Company: **22nd Century Group, Inc.**

Conference Title: **22nd Century Fourth Quarter 2017 Business Update**

Moderator: **John Brodfuehrer**

Date: **March 8, 2018**

Operator: Good day and welcome to the 22nd Century Fourth Quarter 2017 Business Update conference call. Today's call is being recorded. At this time, I would like to turn the conference over to Thomas James, General Counsel of the Company. Please go ahead.

Thomas James: Thank you very much. Before we begin today's call, I need to read the legal Safe Harbor text. The statements on today's call that are not based on historical information are forward-looking statements made pursuant to the Safe Harbor provisions of the Securities Litigation Reform Act of 1995.

Forward-looking statements include but are not limited to statements regarding our Company's business and strategy, future plans and objectives, and future results of operations, or that may predict, forecast, indicate, or imply future results, performance, or achievements. The words estimate, project, intend, forecast, anticipate, plan, expect, believe, will, will likely, should, may, or the negative of such words, or words or expressions of similar meanings are all intended to identify forward-looking statements.

These forward-looking statements are not guarantees of future performance and all such forward-looking statements involve risks and uncertainties, many of which are beyond our Company's ability to control. Actual results may differ materially from those expressed or implied by such forward-looking statements as a result of various factors, including but not limited to the risk factors disclosed in our Company's most recent Annual Report on Form 10-K as filed with the Securities and Exchange Commission yesterday on March 7, 2018. 22nd Century does not undertake and it disclaims any obligations to update any forward-looking statements or to announce revisions to any of the forward-looking statements.

During this conference call, we will disclose certain non-GAAP financial measures, including Adjusted EBITDA, which we define as earnings before interest, taxes, depreciation and amortization, as adjusted by 22nd Century for certain non-cash and non-operating expenses as described in our Company's earnings press release for the year ended December 31, 2017, as publicly issued yesterday on March 7, 2018, and which is available on our Company's website.

And with that I will turn the call over to our Chief Financial Officer, John Brodfuehrer.

John Brodfuehrer: Thanks Tom. Good afternoon and thank you for calling into 22nd Century's fourth quarter 2017 conference call. For those of you who are new to the call, my name is John Brodfuehrer and I am the CFO of 22nd Century Group. Today's call will be approximately one hour in duration and we will conclude at 5:00 pm Eastern Time. We will take questions at the end of the call as time permits. This afternoon I will provide you with a summary of the Company's financial results for the fourth quarter of 2017 and for the year ended December 31, 2017.

As reported in yesterday's press release, net sales revenue for the fourth quarter of 2017 and for the year ended December 31, 2017 were both the highest in the Company's history. The net sales revenue for the fourth quarter of 2017 was approximately $5.94 million, representing an increase of approximately $2.61 million, or 78.1%, over net sales revenue of approximately $3.33 million for the fourth quarter of 2016.

Net sales revenue for the year ended December 31, 2017 was approximately $16.6 million, an increase of $4.32 million, or 35.2%, over net sales revenue of approximately $12.28 million for the year ended December 31, 2016. This increase was primarily the result of additional net sales revenue from a new contract to manufacture existing brands of filtered cigars that began in mid-May of 2017.

Our gross loss on product sales for the year ended December 31, 2017 was $708,000 as compared to a gross loss of $430,000 for the year ended December 31, 2016, an increase in such loss of $278,000.

Although we began fulfillment in the second half of 2017 of a very substantial new manufacturing contract for a third party, as mentioned above, because we added workers in anticipation of this new contract, our manufacturing operations in North Carolina were still not running at full capacity throughout much of the year ended December 31, 2017. The increase in our gross loss was the result of costs associated with the increased capacity expansion at our Mocksville factory in anticipation of this new manufacturing work.

On to our operating expenses. Our net cash operating expenses, that exclude non-cash equity-based compensation, amortization and depreciation, increased during the year ended December 31, 2017 by $1,499,000, or 16.3%, from $9,204,000 for the year ended December 31, 2016 to $10,703,000 for the year ended December 31, 2017.

The increase in our net cash operating expenses of approximately $1,499,000 during the year ended December 31, 2017, consisted primarily of an increase in our research and development expenses mainly relating to sponsored research, personnel costs, and modified risk tobacco product application related expenses of approximately a total of $980,000, a net overall increase in our general and administrative expenses of approximately $1,017,000 primarily related to personnel costs, that were partially offset by a decrease in our sales and marketing costs relating to our advertising and promotional efforts of approximately $498,000.

Our net loss for the year ended December 31, 2017 was $13,029,000, or ($0.13) per share, as compared to a net loss of $11,581,000, or ($0.15) per share, for the year ended December 31, 2016, an increase in the net loss of $1,448,000, or 12.5%. The increase in the net loss was primarily the result of an increase in net cash operating expenses of $1,499,000, as discussed

previously, an increase in non-cash operating expenses of approximately $135,000, and an increase in our gross loss on product sales of $278,000, partially offset by an increase in other income of approximately $464,000.

Our Adjusted EBITDA, a non-GAAP financial metric previously defined by Tom James in his opening statement, for the year ended December 31, 2017 was a negative $11,411,000, or ($0.11) per share, as compared to a negative $9,634,000, or ($0.12) per share, for the year ended December 31, 2016, an increase in the negative Adjusted EBITDA of approximately $1,777,000, or 18.5%.

The Company is in its strongest financial position in its history due to our successful capital raise in October 2017 that produced net cash proceeds of approximately $50.7 million for the Company. As a result, the Company had cash, cash equivalents, and short-term investment securities of approximately $62.6 million as of December 31, 2017. This is an amount we believe will be adequate to cover normal monthly operating expenses of approximately $925,000 and meet all of our current obligations as they come due for a number of years.

That concludes my remarks. Thank you for your time, consideration, and interest in 22nd Century. I will now turn the remainder of the conference call over to our President and CEO, Henry Sicignano, who will provide you with a business review and update. Thank you once again.

Henry Sicignano: Thank you John. Good afternoon and thank you for joining us today.

And so, it begins! I am pleased to report that three FDA Center for Tobacco Products Advanced Notices of Proposed Rulemaking, also known as ANPRMs, cleared the Office of Information and Regulatory Affairs this week. Accordingly, we should expect publication in the Federal Register in

a matter of days. Clearly the most significant of these proposed rules to 22nd Century shareholders is the Tobacco Product Standard for Nicotine Level of Certain Tobacco Products.

This is a hugely important step in the FDA's plan to mandate dramatically reduced nicotine levels in all cigarettes. Every new rule enacted by the FDA must go through this rule-making process. Publishing the ANPRM in the Federal Register will initiate a period of public comment with industry, scientists, public health advocates, smokers, and all others who have an interest in the FDA's proposed rule. And, indeed, publishing the ANPRM will represent a critical milestone in a year that has already seen tremendous change for 22nd Century.

First, as a matter of background for everyone on the call today, 22nd Century's very low nicotine cigarettes contain less than 0.6 milligrams nicotine per cigarette and less than 0.05 milligrams nicotine yield per cigarette. In each case, this represents a reduction of at least 95% less nicotine relative to "Big Tobacco" cigarette brands, including Marlboro®, Camel®, Newport®, and American Spirit®.

22nd Century is the only company in the world growing virtually nicotine free tobacco for use in independent clinical studies paid for by agencies of the U.S. federal government. Without any artificial extraction or chemical processes, our finished Very Low Nicotine cigarettes have the taste and sensory characteristics of conventional cigarettes, but contain only trace amounts of nicotine so that smokers' exposure to nicotine is drastically reduced.

It has been well established that cigarette smoking is toxic and poses health risks to smokers. Cigarette smoking is a complex behavior that is sustained primarily by the pharmacological properties of nicotine. Accordingly, many public health officials believe it is a critically important health need to provide consumers with a product that reduces exposure to nicotine.

Unlike so-called “light” or “ultra-light” cigarettes, which terms are now banned by the FDA from labeling and marketing in the United States, 22nd Century’s proprietary Very Low Nicotine cigarettes are designed to deliver greatly reduced ratios of nicotine to other smoke components.

With the aim of reducing the harm caused by smoking, on July 28, 2017 FDA Commissioner Dr. Scott Gottlieb announced the FDA’s plan to mandate the lowering of nicotine levels in all cigarettes sold in the United States to minimally or non-addictive levels. On September 21, 2017, Dr. Gottlieb together with Mitch Zeller, Director for the FDA’s Center for Tobacco Products, co-authored a paper published in *The New England Journal of Medicine.*

While explaining the Agency’s plan to dramatically lower nicotine in cigarettes Gottlieb and Zeller pointed out that “a nicotine-limiting standard could make cigarettes minimally addictive or non-addictive, helping current users of combustible cigarettes to quit and allowing most future users to avoid becoming addicted and proceeding to regular use. Disrupting that progression -- from experimentation to regular use to tobacco-related disease and even death -- could save millions of American lives.”

More recently, just two weeks ago at the annual meeting of the Society for Research on Nicotine and Tobacco, Dr. Gottlieb reiterated the Agency’s commitment to reducing nicotine in cigarettes when he said “we will solve the tobacco crisis…by addressing the root issue of tobacco addiction -- nicotine.”

Since the FDA first announced its plan to reduce drastically the nicotine level in cigarettes, the Agency has shown resolute determination to see its plan through. In explaining the urgency to lower nicotine levels in cigarettes, Dr. Gottlieb quotes statistics showing the enormous public health toll imposed by tobacco use. And the market is beginning to realize that the FDA is, in fact, truly committed to its plan.

Share prices for Altria Group, Philip Morris International, and British American Tobacco all continue to fall and are substantially lower today than they were last June. At the same time, though 22nd Century remains well below the radar of most of Wall Street, many people are beginning to discover our Company and our potential.

Over the summer, Stanford professor Robert Proctor authored an editorial published in *Tobacco Control Journal* entitled, "FDA's new plan to reduce the nicotine in cigarettes to sub-addictive levels could be a game changer." Professor Proctor reasons that limiting cigarettes to non-addictive levels of nicotine is a moral imperative when he asserts that "smokers would be able to start or quit at will, without suffering the robbery of choice that defines addiction."

Further, Dr. Proctor predicted that the new FDA plan "could save more lives than any other act of a government agency in all of human history. The magnitude of the harm is that great. We hear a lot about tobacco end games; this one could be a game changer."

It is difficult to overstate the importance of FDA's nicotine reduction plan. It could, quite literally, change the scope of tobacco-related disease in the United States and around the globe. And this is precisely what skeptics simply do not understand. The bottom-line significance of 22nd Century's Very Low Nicotine technology is that it has the potential to reduce cigarette smoking, to increase quit attempts, to decrease nicotine dependence and, most importantly, to prevent a new generation of young people from becoming addicted to cigarettes.

Support to mandate reduced nicotine tobacco in cigarettes to minimally or non-addictive levels is taking root in a number of countries. Canada's primary public health agency, Health Canada, recently announced that it is seeking to purchase one million Very Low Nicotine cigarettes at the same nicotine content as our Very Low Nicotine Spectrum cigarettes – 0.4 milligrams per gram of nicotine.

Public health experts in New Zealand also published an action plan recommending such reductions. Canada and Finland say they are looking into regulating amounts of nicotine in tobacco products, while officials in the United Kingdom's Department of Health have also discussed with public health officials in the United States the FDA's plan to drastically reduce nicotine.

To take the greatest advantage of the intense regulatory tailwind now advancing Very Low Nicotine tobacco, we have added significantly to our in-house capabilities. In the fourth quarter of last year, we made two strategic hires who will be very important to our BRAND A Modified Risk Tobacco Product application.

In November 2017, we announced the hiring of Dr. James Swauger as our Company's Senior Vice President of Science and Regulatory Affairs. Dr. Swauger was previously the leader of the scientific and regulatory functions at Reynolds American, where he managed creation, submission, and oversight of numerous scientific applications and regulatory filings with the FDA and other federal, state, and local regulatory agencies. We expect Dr. Swauger to achieve perhaps the first marketing order in history for a Modified Risk Tobacco Product in the form of our BRAND A Very Low Nicotine cigarette.

In December 2017, we appointed Dr. Juan Sanchez Tamburrino as our Company's Vice President of Research and Development. Dr. Tamburrino was previously the head of the plant biotechnology division of British American Tobacco. We expect Dr. Tamburrino's experience with tobacco and its makeup at the molecular level will rapidly advance our second generation Very Low Nicotine plant lines.

Given that the FDA's Advance Notice of Proposed Rule Making for the Tobacco Product Standard for Nicotine Level of Combusted Cigarettes has cleared the Office of Information and Regulatory Affairs at the Office of Management and Budget this week, we expect publication in

the Federal Register in short order and we believe that there is no better time to advance our Modified Risk Tobacco Product Application (MRTP) for BRAND A Very Low Nicotine cigarettes.

The FDA is seeking to regulate the nicotine in all cigarettes for precisely the same reasons we are developing BRAND A. And because 22nd Century's objectives are so closely aligned with the FDA's stated goals, we believe that the FDA's Center for Tobacco Products will regard our MRTP application for Brand A Very Low Nicotine cigarettes as complementing the Agency's own efforts to reduce nicotine.

While our Very Low Nicotine tobacco technology takes center stage, we are also continuing to develop our hemp technology. Through our partnership with Anandia Labs in Canada and with the University of Virginia, we are working to develop hemp plant lines suitable for growing in Virginia and the rest of the traditional tobacco belt in the southeastern part of the United States and in other regions of the country as well.

In this regard, last fall we were granted a license to grow, research, and commercialize hemp products in New York State. Accordingly, we are bringing hemp, including our zero THC hemp, to our Buffalo, New York-based laboratories. We are very excited to advance our hemp technologies right here in our home state.

There has never been a more exciting time for 22nd Century. We believe 22nd Century's patented technology and proprietary Very Low Nicotine plants represent a real solution to the FDA's pending regulation of nicotine levels in combustible cigarettes.

We believe 22nd Century will have the opportunity to license the Company's technology to Big Tobacco at a fraction of the cost they are currently contemplating it will take them to comply with the planned FDA regulations. Our talented team of scientists, regulatory experts, and tobacco industry professionals are laser-focused on achieving our Company's strategic objectives.

Indeed, we are on the verge of accomplishing our Company's lofty goal of significantly reducing the harm caused by smoking.

Thank you so much for joining us today and for your continued interest in our extraordinary technologies and our exciting Company. At this time, I will open the call to your questions. But, as a reminder, today's conference call will end promptly at 5:00 pm. We are open to all questions from any shareholders, but in the interest of making the best use of our available time we suggest that questions not cover topics that have been addressed in our Form 10-K and, as always, we remind you that we cannot discuss on this call any matter that has not been publicly disclosed.

Operator: Thank you. If you would like to ask a question, please signal now by pressing star 1 on your telephone keypad. If you are using a speaker phone, please make sure your mute function is turned off to allow your signal to reach our equipment. Again, that is star 1 to ask a question. We will take our first question from Jamie Burgess with 22nd Century.

Jamie Burgess: Hello?

Henry Sicignano: Hello, how are you?

Jamie Burgess: Hey guys. Doing great. How are you today?

Henry Sicignano: Outstanding.

Jamie Burgess: Great, great. A quick question. I feel pretty confident that we are all in agreement that the ANPRM from the FDA, as well as the Phase 3 patient study results from Dr. Hatsukami, are the two leading catalysts for the Company right now. Is that a pretty safe assumption?

Henry Sicignano: I think in the near term that is right, yes.

Jamie Burgess: All right, well my question is -- as I am sure you guys know -- that the projected timeframe from the time that the proposed rule is put out from the time that the mandate is actually put in place is likely to be several years. My question is what can you disclose of anything that is being done to either increase and/or maintain shareholder value from the time that the advanced notice is put out to the time the mandate actually takes effect?

Henry Sicignano: Okay, well I guess I will start with the fact that we have no idea how long the rulemaking process is going to take. We believe it is about to start any day now, which is very encouraging and very exciting. And we believe that the process itself will represent a half dozen or more catalysts. Each step that is made will represent a very important catalyst for the Company.

We also believe that Dr. Gottlieb has recognized reducing nicotine in all combustible cigarettes in the United States as a primary goal of the Agency and, that said, it suggests to us that he will want to accomplish this goal during his tenure. So, you know, I have no crystal ball, but we believe that the process itself will represent half a dozen or more catalysts in the near term and we believe that it is a top priority for the Agency.

In the meantime of course, we are working on our BRAND A Very Low Nicotine Modified Risk Tobacco Product application, which we think goes hand-in-hand with the FDA mandate. And I think you will find, as we go through the modified risk process, you will see those catalysts, you know, step by step just like the FDA mandate. So, it is not one event to celebrate at the end of the process, it is actually each step and each accomplishment, each achievement through the process, that will be catalysts for our Company and our shareholders. Is that helpful?

Jamie Burgess: Yes sir, yes sir. I appreciate your time and keep up the great work guys. Thank you.

Henry Sicignano: Okay, thank you.

Operator: We'll take our next question from Jim McIlree with Chardan Capital.

Jim McIlree: Thanks a lot, good afternoon everyone.

Henry Sicignano: Hello Jim.

Jim McIlree: Henry, can you lay out the timeline for the BRAND A MRTP and when you expect to file that?

Henry Sicignano: I have not laid out a specific timeline, Jim. All I can tell you is that we have brought in Dr. Jim Swauger to evaluate everything that we have been doing on our MRTP and to resubmit the absolute best application that we can. So, I am actually going to leave that in his capable hands. Obviously, sooner is better than later, but we are not going to rush the process either.

Jim McIlree: Is it reasonable to expect that it would be sometime this year or is it possible that it is next year?

Henry Sicignano: Anything is possible. And our intention is to work as collaboratively as we can with the FDA. So, again, it is a step by step kind of thing. We plan on doing some work, and on discussing the work that we do with the FDA. And if that process goes very quickly, then we will submit it sooner and if that process takes longer, then I guess it will drag out the process a bit.

Jim McIlree: Okay fair enough. As far as the ANPRM goes, is there anything surprising in there to you?

Henry Sicignano: Well, it is not in the Federal Register yet, so I cannot say there is. But, it is following the normal progression of the rulemaking process, so I guess that is to be expected.

Jim McIlree: I was referring more to the content, if you had any knowledge of what the specific content is in the rulemaking.

Henry Sicignano: We do not.

Jim McIlree: Okay and so some of this is out of your hands, it is going to be what the FDA does in going through their process. But along the lines of the prior questioner, so what you do over the next period of time is going to be bolstering your position on the BRAND A MRTP? I am assuming that you are going to continue to protect the IP and advance that technology. Are there any changes or other relevant issues we should be aware of? And then along those lines is your strategy on the contract manufacturing unchanged?

Henry Sicignano: Well, you know, I think part of our strategy going forward is to be far more active in the regulatory affairs world. And Dr. Swauger and Jim Vail, our Director of Communications have a full schedule of conferences and meetings all over the world.

Just this week, we had some public news from South Africa. We also have regulators in the UK and Canada looking at Very Low Nicotine technology. We are actively attending and speaking at international meetings. We had an invitation this morning from a major U.S. tobacco control group to come and talk with them.

We have lots of regulatory affairs opportunities that we never had in the past, but now with FDA's attention focused squarely on reducing nicotine in cigarettes, lots and lots of doors have opened and we have become, I guess, the belle of the ball. So it is going to be a very important initiative for us this year to get the word out there and to explain to people the significance of the technology and what it can do for public health.

In terms of contract manufacturing, we will continue to grow that business and the strategy is to fully utilize the factory which would enable us to make the factory profitable. So, that is exactly what our plan and our intentions are and you will see sales continue to grow and, hopefully, we will decrease the loss or maybe even turn a profit.

Jim McIlree: Okay great. Thanks a lot guys, good luck with everything.

Henry Sicignano: Thank you, Jim.

Operator: And if you do happen to find that your question has been answered, you may remove yourself from the queue by pressing star 2. We will move next to Robert Branciforte with Morgan Stanley.

Robert Branciforte: Hey Henry, thanks for taking the questions.

Henry Sicignano: Thank you.

Robert Branciforte: I have two questions. First, correct me if I am wrong, but didn't I read somewhere that you were estimating that the Phase 3 trial that is undergoing with I think what, 1250 patients, that those results would be out by the end of the first quarter?

Henry Sicignano: Well, let me tell you the facts that I know. That trial concluded last March, in March of 2017. And, I am aware of the fact that partial results of that study have been shared with the public and with public health officials by Dr. Dorothy Hatsukami and Dr. Eric Donny during at least three conferences. I attended two of those conferences. So, I guess what has been publicly revealed is that the immediate reduction to Very Low Nicotine is most beneficial to smokers. That is my understanding of the partial study results that have been made public to date.

It is also my understanding that the entire study will be made public in a peer reviewed journal, but we do not know yet when that will be published. I would hope that perhaps it would be sometime very, very soon, especially given that the study concluded last March, but I cannot guarantee that.

Robert Branciforte: Okay, so then that is what I was thinking was that the peer reviewed part of it, that is what we are waiting for, which could be imminent, it could be, you know, who knows. Okay. The other question, there was a press release yesterday regarding the 17th World Conference and there was a line in there that I just want to read.

It said, "Dr. Gottlieb also revealed we have an article nearing publication that includes updated modeling statistics for the potential positive public health impact of such a standard and the results are significant, emphasis added." Could you comment on that? I am not sure what it is - is there something that he is going to be revealing soon?

Henry Sicignano: I cannot tell you what Dr. Gottlieb means precisely, but I can tell you that those are his words and we are very encouraged by those words. My General Counsel will not allow me to interpret his words; but, we are very excited by those words.

Robert Branciforte: Well, the article is nearing publication that includes updated modeling statistics. Do you think that is as a result of any of the research that you have been doing with them or the research that they have been doing with your cigarettes?

Henry Sicignano: Yes, that is our belief. That is exactly right.

Robert Branciforte: Okay. All right, thanks guys. Keep up the good work.

Henry Sicignano: Thank you so much. We appreciate it very much.

Robert Branciforte: Keep the shorts out of seeking alpha. They are driving me crazy. You know, you have got to get rid of those guys. Anyway, good luck.

Henry Sicignano: All right, thank you very much.

Operator: We will move next to Derek Gregory, a private investor.

Derek Gregory: Hi Henry. How are you?

Henry Sicignano: Good afternoon.

Derek Gregory: My question is regarding your recent patent entitled Reduced Exposure Tobacco Products. I am just wondering if you could elaborate a little bit more on the potential utilization for that, what type of value you see in it, as well as I noticed it was filed in 2004 and just awarded last November in 2017. Maybe you can clarify that a little bit for us. Thank you.

Henry Sicignano: I am going to let Tom James talk about this, but just before Tom gets into it a little more I am going to say, broadly, we have literally dozens and dozens of pending patent applications in process now and they are reviewed and granted all the time. And, we do get lots of feedback from shareholders, many of them saying "Hey you should press release every one of these." But we would be issuing almost a press release a week if we if we did that.

So, we try to be judicious about the press releases that we issue in terms of our IP. They are all important, but we do not want to make a huge deal out of every single one that makes some progress. But, anyway, I will let Tom answer your question more specifically.

Thomas James: Thanks Henry. Hi Derek. This is Tom James, General Counsel for the Company. These things take time in the regulatory review process and the rest of that, so we cannot comment on how soon or short the United States Patent and Trademark Office will issue patents to us. We are certainly pleased to receive the patents.

How the various patents interplay with what we are doing we do not discuss publicly. That is part of our patent strategy. Suffice to say that this all supports what we are doing with Very Low Nicotine and other things that regulate up and down nicotine in the plants. So, it fits within our total mission, but we do not disclose publicly and we do not discuss publicly how this fits into our strategy. Just know overall that it is a good thing to get a patent.

Derek Gregory: Okay, thank you.

Tom James: Thank you.

Henry Sicignano: Thank you.

Operator: We will move next to Marion Green, private investor.

Marion Green: Hi Henry, I am glad everyone is feeling better back in Buffalo.

Henry Sicignano: Well thank you Marion.

Marion Green: You are quite welcome. I have voiced this before, but we still have a lot of areas that really need us like Japan, China, Korea, Mexico, India.

Henry Sicignano: That is true… And?

Marion Green: And I am just wondering, you know, now that we do not have the GMOs, which I know was a big factor into getting into several of those countries, that is not an issue any longer. So, are the doors open a little bit or wide for these areas?

Henry Sicignano: Okay well let's see. First of all, we are working on, but have not yet achieved a very low 95% less nicotine tobacco variety that is non-GMO. We do have low nicotine tobacco varieties that are non-GMO, but we do not yet have a very, very low nicotine tobacco variety that is non-GMO. So, I just want to make sure that is clear. We are pretty close though, we believe, which is very exciting.

But in the meantime, I guess the best way to answer this question is to say that Mike Zercher, our Vice President of Business Development, has lots of frequent flyer miles. You know, he has been -- just in the last month -- he has been all over Asia and Europe. So, we have lots and lots of discussions and lots of meetings with companies and entrepreneurs all over the world. They are well aware of us and we are excited to be working with some of them and growing relationships in the past, I guess, six months. Is that helpful?

Marion Green: Very much. I thank you very much.

Henry Sicignano: Okay, well thank you very much for calling and I am sure I will see you in New York sometime soon.

Marion Green: Absolutely. Thank you, Henry.

Henry Sicignano: Thank you, Marion.

Operator: We will go next to Murray Brown, private investor.

Murray Brown: Yes Henry, congratulations and well done. I was wondering if your general…

Henry Sicignano: Well… thank you, Mr. Brown.

Murray Brown: Hello?

Henry Sicignano: I am sorry, I said thank you, thank you sir.

Murray Brown: Yes, and I was wondering of all the comments you have made, how would you superimpose this on the heat-not-burn market that the FDA is very interested in controlling? Would VLN be used in the heat-not-burn environment?

Henry Sicignano: Well that is a good question. And, I guess anything is possible, but our expectation is that our high nicotine tobacco would be most helpful to the heat-not-burn products because the higher nicotine content would help those products to deliver a satisfactory amount of nicotine when the smoker is using one of those devices.

So that is our expectation. Is that going to happen in the U.S. market? I do not know. When is it going to happen? I am not sure. So right now, our priority strategically for the Company, especially in the United States, is a focus on our Very Low Nicotine products.

We did, as you know, conduct some exposure studies with BRAND B last summer, which is our very low tar-to-nicotine ratio cigarette, which is actually a higher nicotine product. But, because of the FDA announcement at the end of last July, we have really refocused all of our efforts and all of our spending on Very Low Nicotine technology for the U.S. Internationally, that could be different, but again the focus right now is on Very Low Nicotine.

Murray Brown: Okay Henry, thanks very much.

Henry Sicignano: Thank you very much, Mr. Brown.

Operator: And we will go next to Richard Scodnek, private investor.

Richard Scodnek: Hi Henry. Thank you very much. I have been a practicing psychiatrist for many years in the past and I am quite knowledgeable about what you are dealing with about the harms and the addictive nature of cigarette smoking and also I have treated substance abusers and, of course, cigarette smokers who wanted to quit.

My concern is the well-known adage people smoke for the nicotine and are killed by the tar. And my analogy for you, sir, is every year we have more diet foods and yet we have more obesity. And isn't it true that many people will say yes these cigarettes have less nicotine and that psychoactive drug is exactly what I want and they will do end runs around it in any number of ways like the low nicotine cigarettes of the past. What say you sir?

Henry Sicignano: Okay that is an excellent question. It is a really important question and often times doctors pose precisely the question that you have asked. And the best thing for us to do is to share with you the independent research that has been done on the topic.

Because you are right. If you reduce nicotine by say 20%, smokers tend to compensate and smoke more. If you reduce nicotine 50%, they tend to smoke twice as many cigarettes; that is compensation. So, you are precisely right and that is the reasoning behind the FDA's ban of "light," "ultra-light" and "low tar" products because smokers compensated with those products and, in fact, inhaled more toxic compounds or smoked more.

Now if we contrast that with the actual third-party, independent, objective clinical trials that have been conducted with our products, our nicotine levels are so low, so low that compensation is not possible. And that is the key difference.

If you actually look at *The New England Journal of Medicine* article published in October 2015, the 840-patient study, Phase 2/Phase 3 trial, it does show that in the first week typically smokers do smoke a little bit more in that first week. And then after that first week, smoking steadily decreases for cigarettes with 85% to 90% less nicotine and below. And it seems that the World Health Organization and others seem to think that some number -- around 95% less nicotine -- is the optimal level of reduced nicotine for a cigarette.

So at that level, and I am going to paraphrase here, but that *New England Journal of Medicine* Phase 2/Phase 3 clinical trial showed that there is a decrease in cigarettes smoked, an increase in quit attempts, a decrease in exposure to nicotine, no compensatory or minimal compensatory smoking, and no adverse events associated or withdrawal symptoms associated with smoking a Very Low Nicotine cigarette.

So, I want to state very clearly that is not our study, that is not our science. I am paraphrasing a study, a peer-reviewed study, published in *The New England Journal of Medicine*, conducted by Dr. Eric Donny and those are *his* conclusions and that is a seminal study. I think the other Phase 3 trial of 1,250 patients that was done and finished last March -- that we just discussed with a previous caller -- that study I think will reinforce those results. And there are many other studies, actually.

I first invested in the Company in 2010 when I read a study published in the *Journal of Addiction* by Dr. Dorothy Hatsukami, a former FDA TPSAC committee member. In the Dr. Hatsukami study, it was a Phase 2 trial… I think it was 165 patients. And these were all folks who had an intent to quit. But, on the order of half of the patients who smoked cigarettes for six weeks, which

were Very Low Nicotine cigarettes, approximately half, I think 47%, were able to quit smoking after smoking the Very Low Nicotine cigarettes for six weeks.

So, I have just given you a lot of data and I have pointed to a lot of different studies. But at the end of the day what I am saying is Very Low Nicotine cigarettes typically do not result in long term compensation. They typically result in a decrease in cigarettes smoked. The Dr. Hatsukami study showed a decrease from about 19 cigarettes a day at the beginning of the trial, which is almost a pack a day, down to about 12 cigarettes a day for those who failed to quit.

So, a decrease in cigarettes smoked, an increase in quit attempts, a decrease in exposure to nicotine, with no or very few withdrawal symptoms or any other adverse events. Is that helpful or did I miss something?

Richard Scodnek: Yes, that is very helpful. Can you give the citation of that journal article, do you have the specifics?

Henry Sicignano: You know, not in front of me, but you can find them on our website. There are a couple of pages of…

Richard Scodnek: Oh okay.

Henry Sicignano: Yes, on the website. And you know, frankly if you can contact our office, perhaps tomorrow morning, then we could have a more lengthy conversation. We appreciate when physicians like you take an interest in our product and we will send you a whole package of materials if that would be helpful to you.

Richard Scodnek: Very good. Thank you very much sir.

Henry Sicignano: Thank you.

Operator: We will take our next question from Paul Volks with Cougar Capital Management.

Henry Sicignano: Good afternoon.

Paul Volks: Good afternoon, thanks for taking my call. With all this country looking toward the cannabis legalization and spring is, you know, imminently around the corner, have there been any sort of updates or are you guys still pushing forward with the hemp and everything or has everything kind of taken a back burner for waiting for the FDA to make a move?

Henry Sicignano: Well our primary focus is certainly Very Low Nicotine technology and our Modified Risk Tobacco Product application. That is certainly our primary focus. But, we have not ceased efforts on our hemp and cannabis initiatives. So, I will let Tom briefly update you on a little bit of what we have been doing. You know, many of these things are outlined in our Form 10-K. But, I am just going to say briefly we have nine minutes left and it is a hard stop at 5:00pm, so I will just let Tom briefly address that question.

Thomas James: All right thanks Henry. Yes Paul, very quickly I have to direct you to look at the Form 10-K. We have very exhaustive disclosure with respect to what we are doing historically and what we are doing in hemp in the coming year. So, as Henry said, we certainly have a primary focus on our VLN tobacco with respect to the government, but we have not abandoned any of the other work and we are still continuing forward in other plants, including hemp.

Paul Volks: Fair enough. Thank you, Tom.

Thomas James: All right thank you.

Operator: We will take our next question from Paul Slattery, private investor.

Paul Slattery: Yes, good evening. Thank you for taking my questions. My question goes back to the topic of the MRTP application. I recall from the last time we had a conference call that I was listening to that we hoped that it would be submitted early this calendar year, and that would be in part because of your working so closely with the FDA.

And I think that is obviously a good idea to proceed with all due speed. It does seem that since that product is so well aligned with the FDA goals that I am a little bit surprised that you are not more optimistic about when the application might be submitted. Could you comment on that?

Henry Sicignano: Sure. I mean, we are very optimistic. We are actually super excited about it. At the same time, it is a process. As you know, Altria submitted an application and I do not want to get the number wrong, but I want to say it was 3 million plus pages, if I am not mistaken. And, you know, they did not get a marketing order to proceed. So, 3 million pages plus of work and God knows how many hundreds of millions of dollars they spent on that.

We want to make sure that we submit our revised application and make sure that it is unassailable, that it is the absolute strongest application that the FDA has ever seen for a modified risk candidate, which is a large reason or a large rationale behind the hiring of Dr. Swauger, who spent 23 years at Reynolds and I believe has many dozens of applications that he submitted to the FDA and to other regulatory agencies.

We had the backbone of the application finished two years ago, but we are going to dot every “I” and cross every “T” and I am not saying we are going to submit 3 million pages. I do not think we will need to. Most of what we are submitting are our analyses and our references to third-party independent scientific research that has been done by NIDA and other independent researchers

across the country. But, we do want to make that application as robust and as comprehensive as possible to give us the best possible chances of approval.

Paul Slattery: Well, that is wise. Of course, it may take 3 million pages to put in a bunch of “I”s, but maybe less.

Henry Sicignano: I promise you there will be no lies in our application.

Thomas James: He meant dotting “I”s.

Henry Sicignano: Oh, dotting “I”s. Oh, okay.

Thomas James: We understand Paul. Thank you.

Paul Slattery: Okay, well it is a pleasure to be with a Company that is actually doing good.

Henry Sicignano: Thank you very much sir. We appreciate having you as a shareholder.

Operator: We will take our next question from Alan Lorenzi, private investor.

Alan Lorenzi: Gentlemen, congratulations.

Henry Sicignano: Oh well, thank you. Good afternoon sir.

Alan Lorenzi: Yes, I wanted to just touch on something real quick. I know that you do not have much time and I do not want to miss out on saying the third thing I wanted to mention, so I am going to mention it first. I would like to thank you for the employees that you have working for you. When I call to talk and ask a question, I speak to Nathan or Debbie and they always have a smile in

their voice, they are always so welcoming, any question they can answer legally. They always have your back.

And I mean, they are so loyal to this Company. And I just wanted to, you know, send maybe some kudos out to them and I sure enjoy calling in and speaking to them. And, like I say, they never say anything that is not legal to say. They never go beyond anything that they cannot say and they always, like I say, have a smile in their voice. So, if you could maybe give them a little nod, I would appreciate that.

Henry Sicignano: Well thank you very much sir for saying that, thank you.

Alan Lorenzi: Yes and second of all I want to - I read about hemp and the company in North Carolina that is going to plant 25,000 acres of industrial hemp and I was wondering when we would be able to start to sell seeds. I am sorry I have to hurry so much. I know you have only got about four minutes left.

But I have read earlier about a seed company in Colorado called Certified Seed that said that they can sell industrial hemp seeds that will only grow 3% THC, keep it to 3%. And there was a woman farmer in Colorado that doubted that and she said why she doubts that is because the THC in hemp can climb, percentage wise, by what terrain it is planted in, by the weather conditions, the soil conditions. So, she doubted that was true about that company.

And I just felt that opened the door for our Company where if we have zero-THC plants, then why would any of these farmers who plant a hemp crop and want to get insurance on it, why would they not want to use our product and even take a chance on anybody else's seeds? And, like I say, the company in North Carolina is going to grow 25,000 acres of hemp this year and I guess they have got to kind of gamble that the THC in that it does not climb. Can you expand a little bit,

I know we do not have much time, on when we can start selling our THC-free hemp seeds? Thank you.

Thomas James: Alan, thank you. Alan, this is Tom James, General Counsel for the Company. I think you should very carefully look into the companies that put out those press releases, both of them, and if you look at the underlying companies and their publicly available information, especially the one in North Carolina, then you will have a different opinion of what is being said, number one.

Alan Lorenzi: Yes, I know that is a mooch company, I understand that. I do not like what I have read about them. I just did not know that they were going to be allowed to let the farmers grow 25,000 acres of hemp. I do not think they are going to grow it. I think the farmers in North Carolina are going to grow it.

Thomas James: Well, I think the bottom line is everybody would like to grow a crop that has got great potential for the future. There is no question that the hemp crop and the reemergence of this crop in the country will be a wonderful thing and that is why we are involved in it. But we do not comment on what other people are doing. We are very happy to see other people involved in things.

But, let me clarify one other thing. Certified seed is nothing more than a state saying you have grown it enough times that it has the qualities that you say it has. It germinates at this rate, it yields at that rate, and has the following characteristics – that is it. So, you can get your seed certified in various states, but that does not make it something special or different.

And, I will conclude with this. It is not legal to be involved with something that has above 0.3% THC. A THC level of 0.3% or below is legal hemp. But, 3% THC is way out of line and that is marijuana and cannabis and we do not touch it. It is illegal federally. So, in legal hemp, yes our

ZERO-THC plant has greater opportunity and we will bring it out strategically at the right time, but right now as you see we are growing it up at various locations as disclosed in the Form 10-K.

Henry Sicignano: You know, and I will just reiterate sir, I think you are exactly right. We met some farmers in Colorado who told us that they bought some seed and they were successful in the first year with the seed and they were successful in the second year with the seed.

And then all of the sudden in the third year, I do not know if it is because of where they planted it, or how much water it got, or how much sunlight, but all of the sudden in the third year that they grew it, it tested "hot" and they had to destroy the crop. So, you are exactly right, that problem represents great potential for our Company. The opportunity for our Company to come in with a product that guarantees ZERO-percent THC. You are exactly right.

Thomas James: Yes, Alan. I will complement what Henry just said. We looked at this years ago and tried to solve this problem. That is why we did what we did to create the ZERO-THC hemp to solve this problem because it is a big problem for farmers, so we wanted to eliminate it.

Alan Lorenzi: Yes, thank you so much for that. And that is my point. I do not see why anybody would want to buy hemp seed from anybody else but 22nd Century because they can get the insurance and go to sleep every night and not have to worry that they would have to destroy their crop or lose money. So, I would just like to see that being promoted.

And maybe we can get some seeds out to these different states. I think there are 38 or 34 states now that are passing legalized industrial hemp laws and starting to produce it. So, I would like to know if we could advance that somewhat or when we can get into that business of selling in these states the seeds that they want to start to grow this hemp.

Thomas James: Thank you.

Henry Sicignano: You are very right. It is going to be a priority for us. Thank you sir, we appreciate it. It is…

Alan Lorenzi: Remember the employees, complement the employees.

Henry Sicignano: I will do that as soon as we get off the phone.

Alan Lorenzi: Nathan and Debbie. Nathan and Debbie. Nathan and Debbie. Thank you very much you guys. Goodbye.

Henry Sicignano: All right, thank you, bye-bye. It is past the hour and I am sorry, but we are going to have to close the call today. But we do appreciate everyone who called in and all the questions that were asked and we will certainly look forward to meeting more of you at the annual meeting at the end of April and perhaps at some investor conferences in the coming months. Thank you very much.

Operator: And that concludes today's call. Thank you for your participation. You may now disconnect.