



22nd Century Group 2Q 2020 Earnings Transcript

PARTICIPANTS

Corporate Participants

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

James Mish – Chief Executive Officer, 22nd Century Group

John Franzino – Chief Financial Officer, 22nd Century Group

Michael Zercher – Chief Operating Officer, 22nd Century Group

MANAGEMENT DISCUSSION SECTION

Operator

Welcome to 22nd Century Group's Second Quarter 2020 Earnings Conference Call.

At this time all participants are in a listen-only mode. As a reminder, today's conference is being recorded.

At this time, I would like to turn the call over to Mei Kuo, Director of Communications and Investor Relations. Please begin.

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

Thank you, Brock. 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 Chief Operating Officer; and John Franzino, our Chief Financial Officer.

Before we begin, we would like to remind everyone that some of the statements to be made today are forward-looking. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors that may cause actual results to differ materially from those contemplated by these statements. Additional information regarding these factors, can be found in our Form 10-K filed March 11, 2020 and Form 10-Q filed earlier today.

During this call, we will also discuss non-GAAP financial measures, including adjusted EBITDA, which we define as earnings before interest, taxes, depreciation, and amortization as adjusted for certain non-cash and non-operating expenses. All described in today's earnings press release, including a reconciliation of adjusted EBITDA to GAAP net income, which you can find on our website at xxiicentury.com. An archived replay of the webcast will be available shortly after the live event has concluded.

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

James Mish – Chief Executive Officer, 22nd Century Group



Thanks, Mei. Good morning and welcome everyone.

Before we dive into our quarterly update, I'd like to take the opportunity to introduce myself, provide you with some color on my background and my early impressions since joining the company at the end of June.

I started my career as a research chemist for Pfizer Pharmaceuticals before moving on to executive leadership roles at several chemical and ingredients companies, operating in the consumer products, pharmaceutical and cannabinoid spaces, where I sharpened their focus in product innovation and developed and improved their operational and financial performance. My experience in driving transformational growth at these science-driven organizations leads me to believe that there is an opportunity to do the same at 22nd Century.

Since joining the company at the end of June, I spent time getting to know our business by speaking with various stakeholders and familiarizing myself with the tobacco industry. Together with the company's leadership team and Board of Directors, we are now formulating a multiyear strategic plan for our company to include key areas of focus, along with near- and long-term financial targets and operational initiatives.

I appreciate that our investors are eager to hear from management on where we are headed and how and when we are getting there. Suffice it to say, one month isn't sufficient to thoroughly evaluate all of the opportunities ahead. However, I look forward to sharing with you on our next earnings call in early November my vision for the company and the strategies we will pursue to achieve that vision.

I'll end my introduction by saying that, with the addition of our new General Counsel, Steve Przybyla, who joined us last week, we now have a world-class leadership team in place with the deep commercial experience needed for the 22nd Century to be recognized as a leading plant-based biotechnology solutions provider.

Turning now to some financial highlights.

- Net sales revenue grew approximately 11% to \$6.4 million;
- Gross profit continues to show improvement year-over-year, demonstrating the success of targeted actions to improve our margins and cost structure;
- Operating loss improved by approximately \$276,000 in the quarter and \$1.5 million for the first half of the year; and
- Adjusted EBITDA improved 21% for the quarter and 25% for the first half of the year.

I want to thank, in particular, all of our employees who support our contract manufacturing business. They have been the key to keeping our production facility in North Carolina running and fully operational despite the pandemic. Our corporate offices reopened in June and our lab in Buffalo reopened at the end of May. The temporary closure of our lab and the interruption to our workflow resulting from COVID-19 pandemic has caused some modest delays in our internal and external laboratory research operations, as it has with many of our life science counterparts. We will continue to monitor this evolving situation, adapt and remain agile.

Despite the impact of COVID-19, our hemp/cannabis research partnership with KeyGene continued to deliver meaningful results. Over the last few months, we have sequenced more than 250 additional



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hemp/cannabis lines, expanding our knowledge foundation and bolstering the information on our bioinformatics platform. This foundation will enable the identification of the genes and biosynthetic pathways that are responsible for the modulation and production of various cannabinoids and terpenes in the plant.

We have already identified several hemp/cannabis lines that we believe exhibit distinctive levels of key cannabinoids and the associated genetic markers that will allow us to create proprietary plant lines for commercial use. We look forward to continued success with KeyGene and our other partners in the hemp/cannabis and tobacco spaces.

I believe the leadership team at 22nd Century has accomplished much in building a valuable foundation for continued success. I look forward to sharing an update on our progress, our refined growth strategies and our plan to achieve positive cash flow and deliver continued earnings growth.

With that, I'll turn the call over to Mike to provide an update on our tobacco franchise.

Michael Zercher – Chief Operating Officer, 22nd Century Group

Thank you, Jim. I know I speak for the entire management team when I say we're energized by your arrival and commitment to steering the company towards realizing our shared vision of becoming a leading life sciences company.

Since our last earnings call, the public comment period on our MRTTP application has closed. We are now in the "final action" stage of our application. At this time, we've provided the FDA with all of the information they've requested and need in order for them to make a final decision. While the FDA's authorization can come at any time, it is prudent to note that some employees from the FDA Center for Tobacco Products have been redeployed to work for the US Public Health Service in response to COVID-19. Therefore, it is reasonable to expect that this can potentially have an influence on the timing of the FDA's authorization of our application.

That said, just last month, the FDA authorized its second MRTTP application. It is clear that despite COVID, the FDA is still at work and continues to make progress in reviewing outstanding MRTTP applications and more broadly on their comprehensive plan for nicotine – for tobacco control and nicotine regulation. We are hopeful for the FDA's continued momentum and a positive outcome for our application.

In the interim, we are already setting the stage for a successful launch of VLN[®]. We've engaged the agencies developing our marketing and sales programs, and discussions are underway with national, regional and independent retailers and wholesalers to finalize our plans to bring VLN[®] to market. Our most recent crop of reduced nicotine tobacco was harvested last year and is now in the final stages of processing. Our factory is ready to go, and we're already taking steps where we can to complete state-level registrations needed to bring VLN[®] to market.

More importantly, we are eager to offer adult smokers a meaningful alternative to the highly addictive tobacco products offered by others. We have an enormous opportunity here at 22nd Century. We expect VLN[®] to be the first and only tobacco – combustible tobacco cigarette for adult smokers who are looking to reduce their consumption of nicotine.



In the US alone, there are over 30 million adults who smoke and nearly 1 billion worldwide. According to a CDC study, more than two-thirds of smokers in the US want to quit and more than half of them tried to quit in the prior year. However, fewer than 1 in 10 adult cigarette smokers succeed in quitting each year. Nicotine, the highly addictive chemical found in conventional tobacco products, keeps people addicted to smoking and tobacco use.

Our consumer research shows 60% of adult smokers are likely to buy VLN[®]. This is a high level of consumer interest, and we feel very good about the chances of commercial success for VLN, which we believe will be the first and likely the only combustible cigarette to ever receive an MRTP authorization.

Numerous independent scientific studies have conclusively demonstrated that adults who smoke reduced nicotine content tobacco cigarettes:

- reduce their nicotine exposure and dependence;
- smoke fewer cigarettes per day;
- increase their number of smoke-free days; and
- double their quit attempts

These studies, funded largely by the FDA, NIH and other US federal government agencies, clearly indicate the benefits of VLN[®] cigarettes.

In addition to providing 22nd Century with a path to market for VLN[®], the authorization of our MRTP application will also be a key milestone on the path towards implementing FDA's proposed product standard requiring all combustible cigarettes sold in the US to contain minimally or non-addictive levels of nicotine. The science is clear and the consumer benefits of VLN[®] cigarettes are real and significant. The public health opportunity is even greater. VLN[®] will benefit those people who smoke now and will protect future generations from the harm caused by smoking.

In our tobacco R&D program, we continue to expand our portfolio of proprietary reduced nicotine content tobacco plant lines and intellectual property with our non-GMO tobacco research. Despite COVID-19, our team was able to complete the planting of our non-GMO lines for our multi-site field trials. These field trials will help us identify the very best non-GMO plant lines to commercialize and also determine the best growing practices for these proprietary plants.

Our non-GMO technology has already been applied to bright and burley tobacco lines and can be applied to virtually any variety of tobacco. This will enable us to bring to market reduced nicotine cigarettes and other tobacco products with almost any conventional flavor profile. This will be an important factor in the implementation of the FDA's reduced nicotine product standard and will also allow us to access many international markets where GMO products are banned or not well received by consumers. We look forward to adding non-GMO VLN cigarettes to our portfolio.

I'll now turn the call over to John for a review of our financial results.

John Franzino – Chief Financial Officer, 22nd Century Group

Thank you, Mike, and good morning, everyone.



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I'd also like to welcome each of you to today's call and thank you for joining us. I am honored and excited about the opportunity to serve as the company's Chief Financial Officer and to help identify the best path forward for 22nd Century.

My discussion this morning will include a review of our second quarter and year-to-date financial performance, my initial observations, and a sense of what to expect in the near-term. Let's begin by diving into the numbers. Unless I say otherwise, all numbers presented are rounded for ease of reference and comparisons I will be referring to are on a year-over-year basis unless otherwise noted.

Net sales revenue for the second quarter and for the first half of 2020 was up approximately 11%. The increases were primarily driven by higher volume and pricing in our contract manufacturing business. In the second quarter, gross margin improved by 460 basis points, and for the first half of the year, gross margin improved by 520 basis points. The improvements were primarily the result of lower labor and overhead costs and price increases.

Operating loss for the second quarter improved by \$276,000. The improvement was driven by positive gross profit, which was partially offset by higher operating expenses. Year-to-date, operating loss improved by \$1.5 million. This improvement was driven by favorable gross profit of \$488,000 and lower operating expenses.

Operating expenses decreased as a result of lower R&D expense, which was partially offset by an increase in SG&A expense. The majority of the decrease in R&D expense was driven by lower personnel and contract costs this year and a reduction in expenses related to our MRTTP application in the prior year. The increase in SG&A expense was driven by higher consulting and professional services, D&O insurance premiums and one-time personnel expenses.

In the second quarter, the company experienced a net loss of \$5.1 million, representing an improvement of \$3.0 million. In addition to the improvement in operating loss, other income and expense improved by \$2.7 million. This improvement was due to an unrealized gain on Aurora warrants of \$1.7 million recognized this quarter, a legal settlement of \$1.9 million recognized last year and favorable interest income in 2020.

Partially offsetting these improvements is an impairment charge of \$1.1 million in the second quarter related to our Panacea stock warrant investment. Macroeconomic factors, including headwinds to CBD sales and competition in the overall hemp and cannabis industry, FDA uncertainty and continued disruption from COVID-19 which collectively led us to taking this provision.

In the first half of 2020, net loss improved by \$1 million. Operating loss, which improved by \$1.5 million and was offset by an increase to other income and expense by \$443,000, the increase in other income expense was driven by the aforementioned noncash impairment charge related to our investment in Panacea and was offset by interest income from Panacea this year and a legal settlement expense of \$1.9 million recognized last year.

Adjusted EBITDA for the quarter was favorable by 21% and improved 25% year-to-date. As of June 30, 2020, net cash used in operating activities totaled \$11.5 million for the year-to-date period. The company ended the quarter with cash, cash equivalents and short-term investment securities totaling approximately \$29 million.



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Cash burn for the first half of the year included nonrecurring one-time costs related to professional services, executive search fees and professional and personnel expenses. Given the nature of those expenses, we do not expect the same trend to continue into the second half of the year. We are prudently managing our operating expenses while also balancing the need to strategically invest in key areas of focus in front of future growth opportunities that will deliver returns over time.

While we do not have immediate plans to raise capital at this time, we have filed a new shelf registration with the SEC. The new shelf registration will replace our previously expired shelf registration and will provide us with flexibility and optionality to make crucial investments should they be compelling in the future.

In summary, our financial position remains strong. We will continue to exercise strict cost controls, optimize our resource allocation and seek to deploy capital to achieve the greatest return on our investments. In the coming months, I will be partnering with both Jim and Mike to help sharpen our focus and refine our business plans.

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

James Mish –Chief Executive Officer, 22nd Century Group

Thanks, John.

In closing, I look forward to working with our very talented team, our business partners, our shareholders, and other important stakeholders to seize the incredible opportunities ahead. I look forward to communicating my vision and strategic priorities during our third quarter earnings call in early November. Thank you for your time and your continued interest in 22nd Century. If you have any questions following today's call, please reach out to May Quo at investorrelations@xxiicentury.com.

Operator

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