Third Quarter 2020 Earnings Transcript

PARTICIPANTS

Corporate Participants

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James A. Mish – Chief Executive Officer, 22nd Century Group
Michael Zercher – President and Chief Operating Officer, 22nd Century Group
John Franzino – Chief Financial Officer, 22nd Century Group

MANAGEMENT DISCUSSION SECTION

Operator: Welcome to 22nd Century Group's Third Quarter 2020 Earnings Conference Call. At this time, all participants are in a listen-only mode, and the floor will be open for question following management's prepared remarks. As a reminder, today's conference is being recorded.
At this time, I would like to turn the call over to Mei Kuo, Director of Communications and Investor Relations. Please begin.

Mei Kuo – Director, Communications & Investor Relations, 22nd Century Group

Thank you, Jessie. Good morning and welcome to 22nd Century's Third Quarter Earnings Conference Call. Joining me today are James Mish, our Chief Executive Officer, Mike Zercher, our President and Chief Operating Officer, and John Franzino, our Chief Financial Officer.

Earlier today, we issued a press release announcing our results for the third quarter. We have also posted an earnings supplemental presentation that summarizes and highlights the progress we have made this past quarter. We hope this supplemental information will serve as a framework for management's prepared remarks, reinforce key takeaways from today's call and provide additional transparency and insight into our business, strategy and objectives. Both the release and supplemental presentation are available on our website at xxiicentury.com. We'll start today's call with remarks from Jim, Mike and John before moving into a new addition to our earnings call, a Q&A session.

Before we begin, some of the statements made today are forward-looking. Forward-looking statements are subject to risks, uncertainties and other factors that may cause actual results to differ materially from those contemplated by these statements. Additional information regarding these factors can be found in our Form 10-K filed on March 11, 2020 and in our Form 10-Q filed earlier today.

During this call, we will also discuss non-GAAP financial measures including adjusted EBITDA, which we define as earnings before interest, taxes, depreciation and amortization as adjusted for certain non-cash and non-operating expenses. For more details on these measures, please refer to our press release issued earlier today.

And with that, I'll turn the call over to Jim.

James A. Mish – Chief Executive Officer, 22nd Century Group

Thanks Mei. Good morning, everyone and thanks to all for joining 22nd Century's conference call today. In my first few months as CEO, I've met with many stakeholders such as scientists, public health officials, national cigarette retailers, farmers and most importantly our shareholders. I listen carefully. And what I heard from everyone is that 22nd Century's VLN cigarettes have the potential to not only disrupt, but redefine the entire tobacco industry, and in doing so prevent millions of our youth from ever becoming addicted to the only legal consumer product that when used as intended, kills half of all its long-term users. Understanding these facts has really helped me to truly appreciate our company's primary mission of reducing the harm caused by smoking and to reaffirm our priorities.

The tobacco epidemic and make no mistake it is an epidemic is one of the biggest public health crisis the world faces. Worldwide smoking kills more than seven million people each year is responsible for over 1,300 deaths per day in the U.S. To put this in perspective, the U.S. opioid epidemic claims 128 lives per day and approximately 1,100 people are dying each day from COVID-19. Smoking claims more lives per day in the U.S. than these other two threats combined. If smoking continues at its current rates, the CDC estimates that more than five million Americans who are currently younger than 18 years of age will die prematurely from a smoking related illness. This is a staggering ratio of about one in every 13 young Americans alive today. Cigarette smoking is the leading cause of preventable disease and death and is responsible for one in every five deaths in the United States. These numbers are simply not acceptable any longer.

22nd Century has a real solution to help reduce the harm caused by smoking and drive these terrible statistics down. Our reduced nicotine content cigarette VLN is in the final stages of the MRTP review process and once authorized by the FDA will be the first and only combustible cigarette on the market with 95% less nicotine than leading brands or any other cigarette in the U.S. Furthermore, VLN will be the only FDA-authorized MRTP product developed specifically to not create or sustain addiction. This is why securing FDA marketing authorization for our MRTP reduced nicotine content cigarettes is the company's number one near-term priority and obsession.

Our VLN product is truly remarkable and supported by decades of research in over $125 million of the company's FDA and NIH funding. Importantly the imminent authorization of VLN supports the FDA's plan to implement an industry-wide reduced nicotine product standard. We believe the FDA's authorization of VLN and its commercial success will not only benefit 22nd Century and our shareholders will also help advance global tobacco and nicotine regulation and improve public health worldwide. No other consumer product has the opportunity to be so impactful. And so, my enthusiasm for VLN continues to grow. As I said, securing an MRTP authorization from FDA for VLN remains our number one priority.

Separately but at the same time, we've made product launch plans that include a national rollout of them with large well-recognized retail chains in the United States and a marketing campaign that has been designed to introduce adult smokers to the world's lowest nicotine content cigarette. Commercial product launch and licensing discussions with potential strategic partners in the U.S. and globally, will commence within 90 days of MRTP authorization. As a reminder, the tremendous opportunity we have in our tobacco franchise, achieving just one quarter of 1% market share of the U.S. cigarette market could drive the company's market capitalization more than 10 times higher than it is today.

On top of this, we were recently granted a highly valuable U.S. patent that enabled us to rapidly introduce very low nicotine trains into all varieties of tobacco currently used in the production of cigarettes and other tobacco products. Needless to say, with all this, I believe our share price is extremely undervalued.

We continue to believe that the MRTP authorization and VLN launch will happen soon. It is a home run. The grand slam that would drive the market capital position even higher is the equally important initiative to support and advance the FDA's plan to require that all cigarettes sold in the U.S. be made minimally or non-addictive by limiting their nicotine content to just 0.5 milligrams of nicotine per gram of tobacco, a level already achieved by our proprietary VLN cigarettes. When the FDA mandate ultimately goes into effect, we plan to make our proprietary reduced nicotine-content tobacco and related intellectual property available to every cigarette manufacturer in the United States. In addition to all this, we have conducted a comprehensive review of our existing business, extensive IP portfolio and the regulatory climate, and we have identified near-term milestones in medium and long-term opportunities, and they have never been brighter.

Since we last spoke, we have refocused our hemp/cannabis strategy to target the upstream segments of the value chain such as plant biotechnology research, gene modification and engineering and modern plant breeding. This renewed emphasis is a shift away from CBD and hemp-based consumer products in the already saturated U.S. market. We will concentrate our hemp/cannabis efforts on initiatives related to our current and exclusive KeyGene collaboration and on the existing worldwide license agreement with Anandia Laboratories.

I'll talk more about our hemp/cannabis strategy as well as a third plant-based franchise that has similarities in its genome to the hemp/cannabis plant after Mike provides an update on our tobacco franchise. John will discuss in more detail, but I will note that our operating results for the third quarter were strong driven by year-over-year revenue growth and continued gross margin improvement.

Our balance sheet is healthy, and we have an excellent prospects to establish strategic partnerships upon MRTP authorization. So, we are fully prepared to operate and launch our historic VLN product without any plans or the need to raise additional capital at this time.

Mike will provide new details on the progress we have made in our Tobacco franchise and the status of our MRTP process in a few moments. But it's important that you understand that we are proactively using every means possible to highlight to the FDA, how VLN fits perfectly into their overall comprehensive plan. We will never compromise our reduced content cigarette brand and launch without an MRTP designation. And under my watch, we will fight relentlessly and will never surrender our efforts to cross the finish line soon with this remarkable product and solution to a global problem.

To demonstrate our confident with the MRTP timing and our pledge to our primary mission, Mike, John and I have made the decision to defer any bonuses of any kind until our MRTP is approved, and we bring VLN to market to add value to our shareholders.

And with that, I'll turn the call over to Mike to discuss the Tobacco franchise.

Michael Zercher – President and Chief Operating Officer, 22nd Century Group

Thanks, Jim. At the forefront of everyone's mind, including my own is the status of our MRTP application. We continue to believe that we will see a positive outcome from the FDA, and we believe a decision could come at any time. We continue to maintain a dialogue with the FDA, and we know the agency is in the final stage of review. There are no outstanding requests for information by the FDA, and we believe they have everything required to make a final decision about our application.

In addition to our ongoing contact with the agency, we have intensified our proactive efforts with our public and government affairs advisers and lawyers to highlight the public health importance of our MRTP application and encourage a near-term authorization. Our lawyers and advisers are regarded as among the best in the industry and we assure you that we are pulling every lever available to secure an MRTP authorization for VLN.

We continue to feel confident in a positive outcome for several reasons. First, the FDA continues to interact with our company regarding our application, which is often not the case with applications that are bound for rejection. More broadly, the FDA has funded and continues to fund millions of dollars of research to better understand the public health benefits of our reduced nicotine-content cigarettes. Authorizing VLN will support the FDA's comprehensive plan for tobacco and nicotine regulation. VLN cigarettes contained just 0.5 milligrams of nicotine per gram of tobacco, which is the same level the FDA is proposing for all combustible cigarettes to ensure they have "minimally or non-addictive" levels of nicotine.

Finally, in authorizing our PMTA application last year, the FDA decided that the sale of our VLN cigarettes is appropriate for the protection of public health, which is the statutorily mandated standard that all new tobacco products must need to receive FDA authorization. Therefore, the only question left to be answered with our MRTP application is whether our requested claims the primary one being 95% less nicotine meet the same public health standard.

To that point, our MRTP application is very straightforward and is uncontroversial by design. We are simply seeking a reduced exposure claim not a reduced harm claim like other companies have sought. Reduced exposure to nicotine is objective and measurable. We have measured each of the top 100 cigarette brands in the U.S. and shown the FDA that VLN has 95% less nicotine in the tobacco in the smoke and even in the biomarkers associated with the intake of nicotine by smokers. VLN has 95% less nicotine in every way. This is a straightforward claim that is easily proven and clearly supported by the evidence.

To-date, the FDA has authorized only two MRTP applications; one for a smokeless tobacco product and one for a heated tobacco product. Both of these products received their authorizations approximately five to six months after the closing of their public comment period. Our public comment period closed in mid-May, a little over five months ago. With the assumption that our less-complex application will follow a similar timeline, but also taking into account the impact of COVID on the FDA's resources, we expect the agency's decision to come sometime this year.

For these reasons, we have felt comfortable publicly stating that we believe the FDA's positive decision about our application is a matter of when not if and will be in the coming months not years. Upon

authorization VLN will be the first and only combustible cigarette to receive an MRTP authorization, and the only MRTP product not developed to create or sustain addiction.

The opportunity here is massive. We want to provide a solution to the public health crisis caused by smoking and in doing so capture a meaningful share of the market as quickly as possible. This is why we have already laid the groundwork for our commercialization plans, and we are prepared to roll out VLN in select markets within 90 days of our MRTP's authorization.

Today we are in discussions with a number of independent regional and national tobacco retailers, names many of you would recognize to partner with us to bring VLN to market. VLN has been positively received by the trade and our discussions with them have gone very well. They're eager to feature VLN in their stores as the first and only MRTP-designated cigarette. Our market research supports their enthusiasm with incredible with an incredible 60% of smokers indicating an intent to use VLN when shown our 95% less nicotine claim.

Smokers are seeking alternatives to the highly addictive products offered to them today. And with VLN potentially just a few short months away from store shelves, 22nd Century is poised to forever change the face of smoking in America and the world. Our 62,000 square foot production facility is ready to manufacture VLN in commercial quantities. The FDA has inspected and cleared our facility. We have sufficient capacity to manufacture approximately 1% of the U.S. market. And with minimal investment in additional equipment we can easily triple our capacity.

Now that we've discussed our plans for VLN, let's look at the size of the opportunity. We have shared the following statistics before, but they are worth repeating. In the U.S. there are 34 million adult smokers and one billion worldwide. U.S. tobacco industry is worth $100 billion and $800 billion worldwide, with 90% of those sales coming from combustible cigarettes.

According to the CDC two-thirds of smokers in the U.S. want to quit smoking and more than half of them to attempt to quit in a given year, but less than 8% actually succeed. A reduced exposure claim authorized by the FDA, the world's preeminent life sciences regulatory body will be a critical catalyst for 22nd Century sales growth. Achieving just one quarter of 1% of the U.S. market, we believe could result in revenues that may over time given the disruptive nature of VLN drive our market capitalization more than 10 times higher than it is today.

In addition, FDA's authorization will potentially open up multiple strategic partnership opportunities to scale VLN's growth in the U.S. and globally. As with the U.S. market, our international plans for VLN will mature once MRTP authorization is received. While not required for international sales, an FDA authorization is considered by regulators around the world to be the gold standard in public health. And MRTP authorization will be incredibly helpful in navigating the regulatory approvals necessary to bring VLN to market, with labeling claims in international markets.

Introducing VLN into these countries post FDA authorization is an enormous opportunity that we are excited to pursue. Important to VLN's international success, will be our non-GMO bright burley and oriental reduced nicotine tobaccos. In many countries, GMO plants or products are unacceptable to consumers are simply banned, which makes our non-GMO tobacco crucial to developing an international business with VLN. These non-GMO varieties also will allow us to match the century characteristics of any cigarette style.

We have been hard at work developing these new non-GMO plant lines, and earlier this year, we announced the completion of research field trials, validating new non-GMO methodologies for reducing nicotine in tobacco plants. We are already developing prototype reduced nicotine cigarettes using the tobacco from these field trials, and we are very excited about the opportunities created by this next generation of 22nd Century's very low nicotine content tobacco.

While the commercialization of VLN is our immediate opportunity in our tobacco franchise, we also see exciting longer-term opportunities in tobacco. Tobacco is an exceptional bio factory, and we can leverage our expertise with this plan to engineer new tobacco plants, that could produce new medicines and vaccines, sustainable protein sources for food and animal feed and even ingredients for the flavor and fragrance industry.

While there is certainly a long runway for growth and profitability within 22nd Century's tobacco franchise, we remain focused on the opportunities we have in hand today. The COVID-19 pandemic has brought in the sharp focus the importance of respiratory health and the wide-ranging harms of smoking and nicotine addiction. Recently, Mitch Zeller, Director of the FDA Center for Tobacco Products, spoke at the Food and Drug Law Institute's Tobacco and Nicotine Conference. When asked, if the FDA is still considering moving ahead with its comprehensive plan for tobacco and nicotine regulation, including reducing nicotine in cigarettes to non-addictive levels, he indicated that the FDA remains absolutely committed to everything that was in that plan.

Additionally, we note that the FDA and other leading public health institutions continue to fund research studies to investigate the role of reducing nicotine content cigarettes in public health and their potential to reduce and eliminate tobacco-related diseases and death. This is all encouraging evidence of FDA's continued commitment to tobacco harm reduction and in particular to their proposed reduced nicotine product standard, a landmark public health initiative.

We welcome the FDA's ongoing commitment to drive a paradigm shift in the tobacco industry. FDA's decisions about our MRTP application and a reduced nicotine mandate could be the most important public health policy decisions in a generation. Commercialization of VLN and implementation of the FDA's comprehensive plan will be important wins for adult smokers, public health and 22nd Century, and we remain laser-focused on making every move we can to secure FDA's authorization of our MRTP application to bring VLN to market successfully in the U.S. as soon as possible and to support the implementation of FDA's plan to make all cigarettes in the U.S. non-addictive.

I'll now pass you back to Jim for an update on our hemp/cannabis strategy and franchise. Jim?

James A. Mish – Chief Executive Officer, 22nd Century Group

Thanks Mike. While our tobacco franchise is taking center stage, we're making substantial progress of our considerable hemp/cannabis franchise as well. Remember, the genesis of our research in hemp/cannabis was established back in 2014 through a worldwide license agreement with Anandia Laboratories. Today, we maintain exclusive sublicense in the U.S. and co-exclusive sublicense in the remainder of the world for 23 patent and patent applications relating to the hemp/cannabis plant. Licenses for these valuable patents survive Aurora Cannabis's acquisition of Anandia.

In 2019, we continue to pursue and advance our research in hemp/cannabis and entered into a worldwide strategic research and development agreement with KeyGene, a global leader in plant research involving high-value genetic traits and increased crop yield. Our exclusive worldwide collaboration is now focused on developing hemp/cannabis plants with select agronomic traits including lines with stable, ultra-high THC levels, lines with higher levels of rare cannabinoids and lines with ultra-low terpene levels for use in high-growth consumer and life science markets.

Over the past year, we have completed building our proprietary bioinformatics platform. With this encyclopedia of information on hemp/cannabis genome, we can now begin to monetize the vast intellectual property we have developed through our collaborative efforts with KeyGene. Our partnership with KeyGene is a key competitive advantage for us. And through our collaborative efforts with them, we were able to modify and improve the hemp/cannabis plant using the fastest and most cost-effective methods available.

Additionally we have made the decision to refocus our hemp/cannabis strategy to target the upstream segments of the cannabinoid value chain and related intellectual property, in particular in the areas of plant biotechnology research, gene modification and engineering, modern plant breeding and development and extraction.

We will reset our investment with Panacea to focus on and ensure the accelerated delivery of valuable commercial plant lines and technology over CBD and hemp-based consumer products. We expect our cannabis/hemp R&D efforts will generate tremendous growth opportunities for us as we monetize our IP and continue to bring disruptive technology forward.

As a reminder the global cannabis market is projected to be $100 billion industry by 2024 and we believe we are at the forefront of technological development relating to the fascinating plant.
Finally, we have identified a third franchise that we are extremely excited about. I wanted to announce the plant line on this call, but we are still in the process of securing valuable intellectual property and pursuing strategic partnerships to support the development of this franchise. I will identify the plant line, as soon as possible as the competitive situation allows.

What I can say is that we will increase our attention on this franchise only after securing our MRTP designation and executing on our near and medium-term objectives in our tobacco and hemp/cannabis franchises. I can also share with you that this plant species has a very similar genome to the hemp/cannabis plant and offers a very attractive growth opportunities.

Additionally, this new space is not as highly regulated or legislated like our tobacco and hemp/cannabis franchise. So, we believe we were able to add shareholder value in this franchise faster than we have with the first two. And with that I'll now turn the call over to John for a review of our financial results.

John Franzino – Chief Financial Officer, 22nd Century Group

Thank you Jim and good morning to everyone. Operating loss improved by $3.6 million in the third quarter and improved by $5.1 million for the first nine months of 2020. This was driven by higher gross margins and lower operating expenses which I will detail in a moment.

Our net sales revenue for the third quarter was up approximately 13% to $7.3 million and for the first nine months of 2020 was up 12% to $20.8 million. The increase for both periods was primarily driven by higher volume and pricing in our contract manufacturing business.

In the third quarter gross profit improved by $383,000 and for the first nine months of the year gross profit improved by $1.1 million. The improvements were primarily the result of higher volume, price increases and lower labor and overhead costs driven by factory efficiencies implemented over the past nine months.

Total operating expenses also improved by $3.2 million in the third quarter and improved by $4 million on a year-to-date basis. This improvement was primarily due to the following: decrease in R&D expenses of $1 million for the third quarter and $2.2 million year-to-date. This decrease was driven by a reduction in personnel expenses, lower license and contract costs and the absence of a onetime impairment charge taken on research tobacco inventory in the prior year.

Separately R&D expenses related to the MRTP application was favorable this quarter by $65,000 and $1.4 million year-to-date. SG&A expenses improved by $890,000 in the third quarter; the favorability was driven by lower onetime severance expenses and a decreased noncash equity compensation that occurred in the third quarter of 2019.

SG&A expenses were $690,000 higher year-to-date due to an increase in consulting and professional services and an increase in personnel and insurance costs. This was partially offset by lower equity compensation and decrease in onetime severance expense.

Operating expense was also favorable year-over-year due to a decrease in the impairment of intangible assets of $1.1 million which was recorded in the third quarter of last year and by $997,000 on a year-to-date basis. The impairment was related to intellectual property portfolio rationalization that resulted in a onetime impairment charge recorded last year.

Net loss for the quarter improved by $6 million to $4.2 million, which resulted in a net loss per share of $0.03, an improvement of $0.05 on a per share basis. In addition to the improvement in operating loss other income and expense improved by $2.5 million primarily due to a reduction of unrealized loss on Aurora warrants and of $3 million in the comparable quarter last year.

Net loss for the first nine months of 2020 improved by $7.1 to $13.3 million representing a net loss per share of $0.10, an improvement of $0.06 and in addition to the improvement of operating loss of $5.1 million, other income and expense improved by $2 million primarily due to $1.9 million litigation expense in the prior year. This is partially offset in the current year by an impairment of $1.1 million related to Panacea warrant investment.

Adjusted EBITDA for the quarter improved by 26% on -- and by 23% year-to-date. Our liquidity remains strong with cash, cash equivalents and short-term investment securities, totaling approximately $26.8 million at the end of the third quarter.

In summary, we've demonstrated strong performance in the first nine months of the year. We continue to manage our expenditures very carefully. And continue to improve margins in our contract manufacturing operations. Our balance sheet is healthy. And we are confident that we can sustain our

current operations, drive our strategy, achieve our objectives, and launch VLN without the need to raise additional capital at this time.

And with that, operator, please open up the call for questions.

Operator: Thank you. [Operator Instructions] Thank you. We do have a question coming from the line of Jim -- excuse me -- Jim McIlree with Bradley Woods. Please proceed with your question.

Jim McIlree – Bradley Woods & Co.

Yeah. Thank you and good morning. I have a few questions. I'll just ask them all at once, if you don't mind. You talked about, the commercialization of VLN, post-MRTP approval, suggesting you do have, at least some infrastructure in place but you also talked about a marketing campaign.

I was wondering if you can kind of give an indication about, how much that might be in terms of dollars in the first 12 months. And then along those lines, you talked about retail partnerships, but you also said rolling out in select markets.

I was just wondering, if the retail partnerships -- the national retail partnerships you talked about if you have signed agreements that give them exclusivity or either in time or geography?
And then lastly on, the patent, you said that it now gives you genetic control in virtually any variety. And I'm wondering if there are any varieties that we should be aware of, that it doesn't give you genetic control? And then, did you add some varieties with that patent? And I think that will do it for me. Thank you.

James A. Mish – Chief Executive Officer, 22nd Century Group

Thanks for the question, Jim. I'll pass it on to Mike. And I'll chime in. But Mike, go ahead and fill in the blanks for Jim please.

Michael Zercher – President and Chief Operating Officer, 22nd Century Group

Sure Jim. Thanks for the questions. It's good to hear your voice. In terms of our marketing campaign and budgets, we're not prepared to release figures like that. But I can tell you, the first several months of the rollout will be, a phased approach.

So, this is a standard approach with CPG products to start in, select geographies, refine the messaging in the real world, better understand the consumer behavior with the product, and then leverage that learning as you scale up the business. And so, the budgets and the spending there will correspond of course to, the scale of the campaign at that time.

In terms of the retail partnerships, we don't have signed agreements in place, at the moment. We're in discussions with a number of retailers, about geographies, and store counts during these -- the test phase. And so those terms are still in negotiation. And then as far as the new patent, there's no variety that we believe this technology will not work in any variety of tobacco plants are very similar, at least the ones used in commercial production.

And so, we believe, this technology will work in any variety. The ones that we're focused on are bright or what's sometimes referred to as flue-cured Virginia tobaccos, burley tobaccos and oriental tobaccos. And we're focused on those, because they are the three types of tobacco that are used in American blend cigarettes, which is a style of cigarette, a flavor profile that dominates not just the U.S. market but many markets internationally as well.
However, we believe the technology will be useful for other types of tobacco like, dark-fired tobaccos, which are used in some products elsewhere in the world, as well as cigar tobaccos, which we believe little cigars at the very least, will likely be included in the FDA mandate to make all cigarettes non-addictive. That will likely include little cigars as well. Those products typically use cigar varieties tobacco. And this technology we believe it will work in those varieties as well. So hopefully, that answered your questions?

Jim McIlree – Bradley Woods & Co.

That did. Thank you very much and good luck with everything.

Operator: Thank you. We have no additional audio questions at this time. [Operator Instructions] Thank you. We have no additional audio questions at this time. [Operator Instructions]

James A. Mish – Chief Executive Officer, 22nd Century Group

All right. I appreciate everybody's questions coming in here. We're getting a number of them and we're going to get to as many as possible and perhaps some of them we've answered along the way as they rolled in. But I'll pick out a few here that I find -- all of them are very thoughtful questions. I appreciate that as well. But I'll pick out a few here that I think go together and may shed some light on it. But there's a number of questions here regarding the potential for marijuana legalization and how that impacts our overall strategy whether on a state basis or a federal basis.

And I would like to at least shed some light on that with our hemp/cannabis strategy. So, as everyone knows the 22nd Century as a publicly traded company is not in the recreational marijuana space and were primary original objectives were to focus on the consumer end product with the investment in Panacea and combined with upstream plant lines.

As I said during the conversation, we have shifted our focus dramatically to the upstream area. That downstream area was primarily in the consumer space non -- let's call it non-recreational space.
So, we do believe as time goes on, first on a state-by-state basis and then ultimately on a federal basis down the road, we do believe that legalization ultimately will occur. And some of our new targets -- new lines that we're identifying high stable THC lines that we will conduct research offshore are designed to match with that federal legalization.

Now, in the meantime on a state-by-state basis, we have R&D to offer. We can certainly take full advantage of that and also outside of the U.S. So, we're in -- we're watching like everybody else the state-by-state and federal legalization process. We want to be prepared to have some real R&D value and offerings down the road. And that's where the -- where we have turned our attention to the plant lines themselves and in particular to more investment with the -- with KeyGene moving forward. So, there's a number of questions around that. And hopefully that sheds some light on our thinking.

Here's another question I would like to take and it's -- the question reads,' Will more money be invested in Panacea?' And I do want to address Panacea throughout the conversation here and also just shed some light with the shareholder base. So, the original investment with Panacea was again primarily driven by the finished product consumer goods space and at that point lesser to an extent to their upstream capabilities.

The -- that marketplace is very competitive very fragmented. I'm happy to say that Panacea is doing a nice job. They're holding their own in a very complex and competitive marketplace in the finished goods space and I give them all the credit in the world for that.

Our interest in that investment is on there -- because they're fully vertically integrated. Our interest is in the upstream area where they have also expertise and that's in the cultivation the breeding and extraction area. So, we don't intend on investing additional dollars into Panacea, but we will refocus those dollars into their upstream opportunities of extraction breeding and plant cultivation which really matches with our long-term strategy. I leave it to their expertise on the downstream consumer product space. And that's the kind of conversations we're having with them at present.

Still a solid investment. It's well-funded, but we do want to shift our focus to our core strength -- aligned with our core strength which is around the upstream value chain on that.

So, there were a number of questions in there regarding Panacea, and hopefully that again shed some lights on it.

Here's a -- as I said, I like juicy questions. So here is I think a very valid question and one that have been trickling in a couple of different -- from a couple of different angles here. But why have insiders not been buying shares? If you're not able to for some reason, can you at least say that? We need to know that insiders are confident in future SP.

I think it's a great question and I'll answer it from a personal standpoint. As I said during the conversation, I believe that with everything we've got going on, our share price is woefully undervalued. And obviously then our market capitalization is woefully undervalued. We do have to deal with a lot of blackout periods. It's based on the amount of press releases, we're now coming out with and earnings call et cetera. We do have to deal with a lot of blackout periods.

But I personally will be investing in the next open window and looking forward to that, because again I have utmost confidence that the FDA will grant this MRTP I believe that entirely. I do believe that it's measured in months and we have to work our way through that and imply the continued pressure we've talked about. And as such, I do believe that the share price is undervalued and I want to make strong investments for myself.

So I have every intention during the next window to do just that and that window will open up over the course a relatively short period of time here. But we as a operating team have the utmost confidence in this business and the strategy and now that we have really refocused our efforts and gotten back to our roots, highly confident in our capabilities of executing on this across the board.

Mike, there's a question on here I'd like to address and the question is when will Moonlight be available to consumers? If you could -- could you address that please?

Michael Zercher – President and Chief Operating Officer, 22nd Century Group

Sure, Jim. Yes. So, Moonlight is the PMTA product that was authorized for sale by FDA back in December. It's actually exactly the same product as VLN, the MRTP product. We're not bringing Moonlight to market in any significant way and we're not planning to do that in any significant way because the PMTA authorization will simply -- simply allows us to put the product into the market. It does not allow us to describe what makes the product different from every other cigarette on the market. So imagine walking into a store and looking at the cigarette shelf and seeing this new brand Moonlight and not having any more information about it. Why would a consumer -- why would a smoker buy that product, if they don't have any information to tell them what makes it different from the other 100 cigarette brands on the shelf in that store? That's the issue with Moonlight. That's why Moonlight is not going to the market in any significant way, simply because we cannot explain what makes it different. We can't explain to smokers what benefits they might derive from it. We can't even say that it has 95% less nicotine. Those are all statements that require an MRTP authorization. And that's why the MRTP application is so important to this effort.

Internationally, it's a similar situation. Virtually every country in fact every country that I'm aware of has rules has laws against making statements about tobacco products having less of something. And this goes back to the days of tobacco companies marketing supposedly safer cigarettes, light cigarettes for example. And so there's a worldwide treaty from the WHO that virtually every country has signed on to that prohibits claims of tobacco product containing less of something including nicotine. That prevents us from making a 95% less nicotine claim in those countries.

And so our strategy there is to secure the MRTP authorization and then work with the regulators in countries around the world to allow us to go-to-market with a 95% less nicotine claim in their country. And we think that will be a successful strategy. In large part, we think it will be successful because we've talked to regulators and we've talked to regulatory lawyers in many countries about this. And they've all said, yes, when the FDA says that authorizes this claim then it will be relatively straightforward for us to review it and likely authorize it as well for our countries. And so it all comes down to our ability to lawfully -- to legally make -- legally describe the products and make a 95% less nicotine claim.

James A. Mish – Chief Executive Officer, 22nd Century Group

Thank you, Mike. Appreciate that. There's a -- I think a good question regarding our cash position and current levels of burn rate and extension of that position into the future. The exact question is how far out will the current cash last based on the current burn rate?

So I do want to address that directly here myself and I do appreciate the question as well. So we've done a lot to actually reduce our burn rate in the first few months that I've been here. We're working diligently on continuing to do that. And we do see line of sight to additional reductions in our cash burn without mortgaging our strategy or our future. We're going to be implementing them as time goes on here into next year.

With those new opportunities coming into effect, combined with our current healthy balance sheet and with certainly a plan to capitalize the launch of VLN into the marketplace, we believe we have ample cash to do all of the above well into 2022 under the new burn rates that we'll be implementing. So we

have plenty of cash on hand to get VLN onto the shelves to operate efficiently and to execute on not only the tobacco franchise, but the cannabis franchise as well. So it's somewhere between at least 18 months and beyond of cash including all of that. And that doesn't include any revenue stream from VLN coming in, in the second half of next year. So we're very comfortable with that.

And as I've said and as John has said that puts us into a very good position of not needing to or planning to have additional capital raises at this time. We're very comfortable with that moving forward. But it is a combination of cost efficiency that we've taken to reduce the burn rate, new success at the contract manufacturing side with regards to volumes and pricing that has offset that burn rate and we'll continue to work on that and have -- I believe really put us into a good position overall. So I appreciate the question and again did want to add a little bit more color to that than perhaps we got out of the earlier presentation.

And I think we've got time for just a few more questions. I think this is a good question Mike for yourself. My screen just shifted so bear with me.

Will the sale of VLN be exempt from any cigarette excise taxes and our MSA payments or at either the federal or individual state level? Could you address that?

Michael Zercher – President and Chief Operating Officer, 22nd Century Group

Sure. Yes, that's a great question. Currently there are a few states that have put into place some excise tax exemptions or reductions for MRTP products. And once we've secured an MRTP authorization that would apply to VLN. So, the answer is yes, at the state level. We expect that sort of approach to tobacco regulation to continue at the state level and we're hopeful that will be a strategy that can be successful at the federal level as well.

MSA payments are a separate issue from taxation and so taxes are set by legislatures and Congress. MSA payments are governed by an industry settlement agreement. And so again, it's possible that that could -- that settlement could be modified to provide some type of tax benefit for MRTP products, although I have not -- personally have not heard of any activity around that. But certainly, there's a lot of activity with excise taxes.

James A. Mish – Chief Executive Officer, 22nd Century Group

Thank you, Mike. And I think we've got time for just one more question. And these two questions kind of combined I believe they're very solid.

Number one is, can you please explain your backup plan in detail if the MRTP is not approved by the FDA? And also you talk about putting pressure on the FDA for advancing MRTP. What is your leverage? I think I can address both of those questions. As we've said in the earlier part of the conversation, we believe that it is not a matter of if but when FDA will approve this. And it is measured in months. And we continue to believe that very strongly. Our backup plan is more around the ever-increasing effort to apply pressure from the ground up and from a top down with the FDA to enable them to do their job and enable the product to hit the shelves and let the consumers start to decide the value.

The leverage is less about leverage and more about reminding them and ever-increasing channels and ever-increasing levels that this fits into their long-term plan that they establish. They funded a tremendous amount of the clinical studies and have been reinforcing those studies verbally.

And it's a matter really of driving this through the typical bureaucracy of the FDA and they're being very careful about their approach and we respect that. So the backup plan and the leverage that we're utilizing is one and the same.

We anticipate this MRTP coming here by the end of the year. If it should spill into next year we – the backup plan is to continue conversations with them through a variety of different channels and applying more and more pressure to get this resolved once and for all. But the leverage that we have is really all more about their master plan, their long-term strategy and their support for the technology historically. So it's – it will end up being a very collaborative effort we believe. And we'll have the outcome as we've suggested, which is the final MRTP approval. That gives us the opportunity to get the product on the shelves and let the consumers decide its value. And we have utmost confidence that once the consumer tries it that the clinical studies clearly demonstrate that it will be a success in the marketplace.

So that pretty much wraps up our time for questions. And I hope this call and the opportunity for your questions has provided you a sense of how we really value the shareholder base how we're trying to listen to our shareholders and the openness that we're striving for with our shareholders.
We're going to continue to be transparent on our strategy and plans for the company and provide regular updates on new developments, we make across all aspects and all franchises of the business. As always, we thank you for your time for your thoughtful questions and your continued support of 22nd Century. If you have any further questions following today's call please reach out to Mei at InvestorRelations@xxiicentury.com and we'll be sure to try to answer the questions that we could not get to here today moving forward. Thank you again and have a good day.

Operator: Thank you. This does conclude today's call. You may now disconnect.