22nd Century Group, Inc. Files 2019 Annual Report

Maintains Strong Balance Sheet; Momentum Continues for Modified Risk Tobacco Product and Major Milestone Achieved in Hemp/Cannabis Research

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)--22nd Century Group, Inc. (NYSE American: XXII), a leading plant biotechnology company in reduced nicotine tobacco and hemp/cannabis plant genetics research and development, yesterday filed its Annual Report on Form 10-K for the year ended December 31, 2019. A supplemental letter from Michael Zercher, President and Chief Operating Officer to shareholders is available in the Investor section of the Company’s website.

“We are pleased with the Company’s overall progress, achieving major milestones in pursuit of our strategic objectives. We are bullish on what the potential authorization of our Modified Risk Tobacco Product application will represent for the company,” said Mike Zercher, President and Chief Operating Officer of 22nd Century Group.

“In addition, we are making strides in the legal hemp/cannabis space. Through our partnership with KeyGene, we have assembled a high-quality genome sequence of two hemp/cannabis plant lines and established a new proprietary hemp/cannabis bioinformatics platform. These achievements are an example of the valuable and innovative early results that will enable the rapid breeding of novel hemp/cannabis plants which have exceptional cannabinoid profiles for medical and therapeutic use,” Zercher added.

For the fourth quarter of 2019, our accomplishments and notable events include:
In late November, the Company entered into Warrant Exercise Agreements with all of the holders of its outstanding warrants to purchase up to 11,293,211 shares of common stock with an exercise price of $2.15 per share whereby the Company and the exercising holders agreed that the exercising holders would exercise for cash all of their warrants at a reduced exercise price of $1.00 per share, generating gross proceeds of approximately $11.3 million.

In early December, the Company announced that it had conducted an initial closing of an investment in Panacea Life Sciences, Inc., (“Panacea”) a vertically-integrated developer, producer and seller of legal, hemp-derived, CBD products, with extraction, distillation, testing and manufacturing operations located in Golden, Colorado. The Company’s investments in Panacea from such initial closing through the ensuing twelve to eighteen-month period are expected to be approximately $24 million, in a combination of cash and shares of the Company’s common stock in exchange for Panacea-issued debt and Panacea preferred stock.

In mid-December, the FDA publicly announced that it had authorized the Company to sell in the U.S. its very low nicotine content tobacco cigarettes that were the subject of its Premarket Tobacco Product Application (“PMTA”) under the brand names Moonlight® and Moonlight Menthol®.

Subsequent to the end of the fourth quarter of 2019, our accomplishments and notable events include:
In mid-February, the FDA’s Tobacco Products Scientific Advisory Committee (“TPSAC”) conducted a public hearing regarding the Company’s Modified Risk Tobacco Product Application (“MRTPA”) for its very low nicotine content tobacco cigarettes for which the Company is requesting a reduced exposure marketing authorization from the FDA to market its very low nicotine content tobacco cigarettes in the U.S. under the proposed brand name of VLN® and with product labeling and advertising claims stating that VLN ® has 95% less nicotine than conventional cigarettes, among other claims. This meeting was the first time that TPSAC considered an MRTP application for a modified exposure claim, and it was also TPSAC’s first discussion of an application for a combustible tobacco product. The Company presented data in support of its product applications, and FDA also presented perspectives on the applications and posed questions for the committee members to discuss. Recordings of the proceedings, briefing materials for the committee and the FDA, and presentations given by different stakeholders are publicly available on FDA’s website. The public comment period on the Company’s MRTPA remains open at this time, and the FDA continues their comprehensive evaluation of the Company’s application.
In late February, the Company appointed Lisa Parks as its Vice President of Acquisitions and Mei Kuo as its Director of Communications and Investor Relations. Parks will drive the Company’s strategic partnership activities focused on creating a synergistic portfolio of operating companies to commercialize the Company’s proprietary hemp/cannabis plants and intellectual property in development. Kuo will serve as the primary liaison between the Company, its external stakeholders and the investment community with a focus on improving investor engagement.

In early March, the Company announced that it has completed, in just under three months, the first, high-density, hemp/cannabis genome sequencing through its partnership with KeyGene. The data has been integrated into a comprehensive bioinformatics platform developed by KeyGene for visualization and analytics of all available genomic transcriptomic and metabolomic datasets. These achievements are an example of some of the valuable, early results delivered by the exclusive, worldwide strategic research and development collaboration between the Company and KeyGene that is focused on developing proprietary, valuable and new hemp/cannabis plants with exceptional cannabinoid profiles for medical and therapeutic use.

Fourth Quarter & Full Year 2019 Financial Summary

- As of December 31, 2019, the Company’s liquidity remains strong, with cash, cash equivalents, and short-term investment securities totaling approximately $39.0 million. The company maintains working capital of $37.0 million and has total debt of $1.5 million.
- Net sales revenue for the fourth quarter 2019 increased to $7.3 million. Net sales revenue for full year 2019 was $25.8 million, a decrease of $0.6 million, or 2.2% from full year 2018. This decrease in net revenue was primarily from sales of SPECTRUM® research cigarettes during fourth quarter 2018 in the amount of $0.6 million that did not recur in the fourth quarter of 2019.
- Operating loss for the fourth quarter was $5.6 million, a favorable decrease of $0.3 million, or 4.3% from the same quarter in the prior year. The improvement was primarily due to a decrease in operating expenses of approximately $0.5 million. For full year 2019, operating loss was $23.6 million, an improvement of approximately $0.5 million, or 1.9% compared to prior year.
- Net loss for the fourth quarter was $6.2 million, representing earnings (loss) per share of ($0.05), compared to net loss of $8.9 million, or earnings (loss) per share of ($0.07) for fourth quarter 2018. Net loss for full year 2019 was $26.6 million, or ($0.21) in earnings (loss) per share, compared to net loss of $7.9 million or earnings (loss) per share of ($0.06) for the year ended December 31, 2018. The increased net loss for the full year was driven primarily by a one-time gain on investment in 2018 related to the realized gain of $14.5 million in 2018 as a result of the Company’s investment in Aurora, which was not repeated in 2019, as well as impairment charges of $1.1 million, inventory write-offs of $1.0 million, and gross profit reduction of $0.9 million in 2019.
- Operating cash flow for fourth quarter 2019 was ($2.9) million compared to ($5.3) million in fourth quarter 2018. The improvement was driven by a reduction in net loss of $2.7 million for fourth quarter of 2019. For full year 2019 operating cash flow was ($14.6) million, an improvement of $3.3 million.
- For full year 2019, Adjusted EBITDA was ($15.6) million, an improvement of $3.7 million when compared to the prior year. Please refer to Non-GAAP Financial Measures below for a reconciliation of Adjusted EBITDA to net income (loss).

Non-GAAP Financial Measures

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

<table>
<thead>
<tr>
<th>Year Ended December 31,</th>
<th>2019</th>
<th>2018</th>
<th>% Change</th>
</tr>
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<tbody>
<tr>
<td>Net income (loss)</td>
<td>($26,558,544)</td>
<td>($7,966,911)</td>
<td>233%</td>
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Adjustments:
Impairment 1,142,349 - -
Amortization and depreciation 1,186,343 1,199,794 (1%)
Amortization of license fees 238,661 142,541 67% 
Severance expense 880,838 - -
Unrealized loss (gain) on investments 2,419,348 (284,400) (951%)
Realized gain on the sale of investments - (14,492,968) (100%)
Realized (gain) loss on short-term investment securities (220,872) 54,451 (506%)
Litigation expense 1,890,900 - -
Gain on the sale of machinery and equipment (87,351) - -
Warrant liability (gain) loss - (48,711) (100%)
Accretion of interest on note payable and accrued severance 47,775 10,939 337%
Accretion of interest on convertible note receivable (21,978) - -
Equity-based employee compensation expense 3,539,745 3,187,331 11%
Inventory write-off 985,238 - -
Interest Income (1,066,323) (1,069,036) (0%)
Interest Expense 56,382 10,939 415%

Adjusted EBITDA
$(15,567,492) $(19,256,032) (19%)  

About 22nd Century Group, Inc.
22nd Century Group, Inc. (NYSE AMERICAN: XXII) is a leading plant biotechnology company focused on technologies that alter the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering, gene-editing and modern plant breeding. The Company's primary mission in tobacco is to reduce the harm caused by smoking by bringing its proprietary reduced nicotine content cigarettes with 95% less nicotine than conventional cigarettes to adult smokers in the U.S. and international markets. The Company's primary mission in hemp/cannabis is to develop proprietary hemp/cannabis plants with unique cannabinoid profiles and desirable agronomic traits and to commercialize those plants through a synergistic portfolio of strategic partnerships in the hemp/cannabis industry. 

Learn more at xxicentury.com, on Twitter @_xxicentury and on LinkedIn.

Cautionary Note Regarding Forward Looking Statements
This press release contains forward-looking statements concerning our business, operations and financial performance and condition as well as our plans, objectives and expectations for our business operations and financial performance and condition that are subject to risks and uncertainties. All statements other than statements of historical fact included in this press release are forward-looking statements. You can identify these statements by 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. These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and 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 and others that could cause actual results to differ materially from those contained in our forward-looking statements, please refer to "Risk Factors" in our Annual Report on Form 10-K filed on March 11, 2020. 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 otherwise required by law.

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Source: 22nd Century Group, Inc.