22nd Century Group, Inc. (AMEX: XXII)

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WSJ Reports Biden Administration and FDA Considering Low-Nicotine Mandate

The Wall Street Journal reported the Biden Administration and FDA are considering a low-nicotine mandate, a rulemaking initially explored in an ANPRM in 2018. We believe a low-nicotine mandate in the U.S. could be worth over $3.18 per share for XXII.

The Wall Street Journal reported ("Biden Administration Considering Rule to Cut Nicotine in Cigarettes") yesterday on a potential rule to limit nicotine in cigarettes to non-addictive levels. The FDA initially explored a low-nicotine mandate in 2018 with an Advanced Notice of Proposed Rulemaking (ANPRM) that sought public comment on lowering nicotine in combustible cigarettes to minimally or non-addictive levels. A revivification of a low-nicotine mandate would, in our opinion, be highly positive for 22nd Century and a catalyst for the shares.

The possibility of a low-nicotine mandate in the U.S. follows a release last week from the New Zealand Ministry of Health of a Smokefree 2025 Action plan to "reduce smoking prevalence and tobacco availability to minimal levels, essentially making Aotearoa New Zealand smokefree by 2025." The plan includes a low-nicotine mandate. The closing date for public comments is May 31, 2021. The Ministry of Health will analyze the feedback and then draft an action plan, which will be considered by the Cabinet of New Zealand. It is reasonable to believe other countries with aggressive public health agencies would also consider a low-nicotine mandate. Currently, our valuation only includes a U.S. mandate.

Complying with a non-addictive low-nicotine mandate will be a challenge for the industry, and, as the current tobacco vendors admitted in their public comments on the ANPRM, 22nd Century has technology that could solve their problem.

Valuation: 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 its relationship with KeyGene.

Risks to Target: 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 and market share.

Current Price			**$3.55**
Price Target			**$7.00**
Estimates	F2020A	F2021E	F2022E
Revenues ($000s)	$ 28,111	$ 29,000	$ 30,000
1Q March	$ 7,058	$ 7,250	$ 7,500
2Q June	$ 6,435	$ 7,250	$ 7,500
3Q September	$ 7,310	$ 7,250	$ 7,500
4Q December	$ 7,308	$ 7,250	$ 7,500
	F2020A	F2021E	F2022E
EPS (diluted)	$ (0.14)	$ (0.12)	$ (0.12)
1Q March	$ (0.03)	$ (0.03)	$ (0.03)
2Q June	$ (0.04)	$ (0.03)	$ (0.03)
3Q September	$ (0.03)	$ (0.03)	$ (0.03)
4Q December	$ (0.05)	$ (0.04)	$ (0.04)
EBITDA ($Ms)	$ (16.0)	$ (16.2)	$ (16.3)
EV/EBITDA (x)	-31.9x	-31.5x	-31.4x
Stock Data			
52-Week Range	$0.55	-	$4.66
Shares Outstanding (mil.)			152.4
Market Capitalization (mil.)			$541
Enterprise Value (mil.)			$511
Debt to Capital			2%
Book Value/Share			$0.32
Price/Book			11.2x
Average Three Months Trading Volume (K)			1,713
Insider Ownership			2.0%
Institutional Ownership			24.7%
Short interest (mil.)			4.9%
Dividend / Yield			$0.00/0.0%

The Low-Nic ANPRM

A topic of critical import for the ANPRM and for a possible new ruling is how a mandate will be achieved. 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)). 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.

A Revived Mandate

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.

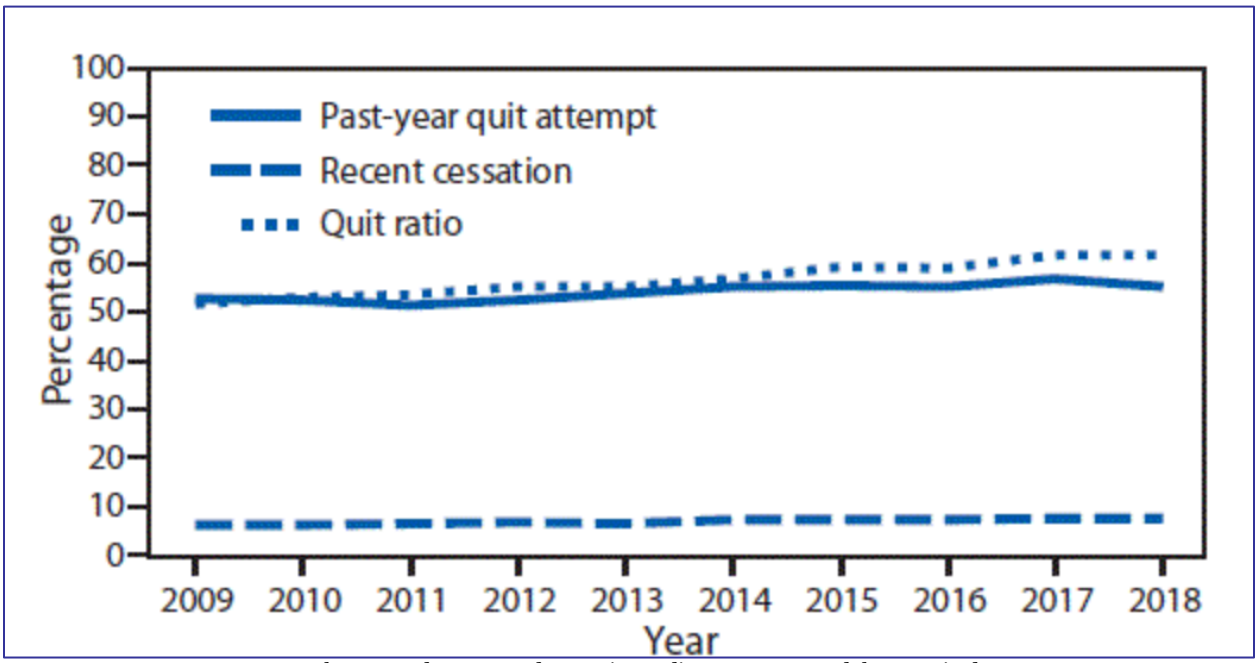
The ANPRM was published in March 2018 and the comment period closed in July 2018. An argument can be made that a similar comment period would be allowed if a Notice of Proposed Rulemaking (NPRM) were issued, but since a lot of the ground has already been covered in the ANPRM, it is also reasonable to 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 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.

Valuing VLN

According to the CDC, "based on 2019 data, about 34 million US adults smoke cigarettes," (https://www.cdc.gov/tobacco/about/osh/index.htm) and about two-thirds would like to quit (Stephen Babb, MPH; Ann Malarcher, PhD; Gillian Schauer, PhD; Kat Asman, MSPH; Ahmed Jamal, MBBS, January 6, 2017, "Quitting Smoking Among Adults — United States, 2000–2015," Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Vol. 65 / No. 52), with more than half making some attempt to quit in the past 12 months. The ratio of smokers making some quit attempt in the past year has remained fairly stable over the past ten years.



Source: CDC. Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018

The Federal Trade Commission Cigarette Report for 2018 reports 216.9 billion cigarette sticks were sold in the U.S. in 2018. At 20 cigarettes per pack and 34 million smokers, this equals daily consumption of about 0.87 packs per day. However, the impact of the very-low-nicotine-content (VLNC) cigarette is a reduction in consumption. From 22nd Century's TPSAC Briefing Document:

> *independent studies of VLNC cigarettes show that daily smokers gradually reduced their cigarette consumption by as much as 50% over 20 weeks of use. (see Hatsukami, 2018; Donny, 2015). Such studies also showed that non-daily smokers reduced their cigarette consumption after extended use of VLNC cigarettes. (Shiffman, 2018).*

According to the CDC, in 2010, there were 45.4 million smokers in the U.S. Over the subsequent 10 years, the number of smokers in the U.S. declined at a 2.8% compound annual rate. If that rate continues, by 2025, the number of smokers will decline to about 29.7 million. Assuming 50% try to quit in a year, the number of smokers who are likely customers of a VLN cigarette are approximately 14.8 million smoking 0.44 packs per day or 2.4 billion packs per year. If we assume prices rise 5% annually from the current $3/pack rate to $3.83 per pack, that is a potential addressable revenue (before excise taxes) of $9.1 billion.

A modest market share would result in substantial value for the company. Currently, tobacco company stocks trade around 5x forward 12-month sales estimates (Source: FactSet consensus estimates). At this multiple, and a 3% market share of the smokers who attempt to quit (about 1.5% of the total market), the value of the VLN franchise, in 2025, would be worth close to $1.4 billion, in our estimation. We believe a take-over would be at higher multiples due to the synergies available. Still assuming a 3% market share of the smokers who attempt to quit (1.5% of the total market), the VLN franchise in 2025 would be valued at close to $2.0 billion if instead we capitalized sales at 7x.

Potential VLN Franchise Values

Market Share of Quitters	3x sales	5x sales	7x sales
0.5%	$ 137M	$ 228M	$ 319M
1.0%	$ 274M	$ 456M	$ 639M
2.0%	$ 547M	$ 912M	$ 1,277M
3.0%	$ 821M	$ 1,368M	$ 1,916M

Source: Dawson James Securities estimates

If the company seeks a partner to achieve these market share estimates, we think that the values above should be reduced by 30% to 50% to reflect the partner's interest. The discounted per-share value of the VLN franchise based on 5x to 7x sales in 2025E, using a 20% discount rate, 3% market share estimate and a 30% interest for a potential partner, is, at the midpoint, $3.08 per share.

Valuing a Low-Nicotine Mandate

The ANPRM has not turned into an NPRM, yet, but we believe it is still possible in the next 12 months. A new administration could be more willing to impose greater restrictions on nicotine in the pursuit of public health. We also believe the FDA is being careful in building a record to withstand the challenges a low-nicotine mandate is likely to encounter and part of that could be the approval of 22nd Century's MRTP. One of the stated objections to the mandate is it would be impossible to comply since the technology does not exist. Marketing of a VLN cigarette would obviate that argument.

Complying with a non-addictive low-nicotine mandate will be a challenge for the industry, and, as the current tobacco vendors admitted in their public comments on the ANPRM, 22nd Century has technology that could solve their problem.

The cost to comply with a mandate has been discussed publicly. For instance, the Director of Product Policy at Philip Morris International, Rolf Lutz, stated in 2016 it would cost $10 billion to $12 billion to extract nicotine from all its EU cigarettes. The company sold about 10 billion packs of cigarettes in the EU at that time, which is similar to the U.S. market currently. Mr. Lutz also indicated it could take up to 20 years to achieve lower nicotine levels with genetically modified plants. Using Mr. Lutz's estimate of time and money required, we believe the opportunity for 22nd Century is large.

If the FDA mandates a non-addictive level of nicotine, we expect the company to pursue a royalty and license model for its technology in addition to marketing a VLN brand on its own. The following table is based on a successful royalty/licensing model in the U.S. There are about 10 billion packs of cigarettes sold in the U.S. annually (Altira Group 2020 10K based on 20 sticks/pack) and we estimate this will decline by 2.8% annually over the next five years. We assume a 5% market share and $0.10 per pack royalty. The table shows per-share discounted values based on different discount rates and revenue multiples. The mean of these estimates is $3.18 per share.

Potential Non-Addictive Nicotine Franchise Values

Per share Value: $0.10/pack royalty; 5% share		Discount Rate	
		15%	20%
Revenue multiple	20x	$ 3.12	$ 2.52
	25x	$ 3.90	$ 3.16

Source: Dawson James Securities estimates

This is not a straight shot for the company. The big tobacco companies will likely resist a mandate, try to push it to the right as far as possible, seek out the lowest-cost solution to comply and continue developing other nicotine delivery systems like iQOS.

The timeline for a mandate is probably 3-5 years. An NPRM will probably take 12-24 months from release to rulemaking and an additional 24- to 36-month transition time.

For now, we are valuing the CBD and KeyGene opportunities at $100 million, or $0.67 per share.

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
($ in 000s, except per-share data)

	2018	2019	2020	Q1 21 E	Q2 21 E	Q3 21 E	Q4 21 E	2021 E	2022 E
Revenue	$ 26,426	$ 25,833	$ 28,111	$ 7,250	$ 7,250	$ 7,250	$ 7,250	$ 29,000	$ 30,000
Cost Of Goods Sold	25,527	25,818	26,673	6,720	6,720	6,720	6,720	26,880	27,000
Gross Profit	899	14	1,438	530	530	530	530	2,120	3,000
R&D	14,990	8,057	4,128	1,250	1,250	1,250	1,250	5,000	5,250
G&A	7,658	12,956	14,971	3,298	3,298	3,298	5,418	15,312	16,078
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	349	349	349	349	1,396	1,396
Opex	24,918	23,581	20,621	4,897	4,897	4,897	7,017	21,708	22,724
Operating Income	$ (24,019)	$ (23,566)	$ (19,183)	$ (4,367)	$ (4,367)	$ (4,367)	$ (6,487)	$ (19,588)	$ (19,724)
Other	14,945	(4,002)	(428)	0	0	0	0	0	0
Impairment Charge	49	0	(1,741)	0	0	0	0	0	0
Interest Income	1,069	1,066	1,751	223	307	274	240	1,044	538
Interest Expense	(11)	(56)	(72)	(18)	(18)	(18)	(18)	(72)	(72)
Pretax Income	(7,967)	(26,559)	(19,673)	(4,162)	(4,079)	(4,111)	(6,265)	(18,616)	(19,258)
Income Tax Expense	0	0	38	0	0	0	0	0	0
Net to Common	$ (7,967)	$ (26,559)	$ (19,711)	$ (4,162)	$ (4,079)	$ (4,111)	$ (6,265)	$ (18,616)	$ (19,258)
Shares (000)	124,299	125,883	138,813	145,730	152,648	153,148	153,648	151,293	154,460
EPS	($0.06)	($0.21)	($0.14)	($0.03)	($0.03)	($0.03)	($0.04)	($0.12)	($0.12)
D&A	1,200	1,425	1,346	348	348	348	348	1,392	1,392
Stock Comp	3,187	3,540	1,654	492	492	492	492	1,968	2,066
Other	0	1,142	176	0	0	0	0	0	0
EBITDA	$ (19,632)	$ (17,459)	$ (16,007)	$ (3,527)	$ (3,527)	$ (3,527)	$ (5,647)	$ (16,228)	$ (16,265)

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

Exhibit 2. Balance Sheet and Cash Flow Statement
($ in 000s)

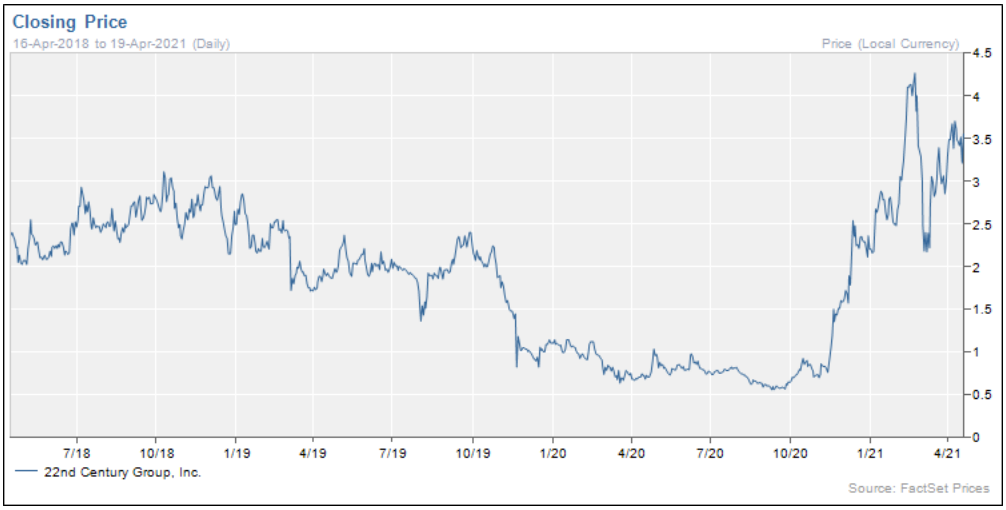
	2018	2019	2020	2021 E	2022 E
Cash	605	485	1,029	1,029	1,029
Short-Term Investments	55,749	38,477	21,313	17,540	1,540
A/R	871	867	2,159	2,159	2,159
Inventory	3,044	2,266	2,034	2,034	2,034
Prepaid Exp.	928	648	1,806	1,806	1,806
Total Current Assets	**$ 61,198**	**$ 42,743**	**$ 28,341**	**$ 24,568**	**$ 8,568**
PP&E	3,261	3,120	2,483	1,723	963
Operating Lease	0	602	247	247	247
Patent, Trademark, other intangibles	9,752	8,494	8,211	8,179	8,147
Equity Investment	3,092	8,403	6,536	6,536	6,536
Convertible Note Receivable	0	5,589	5,876	5,876	5,876
Total Assets	**$ 77,302**	**$ 68,951**	**$ 51,694**	**$ 47,129**	**$ 30,337**
Bank Loans and N/P	689	581	539	539	539
Operating Lease	0	220	247	247	247
A/P	2,575	1,998	1,116	1,116	1,116
Accrued Expenses	1,826	2,619	4,830	4,830	4,830
Accrued Severance	0	359	339	339	339
Deferred Income	83	5	272	272	272
Total Current Liabilities	**$ 5,174**	**$ 5,780**	**$ 7,343**	**$ 7,343**	**$ 7,343**
Long-Term Debt	848	292	0	0	0
Operating Lease	0	382	0	0	0
Accrued Severance	0	446	241	241	241
Shareholders' Equity	71,280	62,051	44,110	39,545	22,753
Total Liabilities And Equity	**$ 77,302**	**$ 68,951**	**$ 51,694**	**$ 47,129**	**$ 30,337**

	2018	2019	2020	2021 E	2022 E
Net Income	(7,967)	(26,559)	(19,711)	(18,616)	(19,258)
Depreciation & Amort.	1,200	1,425	1,345	1,392	1,392
Stock Comp	3,187	3,540	1,654	1,968	2,066
Other	(14,618)	7,249	2,722	0	0
Working Capital	354	(242)	(1,631)	0	0
Operating Cash Flow	**$ (17,844)**	**$ (14,587)**	**$ (15,621)**	**$ (15,256)**	**$ (15,799)**
Acquisition of Patents and trademarks	(657)	(515)	(468)	(500)	(500)
CapEx	(449)	(527)	(54)	(100)	(100)
Other	16,251	5,595	16,991	0	0
Investing Activities	**$ 15,145**	**$ 4,552**	**$ 16,469**	**$ (600)**	**$ (600)**
Debt	(800)	(700)	(354)	0	0
Equity	445	10,616	50	12,083	400
Other	0	0	0	0	0
Financing Activities	**$ (355)**	**$ 9,916**	**$ (304)**	**$ 12,083**	**$ 400**
Change in Cash	**($3,055)**	**($120)**	**$ 544**	**($3,773)**	**($15,999)**

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

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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.
3) **Sell**: The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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: 19-Apr-21

	Company Coverage		**Investment Banking**	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	67%	5	25%
Market Perform (Neutral)	10	33%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	30	100%	5	17%

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