

22nd Century Second-Quarter 2019 Earnings Conference Call

Operator:

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

Thomas James:

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

The statements made on today's call that are not based on historical information are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding our Company's business strategy, future plans and objectives, and future results of operations, or that may predict, forecast, indicate or imply future results, performance or achievements. The words estimate, project, intend, forecast, anticipate, plan, expect, believe, will, will likely, should, may or the negative of such words, or words or expressions of similar meanings, are intended to identify forward-looking statements.

These forward-looking statements are not guarantees of future performance and all such forward-looking statements involve risk and uncertainties, many of which are beyond our Company's ability to control. Actual results may differ materially from those expressed or implied by such forward-looking statements as a result of various factors, including but not limited to the risk factors disclosed in our Company's most recent Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the

Securities and Exchange Commission on March 6, 2019. 22nd Century does not undertake and it disclaims any obligation to update any forward-looking statements or announce revisions to any of the forward-looking statements.

During this conference call, we will also disclose certain non-GAAP financial measures, including Adjusted EBITDA, which we define as earnings before interest, taxes, depreciation and amortization, as adjusted by 22nd Century for certain non-cash and non-operating expenses all as described in our Company's earnings press release for the quarter-ended June 30, 2019, as publicly issued yesterday on August 7, 2019, and which is available on our Company's website.

I would now like to turn the call over to Cliff Fleet, the Company's Chief Executive Officer.

Cliff Fleet:

Thank you, Tom, and thanks to everyone for joining today's call.

I am pleased to be here to discuss 22nd Century, its performance, and what we believe are the Company's bright prospects. I am excited to serve the Company as its newly appointed CEO, and I look forward to working with our shareholders, employees and others to continue building a great business by driving historic change in the tobacco industry to reduce the harm caused by smoking – and by creating a meaningful and profitable business in the emerging, legal hemp/cannabis space. We believe the pursuit of these growth strategies, for which we are very well positioned, will create substantial value for shareholders.

Before we proceed, let me tell you about a few changes to the format of the call. I will talk about the Company's strategies, plans and overall performance, and then John Brodfuehrer, our Chief Financial Officer, will review highlights of the Company's

operational and financial performance for the second quarter and first half of 2019. We will no longer be taking questions from individual shareholders during the call; however, our investor relations team will be happy to address your questions personally after the call. We thank those shareholders and others who submitted questions to us in advance of the call, and we have addressed many of those questions in our communications today. We expect the call will last around 30 minutes.

With that, let's begin.

As the Company recently announced, Henry Sicignano resigned as President, CEO and Board member of 22nd Century for personal reasons. We are thankful for his leadership and contributions to the Company over the past several years as it made tremendous progress against its mission to help reduce the harm caused by smoking, and we are grateful that his expertise, advice and counsel is retained in a consultative capacity to the Company.

Also, as announced earlier this week, I have recently joined the Company as President, CEO and a member of the Board of Directors. As explained more fully in that announcement, my background is in consumer-packaged-goods, particularly tobacco and primarily with Altria, the leading tobacco company in the US, where I was the President & CEO of Philip Morris USA until 2017. Since then, I have worked as an adviser and consultant to several start-ups, high-growth businesses and non-profits, but none proved more interesting than my work with this Company.

Several months ago, I began working with 22nd Century as a strategic advisor because I was intrigued by the work the Company has done in both tobacco and hemp/cannabis. I was impressed by the potential of the organization, and I found it exciting to work with the Company's Board and executive team to develop and refine the Company's strategies to capitalize on its potential. I was flattered and honored when the Board then asked me to step into a leadership role to drive the Company forward.

The success of any organization is predicated upon the strength of its leadership team, and recently the Company made another move of great importance with its elevation of Mike Zercher to the role of Chief Operating Officer, which strengthens what was already a solid leadership team. He has had tremendous success over the course of his career in a variety of domestic and international roles. Mike serves as a vital leader in the organization as we implement our reshaped strategies and pursue the opportunities before us. I am privileged to work with him, the Board and all of our talented employees as we enter the next chapter of growth for the Company.

We believe the Company's prospects are very bright, as we leverage solid foundations in two industries – tobacco and hemp/cannabis – to create future shareholder value.

We are very well-positioned in tobacco as FDA continues moving toward the adoption of a reduced-nicotine product standard that will require all combustible cigarettes sold in the U.S. to contain only minimally or non-addictive levels of nicotine. Moreover, as a recently published survey from the CDC found, 80% of cigarette smokers and 84% of former smokers are in favor of reducing nicotine levels in cigarettes. Clearly, many smokers believe, as we do, along with many in the public health community, that the adoption of this standard is critical to reduce the harm caused by smoking, and so we continue to work to support the efforts of FDA and others to implement this historic change.

We have worked with scientists, clinicians, regulators and others for many years to build the now substantial body of science and evidence to prove conclusively the public health benefits of this proposed standard. We estimate that over the past seven years, FDA and other U.S. federal government agencies have invested more than \$125 million dollars in research using our Spectrum[®] research cigarettes. We believe this research conclusively makes the case that minimally or non-addictive levels of nicotine in cigarettes will significantly reduce the harm caused by smoking – both in our own products and when required for all combustible cigarettes.

Our tobacco-harm reduction efforts also include the recently filed and very important Pre-Market Tobacco Product and Modified Risk Tobacco Product applications for the

Company's proprietary Very Low Nicotine Content cigarettes. With these applications, we are seeking FDA's authorization to commercialize our VLN[®]-branded cigarettes, which contain 95% less nicotine as compared to the 100 leading brands of cigarettes in the U.S.

These applications have been accepted by FDA and are now working their way through FDA's scientific review. Earlier this year, as part of the review, FDA inspected our manufacturing facility where VLN[®] cigarettes will be made. In addition, we continue to have ongoing constructive dialogue with FDA regarding the applications.

We are only the fifth company to have a Modified Risk Tobacco Product application accepted for filing by FDA, and to date FDA has yet to approve any one of those applications. However, we believe approvals of both our PMT and MRTP applications are likely because the products in these applications are identical to the very low nicotine content research cigarettes used in the FDA-sponsored research that I previously highlighted, which underpins the FDA's proposed reduced-nicotine standard. Also, we believe, along with many others, that these products are of critical importance to FDA's regulatory plan for nicotine and for the adoption of a reduced-nicotine product standard, so we remain optimistic about their ultimate approval.

The adoption of the reduced-nicotine product standard and the approval of our VLN[®]-branded products are central to achieving 22nd Century's mission to reduce the harm caused by smoking and to create shareholder value, so we will continue making appropriate investments in these efforts. We continue to develop additional varieties of very low nicotine tobacco, including non-GMO varieties, and we have enhanced our regulatory affairs and scientific capabilities with the addition of John Pritchard as Vice President of Regulatory Science, who was formerly the head of regulatory science for Imperial Brands, U.K. We are actively engaging with various stakeholders around the world to build awareness of our proprietary very low nicotine content cigarettes, our plans to bring these to market, and FDA's plans to require all cigarettes sold in the U.S. to be made minimally or non-addictive.

We believe these efforts will bring about significant benefits to public health and will also create substantial shareholder value. Thus, we will continue to pursue these efforts with vigor and energy as we have over the past few years.

But what is exciting about our future, is that tobacco is just one of the ways we will create value – we believe that by building on our strong base in hemp/cannabis we have another exciting, and potentially even more valuable, path for growth.

The legal hemp/cannabis space in the U.S. is centered around products derived from the hemp/cannabis plant, which is legally defined as cannabis containing less than 0.3% THC. We believe the value of the legal hemp/cannabis products market currently totals one to two billion dollars per year. While not a large market today, with the 2018 Farm Bill legalizing all parts of the hemp plant and with the rapid growth of CBD products, the hemp/cannabis market is believed to be growing faster than even the marijuana industry. Because of this, the value of the hemp/cannabis market could surpass the combined value of the medical and adult-use marijuana markets in just a few years. And because this is a very new, fragmented market, there are no well-established companies and brands.

Rapidly growing spaces with these characteristics present tremendous opportunities for companies who approach such opportunities in a thoughtful manner that builds upon their existing strengths. And we have many strengths that are of value to this emerging space that we plan to leverage to create shareholder value.

22nd Century has what we believe to be a strong position centered on the genetic pathway for cannabinoid production in hemp/cannabis plants that we can leverage for growth. We also bring other strategic assets to this fast-growing category, such as world-class regulatory affairs capabilities, including with FDA, and deep expertise in consumer-packaged-goods branding, marketing and sales. We are seeking the right relationships with emerging organizations in the hemp/cannabis market to leverage these strengths and create long-term value for our shareholders.

Our work in the space began several years ago with our investment in Anandia, which was purchased by Aurora last year. After this purchase, we retained all rights to the research and intellectual property developed in collaboration with Anandia. This includes an exclusive sublicense to the intellectual property that allows us to regulate the genes in the hemp/cannabis plant, as well as the rights to zero-THC hemp plants and other valuable cannabis strains.

We are in the process of making a series of important, thoughtful and comprehensive investments that add to this strong base and strengthen our leadership position around hemp/cannabis plant genetics. We have obtained a license from the State of New York to research and grow hemp in the state. We have enhanced our internal research efforts with a new research lab and additional personnel. We are building a research growing facility, including a greenhouse, in Oregon to support our work in hemp/cannabis. And earlier this year we signed an exclusive, world-wide, multi-year agreement with KeyGene NV. KeyGene is a global leader in plant research involving high-value genetic and agronomic traits. We have partnered with KeyGene to develop hemp/cannabis plants with valuable cannabinoid profiles and other superior agronomic traits. We will hold exclusive worldwide rights to all hemp/cannabis plant lines, intellectual property, and research results that are developed through this exciting and promising relationship.

We believe these efforts to create new plants and IP, in conjunction with other steps that we will take in the future to strengthen our current leadership position in hemp/cannabis plant genetics, will make 22nd Century a sought-after partner and source for unique plants and high value cannabinoid extracts from these plants.

But we aspire to do more, so we are carefully looking at a variety of other ways to become a major player in this emerging space.

We plan to opportunistically create shareholder value through partnerships, investments and other strategic relationships across the entire hemp/cannabis value chain, including branded consumer products. We are thoughtfully surveying the landscape, and

evaluating companies, assets and organizations with the goal of building a platform to drive our growth in this fast-growing and exciting category.

In summary, we feel very good about 22nd Century's position and prospects. We are actively working with FDA and others to implement a new agency rule requiring that all cigarettes sold in the U.S. contain only minimally or non-addictive levels of nicotine. We have successfully filed PMT and MRTP applications which are under review by FDA. We are expanding our strong position built around our hemp/cannabis intellectual property portfolio. We are evaluating opportunities to increase our presence in hemp/cannabis genetics, and we are seeking ways to grow into other areas of the fast-growing hemp/cannabis value chain.

Given the many opportunities before us, it is indeed an exciting time for the Company. I look forward to working with our very talented team, our business partners, our shareholders and others to seize these opportunities and grow our business.

I would now like to turn the call over to John for comments on our operating and financial performance for the second quarter and first half of the year.

John Brodfuehrer:

Thank you, Cliff.

I am going to offer perspectives and highlights on our second quarter and first-half performance for 2019. Details about our Company's performance can be found in our earnings release and quarterly Form 10-Q, both issued yesterday. All financial comparisons in my remarks are against the comparable year-ago time period, unless otherwise noted.

Our financial position remains solid, with the maintenance of a strong balance sheet, adequate liquidity to fund operations, meet obligations as they become due, fund our research and development, and make other potential investments. Our income performance deteriorated from the prior-year periods due to factors I will address in a moment, and our underlying cash utilization rate also increased for the first half of 2019 versus the year-ago comparable time period, but cash utilization improved slightly for the second quarter of 2019 versus the year-ago comparable time period. We expect the comparable numbers for income and cash burn to remain relatively constant as the year progresses, although we remain opportunistic for potential improvement as a result of possible investments to strengthen our business platform for the long-term, which may impact our Company's use of cash and its liquidity position.

For both the three- and six- month periods, net sales revenue decreased from the comparable prior-year periods. For the second quarter, net sales revenue decreased by 15.9% to \$5.8 million dollars, while in the first half of the year net sales revenue decreased by 7.1% to \$12.1 million. This decrease in both periods was principally driven by a decrease in production volume in our contract manufacturing business, in line with industry trends.

Our cost of goods sold increased in both time periods as a percentage of net sales revenue, principally driven by an increase in fees due to the FDA for filtered cigars as well as higher labor and equipment maintenance costs. These cost increases resulted in a slight gross loss on sales during both the second quarter and the first half, versus a slight gross profit in both periods last year.

As context, we maintain our manufacturing operations to produce our Spectrum[®] research cigarettes and in anticipation of FDA's approval of our proprietary, VLN[®]-branded, MRTP cigarettes. In the interim, our contract manufacturing business continues to absorb much of our excess manufacturing capacity and overhead. While tobacco product contract manufacturing is a price-competitive business, we are working diligently to bring our manufacturing costs down to return to a gross profit position on sales.

We are also prudently managing our operating expenses. For example, research and development expense for the Company decreased in both time periods, as the expenses relating to tobacco broadly declined, while expenses related to hemp/cannabis increased, reflecting the shifting strategic priorities of the Company. Last year the Company incurred significant expenses related to its PMT and MRTTP applications, while this year we have increased spending to support work in hemp/cannabis with additional investments in laboratory operations and sponsored research. General and administrative expenses were up in both time periods given a variety of factors. We are going to keep a careful eye on these to ensure we are thoughtful and disciplined.

As a result, and due to items I have already discussed, as well as other items more fully explained in our earnings press release and in our second quarter Form 10-Q filing, 22nd Century had net losses in both time periods this year that were greater than net losses experienced for the comparable year-ago time periods. For the second quarter, the primary reasons for the net loss were a non-cash expense of \$1.9 million relating to the Crede lawsuit settlement and an unrealized loss on our investment in Aurora Cannabis stock warrants of \$1.4 million, although the fair value of the stock warrants was positive at over \$4.6 million dollars at quarter-end. For the first half of 2018, we recorded a significant unrealized gain on our investment related to Anandia. The decrease in this unrealized gain, coupled with the Crede settlement expense were the main reasons for the increased net loss during the first half of 2019.

Our liquidity position remains strong, and we believe that our cash, cash equivalents and short-term investments are adequate to meet our needs for a number of years. However, we must successfully execute our business plan to achieve positive cash flows, which we are working hard to do. Excluding discretionary expenses such as future acquisitions or equity investments, R&D, FDA applications, contract growing and various other items, our monthly cash expenditures are approximately \$1.1 million. We expect that this monthly cash expenditure figure should improve over time as our business growth plan delivers higher revenues and as we thoughtfully manage expenses.

In summary, our financial position remains strong, and we are making thoughtful and necessary investments to strengthen our positions in tobacco and hemp/cannabis. Our strong liquidity position will enable the Company to be opportunistic as we seek future growth opportunities.

Thomas James:

We thank everyone for joining our call today. Listeners with questions may contact our investor relations department through our website. We wish everyone a very good evening.

Operator:

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