WELLS FARGO SECURITIES

Tobacco Talk: XXII Mgmt Mtg Takeaways

FDA Disrupts the Old Order, Making Way For the Small & Nimble

Tobacco

- **XXII Management Meeting Sheds Light on The FDA's New Approach towards Nicotine & the Potential Implications for the Tobacco Industry –** We recently hosted an investor meeting with Henry Sicignano III, CEO of 22nd Century Group, Inc. (XXII). XXII is a plant biotechnology company whose proprietary genetic engineering and plant breeding technology enables it to tailor levels of nicotine (and other nicotinic alkaloids) in the tobacco plant as well as tailor cannabinoid profiles in the cannabis plant. XXII owns, or exclusively licenses, more than 200 patents and has more than 50 patents pending. The meeting was an excellent opportunity to hear from a small, but important player in the business of tobacco-related nicotine - the subject at the core of the FDA's new directive to lower nicotine in combustible cigs to minimally or non-addictive levels. Key takeaways: **(1) The FDA won't rush the process**: While we think there is a sense of urgency at the FDA, we still believe it will take 3-5yrs before any potential changes are implemented given the sheer complexities & risks involved (see pg 2); **(2) critical decision is how quickly to reduce nicotine:** we expect the scientific community to rally around an immediate vs gradual reduction in nicotine levels in cigs – a potential headline risk for big tobacco. It's our understanding there's an additional study that could be released by the end of the year which could find an immediate and sharp reduction of nicotine in cigs is ideal; **(3) "sweet spot" could be an 85% reduction:** recent science suggests reducing nicotine levels in cigs by 85% is optimal (see pgs 2-4); and **(4) The FDA's vision creates supply challenges:** the cost of stripping nicotine out of tobacco presents cost & quality challenges for cig mfrs, but this should be largely manageable for co's with strong cash flows & reduced-risk product (RRP) portfolios (e.g., MO). **Bottom line -** Uncertainty remains as to what the FDA may ultimately propose and how the industry may adapt. However, we continue to believe in an environment where nicotine levels in cigs are reduced, conversion to RRPs will accelerate and MO is strongly positioned with iQOS.
- **XXII Century Is Positioning Itself to Compete in New, Low Nicotine Environment –** XXII has historically focused on the very small, smoking cessation market, but now finds itself in the unique position to have its core, Very Low Nicotine (VLN) product aligned with where the FDA envisions taking the combustible cig industry. In this new environment, XXII's competitive advantage is its patented technology to genetically modify tobacco plants and, to the best of our knowledge, no other company possesses the same capability or scale in genetically modified VLN tobacco.
- **XXII Century Sheds BAT Intellectual Property (IP) Agreement, Targets New Strategic Partnerships** – We expect there will be increasing interest from combustible cig manufacturers seeking ways to meet new nicotine standards to be potentially mandated by the FDA. XXII's unique ability to grow tobacco at very low nicotine levels (0.4mg/g, which is a 95% reduction) should be attractive to companies seeking new lines of supply that are void of the flavor/color/smell challenges that come with chemically stripping nicotine from tobacco.

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Please see page 5 for rating definitions, important disclosures and required analyst certifications. All estimates/forecasts are as of 10/01/17 unless otherwise stated. 10/01/17 20:32:36 ET

Long, Multi-Year Road Still Ahead – With the FDA's announcement occurring just ~2 months ago (7/28), there are still many steps ahead before a potential comprehensive and enforceable nicotine standard can be put into effect (no less than 2 years, by law). The next step is for the FDA to issue an **Advance Notice of Proposed Rulemaking (ANPRM)**, through which it will solicit comments/input from major stakeholders to help inform the rulemaking process. The comment period is typically 30-60 days, but for more complex rulemakings such as this one, it could be 180 days or more. During this period, the FDA will respond to comments and request more information to help form the basis of a viable, scientifically-grounded regulatory plan. Once the FDA is satisfied with the evidence, it will issue a **Notice of Proposed Rulemaking** (NPRM or "Proposed Rule") which explains the agency's plan to address the problem and accomplish its goal. A new comment period follows, after which the FDA issues its **Final Rule** and announces an Effective Date for compliance. For more specifics on the process, see "A Guide to the Rulemaking Process" by the Office of the Federal Register.

Next steps: FDA solicits stakeholder comments via an ANPRM & NPRM, followed by a Final Rule

Exhibit 1

FDA Review Procedure
Next Steps in Moving Toward Implementation of a Potential New Nicotine Strategy

Step	FDA Rulemaking Process	Description	Timing / Other
1.	Advance Notice of Proposed Rulemaking (ANPRM)	FDA solicits comments/input from major stakeholders to help inform the rulemaking process; FDA responds to the comments	30-60 days typically, but 180 days or more for complex rulemakings
2.	Notice of Proposed Rulemaking (NPRM or "Proposed Rule")	FDA explains the agency's plan to address the problem and accomplish its goal	Opens new comment window similar to the ANPRM
3.	Final Rule	FDA issues its final rule (i.e., regulatory standard) and sets an Effective Date for compliance	Throughout the process, the FDA could reconvene the Tobacco Products Scientific Advisory Committee (TPSAC)

Source: Office of the Federal Register

As discussed, this is realistically a multi-year effort, perhaps as much as 3-5 years in our view. While we agree that there could be added incentive for Commissioner Gottlieb to expedite the process given that he may have as little as 3.5 years left in his role as a Presidential appointee (unless reappointed), we think the sheer complexity of the mandate could potentially require more time than Gottlieb has as FDA Commissioner.

A 3.5 year timeframe is optimistic, in our view

What is the Current Science on Nicotine & How Close is the FDA to Having the Scientific Evidence Necessary to Support Its Case? – This gets to the heart of one of the more complex and controversial areas of concern: will the FDA be able to sufficiently ground its effort in science and build enough consensus to avoid: **(1)** unwanted litigation; **(2)** unintended consequences, and/or **(3)** political embarrassment? The critical questions in our mind are: What is the absolute threshold of nicotine addiction? How fast should the FDA reduce nicotine levels in cigs (gradually? immediately?)? While the absolute threshold for nicotine addiction differs by smoker and circumstance, the consensus among researchers and the WHO seems to be that the threshold for addiction is likely close to 0.4mg of nicotine per gram of tobacco (this compares to a standard-strength cigarette at 15.8mg of nicotine).[1] That said, a 2015 study published in the New England Journal of Medicine[2] found that reducing nicotine levels by at least 85% (to 2.4mg from 15.8mg) led to reduced cravings and compensatory behavior, suggesting this may be the 'sweet spot' for regulatory purposes.

85% reduction in nicotine levels could be the "sweet spot" from a regulatory standpoint

Potential Headline Risk 1: FDA Favors Immediate Reduction of Nicotine Levels in Cigs - The problem however is that many studies are relatively short-term (e.g., 6 weeks in the above cited one) and are not necessarily designed to monitor long-term behavior and the potential for smoking relapse. So it raises the next important question: how quickly should the FDA reduce nicotine levels in cigs? We understand that findings from a potentially important study led by Dorothy Hatsukami may be published as early as this fall that could suggest an immediate reduction in nicotine levels by the FDA would be more effective than gradual reduction in terms of discouraging compensatory behavior. This could potentially create headline risk for tobacco manufacturers of conventional cig products and extend the FDA overhang on valuations. We note at least 41 NIH-funded nicotine-related tobacco studies underway this year (see Exhibit 2). We expect funding and research to ramp as the FDA solicits help from the scientific community.

Recommendations for an immediate reduction in nicotine levels would likely create headline risk for big tobacco

[1]See WHO Advisory Note – Global Nicotine Reduction Strategy (2015). [2]See "Randomized Trial of Reduced-Nicotine Standards for Cigarettes," published on October 1, 2015, in the New England Journal of Medicine (NEJM).

Potential Headline Risk 2: "Stripping" Nicotine Out of Tobacco Could Be Costly & Damaging to Quality – A regulatory standard that requires a more immediate than gradual reduction in nicotine levels in cigs (should the FDA lean this way) could certainly make it more challenging for the tobacco industry from a cost, timing and even quality perspective. While we have no real sense as to how this will play out, we expect tobacco manufacturers will be faced with the option of either stripping nicotine from their tobacco plant supplies or licensing the technology to accomplish this organically (at the genetic level). While we don't have a good grasp on what this might cost, we understand that it could potentially cost the manufacturers an incremental cost per pack (possibly around $0.10-0.20/pack per year) to perform this process or possibly license this technology. In addition to cost, another potential downside to stripping nicotine out of tobacco is that the stripping process often strips out more than just nicotine from the tobacco plant, resulting in a degradation of taste, flavor, color, and smell. The alternative is to license the means to have nicotine stripped genetically from the tobacco plant. So far, XXII is the only company we know that owns patents to do this. **While we note this as a potential headline risk for MO (MO, 1, $63.42), we remain confident that it can weather the challenge especially as we expect iQOS to make up an increasingly larger part of its total volume (54% by 2025, by our estimates).**

Exhibit 2

NIH-Funded Nicotine-Related Tobacco Research Studies (2017)

Project Number	Project Title	Contact PI / Project Leader	Organization	FY	FY Total Cost by IC
2U54DA031659-06	EVALUATING NEW NICOTINE STANDARDS FOR CIGARETTES	DONNY, ERIC CHRISTIAN et al.	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2017	$3,471,615
5P01CA200512-02	EVALUATING HOW TOBACCO CONTROL POLICIES ARE SHAPING THE NICOTINE DELIVERY MARKET	CUMMINGS, KENNETH MICHAEL et al.	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2017	$3,033,680
5P50DA036114-05	PROJECT 3: LOW NICOTINE CONTENT CIGARETTES IN VULNERABLE POPULATIONS: P289-358	HIGGINS, STEPHEN T	UNIVERSITY OF VERMONT & ST AGRIC COLLEGE	2017	$823,395
5R01DA038554-02	THE ROLE OF NICOTINE AND NON-NICOTINE ALKALOIDS IN E-CIGARETTE USE AND DEPENDENCE	ROSE, JED E	DUKE UNIVERSITY	2016	$811,286
5P50DA036114-05	PROJECT 2: LOW NICOTINE CONTENT CIGARETTES IN VULNERABLE POPULATIONS: P233-288	HIGGINS, STEPHEN T	UNIVERSITY OF VERMONT & ST AGRIC COLLEGE	2017	$783,396
5R01DA042526-02	EVALUATING CONCOMITANT USE OF VERY LOW NICOTINE CONTENT CIGARETTES AND E-CIGARETTES AMONG DAILY AND NON-DAILY SMOKERS ON ABUSE LIABILITY	CINCIRIPINI, PAUL MICHAEL et al.	UNIVERSITY OF TX MD ANDERSON CAN CTR	2017	$767,719
5P50DA036107-05	PROJECT 2: REDUCED NICOTINE CIGARETTES IN SMOKERS WITH MOOD AND ANXIETY P248-288	MUSCAT, JOSHUA E	PENNSYLVANIA STATE UNIV HERSHEY MED CTR	2017	$742,759
5R01DA042527-02	DOSE EFFECTS OF NICOTINE: BEHAVIORAL ECONOMICS OF CIGARETTE ABUSE LIABILITY	JOHNSON, MATTHEW WAYNE	JOHNS HOPKINS UNIVERSITY	2017	$726,049
5P50DA036107-05	PROJECT 1: SWITCHING TO PROGRESSIVELY REDUCED NICOTINE CONTENT CIGARETT P212-247	MUSCAT, JOSHUA E	PENNSYLVANIA STATE UNIV HERSHEY MED CTR	2017	$709,168
2U54DA031659-06	EVALUATING NEW NICOTINE STANDARDS FOR CIGARETTES - PROJECT 2	DONNY, ERIC CHRISTIAN	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2017	$685,514
1R01DA044756-01A1	E-CIGARETTES: DEPOSITION, ABSORPTION AND BRAIN ACCUMULATION OF NICOTINE	MUKHIN, ALEXEY G	DUKE UNIVERSITY	2017	$676,021
5R01DA034628-04	VERY LOW-NICOTINE CIGARETTES IN SMOKERS WITH SUD: SMOKING, SUBSTANCE USE EFFECTS	ROHSENOW, DAMARIS J.	BROWN UNIVERSITY	2017	$635,206
5P01CA200512-02	NATURAL HISTORY OF CIGARETTE SMOKING AND VAPORIZED NICOTINE PRODUCT USE IN COUNTRIES WITH DIFFERENT POLICY ENVIRONMENTS	FONG, GEOFFREY T	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2017	$560,649
5R01HL120062-04	MEASURING RELATIVE CARDIOVASCULAR HEALTH RISKS OF INHALED TOBACCO PRODUCTS	SPRINGER, MATTHEW LAWRENCE	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2017	$554,950
5R01DA042541-02	ABUSE LIABILITY OF REDUCED NICOTINE CONTENT CIGARETTES IN THE CONTEXT OF CONCURRENT E-CIGARETTE USE	ROSE, JED E	ROSE RESEARCH CENTER, LLC	2017	$548,132
2U54DA031659-06	EVALUATING NEW NICOTINE STANDARDS FOR CIGARETTES - ADMINISTRATIVE CORE	DONNY, ERIC CHRISTIAN	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2017	$545,690
5R01DA036492-05	TASTE, PREFERENCES, AND BEHAVIOR: EFFECTS OF NICOTINE AND FLAVORINGS IN ELECTRONI	LITT, MARK D	UNIVERSITY OF CONNECTICUT SCH OF MED/DNT	2017	$543,202
5R01DA042528-02	NICOTINE REINFORCEMENT AND AVERSION IN YOUNG ADULT LIGHT SMOKERS	SOFUOGLU, MEHMET	YALE UNIVERSITY	2017	$513,547
5P50DA036151-05	PROJECT 2: MENTHOL'S EFFECTS ON THE NICOTINE REINFORCEMENT IN SMOKERS P206-237	KRISHNAN-SARIN, SUCHITRA et al.	YALE UNIVERSITY	2017	$498,834
5P50DA036151-05	PROJECT 1: EFFECTS OF FLAVORS ON NICOTINE CHOICE AND CENTRAL REWARD ME P175-205	KRISHNAN-SARIN, SUCHITRA et al.	YALE UNIVERSITY	2017	$498,834

source: U.S. National Institutes of Health

Exhibit 2 (cont.)

NIH-Funded Nicotine-Related Tobacco Research Studies (2017)

Project Number	Project Title	Contact PI / Project Leader	Organization	FY	FY Total Cost by IC
5R01DA042535-02	ABUSE LIABILITY OF REDUCED NICOTINE CONTENT CIGARETTES WITHIN A COMPLEX TOBACCO MARKETPLACE	BICKEL, WARREN K et al.	VIRGINIA POLYTECHNIC INST AND ST UNIV	2017	$472,123
2U54DA031659-06	EVALUATING NEW NICOTINE STANDARDS FOR CIGARETTES - PROJECT 3	COLBY, SUZANNE M	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2017	$448,423
5R01AA024709-02	REDUCED NICOTINE CIGARETTES IN SMOKERS WITH AND WITHOUT ALCOHOL USE DISORDER	PETERS, ERICA N	BATTELLE CENTERS/PUB HLTH RES & EVALUATN	2017	$433,507
5R01DA042532-02	REACTIONS TO REDUCED NICOTINE CIGARETTES IN YOUNG ADULT LOW-FREQUENCY SMOKERS	MCCLERNON, FRANCIS JOSEPH	DUKE UNIVERSITY	2017	$418,628
5R01CA179246-05	CONSTITUENT YIELDS AND BIOMARKERS OF EXPOSURE FOR TOBACCO PRODUCT REGULATION	STEPANOV, IRINA	UNIVERSITY OF MINNESOTA	2017	$416,088
1P01CA217806-01	PROJECT 1: EFFECTS OF UNVENTILATED FILTERS ON PATTERN OF CIGARETTE USE, TOXICANT EXPOSURE AND UPTAKE OF ALTERNATIVE NICOTINE PRODUCTS	HATSUKAMI, DOROTHY K	UNIVERSITY OF MINNESOTA	2017	$399,540
5R01DA034862-05	ALPHA 5 NICOTINIC RECEPTOR SUBUNIT GENE POLYMORPHISMS AND SMOKING ADDICTION	MUKHIN, ALEXEY G	DUKE UNIVERSITY	2017	$392,501
5R01DA042530-02	TOBACCO: RELATIONSHIP BETWEEN REDUCED NICOTINE CONTENT AND REINFORCEMENT IN RATS	BRUIJNZEEL, ADRIAAN WILLEM	UNIVERSITY OF FLORIDA	2017	$375,442
5P01CA200512-02	NICOTINE AND CIGARETTES ACROSS POLICY ENVIRONMENTS	O'CONNOR, RICHARD J	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2017	$312,103
2U54DA031659-06	EVALUATING NEW NICOTINE STANDARDS FOR CIGARETTES - CORE B	HECHT, STEPHEN S.	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2017	$305,792
2U54DA031659-06	EVALUATING NEW NICOTINE STANDARDS FOR CIGARETTES - CORE C	LE, CHAP T.	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2017	$275,086
5P01CA200512-02	THE EXPERIMENTAL TOBACCO MARKETPLACE (ETM)	BICKEL, WARREN K	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2017	$251,191
5R21DA040718-02	ADOLESCENT ENDS USE, NICOTINE METABOLISM AND TOXICANT EXPOSURE	RUBINSTEIN, MARK L	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2017	$237,750
5R01DA037277-04	MENTHOL: AN ACCOMPLICE OF NICOTINE IN TOBACCO SMOKING	LIU, XIU	UNIVERSITY OF MISSISSIPPI MED CTR	2017	$220,382
5R21DA040138-02	NITRIC OXIDE FACILITATES NICOTINE ABSORPTION DURING CIGARETTE SMOKING	XU, JIANSONG	YALE UNIVERSITY	2017	$209,375
5K01CA189300-04	EVALUATION OF VERY LOW NICOTINE CONTENT CIGARETTES IN ADOLESCENT SMOKERS	CASSIDY, RACHEL N	BROWN UNIVERSITY	2017	$192,132
5P01CA200512-02	MODELING INDUSTRY BEHAVIOR AND THE USE OF VAPORIZED NICOTINE PRODUCTS ON POPULATION HEALTH	LEVY, DAVID THEODORE	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2017	$128,421
5R03DA041870-02	INNOVATIVE STATISTICAL METHODS FOR DETECTING AND ACCOUNTING FOR NON-COMPLIANCE IN RANDOMIZED TRIALS OF VERY LOW NICOTINE CONTENT CIGARETTES	KOOPMEINERS, JOSEPH S et al.	UNIVERSITY OF MINNESOTA	2017	$114,587
1R03DA045197-01	IMPACT OF EXCLUSIVE USE OF LOW NICOTINE CIGARETTES ON COMPENSATORY SMOKING	SMITH, TRACY TAYLOR	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2017	$112,125
7K01DA037950-04	EMA AND LAB ASSESSMENT OF NICOTINE DEPENDENCE AMONG DUAL END USERS	PEARSON, JENNIFER LYNN	UNIVERSITY OF NEVADA RENO	2017	$110,240
1R15DA043045-01A1	AN EXPERIMENTAL EVALUATION OF E-CIGARETTES IN YOUNG ADULTS: REINFORCEMENT ENHANCEMENT AND DEVALUATION BY NICOTINE	KIRSHENBAUM, ARI PHILLIP	ST. MICHAEL'S COLLEGE	2017	$45,865
Total Funding Granted					**$24,000,947**

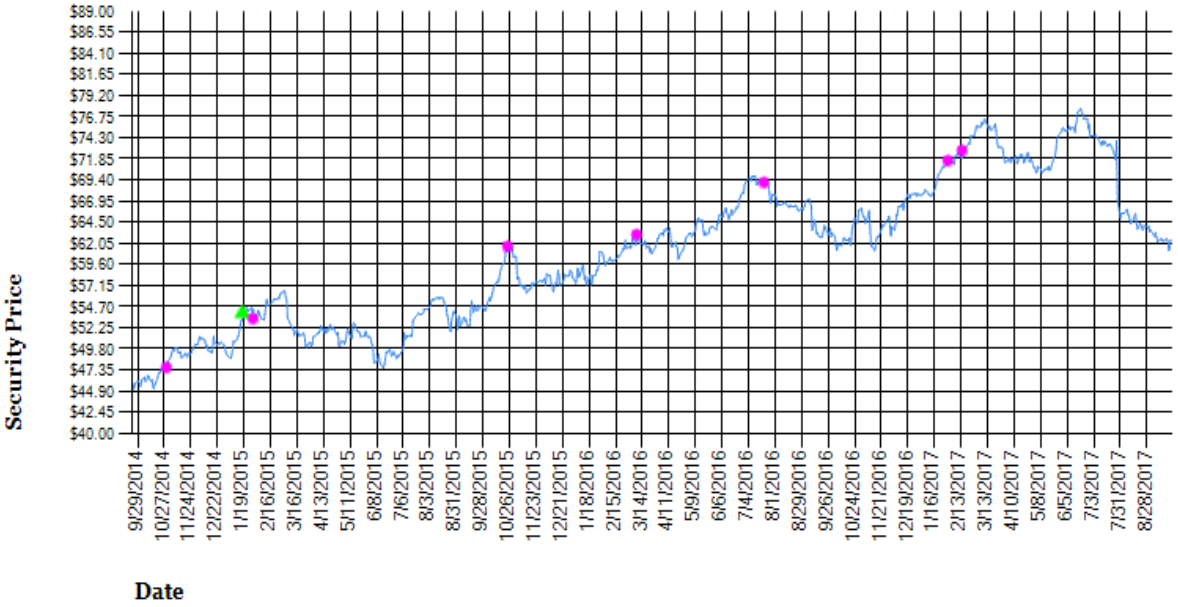
source: U.S. National Institutes of Health

Rating Basis Information:

MO Thesis: We believe Altria is achieving a better balance between stabilizing Marlboro market share and growing profitably. We see further upside from strong pricing trends and potential of vapor/iQOS that isn't currently reflected in the stock.

Required Disclosures

Altria Group, Inc. (MO) 3-yr. Price Performance



	Date	Published Price ($)	Rating Code	Price Target	Val. Rng. Low	Val. Rng. High	Close Price ($)
	9/23/2014		Herzog				
	9/23/2014	NA	2	NE	41.00	43.00	44.82
●	10/30/2014	47.55	2	NE	46.00	48.00	47.50
▲●	1/20/2015	53.05	1	NE	56.00	58.00	53.83
●	1/30/2015	53.10	1	NE	59.00	61.00	53.10
●	10/26/2015	61.05	1	NE	64.00	66.00	61.40
●	3/9/2016	62.30	1	NE	69.00	71.00	62.81
●	7/22/2016	68.86	1	NE	73.00	75.00	68.86
●	2/1/2017	71.39	1	NE	76.00	78.00	71.39
●	2/16/2017	72.71	1	NE	79.00	81.00	72.71

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- ▼ Rating Downgrade
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