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Recording: The conference is now being recorded.

Operator: Good day and welcome to the 22nd Century First Quarter 2019 Business Update Conference Call. Today's conference is being recorded. At this time, I would like to turn the conference over Mr. Tom James. Please begin.

Thomas James: Thank you very much. My name is Thomas James, the Vice President, General Counsel, and Secretary of the Company. We thank everybody for joining the call and I appreciate you bearing with us as we read the required safe harbor text.

The statements made on today's call that are not based on historical information are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding our Company's business 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 intended to identify forward-looking statements.

These forward-looking statements are not guarantees of future performance and all such forward-looking statements involve risk 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 for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on March 6, 2019. 22nd Century does not undertake and it disclaims any obligation to update any forward-looking statements or announce revisions to any of the forward-looking statements.

During this conference call, we will also 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 all as described in our Company's earnings press release for the quarter-ended March 31, 2019, as publicly issued yesterday on May 7, 2019, and which is available on our Company's website.

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

John Brodfuehrer: Thank you, Tom. Good afternoon everyone, and thank you for participating in the 22nd Century business update call for the first quarter of 2019. My name is John Brodfuehrer and I am the Chief Financial Officer of 22nd Century Group. Today's conference call will be one hour in duration and will conclude promptly at 5:00 p.m. Eastern Time. We will take questions at the end of the presentations as time permits. This afternoon, I will provide you with a summary of the Company's financial results for the three months ended March 31, 2019.

I will first start with our net sales revenue. As reported in our first quarter Form 10-Q, filed with the SEC yesterday, and also as stated in yesterday's press release, net sales revenue for the three months ended March 31, 2019 was $6,294,000, as compared to net sales revenue for the three months ended March 31, 2018 of $6,116,000, an increase of $178,000, or 2.9%. The net sales revenue increase is primarily a result of additional net sales revenue generated from our contract

manufacturing of filtered cigars and cigarettes during the first quarter of 2019 as compared to the second quarter of 2018.

However, we did experience a growth loss on our net sales revenue during the first quarter of 2019 in the amount of $103,000, as compared to a gross profit on net sales revenue for the three months ended March 31, 2018 in the amount of $72,000.

This negative change from a gross profit to a growth loss during these periods was primarily the result of additional expenses recorded to the cost of goods sold during the first quarter of 2019 as compared to the first quarter of 2018. Those additional expenses consisted primarily of an increase in fees due to the FDA on filtered cigars of approximately $100,000 and a net increase in other manufacturing expenses charged to the cost of goods sold of approximately $60,000, mainly relating to labor and equipment maintenance costs.

I will now move onto our operating expenses. Our net cash operating expenses, that is operating expenses that exclude non-cash equity-based compensation, amortization and depreciation, for the three months ended March 31, 2019 were $4,476,000, an increase of $292,000, or 7%, from net cash operating expenses of $4,184,000 for the three months ended March 31, 2018.

Included in the operating expenses for both the three months ended March 31, 2019 and 2018 were expenses relating to our Modified Risk Tobacco Product application with the FDA for our Brand A Very Low Nicotine Content cigarettes in the amount of $1,211,000 and $1,296,000, respectively.

Next, I will address our net loss for the quarter. We experienced a net loss for the three months ended March 31, 2019 in the amount of $2,073,000, or a negative $0.02 per share, as compared to net income of $1,386,000 for the three months ended March 31, 2018, or $0.01 per share. The negative change from net income for the first quarter 2018 to a net loss in the first quarter of 2019 amounted to a change of $3,459,000, or 250%.

This negative change of $3,450,000 is attributable to the following:

(1) A decrease in the unrealized gain on investment of $3,174,000. During the three months ended March 31, 2019, we recorded an unrealized gain on the fair value adjustment for the Aurora Cannabis stock warrants that the Company owns in the amount of $2,973,000. During the three months ended March 31, 2018, we recorded an unrealized gain on our then investment in Anandia Laboratories in the amount of $6,147,000 as a result of the adoption of the new accounting standard that became effective on January 1, 2018. The difference between these two unrealized gains is a decrease of $3,174,000; plus

(2) The negative change in the gross profit (loss) on product sales of approximately $174,000 as I discussed above, plus

(3) An increase in operating expenses in the amount of $236,000, as partially offset by

(4) An increase in various other income (expense) items in the amount of $125,000.

Next, I will address our Adjusted EBITDA. Our Adjusted EBITDA, a non-GAAP financial metric previously defined by Tom James in his opening remarks, for the three months ended March 31, 2019 was a negative $4,580,000, or a negative $0.04 per share, as compared to a negative $4,113,000, or a negative $0.03 per share, for the three months ended March 31, 2018, which is an increase in the negative Adjusted EBITDA of approximately $467,000, or 11.4%.

This increase is primarily the result of the previously discussed increase in our net cash operating expenses of $292,000 and the negative change in our gross profit (loss) on net sales revenue in the amount of $174,000.

Finally, I will discuss the Company's cash position as of March 31, 2019. We continue to be in a strong cash position with cash, cash equivalents, and short-term investment securities totaling $51.9 million at March 31, 2019. This is an amount we believe will be adequate to cover normal monthly operating expenses of approximately $950,000 and meet all current obligations as they come due for a number of years.

In addition, we expect to incur an estimated amount of approximately $400,000 in additional expenses relating to our Modified Risk Tobacco Product application with the FDA by the end of the second quarter of 2019.

That concludes my remarks. Thank you for your time, consideration, and continued 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 very much.

Henry Sicignano: Thank you, John. Good afternoon and thank you again to our conference call participants for joining us today. 22nd Century has invested considerable time and capital to accomplish in recent months what I believe is the most important project in our history - the sub mission to the FDA of our Pre-Market Tobacco Product application and our Modified Risk Tobacco Product application for the Company's proprietary Very Low Nicotine Content cigarettes. The final submissions included more than 150,000 pages of data, including research from 187 independent studies. With these PMT and MRTP applications, 22nd Century is seeking the FDA's authorization to commercialize the Company's proprietary VLN™ branded cigarettes and to advertise to consumers that VLN™ cigarettes contain 95% less nicotine as compared to the 100 leading cigarette brands in the United States.

As part of the FDA's review of our PMT application, just two weeks ago the FDA conducted a comprehensive inspection of our manufacturing facility in North Carolina. The FDA's inspection represents an important milestone and the third phase of the FDA's four-phase review process for our PMT application. As such, the FDA inspectors witnessed actual production of 22nd Century's proprietary VLN™ cigarettes.

In addition, FDA inspectors reviewed 22nd Century's raw material receiving and storage procedures, quality control processes, manufacturing equipment and systems, tobacco processing methods, and finished product assessment procedures.

Of course, the big question remains: when will the FDA grant 22nd Century a marketing order for the Company's VLN™ product? As you may know, just last week the FDA granted a Pre-Market Tobacco product marketing order for Altria's IQOS, the first of its kind heat-not-burn product approved in the U.S.

Though it took considerably longer than the FDA's guidance suggests, this approval is welcome news for all companies with pending PMT and MRTP applications. The IQOS approval shows that the FDA is, in fact, moving products through its regulatory process. Historically, the FDA's track record on PMT applications has not been encouraging. Only about 2% of PMT applications ever make it to the "filing" stage. Notably, 22nd Century's PMT application for VLN™ cigarettes received "notice of filing" from the FDA in record time -- just a few months after our submission.

And, in part, because our PMT and MRTP applications for VLN™ cigarettes are considerably less complex than the IQOS applications, we believe that we could see a final action from the FDA on our PMT application much quicker than Altria -- perhaps as soon as this summer for our PMT application – and with the FDA's final action on the Company's MRTP application to follow in due course.

It is important to realize the FDA has expressed publicly strong support for reduced nicotine cigarettes. One former FDA official went so far as to describe Very Low Nicotine Content cigarettes as "the

ultimate harm reduction strategy." Based on many years of research funded by more than $125 million from the FDA and from other U.S. federal government agencies, and using 22nd Century's SPECTRUM® research cigarettes, in 2017, former FDA Commissioner Dr. Scott Gottlieb announced to the world that the FDA plans to actually mandate the amount of nicotine in all cigarettes sold in the United States may not exceed "minimally-addictive or non-addictive levels."

Officials from the FDA have since indicated a “minimally-addictive or non-addictive” level of nicotine in cigarettes could be achieved at approximately 0.3 to 0.7 mg of nicotine per gram of tobacco. Not surprisingly, given the connection between our technology and more than $125 million of federally funded independent research, 22nd Century's VLN™ cigarettes have a target nicotine concentration that is exactly in the middle of the nicotine range that the FDA is expected to mandate.

Drastically reducing nicotine in cigarettes is the very keystone of the FDA's plan to address nicotine. The other part of the plan is to ensure that consumers have options for alternative nicotine delivery products. We believe that 22nd Century's technology, which allows us to grow the world's lowest nicotine tobacco, is the best option to achieve the first part of the FDA's plan: creating minimally or non-addictive cigarettes.

And while the FDA is tightening the leash on Juul and on other e-cigarettes, the FDA also chose to approve IQOS, thus addressing the second part of the FDA's plan: to offer alternatives to consumers. FDA Commissioner Gottlieb described these two product categories, VLN™ cigarettes and non-combustible nicotine delivery products, as two halves of the same strategy.

Not surprisingly, Big Tobacco is opposed to reducing the nicotine in their cash cow legacy products. In throwing up objections to the FDA's plan, these multinational companies have complained that it will "take too long" or "cost too much" to figure out how to make Very Low Nicotine Content cigarettes.

In comments submitted to the FDA on June 13, 2018, RAI Services, which is part of Reynolds American, explained, "if FDA adopts a standard of 0.3, 0.4, or 0.5 mg of nicotine per gram of tobacco filler, the process could easily take more than 20 years.” Doubling down on their inability to comply with the proposed rule by FDA, RAI Services continued by pointing out that our Company, 22nd Century, holds a commanding position as the technology leader in the field of reduced nicotine tobacco. Here is an excerpt of the Reynolds American explanation of why their company cannot comply: Commercialization of tobaccos with very low levels of nicotine is made difficult by "the various patent restrictions on the use of certain genetic engineering techniques. The patents on nicotine synthesis pathway genes, for example, are held almost exclusively by 22nd Century Group."

And for the avoidance of doubt, Altria echoes these same statements. On July 16, 2018, Joe Murillo of Altria Client Services reported to the FDA that "at least 12 years is the absolute minimum amount of time necessary to attempt to address the many issues that must be resolved before VLNC tobaccos could be commercially produced at necessary volumes and cigarettes using those tobaccos could be designed and manufactured to replace currently marketed cigarettes."

In contrast, 22nd Century's proprietary VLNC tobacco plant varieties are already commercially viable, genetically stable plants with acceptable yields and proven nicotine concentrations. 22nd Century's proprietary VLNC cigarettes have important potential public health benefits that have been detailed in dozens of published, peer-reviewed articles. 22nd Century is more than ready for the FDA to approve our applications for VLN™ cigarettes. We are also more than ready to enable the FDA's broader plan to mandate that all cigarettes sold in the United States are minimally or non-addictive. And we are ready to supply any and every country in the world with our VLNC tobacco.

Our current tobacco technology is well protected by multiple overlapping patents, by plant variety protection, and by the multiyear physical hurdle of any third party needing to duplicate our complex assembly of genes and patents that is 22nd Century's proprietary VLN™ technology. But it should be noted, 22nd Century continues to make important strides with our reduced nicotine tobacco technology. We are already successfully developing the next generation of Very Low Nicotine Content tobacco varieties with superior agronomic and sensory characteristics that will form the foundation of our next generation of VLNC tobacco products that will continue to satisfy the FDA's vision of a future with only minimally or non-addictive cigarettes on the market. Considering 22nd Century's achievements, as well a Big Tobacco's own public admissions, it is clear that the rest of the world is playing a long game of catch-up to 22nd Century's Very Low Nicotine Content tobacco technology.

Of course, the FDA is not the only agency looking at reduced nicotine tobacco. The World Health Organization, also known as the WHO, has similarly recommended that all WHO-member nations adopt "a tobacco policy of limiting the sale of cigarettes to brands with a nicotine content that is not sufficient to lead to the development and/or maintenance of addiction."

In addition, countries like Canada, New Zealand and the United Kingdom have expressed interest in dramatically reducing the nicotine in cigarettes. To lead our regulatory efforts on the world stage, 22nd Century recently hired John Pritchard as Vice President of Regulatory Science. Mr. Prichard was formerly the head of regulatory science for Imperial Brands, U.K. He represented 22nd Century last week at the Food and Drug Law Institute conference in Washington, D.C., where acting FDA Commissioner Ned Sharpless indicated that there will be "no pause" in implementing the FDA's priorities, including its nicotine reduction plan.

Mr. Pritchard will lead and oversee global regulatory and compliance activities for 22nd Century. He will engage with the FDA in support of our PMT and MRTP applications for VLN™ cigarettes and will work in support of the planned rule by the FDA to revise the nicotine product standard for all cigarettes. Mr. Pritchard will also lead our initiatives with foreign governments that are interested in 22nd Century's proprietary Very Low Nicotine Content tobacco for use in their countries.

Meanwhile, 22nd Century is also making tremendous strides with hemp and cannabis research. In the same way that we controlled the genetic pathway for nicotine production in tobacco, we see a future where 22nd Century controls the genetic pathway for cannabinoid production in hemp and cannabis. As a part of achieving this future, we recently announced the initiation of a worldwide strategic research and development agreement with KeyGene, a global leader in plant research involving high-value genetic traits and increased crop yields.

This exclusive, worldwide collaboration is focused on developing hemp and cannabis plants with exceptional cannabinoid profiles for medical and therapeutic use, among other applications. Under the KeyGene agreement, 22nd Century will hold exclusive worldwide rights to all hemp/cannabis plant lines, intellectual property on metabolic traits, and research results that are developed through the strategic partnership.

22nd Century's mission in hemp/cannabis is to develop proprietary plant lines for important new medicines and robust agricultural crops in order to improve the health and lives of people around the world. While we are not yet entering the marketplace for hemp/cannabis consumer goods, an area that remains a legal gray area, we are working to become a source of highly coveted hemp/cannabis genetics, unique plant varieties, and high-value extracted cannabinoids.

Combined with 22nd Century's existing hemp/cannabis technology, including our extensive library of hemp/cannabis genetic material, the KeyGene program will bolster 22nd Century's position as a global leader in hemp/cannabis genetics and in the development of proprietary hemp/cannabis super plants. We are in the enviable position of controlling the industry-leading IP in both hemp/cannabis and tobacco and indeed, never before has our Company been so close to achieving our mission to reduce the harm caused by smoking.

With our pending applications at the FDA for our VLN™ cigarettes, coupled with the FDA's ambition to render all cigarettes minimally or non-addictive, we stand at the gateway to a dramatically different tobacco landscape. 22nd Century's remarkable tobacco technology is the cornerstone to achieving this vision. Our proprietary VLN™ cigarettes contain at least 95% less nicotine than any commercial cigarette we have ever tested, including the 100 leading cigarette brands in the United States. Research has shown that the trace amounts of nicotine found in our tobacco is below the addictive threshold.

Health officials from around the world have heard, loud and clear, the conviction expressed by the FDA and are now beginning to develop their own nicotine reduction plans. 22nd Century stands ready to launch cigarettes made with our VLN™ tobacco in the United States and in every nation that wishes to render cigarettes incapable of creating or sustaining addiction. And, in so doing, 22nd Century's technology could be responsible for the greatest life-saving tobacco control initiative ever implemented.

Thank you so much for joining us today and for your continued interest in our extraordinary Company. At this time, I will open the line up to your questions.

Operator: If you would like to ask a question, please signal by pressing star 1 on your telephone keypad. If you are using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Again, press star 1 to ask a question. We will pause just for a moment to allow everyone an opportunity to signal for questions.

Our first question comes from Jim McIlree.

Jim McIlree: Can you talk a little bit about the hemp strategy? I am trying to figure out where you are going with this. If you are looking at it from the same kind of standpoint you have with the tobacco IP or if you are looking to become more of a product company. And maybe how much, you think, capital you might commit to this above and beyond what you have already committed to over the next, say, three to five years.

Henry Sicignano: Well, IP is certainly our priority. As I just mentioned, we intend to control the genetic pathway in the cannabis and hemp plants much the same way we control that genetic pathway in the tobacco plant that is responsible for nicotine production and, in the hemp/cannabis plant, that pathway responsible for cannabinoid production. We think that is where our core competencies lie and frankly that is where some of the greatest value in the chain can be extracted.

So that is our primary focus. I am not going to say we will never go anywhere else in the chain, whether it be extraction or perhaps even consumer products at some point. But initially, our primary focus will be on the development of proprietary plants and enhancing our IP portfolio around hemp and cannabis.

In terms of spending, we made what we think is a very strategic investment in our partnership with KeyGene. We think that this will enable us to develop IP in a fraction of the time that it took us to develop our tobacco IP. But we do not, at this time, envision any substantial investment beyond the levels of the KeyGene investment.

Jim McIlree: All right, well, I wish you the best and I wish that the FDA would be a little bit more forthcoming with what is going on. I would ask you when that is going to happen, but I do not think you are going to give me an answer. So good luck with everything guys.

Operator: Your next question comes from Jim Skelton.

Jim Skelton: Good afternoon, Henry. I have a couple of questions for you and some clarification I would like you to address. I am looking at the press release you put out on April 30, which discussed

the third phase process that the FDA had begun or was involved in, in evaluating the manufacturing facility and so forth there. This came as news to me. In the previous conference call of last quarter, you told us about the role that the Center for Tobacco Products is playing in this entire approval process hopefully going forward.

Up until that moment, I and perhaps other investors had never heard of the Center for Tobacco Products. Everything that had ever been put forth and discussed was done so more or less in terms of Dr. Gottlieb's involvement. And, of course, we all know what happened when he announced his resignation.

I feel that perhaps had we all been more aware that the Center for Tobacco Products was indeed the place where all of the action was happening, and that Dr. Gottlieb in and of himself was not as big of a player in that process moving forward as we thought he might be, had we known that, maybe, just maybe we would not have seen such a dramatic fall of share price.

But, anyway, here is the point. Here is what I would like you to address. We now know that the Center for Tobacco Products is handling this. We know that there is a four-phase process that they go through and each phase has its own various components. Please talk to me a little bit about the remaining components in Phase 3 and then what will happen when we get to Phase 4.

In other words, how many more steps are involved in this process until they will be at a point where they will give us a yea or nay and we will know where we are. Can you talk about that a bit?

Henry Sicignano: Sure. I can give you a broad overview, I guess. Let us start with this. The FDA has two broad departments. One is the Center for Drug Evaluation and Research. And the other is the Center for Tobacco Products. The Center for Tobacco Products – that is where responsibility for tobacco products lies. So that is not a new development. That has been the case since the Tobacco Control Act. That is precisely the department or the division of the FDA that controls Modified Risk Tobacco Products, and PMTs and all of these related things since 2009 when the U.S. Congress passed the Tobacco Control Act.

But let me make this clear too, and sometimes people get confused with Phase 3 studies or Phase 4 studies. Phase 3 or Phase 4 studies are completely different than the FDA's four-phase PMT review process that we talked about in that April 30 press release. So, there are no Phase 2 or Phase 3 clinical trials that are required by the Center for Tobacco Products. Those are primarily - what makes those a Phase 2 or Phase 3 clinical trial is really the size of the study and the statistical significance of the number of patients or participants in the study. So, none of those things apply to the MRTP or PMT application.

That said, IQOS has just -- it took much longer than anyone thought it would -- but IQOS has just received a marketing order and can move forward with actually launching the product without any claims. But they can actually launch the product. We had our application accepted for filing in just a few months' time, which was much quicker than IQOS. And that suggests to us that we are on pace perhaps for a PMT approval as early as this summer. So that is -- I cannot guarantee, but we are optimistic that -- that is the timetable that we are on.

Again, we are now in the last phase of this four-phase PMT review process at the Center for Tobacco Products. I should also say that Dr. Gottlieb presided over both the Center for Drug Evaluation and Research and the Center for Tobacco Products. Dr. Gottlieb was the Commissioner of the entire FDA. Mitch Zeller is the titular head of the Center for Tobacco Products, but he reported to Dr. Gottlieb.

So, I am not sure, but I hope that clears it up. I think we are on track for a quicker PMT approval than IQOS had. We are very encouraged that the FDA came and conducted almost a weeklong factory inspection. And I think, frankly, that MRTP will follow in due course once our PMT is approved.

Jim Skelton: I agree completely that we are going to get approved, in my opinion at least. Everything has been written, and said, and done, and put to bed. What I would like to ask is when you first started all of this with Big Tobacco companies, you made offers to them to come talk to us when they were throwing up all their defenses that they always do about how long it would take and the impossibility of it, et cetera. And we held out the olive branch and said that we will work with you in a number of different ways to see that you get all of the low nicotine tobacco that you need to continue to market Marlboro, and Winston, and the list goes on and on. And they never showed up. At least I do not think they did. You correct me if I am wrong.

I was not really surprised in that because I realized they were not going to do anything whatsoever that might benefit us. I mean, let us face it, they hate us. We will put them out of business eventually at least and they pivoted then, as you well know, into a completely new world for them - vaping. Billions and billions of dollars have been invested there because that is the way that they can continue to addict people to nicotine and not have to worry about any tobacco regulations that may come down the pike.

But have any of them actually approached and said, hey, yes, we would like to keep marketing Marlboro for example, and use VLN™ tobacco, and buy it from you, or license it from you, or whatever? Have you had any approaches of that or am I right? Have they just said no way, no how? We are not going to help you at all.

Henry Sicignano: I have stated publicly that we have certainly had discussions with Big Tobacco companies and we have had ongoing discussions with Big Tobacco companies. And I really, I mean for obvious reasons, I cannot get much more detailed than that. They are very well aware of us. We are very well aware of them. We see them very frequently, certainly at the Food and Drug Law Institute just a week ago. There is an on-going dialogue.

So, let us put it that way. But you are exactly right. Big Tobacco has cash cows that it obviously wants to protect. But I think what we need to think about is what Commissioner Gottlieb said: there is no single answer here. There are two halves of the same strategy. What Gottlieb is focused on or what he focused the FDA on, frankly, is getting consumers off of combustible tobacco products. Dr. Gottlieb wants to make combustible tobacco products non-addictive.

And in so doing, give consumers the ability to either migrate to non-combustible products where they can find nicotine if they so desire, or where they can simply quit. That is the two halves of the same strategy. So, make all combustible cigarettes non-addictive or minimally addictive. But then make "a landing place" for those consumers who still want their nicotine, but from a non-combustible source.

So, in that way, we are sort of allied with these new nicotine delivery products, with Juul, or with different vaping products. Those products are the place where former smokers can go and we just simply accelerate that process. And we prevent a whole new generation of smokers from becoming addicted to combustible products. That is how the two halves fit together in Commissioner Gottlieb's words. So, we are encouraged by those words. Big Tobacco is very aware of those words and I think frankly that is the pathway going forward, including the pathway where 22nd Century comes out with a Modified Risk Tobacco Product while the FDA is going through the national nicotine reduction rule-making process.

Jim Skelton: I understand. Just so you will know, I have been a smoker for 55 years. Why it has not killed me yet, I do not know. I really do not know. But, I have been hoping and praying for the VLN™ to get approved so that I could be the first one at the counter to buy a carton so I can get off this stuff myself before it does do me in. But anyway, I have taken up too much time already. I appreciate your courtesy in hearing me out. Please do keep these notifications of the process as we walk through it with the FDA tobacco center, so that we know what phase we are in, how

close we are coming, and so forth. That is highly informative, helpful, and I think will keep people focused on the goal. Thank you very much for your time, gentlemen.

Henry Sicignano: We will do exactly that. Thank you, sir. We appreciate it. Good luck to you.

Operator: If you find that your question has been answered, you may remove yourself from the queue by pressing star 2. Our next question comes from David Bentrup.

David Bentrup: Good afternoon gentlemen, John, Tom, and Henry. Henry, I have to commend you on your comprehensive summary that you just gave. In college, that would have gotten me an "A" in English comp class. I do have just one question for you. What is your expected production capacity as far as manufacturing the VLN™ product? I mean, are you guys capable of manufacturing enough product for a nationwide rollout in a couple months' period of time?

Henry Sicignano: Well, I think the plan would go a little bit differently. I think you are speaking of our modified risk product. If you are talking about when the FDA rule becomes effective, we would be largely licensing the product to all the other tobacco companies. They would be manufacturing their own cigarettes. We could never manufacture all the cigarettes for all of the different brands in the country. So that would be a licensing opportunity when the FDA rule takes effect.

But, in the meantime, when we have an authorized Modified Risk Tobacco Product, then I believe that we can come somewhere near 1% market share with our existing factory. 1% market share would be equivalent – let's just use dollars and comparing it to American Spirit, it would be worth somewhere in the order of $4 billion in market cap; but that would not be from day one. We would likely launch the product in two to three test markets, much like Altria is doing with IQOS. I believe they are launching in Atlanta and one or two other markets.

We would likely test a couple of markets out West that we have already done some homework on and fine tune the launch and fine tune the distribution network that we have been assembling. And then rollout, frankly, on a regional basis. So, we will have a little bit of time. On day one, we will not have to go out there and supply 1% of the U.S. market. But I think we do have the capacity to do that and we will have plenty of time -- if and when we are going to exceed 1% capacity -- we do have the time to add additional manufacturing capacity. Is that helpful?

David Bentrup: That is very helpful. I would like to congratulate you guys on moving everything forward. I have been a shareholder for about four years now and anxiously anticipating what the future holds. And congratulations and good luck next quarter. Hopefully, we will get some action from the FDA.

Henry Sicignano: Thank you very much sir. You have a good evening.

David Bentrup: Thank you.

Operator: Our next question comes from Joe Stiegel.

Joe Stiegel: Hello?

Henry Sicignano: Yes, sir. Are you there?

Joe Stiegel: Yes, I am sorry. I just needed to take you off speakerphone. Did not want to have too much echo, be rude to everyone listening. I have a couple questions for you, but the first is we talk about reduced harm. And while I understand nicotine is certainly extremely addictive, most of the time when we think about harm from cigarettes, we think of cancer and cancer essentially, it is not the nicotine that is the carcinogen, but it is the tar and the other substances.

So. when we talk about reduced harm and we have already the approval of IQOS, that definitely shows that you can have a non-heated, a smokeless tobacco product, a non-combustible tobacco product that delivers nicotine. That most likely is going to reduce the harm from the tar and the carcinogens. How does your product compare when it comes to tar and other carcinogens?

Henry Sicignano: That is an excellent question and a very important question. Our product does not, and let me be very clear, does not reduce tar or carcinogens and we are not seeking anything from the FDA to say otherwise. What we are seeking from the FDA is a very simple claim: the right to make the claim that our cigarettes have 95% less nicotine, period. That is all we are asking. It is reduced exposure.

So, there are two different branches to the modified risk program. One is exactly what you have outlined as a modified risk branch. The other is a modified or reduced exposure. And so, what we are looking for is a reduced exposure marketing authorization where we can expose consumers to less nicotine, to hopefully a minimally or non-addictive amount of nicotine. And the idea is if you expose consumers to only a minimally or non-addictive amount of nicotine, then the smoker can smoke as much as he or she sees fit, but without becoming addicted to the product so the smoker can smoke fewer cigarettes. The smoker might make also more quit attempts. But, in general, by smoking less, or perhaps by quitting, smokers will lessen their exposure to tar and to smoke, and to the cancer-causing agents in cigarettes by simply smoking less or quitting altogether.

But our claim, our modified risk claim, is actually a reduced exposure claim, a reduced exposure to nicotine and only nicotine. Does that make sense? Does that answer your question?

Joe Stiegel: Yes, thank you for clarifying that. And to follow-up, if a cigarette let us say – I am talking about IQOS -- again, the same company has their own combustible products, if you look at let us say the Marlboro 1s, which look to be 0.1 milligrams of nicotine for the Marlboro Plus 1, 0.1 milligrams of nicotine per cigarette, the question is of course how much tobacco is in each cigarette. Consumers do not look at nicotine per gram of tobacco. They look at nicotine per cigarette.

So, I am very curious with VLN™, what is the nicotine content per cigarette?

Henry Sicignano: I am not exactly sure what you are looking at with Marlboro, but let us also make this very clear because you are making some very excellent points. The old way that nicotine exposure was measured was nicotine yield as measured by a smoking machine. And the FDA said about 10 years ago that that is really not a valid way to measure nicotine exposure because smokers alter their smoking behavior when given a “light” product, or an “ultra-light” product, or a “low tar” product. They take more puffs per cigarette. They inhale more or less deeply. They alter their behavior and basically defeat the filter and the ventilation holes in order to get the nicotine that they are seeking.

So, nicotine yields are not looked at as an accurate measure of the nicotine that consumers are actually inhaling into their bodies. But we have measured our nicotine exposure by cigarette, by content in the tobacco, and by yield. Okay. So, it is important to say by each of those metrics, we have measured the nicotine in the tobacco content, the yield, and the nicotine per cigarette. In all three cases, we are at least 95% less than each and every one of the 100 top-selling cigarette brands in the United States.

So, I can say that definitively, any way you want to look at it, we are 95% less nicotine. But the most accurate way to look at it, scientists believe, is by nicotine content.

Joe Stiegel: In which case then, what would be your nicotine content per VLN™ cigarette?

Henry Sicignano: The range that we target is exactly the range that we believe the FDA will mandate, which is between 0.3 and 0.7 milligrams per gram nicotine per gram of tobacco.

Joe Stiegel: So, between 0.3 and 0.7. So, if I took a Marlboro…

Henry Sicignano: With a target of 0.5.

Joe Stiegel: With a target of 0.5. If I took a Marlboro Plus 1 and cut the filter off and just weighed the tobacco, I'm going to get 0.62, maybe 0.65 grams and they're advertising that as 0.1 milligrams of nicotine. And if do the math that means their tobacco is coming at, gosh, 0.16 milligrams per gram.

Henry Sicignano: You know what, I do not have a chart, and so I do not want to start giving you exact numbers that are not in front of me. I just was looking at a chart a couple hours ago with literally the top 100 brands all marked on there. But whatever they are talking about right now is likely yield, which is what I think you are talking about. I do not think very many folks are publishing anything about content.

But if you want to get into this more deeply, you could certainly email us and we will share with you a chart of all the numbers. And, as a matter of fact, they are all included in our MRTP application and our PMT application. So, we would be happy to share that data with you. It is all publicly available... or it will be.

Joe Stiegel: I will send you an email tomorrow. Let somebody else ask some questions. Thank you for your time.

Henry Sicignano: Very good. Thank you. Have a good evening.

Operator: Our next question comes from Marian Green.

Marian Green: I want to make $10, so I am just going to say show me the money and I will tell you later what that means. Anyway, how close are we to other countries going VLN™? Because I know about a year ago or less, Canada was looking for VLN™ cigarettes.

Henry Sicignano: Well, we have not publicly announced any strategic partnership with another country. But I have disclosed publicly that we have talked to about a half a dozen countries. And I mentioned earlier in my prepared remarks that John Pritchard is going to be instrumental in talking with some of the folks in the regulatory and the public health world about doing exactly that, about bringing Very Low Nicotine Content cigarettes to international markets.

Mike Zercher, our head of business development, is talking with major tobacco companies in international markets, but John Pritchard will be working with public health officials and regulatory experts in these international markets. And I guess I will just say we are certainly talking to folks in North America, in Europe, and in Asia, frankly. But I cannot really make any announcement yet. We do not have something to announce.

Marian Green: Have we sent VLN™ cigarettes to Canada?

Henry Sicignano: We have sent VLN™ cigarettes to dozens of countries.

Marian Green: Okay, good.

Henry Sicignano: That is all I can say.

Marian Green: That is enough.

Henry Sicignano: All right, thank you very much, Marian. Appreciate it.

Marian Green: Thank you.

Henry Sicignano: You have a good evening. Okay. Thank you. We'll take one last call because it is approaching the 5:00pm hour.

Operator: Your final question comes from Ivan Paningsoro.

Ivan Paningsoro: Henry, could you please tell me, you know, I am a long time shareholder, and I will be honest with you. I have been listening to these conference calls for years. It seems to me like we are saying the same old stuff here and I am learning nothing new on these conference calls.

Can you speak a little about what we are doing with the University of Virginia and Anandia as far as research? Are we going to renew some of these contracts? And if not, what are we doing and when are we going to start making revenue off some of these research partners that we are partnering with?

Henry Sicignano: That is an excellent question. I am going to let Tom address some of our strategic partnerships with research institutions, but let me just speak broadly about 22nd Century... I understand what you are saying and I sympathize with you. 22nd Century... though we are growing our revenues each year and that is important to demonstrate that we are capable of doing that, we are capable of running a factory, and we are capable of growing our contract manufacturing business, but that is not how we are going to build substantial shareholder value here.

What that is doing is growing a little part of our business that is enabling us to have a factory and to support the 50 plus people that work there. So, when we do supply research cigarettes to the government or when we do need a factory inspection from the FDA for our Modified Risk Tobacco Product, then we have that factory up, ready, and available at a moment's notice.

So, that is why we are selling whatever we are selling, about $25 million worth of product a year simply to pay the overhead there and to keep the lights on. What you are going to see, I believe, is you are going to see one day a regulatory approval or you are going to see a licensing announcement and that is going to be like an on/off switch. We are not going to get there incrementally. There is not going to be one year where we did $25 million and then the next year we did $45 million, and then the share price went up 10%, and then it went up 15%, and then it went up 20%. It is not going to be like that.

We are going to achieve success. You are been a shareholder for several years. Well, then, obviously you realize our first application that we submitted for our Modified Risk Tobacco Product was a strong one, but we invested, I don't know, approximately $2 million in that application because that was the resources that our Company had at that time.

Ivan Paningsoro: But if that is the case, why did you waste the time in submitting it? The whole thing to me, you submitted that application and at the very end of the year, if I am not mistaken, it was December 31, you let the shareholders know that it did not go through. You waited one whole year without any word throughout the process, like you are doing this year. This is what I am upset about. I have heard this, Henry, since the first…

Henry Sicignano: Let me correct you, sir. We did not wait a year to let you know. The FDA waited a year to respond to us. So, let us just be very, very clear about that. The FDA responded literally 360 days after we submitted our application. We had an initial meeting early on, which we reported publicly.

Ivan Paningsoro: You had conversations with them.

Henry Sicignano: Let me finish. Not on the first application, sir. On the first application, we had a preliminary -- sir, I am not going to argue with you. I am telling you the facts. The facts are we submitted the application. We had some early discussion with the FDA and then we did not hear anything from the FDA for the better part of a year. Okay...

Ivan Paningsoro: Is that what is going to happen to this new application?

Henry Sicignano: Well, it is already different, sir. I have already publicly announced that we have already had some 20 conversations with the FDA. I have publicly announced that we have spent more than $10 million on this application and that we have used all of the guidance that the FDA gave us on our first application in the second application. I have also told you that - I mean let us count how many companies in the world, how many multinational tobacco companies have been granted a Modified Risk Tobacco Product.

Ivan Paningsoro: I am not worried about all the companies, Henry. I am only worried about 22nd Century, which I have been invested in for seven years and I have heard all the things that you…

Henry Sicignano: Me too.

Ivan Paningsoro: … that you discussed. All of it, Henry. From the hemp side, I do not hear anything about Virginia, or University of Virginia. I do not hear something coming from Anandia. I have not heard - when you guys announced about being in the -- oh what is that -- you guys were going to start something in North Carolina and Virginia. I think it was called the I-Hemp platform. That two of your executives were - you guys do not even mention anything like that anymore.

I am interested in new things. I am not interested in the same bologna that I hear every conference call. Anyone can just Google it. Anyone can just understand that. I am not learning anything new.

Henry Sicignano: Okay, well, you are learning as many new things as I am allowed to publicly disclose, sir. But the first thing I suggest you do is you read that Form 10-K very carefully because I think we have done a pretty good job of disclosing a lot. Pay a lot of attention to our press releases and understand that we spend as much money and as much time on our modified risk application as Reynolds spent on theirs. And I am very, very proud of our application and optimistic that we might be the first one authorized in the world.

Ivan Paningsoro: You should not be proud of you guys getting raises without our share price going up. That is ridiculous.

Henry Sicignano: Well, I understand your sentiment and if you feel that way, maybe you will want to sell your shares.

Ivan Paningsoro: You should not say that to a shareholder that has a lot of family in your Company that is listening to it, Henry. That is ridiculous. Because if I lived in New York, I sure definitely would have went to your shareholders meeting.

Henry Sicignano: You would be welcome to attend, sir. You would be welcome to attend. I am very proud of what we have accomplished. I believe that our application is a very strong one and could be the first MRTP approved by the FDA. So that is our focus. We have worked very hard on that. I am proud of the application and I think that is where you should focus as well.

In terms of hemp and cannabis, we have done quite a bit of work there. Our IP status is widely regarded as a world leading status. The KeyGene relationship that we have announced, the partnership with KeyGene, I think will bring us to a place with cannabinoids much faster than we were able to reach with nicotine in terms of controlling the genetic pathway.

So those are our thoughts and those are the things of which we are most proud. That is what we're focused on. I think our successes will lead... and the share price will follow. That is the best I can offer you. My family and friends are also invested in this Company. We are in it for the long haul. And I hope you will be satisfied when we do achieve some successes with the FDA and with our IP in cannabis.

So, with that, I guess I will say thank you very much and we will look forward to talking with you next quarter... Good night.

Operator: Thank you, ladies and gentlemen. This concludes today's teleconference. You may now disconnect.