

22nd Century Group 1Q 2020 Earnings Transcript

PARTICIPANTS

Corporate Participants

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

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

Andrea Jentsch – Chief Financial Officer, 22nd Century Group

MANAGEMENT DISCUSSION SECTION

Operator: Welcome to 22nd Century Group's First Quarter 2020 Earnings Conference Call. 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

Thanks, Brock, and good morning, everyone. We look forward to discussing our first quarter 2020 results with you today. Joining me for 22nd Century Group's conference call are Mike Zercher, our President and Chief Operating Officer and Andrea Jentsch, our Chief Financial Officer.

Before we begin, we would like to remind everyone that 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.

These forward-looking statements are not guarantees of future performance, and all such forward-looking statements involve risks 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 annual report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 11, 2020.

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 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 Group for certain non-cash and non-operating expenses. All is described in our company's earnings press release for the quarter ended March 31, 2020, as publicly issued today, March 7, 2020, and which is available on our company's website.

I would now like to turn the call over to Mike.



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

Thanks, Mei and good morning, everyone. Before I discuss our results, I'd like to first touch on COVID-19, how we are handling this situation and the impact it has had on our business. Our first priority has been and will remain to ensure the safety and well-being of our employees. Our corporate employees have been operating under a work-from-home policy since March 23, and our R&D lab in Buffalo, New York has temporarily closed to comply with state orders. The company's production facility in North Carolina is classified as an essential business and remains fully operational with heightened health and safety protocols in place. We are very proud of our team and would like to thank all of our employees for continuing their great work under these unusual circumstances with minimal disruption to normal business operations. We will continue to monitor this rapidly evolving situation and look forward to reopening our corporate office and R&D facility as soon as it is legally and safely possible.

Now let me provide an update on our first quarter results and year-to-date accomplishments. We had a solid start to 2020, driven by steady sales as first quarter revenue increased 12% over the prior year. The cost reduction efforts we made last year are starting to reflect in our results, with operating loss improving by 23% in the quarter. This was primarily driven by a reduction in operating expenses and costs associated with our MRTP application. Our solid financial results, combined with the progress we are making with the FDA on our MRTP application as well as the headway we have made in the legal hemp/cannabis space, have well positioned us to continue to successfully execute against our key strategies.

We are now in the "final action" stage of our MRTP application with the FDA. Last month, the FDA set May 18 as the deadline for the submission of public comments to our MRTP application, a milestone in the application review process. Once that deadline has passed, we expect the FDA to then complete its final review of our application and the public comments received. FDA's authorization of our application could come any time after the closing of the comment period.

It is important to acknowledge that in response to COVID-19, some employees from FDA Center for Tobacco Products have been deployed to work for the U.S. Public Health Service, therefore, the pandemic could impact the timing of the FDA's decision about our MRTP application. While we have not received any formal notice directly from the FDA of such a delay, the risk of a delay does exist, as noted in our public filings. Nevertheless, we see the FDA's recent announcement of the closing date of the public comment period is a very encouraging sign that the FDA is continuing to advance our MRTP application and we continue to expect a positive outcome once FDA's review is complete.

The majority of our focus, as would be expected, is currently on our VLN cigarettes and the corresponding MRTP application. As a reminder, a PMTA authorization simply allows a new tobacco product to be sold. The addition of an MRTP authorization is needed in order for us to make certain advertising and marketing claims and to use the brand name VLN. VLN's labeling and marketing materials are expected to contain several reduced exposure claims, most importantly, a claim of 95% less nicotine.

These claims will be what differentiates VLN from all the other cigarette brands sitting alongside it on the store shelves and will be instrumental in its commercial success. Therefore, we remain squarely focused on preparing for the authorization of our MRTP application and on the subsequent launch of VLN into the marketplace.



We continued to make significant headway with our R&D efforts in the first quarter and recently announced the successful completion of research field trials, validating new non-GMO methodologies for reducing nicotine in tobacco plants. The research was conducted by North Carolina State University's Department of Crop and Soil Science and overseen by our R&D team. These trials validate that non-GMO methodologies can be applied reliably to reduce nicotine levels in tobacco plants by up to 99%. The next step is to conduct additional field trials on a larger, more extensive scale to test these new non-GMO, very low nicotine content tobacco lines in multiple locations in various environmental conditions. This work is extremely important as these non-GMO methodologies have already allowed us to dramatically reduce nicotine levels in widely used, bright and burley tobacco varieties, and likely will enable us to reduce nicotine levels in oriental, dark-fired and many other varieties of tobacco currently used in many conventional cigarette and cigar products. Additionally, this technology potentially opens up several international markets for VLN, where non-GMO products are often preferred by consumers. We look forward to providing updates as we progress this important R&D.

Moving on to our work in the legal hemp/cannabis space. Last year, we entered into a strategic R&D partnership with KeyGene, a global leader in agricultural biotechnology, and made an initial investment in Panacea, a rapidly growing, vertically integrated consumer-facing company operating in the legal hemp CBD product space. In March, we announced that 22nd Century and KeyGene, who assembled high-quality genome sequences of two hemp/cannabis lines with important traits and established a new proprietary hemp/cannabis, bioinformatics platform. This sequencing work and the establishment of a comprehensive bioinformatics platform are major milestones in building the company's hemp/cannabis genetics knowledge foundation. Further work is underway to enhance the platform with data from additional plant lines. We have also made significant achievements in the rapid cycle breeding and metabolomics with both high CBD and oilseed hemp/cannabis plant lines widely used in the industry.

Our initial investment in Panacea marks 22nd Century's first investment in the legal hemp/cannabis space and will be accelerated in Panacea's branded CBD products business. The second tranche of our investment in Panacea is predicated upon certain milestones being reached in their business. Panacea is performing as expected despite the challenging environment as they have remained open and operational, continuing to manufacture and sell products. Panacea is led by a great management team and an accomplished CEO focused on making Panacea the leading company in the U.S for hemp-derived cannabinoid products, and we are excited to be working with them. We expect our partnerships with both KeyGene and Panacea to create strong shareholder returns in the years ahead, and we continue to explore additional strategic opportunities in the legal hemp/cannabis space.

I would now like to turn the call over to Andrea for more detailed comments on our operational and financial performance for the first quarter 2020.

Andrea Jentsch – Chief Financial Officer, 22nd Century Group

Thanks, Mike. All financial comparisons in my remarks are against the comparable year ago time period, unless otherwise noted.

As Mike discussed at the top of the call, our operational and financial performance was very solid in the quarter with increased revenue and significant reduction to operating expenses. For the first quarter of 2020, net sales revenue was \$7.1 million, a 12% increase from the prior year as a result of increased sales related to contract manufacturing cigarettes.



Operating loss for the first quarter was \$4.1 million compared to a loss of \$5.4 million. This was primarily driven by a reduction in costs associated with our MRTP application in the prior year and our efforts in expense management.

For the first quarter of 2020, net loss was \$4.0 million, representing a loss per share of \$0.03 compared to net loss of \$2.1 million or a loss per share of \$0.02 for Q1 of 2019. The increased loss was due to change in fair value of Aurora warrants due to the decline in Aurora's underlying share price.

Adjusted EBITDA in the quarter was negative \$3.2 million or negative \$0.02 per share compared to a negative \$4.6 million or negative \$0.04 per share for Q1 of 2019, and an improvement of approximately 30% due to returning our contract manufacturing business to positive gross margin and improving the cost structure of our overall operating base.

Cash used in operating activities during the first quarter was approximately \$4.7 million, flat year-on-year when compared to the first quarter of 2019.

The company's liquidity remains strong with cash, cash equivalents and short-term investment securities totaling approximately \$34 million.

We believe we have adequate liquidity to sustain our normal operations and meet all of our current obligations.

And with that, I'll turn the call back over to Mike for his closing comments.

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

Thanks, Andrea. We feel good about our financial position as we have remained thoughtful in managing expenses and maintaining a strong balance sheet, enabling the company to remain agile. This concludes our earnings call today. If you have any questions, please follow-up with Mei Kuo at investorrelations@xxiicentury.com. Thank you for your interest in 22nd Century, and we look forward to providing another update in our second quarter earnings call in August.

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