and our price target depends on approval of the company's MRTP application and a nicotine mandate, which could be delayed or may not be approved. Our price target assumes the company will find a partner for the VLN business and this could take longer than estimated and/or the partner could demand different terms than assumed. The nicotine mandate may take longer to decide, and the transition period could be longer than estimated. There will likely be other paths attempted by the industry to comply or the industry may opt to focus on other nicotine delivery systems as regulation of the combustible cigarette market increases. This could affect our assumptions on the royalty rate as well as market share.

Exhibit 1. Income Statement

<i>(\$ in 000's except per-share data)</i>	2018	2019	2020	Q1 21 A	Q2 21 A	Q3 21 E	Q4 21 E	2021 E	2022 E
Revenue	\$ 26,426	\$ 25,833	\$ 28,111	\$ 6,806	\$ 8,371	\$ 8,000	\$ 10,000	\$ 33,177	\$ 37,300
Cost Of Goods Sold	25,527	25,818	26,673	6,159	7,785	7,360	7,360	28,664	32,040
Gross Profit	899	14	1,438	647	586	640	2,640	4,513	5,260
	3.4%	0.1%	5.1%						
R&D	14,990	8,057	4,128	701	746	1,000	1,000	3,447	4,000
G&A	7,658	12,956	14,971	4,829	6,177	6,177	6,177	23,360	25,638
Impairment Charge	0	1,142	176	0	0	0	0	0	0
Sales & marketing	927	0	0	0	0	0	0	0	0
Depreciation & Amort.	1,342	1,425	1,346	288	303	303	303	1,197	1,212
Opex	24,918	23,581	20,621	5,818	7,226	7,480	7,480	28,004	30,850
Operating Income	\$ (24,019)	\$ (23,566)	\$ (19,183)	\$ (5,171)	\$ (6,640)	\$ (6,840)	\$ (4,840)	\$ (23,491)	\$ (25,590)
Other	14,945	(4,002)	(428)	36	2,372	0	0	2,408	0
Impairment Charge	49	0	(1,741)	0	0	0	0	0	0
Interest Income	1,069	1,066	1,751	112	108	312	283	815	897
Interest Expense	(11)	(56)	(72)	(7)	(14)	(14)	(14)	(49)	(56)
Pretax Income	(7,967)	(26,559)	(19,673)	(5,030)	(4,174)	(6,542)	(4,571)	(20,317)	(24,749)
Income Tax Expense	0	0	38	0	0	0	0	0	0
Net to Common	\$ (7,967)	\$ (26,559)	\$ (19,711)	\$ (5,030)	\$ (4,174)	\$ (6,542)	\$ (4,571)	\$ (20,317)	\$ (24,749)
Shares (000)	124,299	125,883	138,813	144,258	154,811	162,710	162,985	156,191	163,798
EPS	(\$0.06)	(\$0.21)	(\$0.14)	(\$0.03)	(\$0.03)	(\$0.04)	(\$0.03)	(\$0.13)	(\$0.15)
D&A	1,200	1,425	1,346	288	302	302	302	1,194	1,208
Stock Comp	3,187	3,540	1,654	507	1,245	1,245	1,245	4,242	4,980
Other	0	1,142	176	0	0	0	0	0	0
EBITDA	\$ (19,632)	\$ (17,459)	\$ (16,007)	\$ (4,376)	\$ (5,093)	\$ (5,293)	\$ (3,293)	\$ (18,055)	\$ (19,402)

Source: 22nd Century Group, Inc. and Dawson James Securities estimates

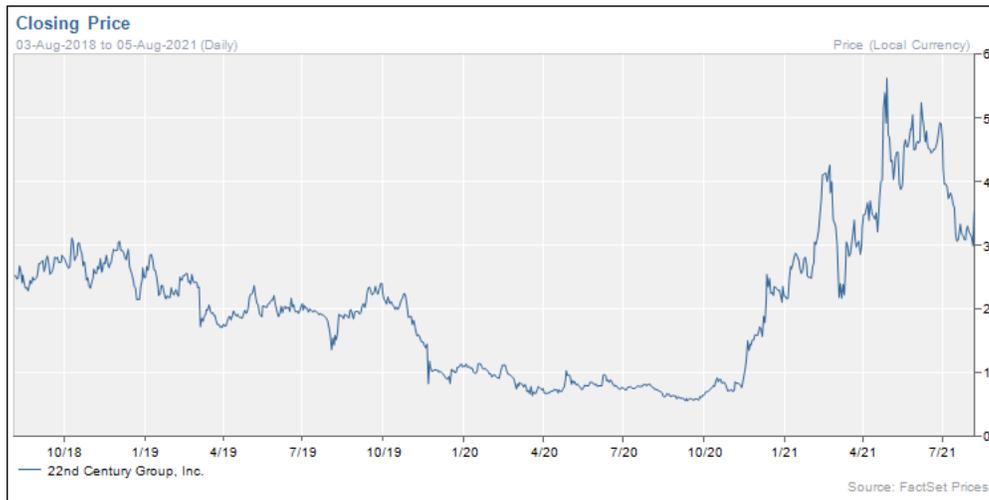
Exhibit 2. Balance Sheet and Cash Flow Statement

(\$ in 000's)	2018	2019	2020	2021 E	2022 E
Cash	605	485	1,029	2,037	2,037
Short-Term Investments	55,749	38,477	21,313	50,354	30,093
A/R	871	867	2,159	3,288	4,027
Inventory	3,044	2,266	2,034	2,823	3,283
Prepaid Exp.	928	648	1,806	3,943	3,943
Total Current Assets	\$ 61,198	\$ 42,743	\$ 28,341	\$ 62,445	\$ 43,383
PP&E	3,261	3,120	2,483	4,747	4,547
Operating Lease	0	602	247	595	595
Patent, Trademark, other intangibles	9,752	8,494	8,211	8,065	7,957
Equity Investment	3,092	8,403	6,536	9,200	9,200
Convertible Note Receivable	0	5,589	5,876	3,684	3,684
Total Assets	\$ 77,302	\$ 68,951	\$ 51,694	\$ 88,736	\$ 69,366
Bank Loans and N/P	689	581	539	2,659	2,659
Operating Lease	0	220	247	174	174
A/P	2,575	1,998	1,116	981	981
Accrued Expenses	1,826	2,619	4,830	5,072	5,072
Accrued Severance	0	359	339	212	212
Deferred Income	83	5	272	145	145
Total Current Liabilities	\$ 5,174	\$ 5,780	\$ 7,343	\$ 9,243	\$ 9,243
Long-Term Debt	848	292	0	0	0
Operating Lease	0	382	0	423	423
Accrued Severance	0	446	241	130	130
Shareholders' Equity	71,280	62,051	44,110	78,940	59,570
Total Liabilities And Equity	\$ 77,302	\$ 68,951	\$ 51,694	\$ 88,736	\$ 69,366
	2018	2019	2020	2021 E	2022 E
Net Income	(7,967)	(26,559)	(19,711)	(20,317)	(24,749)
Depreciation & Amort.	1,200	1,425	1,345	1,194	1,208
Stock Comp	3,187	3,540	1,654	4,242	4,980
Other	(14,618)	7,249	2,722	(2,340)	0
Working Capital	354	(242)	(1,631)	(4,729)	(1,200)
Operating Cash Flow	\$ (17,844)	\$ (14,587)	\$ (15,621)	\$ (21,950)	\$ (19,761)
Acquisition of Patents and trademarks	(657)	(515)	(468)	(429)	(500)
CapEx	(449)	(527)	(54)	(588)	(400)
Other	16,251	5,595	16,991	(39,100)	0
Investing Activities	\$ 15,145	\$ 4,552	\$ 16,469	\$ (40,117)	\$ (900)
Debt	(800)	(700)	(354)	2,115	0
Equity	445	10,616	50	51,030	400
Other	0	0	0	0	0
Financing Activities	\$ (355)	\$ 9,916	\$ (304)	\$ 53,145	\$ 400
Change in Cash	(\$3,055)	(\$120)	\$ 544	(\$8,922)	(\$20,261)

 Source: 22nd Century Group, Inc. and Dawson James Securities estimates

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

Initiated – Buy – April 13, 2021 – Price Target \$7.00
 Update – Buy – April 15, 2021 – Price Target \$7.00
 Update – Buy – April 19, 2021 – Price Target \$7.00
 Update – Buy – May 7, 2021 – Price Target \$7.00
 Update – Buy – June 1, 2021 – Price Target \$7.00
 Update – Buy – June 11, 2021 – Price Target \$7.00
 Update – Buy – July 2, 2021 – Price Target \$7.00
 Update – Buy – July 23, 2021 – Price Target \$7.00
 Update – Buy – August 6, 2021 – Price Target \$7.00

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months.
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months.
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The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

As of: 3-Aug-21

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	71%	4	16%
Market Perform (Neutral)	10	29%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	35	100%	4	11%

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