

## Second Quarter 2021 Earnings Transcript August 5, 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 22nd Century Group's Second 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. Thank you. Please begin.

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

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SECOND QUARTER 2021 EARNINGS PRESENTATION  
August 5, 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 not 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 second 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 second quarter 2021. We'll start today's call with prepared remarks from Jim, Mike and John before moving into Q&A. 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 [xxicentury.com](http://xxicentury.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 may also discuss non-GAAP financial measures, including adjusted EBITDA, which we define as earnings before interest, taxes, depreciation and amortization as adjusted for certain noncash and nonoperating 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 beginning from Slide 3.


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

Thanks, Mei. Good morning, everyone, and thanks for joining 22nd Century's call today. Before I actually turn to my first slide, I really want to take a moment to let you know what headlines to listen for today. First and foremost, you'll hear new details regarding our MRTTP application that we can now share. These


new details continue to drive our high confidence and a successful outcome. You'll hear about us initiating the VLN® launch process across numerous offshore countries that do not require MRTP. You'll also hear that we believe we will be in these target markets by Q1 2022.

You should also make note that the MRTP is the beginning and not the end game for us. It enables the U.S. launch and fuels additional launches in the remaining offshore countries that are contingent upon MRTP. Ultimately, we'll also have a series of announcements with more detail immediately following the MRTP. You'll hear more about our growing contract manufacturing, CMO business, that broke company records in both Q2 and for our first half of 2021. You'll hear about the monetization of our hemp/cannabis that is coming out of the initial two-year development cycle in the second half of 2021. You'll also hear about our operational network that is now complete and about our superior IP and technology to quickly bring disruptive plant lines to the market with our plant engineering and breeders, including our latest and keystone edition Extractas Bioscience. And you'll hear the exact date of the introduction of our third franchise and what to expect.

### Slide 3



## RECENT KEY GROWTH UPDATES

INITIATIVES	Secure MRTP Authorization	Launch VLN® in Select Global Markets	Commence Hemp/Cannabis Revenue Recognition	Announce Third Franchise August 30
RECENT ACCOMPLISHMENTS	<ul style="list-style-type: none"> <li>▪ In regular contact with FDA and CTP through multiple channels at all levels</li> <li>▪ Highly confident MRTP is in the documentation phase, readying for decision</li> <li>▪ Leveraging all resources in support of MRTP authorization</li> <li>▪ Will continue to escalate actions until MRTP success is achieved</li> </ul>	<ul style="list-style-type: none"> <li>▪ Initiated VLN® launch process in well-known global markets with limited regulatory hurdles</li> <li>▪ Targeting international market sales by Q1 '22</li> <li>▪ MRTP catalyzes U.S. launch and additional international countries</li> <li>▪ Planning southern hemisphere VLN® growing program</li> </ul>	<ul style="list-style-type: none"> <li>▪ Initial revenue to commence 2H 2021 from plant lines and IP (license, biomass and distillate/isolate sales)</li> <li>▪ Accelerating 2022 and 2023 plant lines</li> <li>▪ Secured expert breeder partners to create highly differentiated disruptive plant lines</li> </ul>	<ul style="list-style-type: none"> <li>▪ Large global market with lower regulatory barriers</li> <li>▪ Completing IP and operating partnerships for announcement</li> <li>▪ Will detail market opportunity, timing, path to revenue, and commercial partners at introduction</li> </ul>
 <b>Commence Nasdaq Trading on August 16, 2021</b> <ul style="list-style-type: none"> <li>▪ Greater agility in the hemp/cannabis sector</li> <li>▪ Greater recognition of our role as a leading plant science and technology company</li> </ul>				

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Now turning to the slide. The past quarter has been incredibly productive as we accelerated build-out for revenue growth in both tobacco and hemp/cannabis. I'm sure top of mind for everyone today is our MRTP authorization. We are in regular contact with FDA officials at many levels and through many channels, including very recent conversations at the uppermost level of CTP. We are highly confident that our application for VLN® has completed the scientific review process and is in the report documentation phase, the final stage of the process. I recognize that the delay by FDA in authorizing our VLN® is incredibly frustrating for all of us. This process is taking far too long for a product FDA has itself said is critical to public health and begin to reduce the harm caused by smoking and the 1,300 deaths per day in the U.S. alone. I want to make it clear that we, 22nd century, have the expertise to advance


this far, and we possess the expertise to navigate this to a successful conclusion, utilizing a balance of leveraging the FDA in collaboration.


As I said, VLN® is 100% U.S. market ready. And while we continue to press FDA to act in the U.S. and with new capital on our balance sheet, we've initiated the launch process in several countries that do not require MRTP type of approval to go-to-market with a 95% less nicotine claim. These are well-recognized economies with established tobacco distribution channels and premium tobacco markets suitable for a product like VLN®, and we believe that we will be in these markets by the first quarter 2022. In hemp/cannabis, we expect to monetize our lines and IP completing the first two-year development cycle, beginning in the second half of 2021 with upfront license fees from our Aurora IP partnership, plus revenue from offtake commitments for our entire 2021 crop to be harvested this fall in our Colorado farm property. We're also accelerating our next-generation plant lines for 2022 and 2023 revenue as we leverage our highly disruptive breeding capabilities designed to give commercial customers a differentiated market advantage. We've now secured four of the world's most expert alkaloid-based breeding partnerships in both the northern and southern hemispheres to support rapid commercial scale-up and year-round cultivation of disruptive plant lines. Most recently, we have secured Extractas Bioscience, which may not be a household name to you, but I can assure you, it is the single most experienced and expert alkaloid plant breeder in the world.

I can also share that we will introduce our third franchise on August 30. This will include detail on IP, market information, competitive advantages, plus operation and commercial partnerships in this large, growing \$500 billion addressable global market opportunity that is not bound by the same level of regulatory and legal hurdles we face in tobacco and hemp/cannabis. By fully recognizing the importance of MRTP and remain absolutely dedicated to winning that authorization. All these efforts showcase how 22nd Century is building for the long-term revenue growth and value creation across multiple franchises and global market opportunities.

As part of that effort, we also have announced that we intend to uplist on the NASDAQ stock market with our first day of trading on August 16. In fact, 22nd Century will be ringing the closing bell that day. I want to personally thank the NYSE for all of the support and the people over there for the support to 22nd Century over the years. While remaining dedicated to our primary mission to reduce the harm caused by smoke, uplisting to NASDAQ also aligns 22nd Century with other high achieving, innovative and growth-oriented global science and technology companies. The Company believes that joining the NASDAQ will enhance its visibility to a wide audience of institutional investors and increase our exposure to hemp/cannabis investors at this important time of industry progression towards mass production.

With that, I'll turn it over to Mike to detail our tobacco activities further, then I'll come back and discuss our cannabis and third franchise actions with you. Mike?

Slide 4

 22nd Century Group, Inc.

## SMOKERS DESERVE A CHOICE


- Federally funded studies clearly document the benefits of reduced nicotine content cigarettes
- VLN®'s PMTA affirms its importance to public health
- Highly confident MRTP is in the documentation phase of FDA's review process
- 22nd Century is a leader and has expertise in this effort
- We are leveraging all available tools to balance leverage and collaboration toward a positive outcome

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Thanks, Jim, and welcome to everyone joining our call today. Turning to Slide 4. Federal agencies have spent over \$100 million studying the benefits of our reduced nicotine content cigarettes, which continue to play a central role in FDA's own tobacco harm reduction plan. FDA has also confirmed that our reduced nicotine content cigarettes are appropriate for the protection of public health and their positive decision authorizing our PMTA. There remain no outstanding requests for information from the FDA. And as Jim mentioned, based on our recent discussions at the highest levels of CTP, we are highly confident that our MRTP is now in the documentation phase; the final phase before FDA announces a decision. Even with this encouraging news, we continue to escalate our efforts to ensure a positive outcome.

More broadly, we believe adult smokers have a fundamental right to choose a cigarette that is nonaddictive. To make such a choice, smokers need information about the products available to them, including their nicotine content. And we believe companies, like ours, have a right to communicate to their customers about products that could help reduce the harm caused by smoking. This is why our MRTP application is so critical, and it is past time for FDA to act. We have all the knowledge, expertise and resources needed to achieve success here. We have come farther than anyone in the tobacco industry thought we could and we will finish the job.






**Slide 5**




## PILOT MARKETS ARE READY FOR LAUNCH

Fully prepared for pilot launch leading to national rollout

### Fully Prepared For Commercial Launch of VLN®

-  Launch-ready for commercial sales within 90 days of FDA MRTP authorization
-  Identified both initial pilot and subsequent markets for launch
-  Advanced discussions with multiple trade and retail partners
-  Advancing marketing materials and other important aspects of the launch
-  Pilot program enables 22nd Century to test, measure, and refine materials to maximize the commercial success of VLN



\* Trade dress subject to change

22ND CENTURY'S VLN® PILOT WILL EMPHASIZE TRIAL, REPEAT PURCHASE, AND ADVOCACY BY ADULT SMOKERS

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Shifting to Slide 5. We are ready to initiate a pilot launch of VLN® within 90 days of authorization. Our team has run a number of tobacco product launches, giving us critical insight into the importance of a well-planned market entry and solid supply chain. In our market research, most smokers tell us they are likely to use VLN®. Our pilot program will enable us to test, measure and refine our marketing model to maximize our long-term commercial success with VLN® and then advance to full national rollout, leveraging the most effective tools and messaging. Meanwhile, VLN® continues to be very well received in our discussions with potential retail trade partners. Several are ready to go today, others are maintaining close dialogue with us and ready to engage upon MRTP authorization. We believe this is another indication of the market's recognition of the importance of reduced nicotine content cigarettes and the role they play in FDA's tobacco harm reduction plans.

## Slide 6



### MANUFACTURING RAMP

22nd Century can immediately manufacture VLN<sup>®</sup> cigarettes in commercial quantities



**PRODUCTION RAMP IN Q2 '21 CONFIRMS READINESS TO SCALE VLN<sup>®</sup> FOR GLOBAL SALES**

#### Manufacturing Geared For Strong Commercial Launch

-  62,000 sq. ft. manufacturing facility in NC
-  Manufacturing capacity ~1% of the U.S. tobacco market; increasing to ~3% with minimal investment
-  FDA inspected and cleared as part of the Premarket Tobacco Application (PMTA) process
-  Significantly expanded 2021 VLN<sup>®</sup> growing program to ensure adequate leaf inventory for launch
-  Established internal nicotine content test capabilities- 90% cost reduction, results in 1 day vs. 2 to 4 weeks

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Turning to Slide 6. To support our launch efforts, we are ready to scale VLN<sup>®</sup> manufacturing at our North Carolina facility. Our Q2 tobacco contract manufacturing results support this fact, showing 30% growth in revenue and higher margins. Our CMO program accomplishes two important goals: First, it demonstrates that we can indeed generate new business and produce large volumes of product, readying us for VLN<sup>®</sup> production; second, it ensures that the assets needed to manufacture research cigarettes and VLN<sup>®</sup> are ready and not only paying for themselves, but also self-funding capital investments in added capacity and efficiency. For example, we have brought nicotine content testing in-house, reducing our testing costs by 90% and cutting turnaround times from weeks to hours, all with a payback of less than 1 year. Further readying ourselves for VLN<sup>®</sup> production, 2021 looks to be the largest ever VLN<sup>®</sup> crop, and we're working to expand our VLN<sup>®</sup> growing program by adding growers in the southern hemisphere, allowing the Company to grow our reduced nicotine content tobacco year-round.

**Slide 7**



## ACCELERATING INTERNATIONAL LAUNCH IN MULTIPLE MARKETS




- Initiating launch process of VLN® in countries with lower regulatory hurdles
- Targeting launches by Q1 '22
- Funded by proceeds from June 2021 capital raise
- Adding experienced growers in southern hemisphere for year-round growing of VLN®

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Advancing to Slide 7. Given our readiness on manufacturing and increasing interest in VLN® outside the U.S., we are initiating the launch process in key global markets, accelerated by the proceeds from our capital raise in June. While the Company has made efforts in the past to launch its RNC cigarettes in the EU, regulations there made it difficult, if not impossible, to communicate with smokers about what makes VLN® different from every other cigarette. Therefore, we are targeting countries where we believe regulations will allow us to go-to-market with claims today or with minimal interaction with regulators. Many of these markets also have a strong affinity for new reduced risk tobacco products, and they all have adult smokers with large premium segments. Once we have our MRTP in hand, we can then leverage that FDA endorsement to initiate the launch process in additional countries where regulatory barriers may be higher. In closing my comments, we are 100% committed to the success of VLN® because adult smokers have the right to choose a nonaddictive tobacco cigarette. We have the plans and capabilities in place to launch quickly in the U.S., and we are accelerating the launch of VLN® in markets outside the U.S., where we see an opportunity to generate revenue and gain market experience with VLN®.


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



**Slide 8**

## THE CANNABIS MARKET IS ADVANCING RAPIDLY

22nd Century monetizing initial hemp/cannabis lines in 2021, readying 2022 and 2023 plants



- Rapidly increasing demand is driving the need for optimized plant genetics and proprietary, stable plant lines that deliver higher crop yield for commercial use
- Growing support for federal legalization and increased access for medicinal and recreational use

**22nd Century Moving to Monetization:  
First Revenue From Our Hemp/Cannabis Franchise**


- Plant lines and IP revenue commences in 2H '21
- Accelerating next generation plant lines and IP for 2022 and 2023

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

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Thanks, Mike. So let's turn to Slide 8, which includes a recent photo from our Needle Rock Farm in progress, off to the left-hand side. The continued acceptance of cannabis in the U.S. and other markets is driving increasing recognition of the need for plant genetics tailored for large scale production. It's been a productive few months for 22nd Century as we secured operational partnerships to complete our upstream capabilities, began growing these first lines of high CBD and high CBG plants at our farm property in Colorado for harvest later this year and accelerated additional lines for 2022 and 2023 growing seasons. We're also advancing with strategic commercial partners, building on the base we established with Aurora. We anticipate these will become tangible drivers in 2022 revenue. We're expanding our team and enhancing our international reach to do so, which will enable us to accelerate agreements with well recognized pharma, food, nutrition, medical and recreation and CPG customers that we are in continued dialogue with. In short, our hemp/cannabis business is accelerating to revenue at a very rapid pace.

**Slide 9**



## ACCELERATING COMMERCIALIZATION OF NEW, DISRUPTIVE HEMP/CANNABIS PLANTS

Strategic partnerships enable 22nd Century to deliver valuable, commercial -scale plant lines, and IP in two-year cycles, the first of which is coming to completion.

Plant Profile/ Roadmap	Plant Biotechnology	Plant Breeding & Trials	Plant Cultivation	Ingredient Extraction & Purification
				
CannaMetrix's high-throughput proprietary, human cell-based cannabinoid assay technology serves as a roadmap for developing new hemp/cannabis plant lines with tailor-made cannabinoid & terpenoid profiles.	Established proprietary bioinformatics platform and cutting-edge molecular breeding platform in partnership with KeyGene; capabilities include genetic engineering and plant line development.	Multiple partnerships provide 22nd Century with both northern and southern hemisphere, indoor and outdoor, year-round plant breeding and trial capabilities.	Colorado farm operations provide 22nd Century with operational assets including plant cultivation capabilities.	Panacea provides 22nd Century with extraction and purification services utilizing proprietary plant lines in development.

22ND CENTURY HAS SECURED ALL OF THE KEY PARTNERSHIPS NEEDED TO MAXIMIZE AND SUPPORT EACH COMPONENT IN UPSTREAM SEGMENT OF THE CANNABINOID VALUE CHAIN

On Slide 9, we believe 22nd Century now controls the most comprehensive and innovative upstream cannabinoid value chain in the industry, an asset critical to unlocking commercial success for large-scale cultivation. This is our rapid disruptive approach. Importantly, our breeding partners, now including Extractas Bioscience in Tasmania in the southern hemisphere, are the most expert alkaloid-based plant breeders in the world. They can support commercial scale-up and cultivation of disruptive plant lines far beyond the capabilities of independent competitors or in-house breeding in consumer product companies.

We also have a number of -- made a number of advances in the existing elements of this value chain, starting with the recently signed lease for a research lab in Maryland, very close to KeyGene's facilities, key government regulatory constituents, and important research and standard setting is entirely directed and related to our scientific programs.

I also want to take a moment to emphasize here just how favorable our transaction and conversion with Panacea was to 22nd Century. Effectively yielding a valuable farm asset, an over collateralized note and 91 million shares of common equity in Exactas that can be converted to cash. You can run the math for yourself, but in essence, every cent of appreciation is \$1 million of potential cash towards 22nd Century. The Colorado farm assets in this conversion are a state-of-the-art show piece, and we have access to advanced purification techniques to get distillates and isolates as needed for our customers.


Before wrapping up my remarks, I also want to reiterate that we'll be introducing our third franchise on August 30, 2 weeks after the NASDAQ uplisting. The wait is over as we are confident in our competitive position, and we'll now begin filing IP that will be in the public domain for this large and well-known consumer market. Importantly, this market will leverage much of our existing infrastructure and working

knowledge, but without the high regulatory and legal hurdles of tobacco and cannabis, respectively. I cannot wait to get that into your hands, come the 30th of this month.


And with that, I'll now pass you over to John to review our financial performance. John?

**John Franzino – Chief Financial Officer, 22nd Century Group**

**Slide 10**



## 22ND CENTURY GROUP NASDAQ UPLISTING



- Nasdaq listing effective August 16, 2021
- Symbol will remain “XXII”
- No action required of current investors

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Thanks, Jim, and good morning to everyone. Starting off on Slide 10, I'm sure many of you are excited to see that we'll uplist our common shares to the NASDAQ on Monday, August 16, 2021, and continue to trade under our current symbol XXII. Transferring the listing to NASDAQ aligns the Company with other innovative and growth-oriented global science and technology companies. Joining the NASDAQ will also enable the Company to be more agile -- to be a more agile organization in hemp/cannabis and draw more coverage interest and investment. We've also crossed several momentous milestones this quarter, including new research coverage initiated by Vivien Azer, leading beverages, tobacco and cannabis, senior analyst at Cowen & Company, and the addition of 22nd Century to the Russell 2000, Russell 3000 and Russell Global indexes.

**Slide 11**



## SECOND QUARTER 2021 FINANCIAL HIGHLIGHTS

	Net Sales	Gross Profit	Gross Profit Margin	Operating Loss
2Q 2021	\$8.4M	\$586K	7.0%	\$(6.6)M
2Q 2020	\$6.4M	\$201K	3.1%	\$(4.8)M


**+30% YOY NET SALES**  
**+390 BASIS POINTS YOY GROSS PROFIT MARGIN <sup>1</sup>**

1. Gross profit margin is calculated by dividing net sales revenue by gross profit.
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Now turning to the financial results on Slide 11. As Jim and Mike have stated, we've had a great quarter. Net sales increased by more than 30% to \$8.4 million through a combination of higher volumes, price increases in our contract manufacturing cigarette business. This demonstrates our ability to generate new business and to scale up volumes ahead of launching our VLN<sup>®</sup> cigarettes following the authorization of the MRTP. We are working with a number of potential opportunities to further scale this business. Gross profit margin grew by 390 basis points, our sixth consecutive quarter of year-over-year improvement, demonstrating our ability to execute on the objectives and strategies we set to the business.

Every incremental dollar of CMO contributions helps to cover our operating overhead and fund growth investment rather than utilizing our balance sheet cash to do so. I also want to make clear the importance of our decision to position VLN<sup>®</sup> as a premium cigarette brand and how it will affect our revenue model and margins after the launch. VLN<sup>®</sup> will be priced as a premium brand, which will command higher revenue and margins. Initially, we'll use some of that to fund the launch, but in the midterm, it will generate much greater revenue and margin per carton than our CMO business. The costs of production, the taxes and the other expenses as they go into the production will be notably different from our contract business today, which means these additional dollars will result in higher gross margin and provide additional cash for investments in growth.

## Slide 12


 22nd Century Group, Inc.

## FINANCIAL SNAPSHOT

*\$ in millions*

**Select Financials**

	Three Months Ended June 30,	
	2021	2020
Net sales revenue	\$ 8.4	\$ 6.4
Gross Profit Margin	\$.6	\$.2
Operating loss	\$ (6.6)	\$ (4.8)
Net loss	\$ (4.2)	\$ (5.1)
Net loss per common share basic and diluted	\$ (0.03)	\$ (0.04)
Weighted average common shares outstanding basic and diluted (in thousands)	154,811	138,854

**Summary Balance Sheet Items**

	Quarter Ended	
	June 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 62.3*	\$22.3
Total assets	\$ 97.2	\$51.7
Total liabilities	\$ 9.8	\$7.6
Total shareholders' equity	\$ 87.4	\$44.1

\*Additional \$38.3M cash for growth capital from registered direct offering in June 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.

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We have provided a more detailed comparison of our financials for the quarter on Slide 12. Total operating expenses for the first quarter increased by \$2.3 million, driven by \$2.7 million of higher SG&A expenses, partially offset by \$215,000 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, the Chief Financial Officer and General Counsel, higher noncash personnel costs related to equity compensation, D&O insurance, financial and strategic consulting costs and marketing costs as we move quickly to market readiness in both tobacco and hemp/cannabis.


R&D expenses were lower by \$215,000, driven by lower personnel and contract costs, partially offset by higher tobacco field trial costs and patent fees. We expect to increase investments in R&D going forward as we continue to expand our activities across tobacco and cannabis and add the third franchise. For the second quarter, operating loss of \$6.6 million increased by \$1.9 million over the second quarter of last year. Improved gross margin of \$385,000 is more than offset by \$2.3 million of higher operating expenses. Total other income increased by \$2.8 million, \$2.5 million of that increase was the gain resulting from valuing our equity in Panacea Extractas investment to its public market price and further adjusting the arrangement to obtain the Needle Rock Farm as partial payment for the convertible note receivable previously in place.

Turning to our strength in balance sheet, with more than \$60 million of cash at quarter end, we had the resources to fund the significant runway for growth as our reduced nicotine tobacco and cannabis franchises transition to commercial launch. We raised \$40 million of growth capital through a transaction that was brought to us on very favorable terms. We intend to use the proceeds of that offering to accelerate our revenue progression in a number of ways, including VLN<sup>®</sup>, U.S. launch readiness, commencing our international VLN<sup>®</sup> market launches, accelerating the commercialization of our disruptive hemp/cannabis plant lines and IP, and launching our third franchise.

I'll now pass it back to Jim.

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

**Slide 13**

			
<b>2021 PRIORITIES &amp; AREAS OF FOCUS</b>			
<b>Tobacco Franchise</b>	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <b>01 Secure MRTP Authorization from FDA</b> <ul style="list-style-type: none"> <li>▪ VLN® pilot programs ready to launch</li> <li>▪ Engaging with multiple distribution partners to support national launch capabilities</li> <li>▪ Ramping manufacturing capabilities</li> <li>▪ Moving ahead with international launches</li> </ul> </td> <td style="width: 50%; vertical-align: top;"> <b>02 Support, advance, and advocate for proposed nicotine cap mandate for all combustibles</b> <ul style="list-style-type: none"> <li>▪ Favorable political climate</li> <li>▪ Advancing licensing and partnership initiatives to support industry adoption</li> </ul> </td> </tr> </table>	<b>01 Secure MRTP Authorization from FDA</b> <ul style="list-style-type: none"> <li>▪ VLN® pilot programs ready to launch</li> <li>▪ Engaging with multiple distribution partners to support national launch capabilities</li> <li>▪ Ramping manufacturing capabilities</li> <li>▪ Moving ahead with international launches</li> </ul>	<b>02 Support, advance, and advocate for proposed nicotine cap mandate for all combustibles</b> <ul style="list-style-type: none"> <li>▪ Favorable political climate</li> <li>▪ Advancing licensing and partnership initiatives to support industry adoption</li> </ul>
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<b>Financial</b>	<b>05 Maintain efficient operating structure and balance sheet strength</b> <ul style="list-style-type: none"> <li>▪ Strengthened balance sheet with \$40 million in growth capital to accelerate product launch and commercialization</li> <li>▪ Deploying capital to fuel U.S. VLN® launch readiness, commence international sales of VLN®, accelerate cannabis commercialization and launch third franchise</li> </ul>		

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Thanks, John. So summarizing everything on Slide 13. Our 2021 priorities have not changed since the year-end report, we now have made significant progress with even stronger tailwinds propelling us forward. We'll continue to escalate our actions to secure MRTP authorization, which will kick off the launch of our VLN® products in the U.S. We are accelerating our international launch efforts, looking at multiple countries where we have exciting opportunities. We now control the complete upstream cannabis capability we believe to be the best in the industry with first cannabis revenues coming later this year, and our pending third franchise to be announced on August 30 should be generating revenue within 12 to 18 months after launch. Adding to those meaningful milestones in our operations, a strong balance sheet to fund growth programs across all three of our franchises, and we are in an even stronger position than we were when we started the year.

And with that, operator, please open the call for questions. Thank you very much.

**Operator**

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

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**Vivien Azer – Cowen and Company**

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Hi, thank you so much. My first question to follow-up on your comment around your conversations with the senior-most leadership at CTP. Can you expand on that at all? Did they give you any indications around more concrete timing or any type of procedural next steps on their end?

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

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Good morning Vivien, this is Mike. Thanks for the question. There is not a lot of detail we can provide about the call. These are generally confidential discussions, but we know from activities around other MRTTP products that in the documentation phase, FDA is generating essentially the public documents. So press release announcements and the team reports explaining their decision about the MRTTP authorization. So it's our understanding from our conversations that these are the documents they are generating now leading up to an announcement decision.

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**Vivien Azer – Cowen and Company**

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Understand. That's helpful. And I appreciate your commentary on some of the regulatory constraints around potentially launching VLN® in Europe. I think there are probably some obvious candidates that have lower regulatory requirements and the pension for reduced risk products. As you think about that kind of two stage execution, right, where an MRTTP might improve the conversations that you have with regulators in the EU. How are you thinking about approaching kind of a global opportunity using third party partners? Are you looking for an exclusive global relationship or can you create a geographic path forward?

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

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Yes, great question. At this point, our strategy is likely to be focused on engaging partners that are strong in each of the local markets. And so while there are a couple of global tobacco companies, much of the world also has very strong, let's say, #3 and #4 players that we can potentially partner with. And those would be the folks that we're engaged with, in discussions with at the present time. Of course, we're open to partnering with anybody that we believe can commercialize the product successfully and has the intent to do that.

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**Vivien Azer – Cowen and Company**

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That's helpful. And then just following up on the guidance for revenue generation from those efforts in the first quarter of 2022. Well, I think you said commercialization in the first quarter of 2022, are we meant to understand that is the first quarter of revenue recognition or might you be recognizing revenues in the fourth quarter as you ship those products out?

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

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Yes. The timing is -- so we're referring to revenue recognition. In the situations where we're working with a local partner, then that would occur likely upon delivery of the product. And so that pushes us really into first quarter of next year.

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**Vivien Azer – Cowen and Company**

Okay. Understood. Perhaps moving to the hemp/cannabis segment, please. You're calling for revenue contributions in the second half of '21. We are in the second half of '21. So can you be any more specific about how to think about the phasing from a quarterly perspective? Thank you.

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

Yes, sure, Vivien. Thanks for the question. I'll take that up. It's consistent with what we've been saying over recent calls, which is we expect it to come first from two sources: A, upfront licensing revenue from our original legacy IP, the Anandia IP in concert with our partnership with Aurora as we move that forward. And then also revenue stream from our initial crop grow that is as you saw in the photo well along its way in Colorado. Both of which we primarily anticipated more in Q4 than Q3, although there still may be an opportunity to see some initial components of that coming in late Q3, but more likely consistent with what we said before Q4 of this year.

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**Vivien Azer – Cowen and Company**

Got it. And then last one for me, please. As you think about that revenue ramp, perhaps it is not today, perhaps it is more appropriate for the August 30 presentation. But how are you guys thinking about the potential for operating guidance?

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

We're working that through. I mean we don't give our guidance at the moment, but we do want to get as much information out there and be more transparent. As we move through this quarter, we really hope to quantify this a bit better and to lay that out the next call. A big piece of it, of course, is based on the yields of the first grow in Colorado. And as I've said before, we have options of moving that as flower or further refining it and improving the margin on that product significantly. So we're trying to sort out exactly not only the timing, but the form it will move. And obviously, the further we can refine it, the more we'll do that. We hope to have a bit more information around that, either in between now and the next call to share, or certainly at the next call.

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**Vivien Azer – Cowen and Company**

Terrific, thanks very much and congrats on the NASDAQ uplisting.

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

Thank you very much Vivien. Thank you.

**Operator**



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

**Jim McIlree – Dawson James Securities, Inc.**

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Thank you, good morning. Jim, I think in times past, you've talked about a couple to \$3 million in revenue from the upfront licensing and maybe a similar amount for the initial crop grow. Is my memory correct or has anything changed to those values?

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

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It's in the ballpark, Jim, and thanks for the question. Again, the part we're trying to sort out in more detail is around the grow, in particular, because it is our -- it is disruptive plant lines going in there. It is the first grow, and some of that will depend on yields. And again, more importantly, we're looking at refining the product as much as possible to make it truly differential and the commitments that we have lined up for that are open for that based on the market conditions. So we're trying to quantify that as best as possible, but those types of ranges are certainly what we're targeting.

**Jim McIlree – Dawson James Securities, Inc.**

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Okay, great, thank you. And John, on the operating expenses, are we at a new higher level or was there something temporary in the increase this quarter that we should be aware of that might be coming out in subsequent quarters?

**John Franzino – Chief Financial Officer, 22nd Century Group**

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Can everyone hear me? Yes, thank you, I'm sorry, I pressed the wrong button. Yes, thanks for the question. I think that overall, we are anticipating a higher level of operating expenses, but they'll be characterized in different ways as we move forward. In the quarter we had higher operating expense than last year, having to do with the higher management costs and so on, what you characterize as being in the following half of the year that will be in place. We do plan on increasing our investments in R&D and operating expenses around getting personnel in place with the third franchise to and to further develop the business in both cannabis and tobacco as we move forward. I'd anticipate that our operating expenses will carry forward at a comparable rate to where we are at now through the first half to the second half of the year.

**Jim McIlree – Dawson James Securities, Inc.**

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Okay, thank you. Along those lines, Mike, do you need to increase either physical resources, human resources, anything else for the international launch of VLN®?

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

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Good morning Jim. At the moment, we're not planning to increase any personnel resources. Our strategy is to work with local partners in each country. And so, we have the personnel already in the Company to manage those relationships and develop them. All of the manufacturing resources and tobacco inventory that we need is also sufficient to launch the international market. So right now, as we

have it planned, we can leverage all the resources and the assets that we have today to launch these markets.

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**Jim McIlree – Dawson James Securities, Inc.**

Got it, thank you. And Jim, on the third franchise, should we expect there to be some upfront licensing fees or some sort of IP acquisition or asset acquisition? Do we need to expect that when you announce the franchise on the 30th?

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

The same business model that we are applying on the hemp/cannabis side will apply to the third franchise. So it will have us optionally open towards upfront licensing fees to refine and develop disruptive new strains with commercial partners, utilizing our operational partnership network that already exists with CannaMetrix, KeyGene and the breeders. So the business model will stay the same for upfront revenue stream for large programs and then royalty streams off of that. So we'll quantify that as we move forward, but it will be kind of a two phased approach. There are also opportunities as we're working in hemp/cannabis to drive it out as an ingredient in some form and that we're considering as well. But I'd say the first revenue stream that will come in for that franchise more than likely will be upfront licensing fees to secure these particular programs and strains and then quickly develop them into royalty streams and/or ingredient sales.

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**Jim McIlree – Dawson James Securities, Inc.**

I was asking more on your potential payments to license holders or IP holders?

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

No, we work the same. It's all captured in the same network. So certainly the same type of relationship we have with KeyGene, in particular, will be duplicated in the third franchise. So we don't expect any significant upside payments for that required. That's why we've built a network that is adjacent within these alkaloid plants in order to take full advantage of that. Now if we happen to see additional opportunities that can accelerate this, then I wouldn't rule it out. But right now, we don't feel that as necessary to make significant progress in the franchise.

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**Jim McIlree – Dawson James Securities, Inc.**

And on the hemp/cannabis side, you've built out this soup to nuts network in order to address that market. Are there any holes that you need to fill when the third franchise is complete?

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

No, there is not because the activity that goes on at CannaMetrix can also be applied to the third franchise. In fact, they're already doing it. Likewise, with KeyGene, likewise with the breeders, they're already heavily engaged in this franchise as we've been working it through. So haven't remained idle. We've certainly kept it behind the confidentiality shield for protection. But all these components have

been active, even the ones that we've secured recently by -- on the paperwork, such as Extractas has been engaged in the third franchise. So no, there is really no holes to plug. It's more about keeping our eyes open for ways to accelerate to revenue if we find some new technology that applies or a new partnership that may allow for that.

**Jim McIlree – Dawson James Securities, Inc.**

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Okay, fantastic, thanks a lot. Good luck with everything.

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

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Sure, thanks Jim.

**Operator**

Our next question comes from Aaron Grey with Alliance Global. Please state your question.

**Aaron Grey – Alliance Global Partners**

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Hi, thanks for the questions. Two quick ones for me. So first off, you guys talked about the global hemp/cannabis breeders, could you just if you could give some additional commentary there, maybe how you look for those to be differentiated and how for them to be value-add to your clientele? Thanks.

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

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Sure. And thanks for the question, Aaron. Happy to address it. I think what is most important, and I think some folks fail to recognize as the marketing has developed is that at the end, the hemp/cannabis from a plant biotechnology is really in a nascent phase. It's a start-up phase, whereas it has expanded, the breeding expertise that has primarily found its way into large consumer-based products, Canadian LPs, MSOs, etc. have tapped into the smaller scale breeders that have had wonderful success of bringing artisanal based plants to bear, but at relatively small-scale in greenhouses under very expensive costly conditions.

The requirements in order to get to large commercial scale for the mass markets, whether it is in Canada or the U.S. or what have you, it really requires a much more in-depth knowledge around the alkaloid plant approach itself. It is a very challenging plant to modulate. And especially what has been happening, I think, over the past several years that we have been following it, is that there have been improvements in the plant strains to get them to scale, but they have been incremental. I wouldn't call them disruptive on, for example, the levels of cannabinoids or the yields of cannabinoids or even some of the disease protection around the hemp cannabis. They've been incremental, and they have taken quite some time. A lot of people are working on it. It's moving in the right direction, but it is incremental steps and taking years and years to get there. What we've assembled in this network are these breeders who are not household names, but they have spent their entire legacy of the companies, Extractas over 70 years alone, perfecting ways to modulate the alkaloid plant species, including hemp/cannabis and others. And that expertise tremendously consolidates the time to get truly disruptive technologies and strains to the market.

So our strains as they're coming through the development pipeline and coming out of the back end of the first two-year cycle are not tens of basis points higher in cannabinoids, but hundreds of basis points of active cannabinoids or higher -- much higher yields or much more protective from a disease perspective. So those are what we're trying to bring to commercial scale in this two-year development cycle. So the speed of our network and the disruptive technology that can come from that is where we have carved out a space for ourselves. And that's what's enticing the conversations with commercial partners based on this operational partner network that we have created. Otherwise, there is breeding going on within all these companies, but as you can see, for the past several years, the improvements have been fairly incremental.

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**Aaron Grey – Alliance Global Partners**

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Thanks for that color, that is really helpful. And then just kind of switching gears to MRTP and the potential launch, I think you said pilot launched within 90 days after that is received on very low nicotine. I just wondering now, if you could perhaps provide some incremental color in terms of planned efforts to kind of get in front of consumers through those pilot efforts either through you'd be able to do marketing or kind of how to get consumer initial adoption from whether it be cigarettes or other nicotine products?

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

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Good morning Aaron, this is Mike. Thanks for the question and for joining us. So our plans here, as we mentioned or as I mentioned in my comments, it's a pilot launch. This will be in a limited number of geographies where we will be testing all of the marketing tools available to us. So that will include digital marketing, direct mail as well as advertising at the point of sale. And we'll be testing all of those programs to see where we get the best ROI, and we'll also be testing various messaging options. So how we go about explaining to smokers, what is VLN®, what it is, how it's different from what they're buying and smoking today and why they should be considering it and purchasing it. We'll also be using different tools to generate trial, probably some couponing, probably some activities at the point-of-sale to talk directly with smokers. So essentially, all the tools available to us, which are compared to many consumer products are rather limited because it is a tobacco product. But nevertheless, we know from our prior experience with other tobacco products as a team that there are good tools available to us. And so really, that will be the emphasis on pilot. We'll then take that learning as we plan to scale up the distribution and the sales of the brand nationally and same process internationally, learning and then scaling.

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**Aaron Grey – Alliance Global Partners**

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Okay, great. Thank you so much for the color.

**Operator**

Thank you, I'll now turn the floor back over to Mei Kuo. Thank you.

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

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Great. Thank you. Our first question for Mike, how fast can you generate revenue in these overseas markets? How big are these international markets you referenced today? And are any of the early markets you alluded to meaningful in size?

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

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Yes. Thanks, Mei, and thanks to the audience for the question. Good questions here. There's several of them, so I'll unpack each of them. So we're looking at several markets, at least half a dozen that we're evaluating and zeroing in on the details. Our goal is to launch at least two by first quarter of next year. All of the markets that we're looking at are recognizable, they're well-developed countries. Many of you have probably even visited these places. They are markets where we believe we can go-to-market with MRTTP type claims, including a 95% less nicotine claim right out of the gate on day one without any regulatory review or they are countries where we believe with minimal interaction with the regulatory authorities, we can go-to-market with claims.

So less onerous, more permissive regulations in these markets than what we have in the U.S. or the EU. These are also all markets with established tobacco distribution channels, they have well-developed premium market segments, and they have smokers, in many cases, that have shown a great interest in reduced risk products. And so while the U.S. is after China, the largest market in the world and the most profitable, these are also -- these are the international markets we're looking at, in many cases, are large markets. They are sizable, and they can be meaningful contributors to revenue and gross margin in post-launch and hopefully, in 2022 in terms of margin contribution. However, we're not launching these markets lightly. Our objective is to launch and then achieve profitability as soon as we can. And so as the plans develop, we'll have a -- we'll be able to comment more on revenue recognition and margin contribution as the plans develop. So as background, this is work that I did for many years on the American Spirit business, a brand and a business that I worked on for about 15 years. So this is a familiar area to me as it is to a number of folks on our team, including John, our CFO. So we've got a high level of confidence in our ability to be successful here.

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

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Thanks, Mike. Next question is for Jim. Jim, can you elaborate on what makes our cannabis strains unique or special in the market compared to the synthetic cannabinoids or other approaches to generating higher cannabinoid or THC content?

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

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Yes. Thanks for the question. And look, I'll first start by saying I'm a big proponent of all the various technologies that are out there, the synthetic cannabinoids that I helped found -- co-found that technology is wonderful chemistry put out by really the leader on API base is Purisys. But it's really primarily dedicated to the ultra-high purity pharmaceutical industry based on some of its restrictions. We are also very optimistic, for example, on the biosynthetic approach, we're partnered with the Aurora on the original Anandia IP. But the biggest part of the market today and as it moves forward on a volume and ultimate profit basis to serve all of these consumer end-use markets is the natural basis. So that is why we have turned our attention primarily to the natural grow process.

What makes us unique, again, is the -- certainly, the keystone of it is what happens within KeyGene, the ability to modulate the plant quickly and disruptively. So in other words, moving a THC level or a CBD level from 20% to 22% or 24% is an incremental gain that could take years in order to achieve. Our technology focuses in with the modulation in KeyGene and then accelerants and combining all these new pieces, breeders, CannaMetrix on the targeting side, the farms, etc., one-stop shop by bringing all this together creates this two-year cycle to give you not incremental gains of 2% to 4%, but disruptive gains of 10%, 20%. So you could be yielding CBD levels in the 30 percentages and 40 percentages. So that's what -- the combination of that, along with the speed is our value proposition throughout this entire network. We, 22nd Century, control the IP, we own the IP. We're utilizing and driving this from the highest level, but obviously, setting up win-win partnerships to make sure everyone is heavily engaged and incentivized to move these things through as quickly as possible towards the commercialization with commercial partners. That's why our position is unique. That's why this network is unique, and it's really set up to establish a leadership role, both on a thought leadership with cannabinoids in general, but in a production and disruptive commercial level with this entire network in place, which again, we direct and we control the IP.

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

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Thanks, Jim. And our last question before concluding remarks is for Mike. Why not launch the VLN® in the U.S. given FDA's existing PMTA and lack of timeliness on the MRTP or take FDA to court for a decision?

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

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Yes. Thanks for the question. I'll respond, and then maybe Jim would like to weigh in as well because it is a great question. I'm glad it was asked, and this is a key strategic question. I will say we have -- you can be sure that we've explored all the options, including the ones suggested here, and we continue to explore those. And while they certainly sound appealing given the frustration that we have, and I'm sure many of the listeners here have about FDA's glacial pace, there are certainly downsides or negative consequences to many of these options that take more of a confrontational approach.

And such an approach is likely to change our relationship with the FDA from one that's collaborative to one that's adversarial and counterproductive. And so, for now, at least, we prefer to maintain that collaborative relationship with FDA. And we think that's the best way -- the best thing for smokers in the long run is to work with FDA to get the right information to market and be able to communicate and educate adult smokers about how VLN® can help them reduce their exposure to nicotine. So again, while we're evaluating all the options, we still have a high level of confidence in the approach that we've been taking so far, which is the collaborative approach. But Jim, not sure if you want to weigh in here as well.

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

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Yes, just to add to that, I think the way to look at it is, look, we're in this for both the short-term and the long term, right? So we're doing everything possible to take a look at the short-term gains, which means launching offshore in countries that do not require this MRTP to get moving now that we've got everything buttoned up and ready to go for the VLN® launch in the U.S. So we're getting moving on that for the short term. The MRTP ultimately is going to be required in these other offshore countries to do it

in the most impactful way and probably the most profitable way. But in the U.S., we're in this for the long term. And the upside opportunity, the profitability towards the organization and the growth opportunities are tremendously higher, taking the patience to make sure that we're doing everything with the FDA, the launch in collaboration with them and all the work that they've done on the scientific basis and clinical basis to make the most impact on the harm reduction.

So we don't want to let them off the hook on that. And if we thought for a moment, this is going to take a longer period of time, and we keep all of our options open, but all signs are pointing towards this moving forward in a very collaborative basis, and that will tremendously drive the upside potential not only for the short term, but the longer-term as well. So we have the luxury of a good mix here as we've gotten ourselves organized, both on the short-term offshore launches and still staying in a very collaborative basis with FDA, which ultimately will drive things forward because remember, behind VLN<sup>®</sup> 1.0 is also VLN<sup>®</sup> 2.0, and the impact of that with the new strains coming out, the new non-GMO based strain, the ability to blend doing that, in collaboration with MRTP for the long-term in the U.S. is our driving force. There, we want to make sure that is a long-term play and it adds to Mike's comments as well. But that's all I've got to add to it.

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

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Thanks, Jim, and that was our -- we ran out of time for questions. So we'll just wrap it up here. Do you want to say any concluding remarks?

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

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No, I just want to thank everybody again for their great questions. We'll follow-up with more of them offline that have come in as best as we can. Thank you again for the time. It's a real privilege to always talk to you and look forward to the next get together and the news that will come in between now and then. Thank you, and have a great day.

**Operator**

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