

First Quarter 2021 Earnings Transcript May 6, 2021

PARTICIPANTS

Corporate Participants

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

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 the 22nd Century Group's First Quarter 2021 Earnings Conference Call. At this time, all participants are in a listen-only mode and the floor will be opened for questions 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



FIRST QUARTER 2021 EARNINGS PRESENTATION
May 6, 2021



Slide 2**CAUTIONARY NOTE
ON FORWARD-LOOKING STATEMENTS**

This presentation contains forward-looking statements concerning our business operations, and financial performance and conditions, as well as our plans, objectives, and expectations for our business operations and financial performance and conditions that are subject to risks and uncertainties. All statements other than those of historical fact are forward-looking statements.

These types of statements typically contain words such as “aim,” “anticipate,” “assume,” “believe,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “potential,” “positioned,” “predict,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends. Forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business, the industry in which we operate, and our management’s beliefs and assumptions.

These statements are no guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. All forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those estimated. The contents of this presentation should be considered in conjunction with the risk factors, warnings, and cautionary statements contained in the Company’s annual, quarterly, and other reports filed with the U.S. Securities and Exchange Commission. We undertake no obligation to publicly update or revise any forward-looking statement as a result of new information, future events, or otherwise, except as required by law.

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Thank you, Diego. Good morning and welcome to 22nd Century's first quarter earnings conference call. Joining me today are Jim 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 first quarter 2021. We'll start today's call with prepared remarks from Jim, Mike, and John before moving into a Q&A session.

During our prepared remarks, we will be referring to slides, which are available for viewing in the webcast and posted in the Investors section of our website at xxiicentury.com under the Events subheading. We hope these slides will serve as a framework for management's prepared remarks, reinforce key takeaways, and provide additional transparency and insight into our business, strategy, and objectives.

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 annual, quarterly, and other reports filed with the SEC.

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 for joining 22nd Century's call today.

Before turning to the slides, let me start by saying that my energy level and excitement is really the highest it's been in my 35-year career based on what's happened for 22nd Century since our last earnings call, and what's on our doorstep. 2021 is off to an extremely exciting start.

First, let me again confirm that I remain absolutely confident in our MRTP authorization and that we are in the final stage. I also continue to believe that our stock and market cap are still tremendously undervalued, regardless of the significant increase that we've seen in the past quarter and especially with the recent pullback, based only on extremely favorable news.

Every turn of macro events that we could have possibly hoped for have gone in our favor. And they'll dramatically accelerate and expand the commercial opportunities for both our tobacco and hemp/cannabis franchises.

I'll speak in more detail as the day goes on. But this includes:

- Federal and state administration changes
- Continued dialogue and signals from FDA regarding our MRTP authorization
- New emphasis placed on nicotine mandate in both the U.S. and New Zealand
- FDA's commitment to advancing two new product standards
- Administration support for cannabis legalization and safe banking
- Not to mention our pending rejoining the Russell, and
- Eliminating all warrants in exchange for \$11.8 million onto our balance sheet.

In fact, it's been quite a quarter.

Slide 3



Q1 DEVELOPMENTS: SHIFT IN FEDERAL POLICY POSITION

Reduced Nicotine Mandate Now at the Forefront

- WSJ reports¹ the Biden Administration is actively considering moving forward with the ANPRM that will require Big Tobacco to reduce the amount of nicotine in all combustible cigarettes to be “minimally or nonaddictive”
- 22nd Century has the first and only reduced nicotine content combustible cigarette product authorized for sale by the FDA
- Extensive research² largely funded by U.S. government agencies – consistently confirms the benefits of a reduced nicotine mandate for adult smokers
- When implemented, FDA’s nicotine cap will help 5 million adult smokers quit within one year and save more than 8 million American lives by the end of the century

Changing Federal Policy Priorities

- New administration demonstrating commitment to advancing critical public health initiatives:
 - Xavier Becerra appointed head of Health and Human Services long-time advocate of tougher cigarette industry regulation and reduced nicotine mandate
 - Acting FDA Commissioner Janet Woodcock has a strong history of support for divisional autonomy, including CTP
- FDA announced a decision to begin the rulemaking process to eliminate the use of menthol in highly addictive cigarettes
- Increasing momentum as 36 states have legalized medical use and 16 states have legalized recreational use of marijuana
- House passed SAFE Act and advanced to Senate; Senate Majority Leader Schumer (D-NY) proposing wider legalization legislation

CHANGES IN FEDERAL POLICY MAY ACCELERATE MARKET OPPORTUNITIES FOR 22ND CENTURY

¹ <https://www.wsj.com/articles/biden-administration-considering-rule-to-cut-nicotine-in-cigarettes-11618859564>
² https://www.nimh.org/daj/full/10_1056/NFIMsr1714617?query=featured_home
³ Center for Tobacco Products

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Now turning to Slide 3, fundamental change underlying all of our efforts in recent news that the Biden administration is actively considering the reduced nicotine mandate requiring all cigarettes to be made minimally or non-addictive. This idea was promoted in the Obama administration, and four former FDA commissioners recently supported the reduced nicotine mandate during a March panel discussion about the future of the FDA.

Xavier Becerra, the newly appointed Secretary of Health and Human Services, is a long-time proponent of a reduced nicotine cap for cigarettes and tougher regulation for the tobacco industry. And the idea has momentum offshore as well – a reduced nicotine proposal was recently advanced in New Zealand, one of the bellwether countries for global tobacco and market regulations. This all greatly reinforces our grand slam scenario we have discussed before and gives us an accelerated commercial opportunity offshore. The nicotine cap mandate is a potential game-changer for our company.

22nd Century has the first and only reduced nicotine combustible cigarette product already authorized for sale by the FDA. Our pending MRTP authorization will unlock our home run scenario and our ability to market this product and educate smokers about its key characteristics.

The recent move by FDA to use its regulatory authority to aggressively address cigarette addiction and youth smoking initiation with a menthol product standard is also fantastic news for us, and helps pave the way for the overall reduced nicotine standard as well. We believe VLN[®] Menthol King cigarettes will remain on the market to help menthol smokers reduce their

consumption of nicotine and quit highly addictive menthol cigarettes, while mitigating risk of illicit markets and product adulteration.

We are also seeing major progress on potential reforms to hemp/cannabis laws in recent weeks. With 36 states now legalizing cannabis in some form, house passage of the SAFE Act for a second time and Senate Majority Leader Schumer's public statement of desire to pursue broader legislative changes on cannabis at the Senate level, federal legalization seems increasingly likely.

Slide 4



Q1 DEVELOPMENTS: TOBACCO AND CANNABIS FRANCHISES

Tobacco Franchise	Hemp/Cannabis Franchise
<ul style="list-style-type: none"> ▪ Steadily raising the intensity and frequency of communications to secure FDA Modified Risk Tobacco Product (MRTP) designation of VLN® across FDA, executive, congressional and state leadership ▪ Fully prepared for commercial launch of VLN® within 90 days of receiving MRTP designation ▪ Expanded VLN® tobacco growing program to support anticipated consumer demand ▪ Manufacturing capabilities geared for a strong commercial launch and growth; adding in-house test and measurement capabilities lowers cost, increases speed ▪ Willing to license reduced nicotine technology to facilitate a nicotine cap proposal to significantly reduce the harm caused by smoking 	<ul style="list-style-type: none"> ▪ Changing regulations driving market growth, capital investment and increased need for competitive differentiation ▪ Advancing development of end-to-end upstream cannabinoid value chain capabilities to create disruptive, valuable plant lines ▪ Key partnerships in place to accelerate commercialization of next-gen hemp/cannabis plant lines and IP in as little as two years from trait identification to viable plants ▪ Extended and expanded our exclusive partnership with KeyGene to lock in long-term strategic advantage and future development ▪ Advancing monetization for 2H 2021 from initial plants and IP; readying next generation of plants lines for prospective customers

DISRUPTING THE +\$1.3 TRILLION GLOBAL TOBACCO, HEMP/CANNABIS MARKETS, AND THIRD PLANT-BASED FRANCHISE (TO BE ANNOUNCED)

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Turning to Slide 4, no matter how long the federal initiatives play out, our VLN® product is poised to play a leading industry role upon MRTP authorization. Again, we remain highly confident we are in the final stage of authorization, but we continue advocating for authorization at the highest levels of multiple legislative, executive and administrative government offices, and steadily increasing both the frequency and strength of those interactions.

We are fully prepared to launch sales of VLN® in just 90 days after securing MRTP authorization and scale our proven manufacturing capabilities for a strong commercial launch. This is not a theoretical exercise. We have already produced significant quantities of variable nicotine contact research cigarettes, enabling us to refine and prove our capabilities. Our current contract manufacturing operations provides rapid readiness to scale into full VLN® production. We are expanding our VLN® growing program. Upon our own initiatives to achieve the highest standards, our internalizing nicotine content assessment capabilities to reduce cost by 90% and

decrease the result window from weeks to less than a day. Again, I'll stress that was on our own initiative.

And when a federal reduced nicotine mandate comes to fruition in addition MRTP, we stand ready to facilitate full participation by every combustible manufacturer. This would position 22nd Century is the clear leader in reduced nicotine content combustible products for the U.S. cigarette market with a pathway to global market leadership through both GMO and non-GMO technologies.

We are also in continued discussions with global strategic partners based on the regulatory changes outside the U.S., including the recent exciting news of New Zealand's proposed reduced nicotine mandate on cigarettes sold in that country.

On hemp/cannabis, we're moving to begin monetizing our assets by year-end. As changing regulations enable the market to open further, it will attract more capital, more competition, and a greater need for differentiation as companies seek a competitive edge.

22nd Century is moving swiftly to become the critical link in cannabis production with our highly differentiated upstream capabilities. We've expanded and advanced our relationship with KeyGene as we recently announced, and secured important capabilities with CannaMetrix for high throughput testing and identification of key traits. I'll talk more about cannabis after Mike speaks to tobacco.

Slide 5

			
2021 PRIORITIES & AREAS OF FOCUS			
Tobacco Franchise	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> 01 <ul style="list-style-type: none"> ▪ Secure MRTP Authorization from FDA ▪ Fully prepared for commercial launch of VLN® within 90 days post authorization ▪ Execute on licensing and partnership initiatives </td> <td style="width: 50%; vertical-align: top;"> 02 <ul style="list-style-type: none"> ▪ Support, advance, and advocate for FDA to enact its proposed nicotine cap mandate for all combustibles ▪ Favorable political climate for critical public health initiatives </td> </tr> </table>	01 <ul style="list-style-type: none"> ▪ Secure MRTP Authorization from FDA ▪ Fully prepared for commercial launch of VLN® within 90 days post authorization ▪ Execute on licensing and partnership initiatives 	02 <ul style="list-style-type: none"> ▪ Support, advance, and advocate for FDA to enact its proposed nicotine cap mandate for all combustibles ▪ Favorable political climate for critical public health initiatives
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Hemp/Cannabis & Third Plant-based Franchise	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> 03 <ul style="list-style-type: none"> ▪ Target upstream segments of cannabinoid value chain ▪ Enable development of commercially valuable plant lines and related IP with stabilized genetics within two years ▪ Monetize our hemp/cannabis IP beginning in 2021 and continue to bring disruptive technology forward </td> <td style="width: 50%; vertical-align: top;"> 04 <ul style="list-style-type: none"> ▪ Initial development of a third, plant-based franchise in process ▪ Operates in industry that is not as highly regulated and legislated; faster route to commercialization than first two franchises ▪ Pursue strategic partnerships to support development of this franchise </td> </tr> </table>	03 <ul style="list-style-type: none"> ▪ Target upstream segments of cannabinoid value chain ▪ Enable development of commercially valuable plant lines and related IP with stabilized genetics within two years ▪ Monetize our hemp/cannabis IP beginning in 2021 and continue to bring disruptive technology forward 	04 <ul style="list-style-type: none"> ▪ Initial development of a third, plant-based franchise in process ▪ Operates in industry that is not as highly regulated and legislated; faster route to commercialization than first two franchises ▪ Pursue strategic partnerships to support development of this franchise
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Financial	05 <ul style="list-style-type: none"> ▪ Maintain diligent financial execution, efficient operating structure, and balance sheet strength to support growth initiatives 		

Turning to Slide 5, our priorities for 2021 have not changed one bit. If anything moves by federal and state governments in the first quarter indicate that we are exactly on track with these areas of focus.

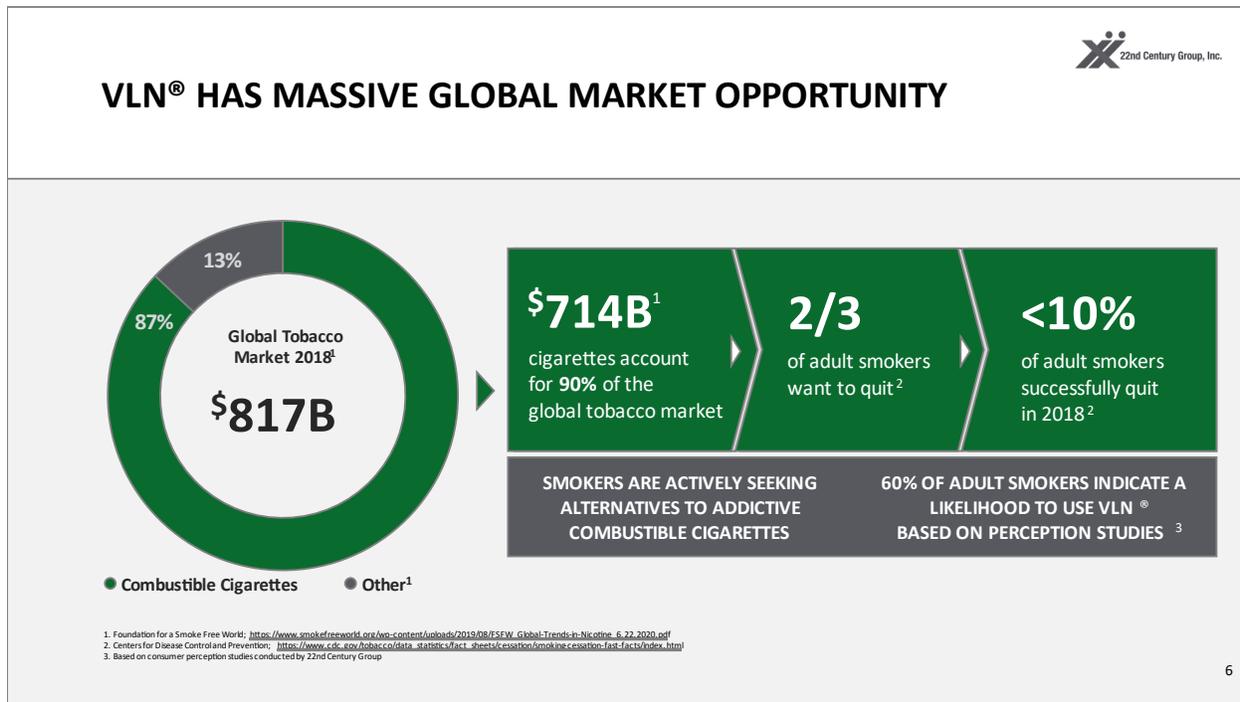
Securing MRTP authorization is our number one priority. We will continue to increase our advocacy activities directed towards FDA and other influential audiences needed until we achieve success. Additionally, we believe the single most impactful action in public health would be the enactment of a mandate to require all combustible cigarettes to be made minimally or non-addictive.

On hemp/cannabis, we are committed to monetizing the first portion of our existing hemp/cannabis IP portfolio before year-end. In addition, I'm announcing this morning, we are beginning our first grow of hemp/cannabis on the Colorado farm with customers already lined up for sales in Q4. I'll talk more about that in later slides.

Although we have not announced the identity yet, I can assure you that we are actively advancing work in our third plant-based franchise. A massive complimentary market with far lower barriers to entry and commercialization, which we will announce in advance once we secure MRTP designation. And we remain committed to prudent operating decisions and financial stewardship, including the \$11.8 million in additional balance sheet cash generated from warrant exercises in the first quarter.

With that framework in place, I'll pass you over to Mike for more detail about progress in our tobacco franchise, then come back to discuss our hemp/cannabis advancements in more detail. Mike?

Slide 6



Thanks, Jim. And good morning, everyone. On Slide 6, it's important to understand how critical combustible cigarette products are to the global tobacco market. This slide illustrates that while vaping and other alternative tobacco products may capture a lot of media attention, combustible cigarettes make up the lion's share of the market, with 90% of the \$800 billion global tobacco industry.

Any public health strategy addressing the enormous amount of death and illness caused by tobacco must address combustible cigarettes head on. Two-thirds of smokers are trying to quit, but less than 10% are succeeding. It's clear that products available today simply do not get the job done. With 60% of smokers in our research telling us they'll use our product, we believe VLN® will change the face of the tobacco industry forever.

We see the need for VLN®, and an enormous body of independent clinical research tells us what the benefits will be for smokers: reduced nicotine exposure and dependence, fewer cigarettes smoked per day, an increased number of smoke-free days - all with minimal to no withdrawal symptoms or compensatory smoking. It's clear that removing nicotine from the equation will be a winning proposition for public health and most importantly, for smokers looking to take back control.

Slide 7



VLN® IS IN FINAL STAGES OF REVIEW WITH THE FDA



*For descriptive purposes only. Final trade dress subject to the FDA review and authorization.

Obtaining both PMTA & MRTP designation is critical to the success of VLN®.	
Premarket Tobacco Product Application (PMTA)	Modified Risk Tobacco Product Application (MRTPA)
<p style="color: green; font-weight: bold;">“Authorizing these reduced nicotine products for sale in the U.S. appropriate for the protection of public health”</p> <p style="color: green; font-size: 10px;">– FDA press release on 12/1</p>	<p style="color: green; font-size: 10px;">MRTP authorization will allow 22nd Century VLN® to carry headline claim of “95% less nicotine” on packaging, distinguishing the product from conventional cigarettes</p>

- FDA is in the final stages of the review process; no outstanding requests for information from the FDA

- Working with legal advisers, regulatory consultants, and government affairs specialists to highlight the public health importance of MRTP application

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Turning to Slide 7, every indication is that our application is in the final stages of review with the FDA, and there are no outstanding requests for information. We believe that a positive response to our MRTP application is one of the most important decisions FDA can make right now for public health.

To that end, we continue to ramp up our outreach activity at the highest levels of the administration, Congress, and the FDA about VLN® and a reduced nicotine mandate. We will continue to increase pressure as needed until we achieve success and will then advance to launching VLN® within 90 days of securing our MRTP.

Slide 8



PREPARED FOR LAUNCH AND MANUFACTURING RAMP

22nd Century is positioned to manufacture VLN[®] cigarettes in commercial quantities through existing facility footprint.

Fully Prepared For Commercial Launch of VLN [®]	Manufacturing Geared For Strong Commercial Launch
 Launch-ready for commercial sales within 90 days of FDA MRTP authorization	 62,000 sq. ft. manufacturing facility in NC; expanded VLN [®] planting program in 2021
 Identified both initial and subsequent markets for launch	 Manufacturing capacity ~1% of the U.S. tobacco market; increasing to ~3% with minimal investment
 Advanced discussions with multiple trade and retail partners	 FDA inspected and cleared as part of the Premarket Tobacco Application (PMTA) process
 Advancing marketing materials and other important aspects of the launch	 Subsequent Participating Manufacturer of the Master Settlement Agreement
 Test, measure, and refine to maximize commercial success of VLN [®]	 Internalizing nicotine content test capabilities – 90% cost reduction, results in 1 day vs. 2 to 4 weeks

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Slide 8 explains how we are launch-ready in both initial and subsequent markets. Our launch will enable us to test, measure and refine our marketing model to maximize our commercial success with VLN[®].

We're in discussions with numerous major tobacco retailers for Phases 1 and 2 of the launch as we look to introduce VLN[®] to market and then expand availability across the country. VLN[®] is being very well received with high interest from these potential partners, who are ready to offer our product as soon as possible after MRTP authorization.

We are also fully prepared to produce enough VLN[®] to secure our market position. We own and operate a fully licensed 62,000 square foot facility in North Carolina that currently makes conventional cigarettes and cigars for third parties, as well as research cigarettes for the many clinical studies done using our reduced nicotine content cigarettes. Our manufacturing capacity is nearly 1% of U.S. cigarette market volume. And with minimal investment, we can triple that capacity.

Our production readiness for reduced nicotine products is well established, shown most recently by the fulfillment of an order for 3.6 million variable nicotine content research cigarettes. These cigarettes are used in independent scientific studies funded by the FDA, NIH and other agencies to further validate the already well-established public health benefits of implementing a national standard, requiring all cigarettes to contain minimally or non-addictive levels of nicotine, a level already achieved by 22nd Century's VLN[®].

We've also increased the planting of VLN[®] tobacco for the 2021 crop year as part of a significant expansion of our VLN[®] growing program, in addition to our already sizeable inventory. We are also looking at ways to enhance our production capabilities and improve efficiency ahead of a VLN[®] launch in anticipation of a positive FDA decision on our MRTP application.

This includes a recent decision to bring our nicotine content testing capabilities in-house. We estimate that with the installation of this new lab equipment, our testing costs will be reduced by 90%, and testing turnaround times will decrease from weeks to hours. We'll recoup our investment in this upgrade in less than one year, and we'll be able to move product to market much more quickly.

Slide 9



MRTP DESIGNATION IS A CATALYST FOR ADDITIONAL GROWTH OPPORTUNITIES



- MRTP designation opens multiple U.S. distribution, international licensing, and partnership opportunities for reduced nicotine tobacco technology and IP
- Advancing next-generation non-GMO plant research key to markets where non-GMO products are preferred, or GMO products are banned
- Successfully applied non-GMO technology to Bright and Burley varieties of tobacco and developed VLN[®] 2.0 cigarette prototype
- Introducing reduced nicotine traits into Oriental varieties of tobacco

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Closing out my tobacco comments today on Slide 9. MRTP designation is only the first step in our launch plans. It will be a catalyst for both domestic and international markets. We are advancing our VLN[®] 2.0 development program to enable additional tobacco blending capabilities, as well as meet specific market expectations for certain flavor profiles and for general demand for non-GMO reduced nicotine tobacco.

Our factory is currently using our VLN[®] 2.0 tobacco to develop and test non-GMO versions of our VLN[®] cigarettes. We have confirmed successful application of our non-GMO technology to bright and Burley varieties of tobacco, and are applying this technology to introduce reduced

nicotine traits into other varieties of tobacco including Oriental, further enabling our development of VLN® 2.0.

We believe this combination of near-term U.S. drivers and longer-term global drivers creates a compelling and exciting opportunity within our tobacco franchise. Capturing just a fraction of the U.S. market with VLN® will transform 22nd Century's income statement even before considering the additional opportunities to come from international sales and licensing of our technology as part of a broader industry transition.

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

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

Slide 10



FEDERAL LEGALIZATION OF CANNABIS INCREASINGLY LIKELY

<p>Federal Advancements</p> <ul style="list-style-type: none"> ▪ House passed SAFE Act for a second time, removing limitations on cannabis banking activities ▪ Senate Majority Leader Chuck Schumer is pushing the Senate toward lifting the federal prohibition on marijuana with legislation that would represent the biggest overhaul of federal drug policy in decades ▪ Bipartisan State Attorneys General urged congress to pass marijuana banking bill, protecting banks that service state-legal marijuana markets from being penalized by federal regulators ▪ The Cannabis Freedom Alliance (CFA) was launched to end the prohibition of cannabis while reducing overregulation, including unreasonable tax rates, and to promote innovation and entrepreneurship in the space. <p style="font-size: small; margin-top: 10px;">Source: Cowen Cigarette & Cannabis Circular, April 10, 2021</p>	<p>State Advancements</p> <ul style="list-style-type: none"> ▪ New York: Governor Andrew Cuomo signed bill legalizing adult use cannabis and expunging all convictions for cannabis related charges that would become legal under the bill ▪ New Mexico: Legislation to allow adult use cannabis sales, which would become effective on April 1, 2022, was passed in a special session ▪ Illinois: Department of Financial and Professional Regulation reported adult use monthly sales for March of \$109M, ~20% sequential growth (adjusted for selling days) ▪ Montana: House Bill 701, which aims to legalize adult use cannabis, will be reintroduced by Governor Greg Gianforte (R) after failing to achieve necessary votes earlier this year.
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LEGALIZATION WILL LIKELY INCREASE COMPETITION AND INCREASE THE NEED FOR HIGHLY DIFFERENTIATED PRODUCTS GROWN AT COMMERCIAL SCALE – EXACTLY WHERE 22ND CENTURY IS UNIQUELY FOCUSED. 10

Thanks, Mike. Let's turn to slide 10. We believe the Biden administration will be more open to updating hemp and cannabis regulations at the federal level, including both medical and recreational uses, as more and more states have done across the country. We are now at 36 states that have legalized medical use of cannabis and 15 states so far that have approved recreational use, including announcement by New York State a few weeks ago.

Momentum is coming from both sides of the aisle and across the country, as this slide illustrates. Legalization will increase competition, which will increase capital flowing into the market, which increases the need for highly differentiated products grown at scale. Exactly where 22nd Century is uniquely focused.

Slide 11



CREATING THE “MONSANTO OF CANNABIS”

Accelerated modification of cannabis plants to the highest levels of quality, stability and scale



- Industry leadership will require specific genetic profiles to produce desired taste, scent, and psychoactive effects — and ensure the product can be replicated consistently at commercial scale
- Ability to control the expression of CBD, THC, CBG, CBN, terpenes, and other cannabinoids is critical to financial returns and quality metrics
- Companies with deep IP and genetics capabilities will be able to more easily move into new markets and applications
- Control of traits and consistency will command a premium price and higher margin

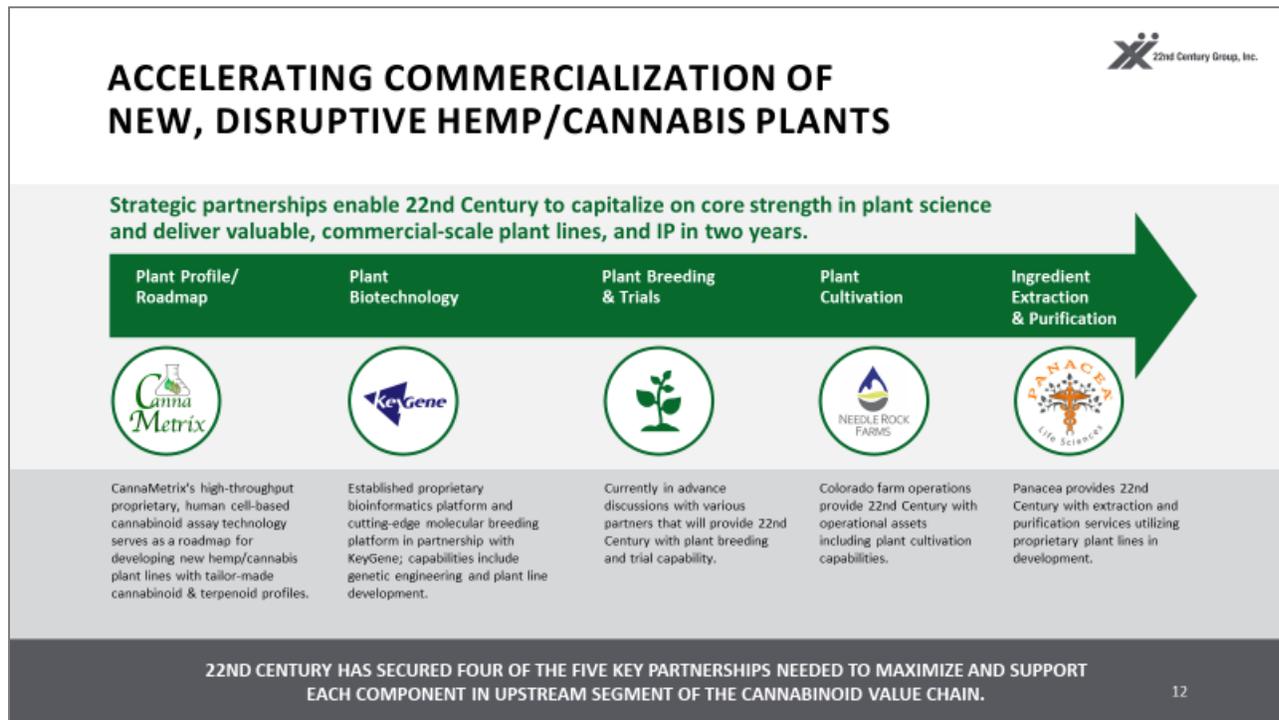
22ND CENTURY HAS ESTABLISHED A LEADERSHIP POSITION IN GENETIC IP CRITICAL TO HEMP/CANNABIS ACHIEVING ITS FULL COMMERCIAL POTENTIAL

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Moving to Slide 11. Our vision about what we've been building and the fact that we believe that we are now positioned as the Monsanto of cannabis – steeped in plant science and genetic IP critical to quickly transform the cannabis plant into a high quality, large scale and stable commercial asset. It is this plant science focus that will serve as the critical link to create the specific characteristics needed to optimize consumer products and generate the financial returns, consistency, and quality necessary for success in highly competitive markets.

We also believe that companies able to closely control the traits and consistency of the plants will be the all-time winners, and will be able to command a premium price and margin in the markets.

Slide 12



On slide 12, to position 22nd Century in this Monsanto-like position, we have built an outstanding chain of partnerships to maximize our value in each component of the upstream hemp/cannabis market. The growing demand for hemp and cannabis products means the industry will increasingly face a key fundamental challenge - growers require stable, consistent and predictable plant lines to scale commercial production and keep up with demand.

The five components on this slide enable us to identify a desirable plant profile through CannaMetrix, feed that profile to KeyGene to bring out a small-scale clone and seed technology, scale up with the breeders that we'll be announcing shortly, take that plant to the Colorado Farm assets that is a state-of-the-art showpiece farm to demonstrate, and then utilize Panacea's purification techniques to get distillates and isolates as needed for production of consumer products.

Importantly, the combination of our core strength in plant science and vertically integrated capabilities will enable us to deliver new valuable plant lines and IP in two years, whether seeds, clones, or licensed IP - far, far faster than current breeding techniques.

But we are also able to take it even further – for example, through CannaMetrix, we can identify specific genetic sequences that facilitate cannabis use in dermatological applications or create a better genetic sequence for applications to the nervous system. Through Key Gene, we

can select specific traits to maximize yield of a specific cannabinoid, or to create a certain taste or fragrance profile needed to make a consumer product more competitive in the marketplace.

Slide 13



MONETIZING KEY PLANT LINES IN A GROWING MARKET

<p>Industry Problem Existing plant genetics result in low quality and unreliable yield for large-scale, commercial production of hemp/cannabis plants</p> <p>Market demand for hemp/cannabis</p> <ul style="list-style-type: none"> ▪ Global legal cannabis market is projected to be worth +\$100B by 2024 driving demand, competition and capital investment, transforming the U.S. cannabis market ▪ 36 states have legalized medical use of cannabis and 17 states have approved recreational use 	<p>22nd Century Group Solution: Optimize hemp/cannabis plant genetics and create disruptive, proprietary and stable plant lines that deliver higher crop yield for commercial use</p> <p>Moving to Monetization</p> <ul style="list-style-type: none"> ▪ Revenue from existing work to begin in late 2021, expand in 2022 ▪ Plants will be grown in Colorado targeting higher levels of specific cannabinoids for end product/ use ▪ Preparing second generation of plant lines; deploying KeyGene technology for subsequent season
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22nd Century will enable large, commercial growers to improve hemp/cannabis crop yield and improve stability, achieving artisanal quality hemp/cannabis plants in high volume production

1. Prohibition Partners; "The Global Cannabis Report- November 2019"
 2. Grandview Research; "Legal Marijuana Market Size Worth \$73.6 Billion by 2027 | CAGR 18.1%"

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These unique capabilities are important, because the global legal cannabis market is still projected to be more than \$100 billion dollars in just a few years, indicated here on Slide 13.

We expect revenue from monetizing a portion of our existing IP library in Q3 to Q4 of this year as I have discussed before.

As I indicated earlier in the conversation, additional revenue will now come in Q4 from existing plant lines we are now beginning to grow in Colorado. And we have offset commitments in place in Q4. Then additional new plant lines coming through the development pipeline will expand growing and revenue generation next year.

These initial projects will demonstrate how 22nd Century can leverage our unique expertise to identify specialized plant strains with higher levels of specific cannabinoids for end products, develop those strains, then execute on revenue.

We are now working with naturally grown products and strategic partners for outside of the U.S. markets to meet specific regulations around end-use consumer applications. The European market is a good example including their move to reset the requirements around use of cannabinoids in food and related products. We are participating in this activity.

In short, our cannabis portfolio is positioning 22nd Century to be the critical link between growers and product makers across this rapidly expanding market. And we have the first fruits of those efforts in sight later this year.

I'll now pass you over to John to review our financial performance. John?

John Franzino – Chief Financial Officer, 22nd Century Group

Slide 14



FIRST QUARTER 2021 FINANCIAL HIGHLIGHTS

	Net Sales	Gross Profit	Gross Profit Margin	Operating Loss
1Q 2021	\$6.8M	\$647K	9.5%	\$(5.2)M
1Q 2020	\$7.1M	\$287K	4.1%	\$(4.1)M

540 BASIS POINTS IMPROVEMENT YOY IN GROSS PROFIT MARGIN ¹

¹ Gross profit margin is calculated by dividing net sales revenue by gross profit.

² Adjusted EBITDA, which the Company defines as earnings before interest, taxes, depreciation and amortization, as adjusted by the Company for certain non-recurring cash and non-operating expenses, as well as certain one-time expenses, is a financial measure not prepared in accordance with generally accepted accounting principles ("GAAP"). In order to calculate Adjusted EBITDA, the Company adjusts the net (loss) income for certain non-cash and non-operating income and expense items in order to measure the Company's operating performance. The Company believes that Adjusted EBITDA is an important measure that supplements discussions and analysis of its operations and enhances an understanding of its operating performance. While management considers Adjusted EBITDA to be important, it should be considered in addition to, but not as a substitute for or superior to, other measures of financial performance prepared in accordance with GAAP, such as operating income, net (loss) income and cash flows from operations. Adjusted EBITDA is susceptible to varying calculations and the Company's measurement of Adjusted EBITDA may not be comparable to those of other companies.

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Thanks, Jim. And good morning to everyone. The summary of our Q1 financial results are depicted on Slide 14. And overall, as Jim and Mike have stated, we've had a great quarter - solid quarter, and that is essentially evidenced by the improved gross margin performance.

Some of the actions that we took in 2020 to optimize our contract manufacturing operations have been successful. While sales volume from the contract manufacturing business was impacted at the beginning of the quarter. In March, we fulfilled a large SPECTRUM® order that had dramatically higher margins. This demonstrates our ability to manage costs and meet our obligations to fulfill that order. The SPECTRUM® cigarette order is similar to our reduced nicotine VLN® cigarettes, and for which we are ready to begin commercial scale production immediately upon MRTP authorization.

The higher gross profit margin realized from the combination of SPECTRUM® sales and cost containment measures was more than offset by costs incurred this quarter over the first

quarter of last year due to higher SG&A costs associated with building a strong management team and the branding and launch readiness for VLN®.

Net sales revenue for the first quarter decreased by \$252,000 to \$6.8 million. The decrease was primarily driven by lower volume in the earlier part of the quarter in our contract manufacturing cigarette sales, it was partially offset by the increase in volume in March driven by successfully completing the order for the SPECTRUM® cigarettes and increased pricing during the quarter in the Company's contract manufacturing business.

Gross profit margin improved year-over-year for the fifth consecutive quarter, demonstrating our ability to execute on the objectives and strategies we set to the business. Gross profit for the first quarter increased by 540 basis points over \$360,000 to \$647,000. The improvement in gross margin was primarily the result of higher margin on SPECTRUM® cigarettes, price increases, and lower labor and overhead costs driven by factory efficiencies implemented in 2020, partially offset by lower overall volume in some contract manufactured cigarettes.

For the remainder of the year, we anticipate our gross profit margin percentage on contract manufacturing volumes to be similar to the full year 2020 mid-single digit range. This contract manufacturing volume, I remind everyone, does not include any introduction of our VLN® product which would take place following authorization of the MRTTP.

Slide 15



FINANCIAL SNAPSHOT

\$ in millions

Select Financials	Three Months Ended March 31,	
	2021	2020
Net sales revenue	\$ 6.8	\$ 7.1
Operating loss	\$ (5.2)	\$ (4.1)
Net loss	\$ (5.0)	\$ (4.0)
Net loss per common share - basic and diluted	\$ (0.03)	\$ (0.03)
Weighted average common shares outstanding – basic and diluted (in thousands)	144,258	138,610
Adjusted EBITDA	\$ (4.4)	\$ (3.2)

Summary Balance Sheet Items	Quarter Ended March 31,	
	2021	2020
Cash and cash equivalents ¹	\$ 30.9*	\$ 22.3
Total assets ²	\$ 59.7	\$51.7
Total liabilities ³	\$ 7.2	\$7.6
Total shareholders' equity ⁴	\$ 52.5	\$44.1

*Additional \$11.8M cash received from warrants exercised in Feb/March 2021

1. Cash and cash equivalents includes short-term investment securities.
 2. Total assets is the sum of total current assets, total property, plant and equipment, and total other assets including intangible assets, net, investments and convertible note.
 3. Total liabilities includes current liabilities and long-term liabilities and excludes shareholders' equity.
 4. Total shareholders' equity excludes any liabilities, as per press release issued on May 6, 2021.

We have provided a more detailed comparison of our financials for the quarter on Slide 15.

Total operating expenses for the first quarter increased by \$1.4 million, driven by \$1.7 million of higher SG&A expenses partially offset by \$259,000 of lower R&D expenses. The increase in SG&A included the addition of new members of the Company's management team, including the Chief Executive Officer and the Chief Financial Officer, higher personnel, insurance, and consulting costs. This increase was partially offset by lower legal fees.

R&D expense was lower by \$259,000 driven by \$137,000 of lower MRTP application costs, and lower personnel, licensing, and contract costs partially offset by higher costs of patents and legal fees. MRTP application costs related to expenses incurred in 2020 were associated with the preparation of TPSAC meeting, which occurred on February 14, 2020.

For the first quarter, operating loss of \$5.2 million increased by \$1 million over the first quarter of last year. Improved gross margin of \$360,000 is more than offset by \$1.4 million of total higher operating expenses.

Net loss for the quarter increased by \$1 million, representing a net loss per share of \$0.03. Adjusted EBITDA decreased by \$1.2 million for the quarter. Net cash used in operating activities was \$3.9 million. We believe the improvement in our quarterly cash burn rate, our healthy cash position of \$30.9 million, which is 39% higher, and our continued initiatives to manage expenses, provide us with additional runway to execute on our plans for the foreseeable future.

We announced on March 12, 2021, total net proceeds of \$11.8 million from the completion of the cash exercise of warrants during February and March of 2021. The Company is now free of any warrants outstanding.

Our foundation is solid and we believe we can support our current operations including our contract manufacturing operations, and our growth initiatives for both our tobacco and hemp/cannabis franchises.

I'll now pass you back to Jim.

Slide 16



22ND CENTURY INVESTMENT HIGHLIGHTS

+\$1.3T global addressable market across tobacco ¹ , hemp/cannabis ² , & third plant-based franchise ³	Clear growth strategy with continuous, rich pipeline of revenue opportunities	Financial strength
<ul style="list-style-type: none"> ▪ VLN[®] is the first and only reduced nicotine content cigarette anticipating FDA's Modified Risk Tobacco Product (MRTTP)⁴ designation ▪ Fully prepared to launch VLN[®] within 90 days of authorization; designation is a catalyst for VLN[®] brand and tobacco franchise opportunities ▪ Developing new disruptive, proprietary hemp/cannabis plant lines with stable, higher yields, and other commercially desirable traits through accelerated breeding processes ▪ Potential legislative tailwinds including enactment of reduced nicotine mandate and legalization of cannabis would open tremendous revenue opportunities 	<ul style="list-style-type: none"> ▪ Exclusive, pure-play plant biotechnology core competencies ▪ Creating disruptive, proprietary commercial plant lines and new intellectual property in tobacco, hemp/cannabis, and other large adjacent market ▪ Over 200 issued and pending patents in plant-based biotechnology applications supports entry into adjacent high-value markets. ▪ 20+ years of expertise in developing new, disruptive technologies 	<ul style="list-style-type: none"> ▪ Efficient operating model with multiple routes to market – commercialization, licensing, and partnership opportunities ▪ Clear path to profitability through existing platforms, cultivating large adjacent markets to leverage core technologies for additional growth ▪ Healthy balance sheet with more than \$30M in cash, including \$11.8M additional cash received from warrants exercised in Feb/March 2021

1. Foundation for a Smoke Free World; http://www.smokefreeeworld.org/wp-content/uploads/2019/08/ESFW_Global-Trends-in-Nicotine_6.27.2020.pdf
 2. Prohibition Partners; "The Global Cannabis Report – November 2019"
 3. Addressable market of third plant-based franchise is based on a global estimate in 2019.
 4. Modified Risk Tobacco Product; <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products>

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Thanks, John. Now turning to Slide 16. Our investment summary has not changed since the year-end report, but we now have even stronger tailwinds propelling us forward.

Our market opportunity is more than \$1.3 trillion across three exciting franchises and well-established growth opportunities layered in from now and for the next several years.

We continue our relentless approach to securing MRTTP authorization and truly believe we are on the verge of a transformative tobacco franchise for both product sales and licensing on a global scale. The recent and significant move on reduced nicotine mandate makes our reduced nicotine contact technology even more important, positioning 22nd Century to become a clear leader in this category.

Our research in tobacco extends beyond just VLN[®], and our reduced nicotine content technology. We look forward to developing more tobacco-based technologies for various high-value end-use markets.

In addition, we are well-positioned as the potential linchpin technology provider in the upstream segment of the cannabinoid value chain as that industry makes the turn to mass production. We will begin to monetize a portion of our hemp/cannabis IP this year, and have built a network of partnerships giving us a unique and disruptive capability to accelerate the development of new disruptive hemp/cannabis plants and IP on a highly accelerated basis.

As always, we will continue to work hard to execute on the strategic plans we've laid out, and continue to communicate regularly on our successes.

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

Operator

Thank you. At this time, we'll be conducting a question-and-answer session. [Operator Instructions] Our first question comes from Vivien Azer with Cowen. Please state your question.

Vivien Azer – Cowen and Company

Hi. Good morning.

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

Good morning, Vivien.

Vivien Azer – Cowen and Company

Good morning. My first question is on the tobacco side, please. Appreciate the conversation around VLN® is certainly encouraging from your perspective, but I'm just curious to understand how much capacity you really think there is at the agency, given that they are going to be pursuing menthol and there is a pretty heavy lift on the PMTA process on e-cigarettes as well?

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

Good morning, Vivien. This is Mike. It's great question. Clearly, those are all major undertakings when you're talking about two product standards and the PMTA applications that they're processing. Our understanding is that FDA geared up ahead of time on the PMTAs, staffed up in anticipation of that. All of our indications are that it is not impacting the work that is being done to move the nicotine mandate forward, nor the work being done on our MRTP application. So we believe FDA's got the capabilities to manage all of those.

Vivien Azer – Cowen and Company

Okay, that's helpful. Thank you for that perspective. And then just on the cannabis side, I think I heard the word likely, in terms of regulatory change. Certainly, the commentary from Majority Leader Schumer is encouraging, but can you just be a little bit more specific about how you guys are kind of thinking about the timing? At Cowen, we are taking a slightly more conservative approach given that the democrats don't seem inclined to get rid of the filibuster.

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

So the way - great question, Vivien. The way we look at it is there is two compartments. There is the hemp component, which even with the Farm Bill, there is still some uncertainty and confusion out there. And we believe that at the very least, that will be clarified in the relatively short term, certainly this year. That will help at least on the consumer product side. I think that will set the stage for advancements on the consumer product side in the U.S. The legalization on recreational and medical use, that will go through a process. That is where we are focusing our attention offshore, to get the new strains into countries where it has legalization in the appropriate manner.

So our initial strains, we have a combination of the new strains. We've got a combination of such things as high CBG level strains, higher cannabinoid level strains in general. That even with the clarification and the movement on the hemp side in the U.S., we think we can move quickly, and we are in dialogue with several strategic partners in the U.S. to advance that who are encountering these quality issues.

And then right behind that, we do think legalization on the recreational side federally, we think will take place. That is going to take some more time to play out. But in that meantime, we're active on higher quality THC strains offshore and getting those into the hands of strategic partners where the legalization has occurred on a country basis. So for example, the Canadian region.

So that is the way we are looking at it. We will be fully prepared when the U.S. moves on the recreational side to have these strains available. And there's no doubt and the more we have these dialogues with the strategics, the combination of quality and scale really everywhere around the world on the recreational side is becoming more and more of a problem with the strains that they're growing out there.

Vivien Azer – Cowen and Company

Understood. That's very helpful. Thank you.

Operator

Our next question comes from James McIlree with Dawson James. Please state your question.

Jim McIlree – Dawson James Securities, Inc.

Thank you. Good morning. John, is the G&A a new good level going forward or was there some unusual things, one-time things in there that would suggest it's too high or too low for the rest of the year?

John Franzino – Chief Financial Officer, 22nd Century Group

Thank you for the question, Jim. Essentially, we did pull forward some expenses related to developing brand strategies around VLN®, anticipate that for the balance of the year, we have it

budgeted well out, and that is discretionary, some of the expenses are discretionary as we would pursue it.

Overall, we've been focusing on cash burn, and to maintain our cash burn rate, which was similar to the first quarter of about \$1.3 million a month, which given our cash resources will sustain us over a period of time. There may be some shifting around with the G&A expenses. But overall, we anticipate that we will manage them accordingly with the cash burn, and with the margin we gained from contract manufacturing at this point.

Jim McIlree – Dawson James Securities, Inc.

Okay, that's great. Thank you. Jim, you talked about revenue in the second half from the hemp business. I was wondering if you could put ranges around that? Are we talking small amounts, like less than a million for the second half? And then in 2022, are you thinking it's \$1 million to \$5 million? Or is it larger than that?

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

Thanks for the question, Jim. There are two components. There is monetization of the existing library of IP through an upfront license fee that we are in advanced dialogue with. That will come as I said in Q3 to Q4. It's tough to put an exact figure around it. But it's substantive, I'd say in the \$2 million to \$3 million range. But that all drops to the bottom - obviously drops to the bottom line.

In addition to that, based on how we have been resetting things in our network, and this is what I announced earlier, we are starting our first grow of hemp cannabis with our higher strain, plant line strain of CBG, and CBD-CBG combinations. We are putting about five separate lines in the ground. As we speak, the seedlings are on route and we are beginning that growing process.

It will all depend on the exact yields as we get into the October timeframe and harvest. You try to push that time period as far as you can, because the later you harvest, the higher these cannabinoid levels go – we are going to push that to the optimum levels. And then harvest and we have off-take agreements for that biomass, as biomass for the most part in Q4.

That range, again is going to depend on yields. But could be in that \$2 million to \$3 million range in that time period. Some of it could spill into Q1 of 2022, based on the needs of perhaps distillates or isolates if we need to process it that far.

That is, you know, putting a framework around it. It is modest, but it is our first grow. These are highly profitable, high margin strains, and off take commitments that we have put in place.

Jim McIlree – Dawson James Securities, Inc.

Okay, those license fees you are talking about are onetime fees. Those are not annual fees. Is that correct?

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

The first bucket that I was talking about is a one-time with that product for that strategic partner. That could be expanded because it is not exclusive. That particular one is a one-time for that strategic partner.

Jim McIlree – Dawson James Securities, Inc.

Okay. Mike, I was hoping you could help me understand what you think the implications of the menthol ban would have on your VLN[®] application as it relates to menthol. It seems like it's possible that the FDA says to you, wait until menthol is figured out or --?

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

Jim, it's a great question.

Jim McIlree – Dawson James Securities, Inc.

Leave it or -

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

Sorry. I didn't mean to interrupt you there. We don't believe it will impact our application for a couple of reasons. One, the FDA has been working on this issue of a menthol ban for many years going back to the Tobacco Control Act, when they were first granted authority to regulate tobacco.

So it's not a new issue for them. Despite that, they did authorize our PMTA application as you know for both the menthol and non-menthol versions of our reduced nicotine cigarette. The PMTA product is exactly the same product as the MRTP product. They have already decided that a menthol, very low nicotine cigarette is appropriate for the protection of public health. That is the regulatory standard that a PMTA product has to meet.

We don't see that equation or that analysis changing simply because they have announced their intention to put a menthol ban into place. Then secondarily, there is a solid body of science, using menthol reduced nicotine cigarettes to understand what differences there might be between menthol and non-menthol reduced nicotine cigarettes. The results are consistent across both products, whether menthol or non-menthol, that smoking consumption is reduced, quit attempts are increased, it doesn't change the compensatory smoking or withdrawal symptoms. The public health benefit is there based on the science. Clearly a rule, or even a proposed rule that has not been published yet around menthol, we would expect ultimately for

our menthol VLN® cigarettes to be included in the MRTP approval and for it to be accepted from any menthol ban that might come in the future.

Jim McIlree – Dawson James Securities, Inc.

Similar to the prior question, or asking about capacity at the FDA, is it the same group at the FDA that is tasked with the menthol ban as it is with evaluating or approving the MRTP?

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

My understanding - again, this is based from multiple pieces of information - my understanding based on that body of information is that the groups responsible for drafting product standards, reviewing comments that are submitted in response to the proposed rules is a different group than the group that does the bulk of the work on an MRTP application.

I don't think there is any significant overlap, I should say, as it relates to our application. I don't think it slows things down.

Jim McIlree – Dawson James Securities, Inc.

My last one, the 10-K talks about the restructuring of your agreement with Panacea? If you can say, is there anything that has occurred since the end of the quarter that is useful to know, or where are you on that restructuring?

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

We continue down the same path that we have been working towards, it has been very collaborative, and really a win-win approach with Panacea. We're turning our attention to the farm. We have talked through that already and also kind of working with them on the extraction and isolation equipment.

We continue to work on really papering that up. At the same time, working with them to help promote their finished products into the marketplace with the concept of these higher strains are more valuable strains coming through.

We are in the process of heading down the same path that we have been talking about, just a matter of papering everything up. It continues to be a great relationship, and it is very much going in the right direction. The end result is Panacea will undoubtedly have stronger channels to market. It will be able to truly get their finished products moving in the right directions, we are helping to coordinate that as well.

I would think that sometime in the current quarter, we hope to button everything down, and we will communicate when that is all complete. It is heading down the same path we have been talking about, Jim.

Jim McIlree – Dawson James Securities, Inc.

Okay, fantastic. Thanks a lot. And good luck with everything.

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

Thank you.

Operator

[Operator Instructions] I'll now pass it to Mei Kuo to go through some web questions. Thank you.

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

Thanks, Diego. Our first question is, can you elaborate on the genetic modifications you are making to the cannabis plants? And how and why there would be incentive for growers and dispensaries to be using your product? What is preventing you from bringing some of your current developed hemp/cannabis strains to market in the U.S. or elsewhere?

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

Thanks Mei, I'll take that. It is a great question. Let me just create the foundation again, the real critical challenge in the entire industry right now, you can go talk with major Canadian LPs, you can talk with MSOs, or everywhere around the world - as they go into mass production the quality and the stability of the plant strains that they are growing basically implode. They are very problematic. The level of cannabinoids are not consistent. They fluctuate from batch to batch. It just yields a poor consumer experience.

This Monsanto approach we have been talking about - I give Monsanto the gold standard in being able to modulate plants, work in these strategic partnerships in a rapid basis at scale at high quality – we are a boutique version of that. We are only focused on three plant lines, all alkaloid in fact. We have talked about tobacco, hemp, and a third plant line that we will soon announce. That is really our specialty. The opportunity is to address that large scale production.

Now we have several new strains. One of which is ultra high-end THC, one of which is ultra high-end cannabinoids in general, in particular CBG, another one is modulated terpenes lowered to impact the fragrance profile, and the flavor profile. We are continuing to move those move those forward. In fact, the CBG line is one of the ones we are putting in the ground over the next several weeks. CBG, in particular plant strains with CBG, stable plant strains, are kind of a hot property going into the second half of this year and into beginning of next year.

We are in fact moving forward with existing plant lines. We will then turn our attention to the next generation. I have always said, the existing plant lines were a great proof of concept and better than what is in the marketplace today, is still not anywhere near optimized. We will continue to do that with the next strains coming through and hopefully growing in this roughly two-year cycle that we've talked about.

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

Thanks, Jim. Our next question is, do you have any fear that big tobacco has a solution for if/when a nicotine mandate is implemented? They stated publicly that they are decades away, but what if they are just saying this to prevent the government from taking action, and they have actually identified a way to produce low nicotine tobacco?

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

Mei, thanks for the questions. A great question from one of our listeners here. So the-- we do know - we're not afraid here that there are alternative technologies. We do know that one other way that they can produce nicotine cigarettes could be produced would be simply by extracting the nicotine from tobacco plants using well-known extraction processes. In fact, there was a product – a cigarette on the market back in the 80s called Next. It was referred to as a de-nicotinized cigarette, it was launched by Philip Morris. It achieved about 1% market share before they yanked it from the market realizing that wasn't a path that made sense for them to go down as a company that profits from nicotine addiction. They built a \$250 million extraction facility to produce that tobacco. One of the problems that they also had with the product was that smokers didn't really like the taste of it. And the reason for that is because when you extract nicotine, you extract a lot of other things from the plant, including flavor and aroma compounds. So really what you end up with in that process is something that's more akin to paper or saw dust than it is tobacco, because you've taken out all of the flavor alongside the nicotine.

So we believe with our technology, where we are growing tobacco without nicotine as opposed to extracting the nicotine, is a far superior technology, simply because it will be more acceptable to smokers.

We do believe it is true that it will take years for big tobacco to try to duplicate what we have done, if they were to use a genetic editing technology. But we have a very strong intellectual property portfolio, really a very deep and wide moat around all of the genes related to nicotine biosynthesis in the tobacco plant. So while they may be able to use certain tools to create tobacco, they can't commercialize those because of our patents. The industry has acknowledged all of this in their public comments to the ANPRM around the proposed nicotine mandate. We are quite comfortable in our position, that we've got the leading technology to meet the mandate, and other tobacco companies will want to use our technology to comply with the mandate as well.

We have been very clear that we are willing to license our technology across the industry if the mandate were to be put into place. Therefore, that makes it possible for FDA to implement such a mandate. FDA does have to take into consideration whether or not industry can comply. Because we are willing to help the industry comply, that is not a consideration at the end of the day for FDA and considering a mandate.

In short, we are in a very solid position to support the FDA's implementation of a mandate and to help the industry to comply with it, and to monetize our IP in the process of doing that.

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

Thanks, Mike. And speaking of the FDA, was the new equipment to measure nicotine levels in-house a strong suggestion by the agency? Was installing testing and calibrating it a factor in the slow action on the MRTP?

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

It was not a suggestion at all from the FDA. This was a decision - an idea that was brought forward by our team, our operations team. We made the decision to make this investment based simply on the fact that it reduces our costs quite significantly, 90% approximately around testing, and also really speeds things up when it comes to testing. We want to and need to test tobacco when it comes in from the farms to make sure that it is the right nicotine levels and to know what we have in our inventory. Then we test it at every step of the processing manufacturing chain. There is a lot of testing that is involved in that. We want to ensure that every product that leaves our factory is compliant with what we've said it would be. We test every step along the way. That is a lot of testing, it has been costly. When we do the SPECTRUM®, the research cigarette manufacturing orders, this simply reduces our costs and allows us to do all of this much more quickly, which will become of critical importance when we go to market with VLN®. So we made this investment in anticipation of that positive decision on the MRTP coming soon.

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

Thanks, Mike. We have time left for a couple of questions here. There have recently been some news reports about possible IP waiver for COVID-19 vaccines. Are there any similar concerns for 22nd Century or VLN® IP protection?

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

Go ahead, Mike, please.

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

Sure. I think, obviously, this is big news this morning with COVID-19 IP. There are really no similarities between these vaccine situations and our IP related to tobacco. COVID is a global

pandemic that is raging in other parts of the world, while tobacco is certainly an epidemic, it is a well-studied thing, and we have the solution. We have made it clear to the FDA and other regulatory bodies around the world we are willing to license this technology. Unlike some of the COVID vaccine manufacturers, who fought against licensing. So there's really no comparison there. And ultimately growing our tobacco and making it into reduced nicotine cigarettes is virtually the same process as it would be for conventional tobacco and conventional cigarettes. So unlike vaccines, with specialized processes, there is no concerns around that, either. At the end of the day, we are willing to license our IP, and we will do that, at any point in time when the government asks us to do it.

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

Thanks, Mike. And just one last question. I want to make sure we touch on the cannabis side of the business. You raise this idea of a Monsanto of cannabis. Are there other companies with similar approaches? What about large growers? Why can't they move faster than 22nd Century to achieve this?

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

There are really just a few pathways to get to improved product lines. There is a purely synthetic approach, which I helped develop prior to coming to 22nd Century, but that is very expensive and really targeted towards the clinical pharmaceutical use.

There is a biosynthetic approach, fermentation, but there has been a lot of fluff without substance on that approach. I would continue to believe that at least five to seven years just in development. And what you get out is a single cannabinoid, CBD or CBG. Those companies have not been hitting their milestones.

Then there is the standard breeding approach, which is like shooting in the dark. And it's clear that, to get strains that are high quality, high scale - is at least a 7 to 10 year adventure. That's been documented very much.

I just had a call with KeyGene yesterday, again. I continue to be amazed with what they can really do and the speed at which they can work. We apply a different type of science. It's very much like what Monsanto does in the more commodity products like soy and corn. They do not participate in this cannabis hemp space or the alkaloid plants that were homed in on.

We are certainly learning off of that gold standard type of approach. Our technology approach is very unique with KeyGene. Then when you combine that with CannaMetrix and the specific alkaloid specialist breeders we are going to be using in this particular area, plant-based biotechnology that is alkaloid based into large end use markets.

I can assure you there is no one else doing it this way. Where we have a two-year cycle, the closest nearest competitor is in the standard breeding approach, which is realistically 7 to 10 years.

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

Thanks, Jim. I think we ran out of time for questions. But if you have any closing remarks.

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

I just wanted to thank everybody for their time. We continue to have high levels of optimism across all three of our franchises. We look forward to communicating more and moving things forward. So thank you all for your time, and we'll be talking soon.

Operator

Thank you. This concludes today's conference. All parties may disconnect. Have a great day.