



2019 | **ANNUAL
REPORT**

Letter to Shareholders

Dear Fellow Shareholders,

It has been an exciting year at 22nd Century Group as we strengthened and expanded our leadership position in the development of reduced nicotine tobacco products and hemp/cannabis plant genetics and intellectual property.

The two industries in which we operate – tobacco and legal hemp/cannabis – are plant-based, highly regulated and consumer facing. They also differ in important ways. The tobacco industry is mature, under fire and dominated by a few major players thereby making it a target for disruption. The legal hemp/cannabis industry is emerging, rapidly-growing and highly fragmented with an unmet but meaningful consumer demand for differentiated products backed by trusted companies. We believe we are very well positioned to create value in these two large industries by leveraging our strengths and expertise in plant genetics, intellectual property, regulatory affairs and consumer packaged goods.

Our two applications to the U.S. Food and Drug Administration (FDA) to bring our proprietary Very Low Nicotine Content (VLNC) tobacco cigarettes to market have moved steadily through the regulatory review process. In December 2019, FDA authorized our initial application to allow the sale of our VLNC tobacco cigarettes, stating that the sale of our products is “appropriate for the protection of the public health because of the potential to reduce nicotine dependence in addicted adult smokers.” In February 2020, we successfully presented our second application to FDA’s Tobacco Products Scientific Advisory Committee (TPSAC). The presentation of this application, requesting authorization of the brand name VLN® and certain labeling and advertising claims, including “95% Less Nicotine,” was a key milestone in the application review process.

Our consumer market research indicates an astonishing 60% of smokers are likely to buy our VLN® cigarettes. With over 34 million smokers in the U.S. and nearly 1 billion smokers worldwide, the commercial and public health opportunities for 22nd Century’s VLN® cigarettes are enormous. As our regulatory team continues to work closely with the FDA on the final steps of the application review process, we look forward to the launch of our reduced nicotine tobacco cigarettes in the U.S. with FDA’s authorization of our brand name, VLN®, and marketing claims.

Our science and regulatory teams continue work in support of the FDA’s implementation of a proposed rule mandating minimally or non-addictive levels of nicotine in all cigarettes in the U.S. This proposed product standard, which our products already meet, could lead to industry-wide demand for access to our VLNC tobacco plants and patents. Also, this important public health proposal by FDA, which is backed by over \$100 million of independent, clinical research conducted using our VLNC tobacco cigarettes, could save millions of lives and prevent millions more people, in particular youth, from becoming addicted to nicotine. We look forward to FDA’s continued progress in the rule-making process in the coming year.

In legal hemp/cannabis, we continue to leverage our scientific assets and our expertise in plant research and development to create value in this emerging, rapidly-growing industry. In our own labs and in our hemp/cannabis plant research partnerships, we are focused on producing proprietary and unique hemp/cannabis plants with valuable, new cannabinoid profiles and agronomic traits. In the past year, we further established our position as a leader in hemp/cannabis plant science through an exclusive, global research partnership with KeyGene, a Netherlands-based company that is itself a leader in agricultural biotechnology. Through the use of cutting-edge sequencing technologies and KeyGene’s proprietary bioinformatics platform, we created one of the first high-quality maps of the hemp/cannabis plant genome in just a few short months. We will continue our genetic mapping work as well as other activities already underway applying KeyGene’s plant research know-how and development tools to hemp/cannabis plant mutagenesis, transformation, regeneration, rapid-cycle speed breeding and metabolite quantification. This first year in our KeyGene partnership was thus an

exciting start to a novel process in the world of hemp/cannabis plant genetics that is expected to yield valuable, new, proprietary hemp/cannabis plants and intellectual property for 22nd Century.

To complement our hemp/cannabis plant research, we have implemented a strategy to develop strategic partnerships to generate profitable revenue in the legal, hemp-derived CBD products space and to commercialize our proprietary plants and intellectual property in development. Our first partnership was formed last year with Panacea Life Sciences (Panacea), a vertically integrated company located in Golden, Colorado. We look forward to Panacea’s continued growth as they focus on their branded, legal, hemp CBD products business. We believe 22nd Century’s leadership position in the legal hemp/cannabis space will be well-supported by the marketplace differentiation resulting from the commercialization of our proprietary, unique and valuable hemp/cannabis plants and intellectual property through our strategic partnerships.

In conclusion, we continue to advance our reduced nicotine tobacco plant science, intellectual property and commercialization strategies, and we look forward to a positive decision from FDA authorizing the launch of our VLN® reduced nicotine tobacco cigarettes in the U.S. with our requested claims. We also continue to execute our hemp/cannabis strategies to leverage our scientific and commercial assets and capabilities to further establish our leadership position in the emerging, fast-growing and legal hemp/cannabis space. We thank you for your continued interest in and support of 22nd Century and the important work we are doing to improve and enhance quality of life through innovative and leading plant science.



Michael J. Zercher
President & Chief Operating Officer



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

Annual Report under Section 13 or 15(d) of the Securities
Exchange Act of 1934

For the fiscal year ended December 31, 2019

or

Transitional Report under Section 13 or 15(d) of the
Securities Exchange Act of 1934

Commission File Number: 001-36338

22nd Century Group, Inc.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

98-0468420
(IRS Employer
Identification No.)

8560 Main Street, Suite 4, Williamsville, New York 14221
(Address of principal executive offices)

(716) 270-1523
(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, \$0.00001 par value	XXII	NYSE American

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act
Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.
Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.
Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files)
Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer Accelerated Filer Non-Accelerated Filer Smaller Reporting Company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Act). Yes No

As of June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate value of the registrant's common stock (excluding approximately 5.8 million shares held by affiliates), based upon the \$2.09 price at which such common stock was last sold on June 28, 2019, was approximately \$249 million.

As of March 11, 2020, there were 138,856,809 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2020 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of December 31, 2019.

Table of Contents

PART I.		4
	Forward Looking Statements	3
Item 1.	Business	4
Item 1A.	Risk Factors	16
Item 1B.	Unresolved Staff Comments	28
Item 2.	Properties	28
Item 3.	Legal Proceedings	28
Item 4.	Mine Safety Disclosures	29
PART II.		30
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	30
Item 6.	Selected Financial Data	32
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	33
Item 8.	Financial Statements and Supplementary Data	44
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	44
Item 9A.	Controls and Procedures	44
Item 9B.	Other Information	47
PART III		47
Item 10.	Directors, Executive Officers and Corporate Governance	47
Item 11.	Executive Compensation	48
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	48
Item 13.	Certain Relationships and Related Transactions and Director Independence	48
Item 14.	Principal Accountant Fees and Services	48
PART IV		48
Item 15.	Exhibits and Financial Statement Schedules	48
SIGNATURES		53

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 that may cause actual results to differ materially from those that we expected, including:

- Our ability to achieve profitability and positive cash flows;
- The timing of the implementation by the U.S. Food and Drug Administration (“FDA”) with respect to regulations that will require all cigarettes sold in the United States to contain only minimally or non-addictive levels of nicotine;
- Our ability to obtain FDA authorization to market our Very Low Nicotine Content cigarettes as a Modified Risk Tobacco Product with product labeling that includes the proposed brand name of VLN® and states that the VLN® product has 95% less nicotine than conventional cigarettes;
- Our ability to obtain revenue from the licensing of our technology and/or our sale or licensing of our Very Low Nicotine Content tobacco and/or product;
- Our ability to manage our growth effectively;
- Our ability to retain key personnel;
- Our ability to enter into additional licensing transactions;
- Our ability to gain market acceptance for our products;
- Any potential negative impact from doing business in the legal hemp and medical cannabinoid space;
- Our ability to develop new or proprietary hemp strains for new medicines and agricultural crops;
- The strict enforcement of federal laws regarding state-legal cannabis/marijuana;
- Our ability to comply with government regulations;
- Our ability to compete with competitors that may have greater resources than we have;
- The potential for our competitors to develop products that are less expensive, safer or more effective than ours;
- The potential exposure to product liability claims, product recalls and other claims;
- The expected outcome or impact of any on-going or new litigation matters; and
- Our ability to adequately protect our intellectual property and to avoid infringement on rights of third parties.

For the discussion of these 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 this Annual Report on Form 10-K. The forward-looking statements included in this Annual Report on Form 10-K are made only as of the date hereof. 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.

Unless the context otherwise requires, references to the “Company” “we” “us” and “our” refer to 22nd Century Group, Inc., a Nevada corporation, and its direct and indirect subsidiaries.

PART I

Item 1. Business.

Background

22nd Century Group, Inc. was incorporated under the laws of the State of Nevada on September 12, 2005 under the name Touchstone Mining Limited. On January 25, 2011, we entered into a reverse merger transaction with 22nd Century Limited, LLC, which we refer to herein as the “merger.” Upon the closing of the merger, 22nd Century Limited, LLC became our wholly-owned subsidiary. After the merger, we succeeded to the business of 22nd Century Limited, LLC as our sole line of business.

22nd Century Limited, LLC was originally formed as a New York limited liability company on February 20, 1998 as 21st Century Limited, LLC and subsequently merged with a newly-formed Delaware limited liability company, 22nd Century Limited, LLC, on November 29, 1999. Since inception, 22nd Century Limited, LLC has sponsored research and subsequently used biotechnology to regulate the nicotine content in tobacco plants.

Overview

We are a plant biotechnology company focused on technology that allows us to alter the level of nicotine and other nicotinic alkaloids in tobacco plants and the levels of cannabinoids in hemp/cannabis plants through genetic engineering and modern plant breeding. Our mission in tobacco is to reduce the harm caused by smoking by introducing adult smokers to our proprietary, Very Low Nicotine Content (“VLNC”) tobacco and cigarettes. Our mission in hemp/cannabis is to develop proprietary varieties of hemp with valuable cannabinoid profiles and other superior agronomic traits. We have a significant intellectual property portfolio of issued patents and patent applications relating to the tobacco and hemp/cannabis plants.

In tobacco, we have developed unique and proprietary bright and burley VLNC tobaccos that grow with at least 95% less nicotine than tobacco used in conventional cigarettes. In the year 2011, we developed our SPECTRUM[®] research cigarettes in collaboration with independent researchers and officials from the FDA, the National Institute on Drug Abuse (“NIDA”), which is part of the National Institutes of Health (“NIH”), the National Cancer Institute (“NCI”), and the Centers for Disease Control and Prevention (“CDC”). Since 2011, we have provided more than 28 million research cigarettes containing our VLNC proprietary tobaccos for use in numerous independent clinical studies at many well-known study locations, with agencies of the United States federal government investing more than \$125 million in such independent clinical studies. The results of these independent clinical studies have been published in peer-reviewed publications (including but not limited to the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and many others) and demonstrate that our VLNC tobaccos have been associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events. A list of completed and published clinical studies using cigarettes made with our VLNC tobaccos is shown on our website at <http://www.xxicentury.com/published-clinical-studies/>. A list of on-going clinical studies using our SPECTRUM[®] research cigarettes is shown on our website at <http://www.xxicentury.com/on-going-clinical-studies/>. We do not incorporate the information on our website into this Annual Report on Form 10-K.

The results of such numerous completed and on-going clinical studies provide the independent scientific foundation for the public announcement on July 28, 2017 by the FDA that the FDA plans to enact a new rule to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. On March 19, 2018, the FDA publicly announced its Advance Notice of Proposed Rulemaking (“ANPRM”) to solicit public comments on the FDA’s plan to enact a new nicotine reduction rule. On July 16, 2018, we publicly submitted to the FDA our formal written response to the ANPRM in which we described how (i) the FDA’s proposed new rule is supported by rigorous independent, published science, (ii) the FDA’s stated goal to render cigarettes minimally or non-addictive is immediately feasible as evidenced by our production and delivery of more than 28 million VLNC research cigarettes since the year 2011, and (iii) the FDA’s proposed new rule is exceedingly practical and urgently needed in the interests of public health. After we obtain all necessary regulatory approvals, we plan to offer our proprietary VLNC cigarettes for domestic sale, for international sale, and for licensing by third parties.

Since our proprietary VLNC tobaccos have been the subject of numerous completed and on-going, independent clinical studies paid for by agencies of the U.S. federal government, we are investigating the use of our VLNC tobaccos in our own products that will be intended to comply with the new proposed FDA regulations. On December 5, 2018, we submitted to the FDA a new Pre-Market Tobacco product application (“PMTA”) and on December 27, 2018, we submitted to the FDA new Modified Risk Tobacco Product application (“MRTPA”), in each case for our VLNC tobacco cigarettes for which we are requesting a reduced exposure marketing authorization from the FDA to market our VLNC tobacco cigarettes as a Modified Risk Tobacco Product with product labeling that includes the proposed brand name of VLN[®] and states that the VLN[®] product has 95% less nicotine than conventional cigarettes.

On December 17, 2019, the FDA publicly announced that it had authorized us to market in the U.S. our VLNC tobacco cigarettes under the product names of Moonlight[®] and Moonlight Menthol[®] that were the subject of our PMTA. Our Moonlight[®] and Moonlight Menthol[®] cigarettes are made with our proprietary VLNC tobacco and, as a result, contain very low levels of nicotine. Our Moonlight[®] and Moonlight Menthol[®] cigarettes were modeled after our VLNC SPECTRUM[®] research cigarettes. Our PMTA reference more than 50 independent studies conducted using our proprietary SPECTRUM[®] research cigarettes. In its public announcement relating to our PMTA, the FDA stated that following a rigorous science-based review of our PMTA, the FDA had determined that authorizing these reduced nicotine products for sale in the U.S. is appropriate for the protection of the public health because of, among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure and cigarette consumption. The FDA further stated that the FDA had determined that non-smokers, including youth, are also unlikely to start using these products, and those who experiment are less likely to become addicted than people who experiment with conventional cigarettes.

On February 14, 2020, the FDA’s Tobacco Products Scientific Advisory Committee (“TPSAC”) conducted its public hearing regarding our MRTPA for our VLNC cigarettes. This meeting was the first time that TPSAC considered an MRTP application for a modified exposure claim and also TPSAC’s first discussion of an application for a combustible tobacco product. We presented data in support of our product applications and FDA also presented perspectives on the applications and posed questions for the committee members to discuss. Recordings of the proceedings meeting materials, including briefing materials for the committee provided by the Company and FDA, and presentation given by the different stakeholders are publicly available for review via FDA’s website. The public comment period on the applications remains open at this time. The FDA continues to conduct a comprehensive evaluation of our applications.

We are also investigating licensing the use of our VLNC tobaccos by third parties as well as opportunities relating to our VLNC tobaccos outside of the United States.

In hemp, we are developing proprietary hemp strains for potential important new medicines and agricultural crops. Our current activities in the United States involve only work with legal hemp in compliance with U.S. federal and state laws. The hemp plant and the marijuana plant are both part of the same *cannabis* genus of plant, except that hemp has not more than 0.3% dry weight content of delta-9-tetrahydrocannabinol (“THC”). The federal Agricultural Improvement Act of 2018 (the “2018 Farm Bill”) legalized hemp and cannabinoids extracted from hemp in the U.S., but such extracts remain subject to state laws and the regulation by other U.S. federal agencies, such as the FDA and the U.S. Department of Agriculture (“USDA”). The same plant, with a higher THC content, is marijuana, which is legal under certain state laws, but which is currently not legal under U.S. federal law. The similarities between these plants can cause confusion. To reflect this difference in law, sometimes we refer to legal hemp and the legal hemp industry as hemp/cannabis to distinguish this as being separate and apart from marijuana/cannabis currently not legal under U.S. federal law. Our activities with legal hemp have sometimes been incorrectly perceived as us being involved in federally illegal marijuana. This is not the case. In the United States, we work only with legal hemp in compliance with federal and state laws.

We have a license in the State of New York to research and grow hemp in response to the numerous public announcements by New York Governor Andrew Cuomo that New York State intends to become a leading grower and producer of hemp and hemp-derived products. Elsewhere in the United States, we have previously worked with the University of Virginia (“UVA”) to (i) create unique industrial hemp plants with guaranteed levels of THC below the legal limits that define hemp for optimal growth in Virginia, (ii) optimize other desirable hemp plant characteristics to improve the plant’s suitability for growing in Virginia and in similar legacy tobacco regions of the United States, and (iii) utilize high-value medical cannabinoid hemp varieties and specialized cannabinoid extraction processes for use in human therapeutics. In Canada, we have previously conducted sponsored research on the hemp plant with Anandia Laboratories (“Anandia”) in Vancouver, British Columbia, in compliance with Canadian regulations. In Europe and the United States, we are working with KeyGene NV (“Keygene”), global leader in plant research involving high-value genetic traits and increased crop yields, in an exclusive, worldwide collaboration that will focus on developing hemp/cannabis plants with exceptional cannabinoid profiles, including zero-THC content and other superior agronomic traits for medical, therapeutic and agricultural uses, among many other applications.

On December 3, 2019, we 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 a 51,000 square foot facility in Golden, Colorado. Our 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 our commonstock in exchange for Panacea-issued debt and Panacea preferred stock. We also received a warrant from Panacea to purchase additional shares of preferred stock of Panacea, which upon full exercise will provide us with a controlling equity position in Panacea.

We currently are primarily involved in the following activities:

- Continuing to work with the FDA on our MRTPA that we have submitted to the FDA to obtain a reduced exposure marketing authorization for our VLNC cigarettes to be marketed in the United States under the proposed brand name of VLN[®] as containing 95% less nicotine than conventional tobacco cigarettes, and other related claims as may be approved by the FDA;
- Facilitating the implementation of the plan by the FDA to require that all combustible cigarettes in the United States contain only minimally or non-addictive levels of nicotine.
- Seeking licensing agreements and strategic partnerships to commercialize our VLNC tobacco technology and/or our proprietary VLNC tobaccos in the U.S. and internationally;
- Continuing to produce *SPECTRUM*[®] research cigarettes for the National Institute on Drug Abuse (“NIDA”), which is part of the National Institutes of Health (“NIH”), for use in independent clinical studies;
- Continuing to expand our legal hemp activities and development of unique plant varieties of hemp, including (i) hemp plants with other desirable agronomic traits in addition to low to no amounts of THC for the legal hemp industry, and (ii) hemp plants with high levels of CBD and other non-THC cannabinoids for the legal medical cannabinoid markets;
- Continuing to explore opportunities to create shareholder value through partnerships, investments and other strategic relationships across the entire legal hemp/cannabis value chain, including branded consumer products; and
- Continuing to seek additional customers to increase our contract manufacturing business for third-party branded tobacco products.

Our future prospects depend on our ability to generate and sustain revenues from (i) licensing and/or sale of our proprietary tobacco, technology and/or products; (ii) regulatory approval by the FDA of our MRTPA for our Very Low Nicotine Content cigarettes with product labeling that includes the proposed brand name of VLN[®] and states that the VLN[®] product has 95% less nicotine than conventional cigarettes; (iii) the manufacture of filtered cigar and cigarette brands of third-parties at our manufacturing facility in North Carolina; and (iv) our expanding activities in the legal hemp industry. Our ability to generate meaningful revenue from our proprietary tobacco, technology, and products in the United States depends on: (i) the implementation by the FDA of regulations that require all combustible cigarettes sold in the United States to contain only minimally or non-addictive levels of nicotine; (ii) obtaining FDA authorization to market our potential Modified Risk Tobacco Product, VLN[®], in the United States as a modified risk or reduced exposure product; and (iii) our ability to license our technology and/or to sell our proprietary tobacco and products in international markets. Even after we receive regulatory approvals necessary to market our products in the United States or internationally, we must still meet the challenges of successful marketing, distribution, and consumer acceptance.

Very Low Nicotine Content Tobacco

Our mission in tobacco is to reduce the harm caused by smoking by introducing adult smokers to our proprietary, VLNC tobacco and cigarettes. The FDA publicly announced on July 28, 2017, that tobacco use remains the leading cause of preventable disease and death in the United States. The website of the U.S. Centers for Disease Control and Prevention (“CDC”) states that tobacco use causes more than 480,000 deaths per year and with direct health care and lost productivity costs totaling nearly \$300 billion each year in the United States. The CDC website also states that in 2015, nearly 7 in 10 (68.0%) adult cigarette smokers wanted to stop smoking and more than 5 in 10 (55.4%) adult cigarette smokers had made a quit attempt in the prior year.

Our proprietary VLNC tobaccos, which grow with at least 95% less nicotine than tobacco used in conventional cigarettes, have been shown in numerous published, independent clinical studies as being associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events. These clinical studies, which were conducted by independent researchers and paid for by United States federal government agencies, provide a foundation of independent scientific support for recently proposed changes by the FDA in the regulatory approach in the United States to address the harm caused by smoking combustible tobacco cigarettes. We believe these changes will significantly benefit us in the future as discussed in greater detail below.

Very Low Nicotine Content Cigarettes

The proprietary tobacco in our VLNC cigarettes contains at least 95% less nicotine than conventional cigarette brands. The strategy behind our VLNC tobacco cigarettes is to reduce smokers' exposure to nicotine, which is the primary addictive component of cigarettes.

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of Modified Risk Tobacco Products, which includes cigarettes marketed to (i) reduce harm or the risk of tobacco-related disease or (ii) reduce or eliminate exposure to a substance ("Modified Risk Cigarettes"). The Tobacco Control Act required the FDA to issue specific regulations and/or guidance regarding applications submitted to the FDA for the authorization to label and market Modified Risk Tobacco Products. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance*. We believe that our VLNC tobacco cigarettes will qualify as Modified Risk Cigarettes.

On December 5, 2018, we submitted to the FDA a new PMTA and on December 27, 2018, we submitted to the FDA a new MRTPA, in each case for our VLNC tobacco cigarettes for which we requested a reduced exposure marketing authorization from the FDA to market these products as Modified Risk Cigarettes with product labeling that includes the proposed brand name of VLN[®] and states that VLN[®] has 95% less nicotine than conventional cigarettes.

On December 17, 2019, the FDA publicly announced that the FDA had authorized us to market in the U.S. our VLNC tobacco cigarettes under the product names of Moonlight[®] and Moonlight Menthol[®] that were the subject of our PMTA. Our Moonlight[®] and Moonlight Menthol[®] cigarettes are made with our proprietary VLNC tobacco and, as a result, contain very low levels of nicotine. Our Moonlight[®] and Moonlight Menthol[®] cigarettes were modeled after our VLNC SPECTRUM[®] research cigarettes. Our PMTA reference more than 50 independent studies conducted using our proprietary SPECTRUM[®] research cigarettes. In its public announcement relating to our PMTA, the FDA stated that following a rigorous science-based review of our PMTA, the FDA had determined that authorizing these reduced nicotine products for sale in the U.S. is appropriate for the protection of the public health because of, among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure and cigarette consumption. The FDA further stated that the FDA had determined that non-smokers, including youth, are also unlikely to start using these products, and those who experiment are less likely to become addicted than people who experiment with conventional cigarettes.

The FDA's Tobacco Products Scientific Advisory Committee ("TPSAC") conducted a public hearing on February 14, 2020, regarding our MRTPA for our VLNC tobacco cigarettes for which we are requesting a reduced exposure marketing authorization from the FDA to market our VLNC tobacco cigarettes in the U.S. as a Modified Risk Tobacco Product with product labeling that includes the proposed brand name of VLN[®] and states that the VLN[®] product has 95% less nicotine than conventional cigarettes.

This meeting was the first time that TPSAC considered an MRTP application for a modified exposure claim and also TPSAC's first discussion of an application for a combustible tobacco product. We presented data in support of our product applications and FDA also presented perspectives on the applications and posed questions for the committee members to discuss. Recordings of the proceedings meeting materials, including briefing materials for the committee provided by the Company and FDA, and presentation given by the different stakeholders are publicly available for review via FDA's website. The public comment period on the applications remains open at this time. FDA continues to conduct a comprehensive evaluation of our applications.

SPECTRUM[®] Government Research Cigarettes

NIDA, which is a part of NIH, provides the scientific community with controlled and uncontrolled research chemicals and drug compounds through its Drug Supply Program. In 2010, NIDA included an option to develop and produce research cigarettes with various levels of nicotine (from very low to high) in its request for proposals for a five-year contract for Preparation and Distribution of Research and Drug Products. We agreed, as a subcontractor to RTI International (“RTI”), to supply cigarettes with different nicotine contents (from very low to high) to NIDA. In August 2010, we met with officials from NIDA, FDA, RTI, CDC and the National Cancer Institute (“NCI”) to finalize certain aspects of the design of these research cigarettes. These government research cigarettes produced by us under the mark *SPECTRUM[®]* have been, and continue to be, distributed by RTI for NIDA to independent researchers for scientific clinical studies. The *SPECTRUM[®]* research cigarette contract was renewed in 2019 for an additional five years.

Since 2011, the FDA, NIDA and other federal government agencies have invested more than \$125 million in independent clinical studies utilizing our proprietary tobaccos, with such studies being conducted at many well-known locations, including the Mayo Clinic, the MD Anderson Cancer Center at the University of Texas, the Johns Hopkins University, Duke University, the University of Pittsburgh, the University of Minnesota, the University of Vermont, the University of California, and others. Since 2011, we have provided more than 28 million *SPECTRUM[®]* research cigarettes for use in these independent clinical studies. The *SPECTRUM[®]* product line consists of a series of 24 cigarette styles (11 regular and 13 menthol versions) that have 8 different levels of nicotine – from very low to high. A list of the completed, independent clinical studies on our proprietary tobaccos can be found on our website at <http://www.xxiicentury.com/published-clinical-studies/>. A list of the on-going, independent clinical studies on our proprietary VLNC tobacco can be found on our website at <http://www.xxiicentury.com/on-going-clinical-studies/>. We do not incorporate the information on our website into this Annual Report on Form 10-K.

FDA’s Proposed Mandate to Require Minimally or Non-Addictive Levels of Nicotine in all Cigarettes in the United States

The Family Smoking Prevention and Tobacco Control Act of 2009 (“Tobacco Control Act”) granted the FDA authority over the regulation of all tobacco products in the United States. While the Tobacco Control Act prohibits the FDA from banning cigarettes outright, it allows the FDA to require the reduction of nicotine or any other compound in tobacco and cigarette smoke.

In a June 16, 2010 press release, Dr. David Kessler, the former FDA Commissioner, recommended that “the FDA should quickly move to reduce nicotine levels in cigarettes to non-addictive levels. If we reduce the level of the stimulus, we reduce the craving. It is the ultimate harm reduction strategy.” Shortly thereafter in a *Washington Post* newspaper article, Dr. Kessler said that the amount of nicotine in a cigarette should drop from about 10 milligrams to less than 1 milligram.

In 2015, the World Health Organization (“WHO”) Study Group on Tobacco Product Regulation published an advisory note on a global nicotine reduction strategy of limiting the sale of cigarettes to brands with a nicotine content that is not sufficient to lead to the development and/or maintenance of addiction. The WHO study stated that no specific amount of nicotine has yet been identified by the WHO as the absolute threshold for addiction; however, the WHO report stated that it is likely to be equal to or possibly less than 0.4 mg/g of dry cigarette tobacco filler. The WHO report cites 22nd Century’s proprietary *SPECTRUM*[®] research cigarettes as meeting such a low level of nicotine of 0.4 mg/g of cigarette tobacco filler. The WHO report concluded that the evidence indicates that setting a maximum allowable nicotine content for all cigarettes could (i) reduce the acquisition of smoking and progression to addiction, (ii) reduce the prevalence of smoking in a proportion of addicted smokers as a result of behavioral extinction, (iii) increase the rate of quitting and reduce the number of smokers who relapse, and (iv) increase the development, availability, and use of alternative forms of nicotine, e.g. smokeless tobacco products, nicotine aerosol products, and medicinal nicotine, which have potential adverse health effects, including maintenance of addiction, but less than those of combusted products or conventional cigarettes. The WHO report stated that population benefits will result from decreased use of combusted tobacco by current cigarette smokers and from the prevention of addiction of non-smokers to cigarettes, especially among young people.

On July 28, 2017, FDA Commissioner Scott Gottlieb, M.D., announced the FDA’s plan to exercise its authority under the Tobacco Control Act to require that all combustible cigarettes sold in the United States must contain only minimally or non-addictive levels of nicotine. In that public announcement, FDA Commissioner Gottlieb stated that (i) the overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes – the only legal consumer product that, when used as intended, will kill half of all long-term users, (ii) unless this course is changed, 5.6 million young people alive today will die prematurely later in life from tobacco use, (iii) envisioning a world where cigarettes would no longer create or sustain addiction, and where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of the FDA’s efforts, and (iv) tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths per year and direct health care and lost productivity costs totaling nearly \$300 billion each year.

On August 16, 2017, *The New England Journal of Medicine* published an article by FDA Commissioner Scott Gottlieb, M.D. and Mitchell Zeller, J.D., the Director of the FDA/CTP, entitled “A Nicotine-Focused Framework of Public Health.” In this article, FDA Commissioner Gottlieb and FDA/CTP Director Zeller stated that the Tobacco Control Act gives the FDA a regulatory tool called a tobacco “product standard” that can be used to alter the addictiveness of combustible cigarettes, and that such standards may set requirements related to an ingredient or constituent in a tobacco product, or related to any other aspect of product composition, construction, or other property, and that the establishment of the right product standard could alter the addictiveness of combustible cigarettes by setting maximum nicotine levels in such products. The article further stated that Section 907 of the Food, Drug, and Cosmetic Act authorizes the FDA to establish tobacco product standards that the FDA has determined to be appropriate for the protection of the public health, with the statute specifically noting that such a standard may address nicotine yields, among other characteristics. Although the statute prohibits the FDA from requiring the reduction of nicotine yields of a tobacco product to zero, the FDA stated in this article that the FDA has clear authority to otherwise reduce nicotine levels. The FDA concluded in this article that a nicotine-limiting standard could make cigarettes minimally addictive or non-addictive, helping current users of combustible cigarettes to quit and allowing most future users to avoid becoming addicted and proceeding to regular use, and that disrupting that progression – from experimentation to regular use to tobacco-related disease and even death – could save millions of American lives. In this article, the FDA also stated that the FDA will consider peer-reviewed, scientific studies in proposing a maximum nicotine level, but that rigorous studies of Very Low Nicotine Content cigarettes have evaluated the potential effects of various nicotine levels on smoking behaviors and biomarkers, and findings from such studies could inform decision-making on a possible maximum nicotine level in tobacco filler. The FDA stated that, as in all matters of public health policy, the FDA will be led by the science in this important area.

In summary, since 2011, the FDA, NIDA and other federal government agencies have invested an estimated \$125 million in independent clinical studies utilizing 22nd Century’s proprietary tobaccos, with such studies being conducted by scientists at many different and well-known clinical study centers. During that same time, we have provided more than 28 million proprietary *SPECTRUM*[®] research cigarettes for use in such independent clinical studies. The results of these studies have been published in peer-reviewed articles and reflect the independent scientific support for the planned mandate by the FDA that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. We believe that our VLNC tobacco technology and our production and delivery of more than 28 million proprietary research cigarettes since 2011 reflects that the FDA’s plan to dramatically reduce nicotine in cigarettes is technically achievable. Since our proprietary VLNC tobacco has been the subject of numerous completed and on-going independent clinical studies, we are investigating the potential use of our VLNC tobacco in our own products that will be intended to comply with the new FDA regulations, as well as investigating the potential license of the use of our VLNC tobacco by third-parties. In the United States, we are focused on working with the FDA on its nicotine reduction mandate and on our Modified Risk Tobacco Product application (“MRTPA”) that we submitted to the FDA in December 2018 for our Very Low Nicotine Content cigarettes with product labeling that includes the proposed brand name of VLN[®] and states that the VLN[®] product has 95% less nicotine than conventional cigarettes. Outside the United States, we will focus on working with WHO-member countries that desire to utilize our proprietary VLNC tobacco to implement the WHO recommendation of limiting the sale of cigarettes to brands with a nicotine content that is not sufficient to lead to development and/or maintenance of addiction.

A list of the completed, independent clinical studies that used our proprietary VLNC tobacco can be found on our website <http://www.xxicentury.com/published-clinical-studies/>. A list of the on-going, independent clinical studies on our *SPECTRUM*[®] research cigarettes can be found on our website <http://www.xxicentury.com/on-going-clinical-studies/>. Information on our website (including links to third party websites) is not incorporated into this Annual Report on Form 10-K.

Hemp/Cannabis

Our mission in hemp/cannabis is to develop proprietary varieties of hemp with valuable cannabinoid profiles and other superior agronomic traits. Our current activities in the United States involve work with only legal hemp in compliance with U.S. federal and state laws. The hemp plant and the marijuana plant are both part of the same *cannabis* genus of plant, except that hemp has not more than 0.3% dry weight content of delta-9-tetrahydrocannabinol (“THC”). The federal Agricultural Improvement Act of 2018 (the “2018 Farm Bill”) legalized hemp and cannabinoids extracted from hemp in the U.S., but such extracts remain subject to state laws and the regulation by other U.S. federal agencies, such as the FDA and the U.S. Department of Agriculture (“USDA”). The same plant with a higher THC content is defined as marijuana, which is legal under certain state laws, but which is not legal under U.S. federal law. The similarities between these plants can cause confusion. To reflect this difference in law, sometimes we refer to legal hemp and the legal hemp industry as hemp/cannabis to distinguish this as being separate and apart from marijuana/cannabis currently not legal under U.S. federal law. Our activities with fully legal hemp have sometimes been incorrectly perceived as us being involved in federally illegal marijuana. This is not the case. In the United States, we work only with legal hemp in compliance with U.S. federal and state laws.

We have developed various types of hemp plants with agronomically desirable traits for commercial uses and/or unique cannabinoid levels for possible extraction purposes. We believe that we have many types of superior and unique hemp plant varieties, including (i) hemp plants with low to no amounts of THC and other desirable agronomic traits for the legal hemp industry and (ii) hemp plants with high levels of cannabidiol (“CBD”) and other non-THC cannabinoids for the legal medical cannabinoid markets. In the United States, we have worked with the University of Virginia (“UVA”) to (i) create unique industrial hemp plants with levels of THC below 0.3%, which is the legal limit that defines hemp for optimal growth in Virginia, (ii) optimize other desirable hemp plant characteristics to improve the plant’s suitability for growing in Virginia and in similar legacy tobacco regions of the United States, and (iii) utilize high-value medical cannabinoid hemp varieties for use in human therapeutics. We also have a license in the State of New York to research and grow hemp in that state. In Canada, we previously conducted sponsored research on the hemp plant with Anandia in Vancouver, British Columbia, in full compliance with Canadian regulations.

In Europe and the United States, we are currently working with KeyGene NV, a global leader in plant research involving high-value genetic traits and increased crop yields, in an exclusive, worldwide collaboration that is focused on developing hemp/cannabis plants with exceptional cannabinoid profiles and other superior agronomic traits for medical, therapeutic and agricultural uses, among many other applications. Through our partnership with KeyGene, we completed a deep analysis of several hemp/cannabis lines, established and expanded a proprietary cannabis genomic database, began the sequencing and development of high-quality de novo assemblies of several hemp/cannabis plant lines, and developed novel laboratory analysis techniques. These activities will facilitate our on-going hemp/cannabis research efforts focused on developing hemp/cannabis plants with exceptional cannabinoid profiles and other superior agronomic traits for medical, therapeutic and agricultural uses.

On December 3, 2019, we conducted a closing of an initial investment in Panacea, a vertically-integrated developer, producer and seller of legal, hemp-derived, CBD products, with extraction, distillation, testing and manufacturing operations located in a 51,000 square foot facility in Golden, Colorado. Our 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 our common stock in exchange for Panacea-issued debt and Panacea preferred stock. We also received a warrant from Panacea to purchase additional shares of preferred stock of Panacea, which upon full exercise will provide us with a controlling equity position in Panacea.

We continue to review other potential candidate companies in the hemp/cannabis field for strategic collaborations, affiliations, joint ventures, investments and/or acquisitions.

Intellectual Property

Our intellectual property enables us to alter the level of nicotine and other nicotinic alkaloids in tobacco plants and the levels of cannabinoids in hemp/cannabis plants through genetic engineering and modern plant breeding. The basic techniques include, but are not limited to, those that are used in the production of genetically modified (“GM”) and gene-edited varieties of other crops, which are also known as “biotech crops.”

We have extensive patent protection and exclusive rights covering tobacco plants with altered nicotine content produced from modifying expression of certain genes in the tobacco plant, including NBB, QPT, A622, MPO and several transcription factor genes, and tobacco products produced from these plants. A portion of the QPT patent family expired in 2018, and the remainder of the QPT patent family is expected to expire in 2020, although a Brazilian application of the family, now under appeal, could expire later if granted. The majority of our other patent families related to nicotine biosynthesis are expected to expire between 2021 and 2036, with certain extensions of terms in the U.S. applications resulting from patent term adjustments at the U.S. Patent and Trademark Office. (A “patent family” is a set of patent applications and patents, filed in various countries, that relate back to at least one common earlier application.). Our Vector 21-41 VLNC tobacco plants with the QPT modification are also protected by plant variety protection (“PVP”) through 2023, which further restricts third-parties from using such plants.

The creation and production of unique tobacco plants with agronomic traits of VLNC levels, with sufficiently high germination rates and sufficiently large plant yields at harvest, among many other desirable qualities, are necessary for the plants to be sufficiently reliable to be planted at commercial scale. The expiration of a portion of the QPT patent family in 2018 provides third parties with the freedom to target the QPT gene in the tobacco plant, but such targeting of the QPT gene alone does not mean that a third party will be successful in creating a tobacco plant with altered levels of nicotine. The freedom to target the QPT gene means that a third party may conduct scientific experiments to try to discover how to alter or affect the QPT gene in ways that may or may not result in a change in nicotine levels in the tobacco plant. If a third party is able subsequently to learn, over time, how to utilize the QPT gene to alter nicotine levels in the tobacco plant, then such third party would still need to develop and create a unique tobacco plant with *very low* levels of nicotine (not just a “low nicotine” or “reduced nicotine” plant), which would involve, among many other things, multiple plantings over multiple generations of the plants to try to create stable and reliable VLNC plants, with no assurance that any third party could be successful in such efforts. We believe that targeting of the QPT gene alone will not result in a VLNC tobacco plant and, hence, that other genes will have to be targeted in the tobacco plant, possibly (and we believe likely) including genes and other intellectual property for which we have continuing patent protection that would need to be used, in combination with QPT to result in VLNC tobacco. However, if a third party is able, over time, to develop a tobacco plant with very low levels of nicotine, then the third party still would need to develop a VLNC plant with sufficiently high germination rates and sufficiently large plant yields at harvest for the plant to be sufficiently reliable to be planted in large quantities to support its use at commercial scale, which again would involve, among many other things, multiple plantings over multiple generations of the plants to determine the reliability and stability of the germination rates and plant yields at harvest.

We also have exclusive plant variety rights in the United States (plant variety protection certificates are issued in the United States by the U.S. Department of Agriculture (“PVP”)) and Canada. A PVP certificate prevents anyone other than the owner/licensee from planting, propagating, selling, importing or exporting a plant variety for twenty (20) years in the U.S. and, generally, for twenty (20) years in other member countries of the International Union for the Protection of New Varieties of Plants, known as UPOV, an international treaty concerning plant breeders’ rights. There are currently more than 70 countries that are members of UPOV. Our current VLNC tobaccos are protected by our patent portfolio and our Vector 21-41 VLNC tobacco is additionally protected by PVP.

In September 2014, we entered into a Sublicense Agreement with Anandia (the “Anandia Sublicense”). Under the terms of the Anandia Sublicense, we were granted an exclusive sublicense in the United States and a co-exclusive sublicense in the remainder of the world, excluding Canada, to four U.S. patents and 26 patent applications relating to genes in the hemp/cannabis plant that are required for the production of cannabinoids, the “active ingredients” in the hemp/cannabis plant. The Anandia Sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035

In addition to our patents, patent applications, and PVP certificates, we own various registered trademarks in the United States and around the world.

During the year ended December 31, 2019, we decided on a going-forward basis that we will be concentrating our business and scientific resources, personnel and efforts on the portion of our intellectual property portfolio (patents, patent applications and trademarks) that relate to very low nicotine tobacco plants and potential products, as well as unique hemp/cannabis plants and potential products, in order to more strategically pursue our objectives. Accordingly, we decided to no longer support and maintain the portions of our intellectual property portfolio that are no longer areas of our focus on a going-forward basis, such as the portion of our intellectual property portfolio relating to increased nicotine in tobacco; potentially reduced exposure products involving higher nicotine products; older scientific methods of working with genes in tobacco plants; methods of utilizing the biomass of tobacco plants; and trademarks that do not fit within the types of products that we desire to commercialize in the future. We further decided on a going-forward basis to narrow the countries in which we will support our intellectual property filings to more strategically focus on protecting our intellectual property in countries that are scientifically or commercially of highest importance rather than a broader focus. We intend to continue to review and refine our business and scientific focus, resources and efforts in the future in order to continue to strategically pursue our objectives in cost-effective ways. We also believe that certain portions of our intellectual property portfolio that we will not be utilizing in the future nevertheless still have value, so we will be investigating potential opportunities to out-license to third-parties those portions of our intellectual property portfolio that we will not be utilizing in the future, but which may be desirable by third-parties.

Research and Development

Since our inception, the majority of our research and development (“R&D”) efforts have been outsourced to highly qualified groups in their respective fields. Since 1998, we have had multiple R&D agreements with North Carolina State University (“NCSU”) and others resulting in exclusive worldwide licenses to various patented technologies. We have utilized the same model employed by many public-sector research organizations, which entails obtaining an exclusive option or license agreement to any invention arising out of funded research. In all cases, we fund and control all patent filings as the exclusive licensee. This model of contracting with public-sector researchers has enabled us to control R&D costs while achieving our desired results, including obtaining exclusive intellectual property rights relating to our outsourced R&D.

In August 2016, we opened our own laboratory on the Buffalo Niagara Medical Campus in Buffalo, New York where we are conducting our own proprietary research and development activities in tobacco and hemp. On October 30, 2017, we obtained a New York State hemp research and grower license to support our expanding hemp activities in New York.

In December 2016, we entered into a sponsored research agreement with the University of Virginia (“UVA”) and an exclusive license agreement with the University of Virginia Patent Foundation d/b/a University of Virginia Licensing & Ventures Group (“UVA LVG”) pursuant to which we invested approximately \$1,000,000 over a three-year period with UVA to work on the creation of unique industrial hemp plants with guaranteed levels of THC below the legal limits and to optimize other desirable hemp plant characteristics to improve the plant’s suitability for growing in Virginia and other legacy tobacco regions in the United States.

On October 19, 2017, we announced that UVA had completed its first successful harvest of our hemp plants and identified several promising hemp varieties that could form the foundation for commercial hemp production throughout the legacy tobacco regions of the United States. The 22nd Century-UVA hemp field trials used multiple oil and fiber varieties of hemp. Our hemp harvest with UVA identified proprietary varieties of hemp that have excellent agronomic properties for growth in Virginia. In 2018 and 2019, we continued to use our proprietary hemp plants for plantings with UVA in Virginia. We incurred \$287,535 of expenses for the R&D agreement at UVA for the year ended December 31, 2019. UVA and 22nd Century conducted all activities in this scientific collaboration within the parameters of state and federal licenses and permits held by UVA for such work. The agreements with UVA and UVA LVG grant us exclusive rights to commercialize all results of the collaboration in consideration of royalty payments by our Company to UVA LVG.

On June 22, 2018, the Company entered into an amendment to its existing license agreement with NCSU under which the Company exclusively licensed several bright and burley tobacco plant lines with Very Low Nicotine Content that are not genetically modified (non-GM) plants. The amendment provides for the Company to pay NCSU a total exclusive license fee of \$1,200,000, of which \$500,000 was paid by the Company to NCSU within five business days after the execution of the amendment, \$400,000 was paid on the one-year anniversary of the execution of the amendment, and \$300,000 will be paid on the two-year anniversary of the execution of the amendment. The Company will also pay running royalties to NCSU based on a portion of the net sales revenue received by the Company from sales of products that contain any portions of the plant materials that have been received by the Company from NCSU.

On October 22, 2018, the Company entered into a license with the University of Kentucky (“UK”) to license on a non-exclusive basis a next-generation very low nicotine burley tobacco plant line. The UK license agreement provides for the Company to pay UK a total exclusive license fee of \$1,200,000, of which \$300,000 was paid by the Company to UK after the delivery by UK to the Company of certain very low nicotine burley tobacco seeds, \$300,000 was paid on the one-year anniversary of the license agreement, \$300,000 will be paid on the later of the two-year anniversary of the license or the delivery by UK to the Company of certain other very low nicotine burley tobacco seeds, and the final installment payment of \$300,000 will be paid on the later of the three-year anniversary of the license agreement or the delivery by UK to the Company of seeds of male sterile versions of each of the very low nicotine plants grown by UK for the Company from the seeds provided by UK to the Company. The Company will also pay running royalties to UK based on a portion of the net sales revenue received by the Company from sales of products that contain any portions of the plant materials that have been received by the Company from UK.

During the years ended December 31, 2019, 2018, and 2017, we incurred total R&D expenses of \$8,057,147, \$14,989,746, and \$3,366,468, respectively. The R&D expenses for the year ended December 31, 2019 include approximately \$1,675,000 in expenses relating to our PMTA and MRTPA.

MSA Membership

In September 2013, we entered into a Membership Interest Purchase Agreement (the “NASCO Acquisition”) to purchase all of the issued and outstanding membership interests of NASCO, a federally licensed tobacco product manufacturer and subsequent participating manufacturer under the Master Settlement Agreement (“MSA”). The MSA is an accord reached in November 1998 between the State Attorneys General of 46 states, five U.S. territories, the District of Columbia and the five largest tobacco companies in the United States concerning the advertising, marketing and promotion of tobacco products. The MSA also set standards for, and imposes restrictions on, the sale and marketing of cigarettes by participating cigarette manufacturers. On August 29, 2014, we entered into an Amended Adherence Agreement with the 46 Settling States under the MSA pursuant to which the Company was approved to acquire NASCO and become a subsequent participating manufacturer under the MSA. On that same date, we closed the NASCO Acquisition and became a subsequent participating manufacturer under the MSA. NASCO has since been a wholly-owned subsidiary of our Company.

Manufacturing

We lease a cigarette manufacturing facility and warehouse located in Mocksville, North Carolina. In 2013, we purchased certain (i) cigarette manufacturing equipment, and (ii) equipment parts, factory items, office furniture and fixtures, vehicles and computers from the bankruptcy estate of PTM Technologies, Inc. for approximately \$3.22 million.

The facility was primarily in a pre-manufacturing stage during 2014 as we sought approval during that time for us to become a subsequent participating manufacturer under the MSA. Since August 29, 2014, the Company has been a subsequent participating manufacturer under the MSA. Since 2015, we have manufactured and sold our *SPECTRUM*[®] government research cigarettes, together with a third-party MSA cigarette brand and several third-party filtered cigar brands, at our factory in North Carolina.

Our strategic acquisition of our factory has allowed us to become vertically integrated so that we can control production priorities/timing and maintain the required high quality of our products, including our *SPECTRUM*[®] research cigarettes. In the future, our factory will also allow us to produce our own VLNC cigarette brands in the event they comply with the FDA mandate for reduced nicotine in cigarettes, as well as our VLNC cigarettes under the Moonlight[®] brand under our PMTA as authorized by the FDA on December 17, 2019 and if/when the FDA authorizes our MRTPA submissions under our proposed product name of VLN[®].

Sources of Raw Materials

We obtain a large portion of our tobacco leaf from farmers in multiple states in the United States who are under direct contracts with us. These contracts prohibit the transfer of our proprietary tobaccos, seeds and plant materials to other parties. We purchase the balance of our tobacco through third parties. As we prepare for the increased need for our proprietary VLNC tobacco in the United States as a result of the FDA authorization of our PMTA for our Moonlight[®] brand of VLNC cigarettes on December 17, 2019, and as we also prepare for the anticipated increased need for our proprietary VLNC tobacco in the United States in the event the FDA mandates that all combustible cigarettes contain only minimally or non-addictive levels of nicotine and/or in the event the FDA authorizes our MRTPA for our VLNC cigarettes under the proposed product name of VLN[®], we intend to increase the amount of tobacco leaf we obtain directly from farmers under contract, both in the United States and in foreign countries.

We likewise grow hemp ourselves and under contracts with farmers that prohibit the transfer of our proprietary seeds and plant materials to other parties.

Government Regulation

FDA Mandate to Require Minimally or Non-Addictive Levels of Nicotine in all Cigarettes in the United States

The Tobacco Control Act, which became law in June 2009, granted the FDA authority over the regulation of all tobacco products in the United States. While the Tobacco Control Act prohibits the FDA from banning cigarettes outright, or mandating that nicotine levels be reduced to zero, it does allow the FDA to require the reduction of nicotine or other compounds in tobacco and cigarette smoke. In 2009, the Tobacco Control Act also banned all sales in the United States of cigarettes with flavored tobacco (other than menthol). As of June 2010, all cigarette companies were required to cease use of the terms “low tar,” “light” and “ultra light” in describing cigarettes sold in the United States.

On July 28, 2017, FDA Commissioner Scott Gottlieb, M.D., announced the FDA’s plan to exercise its authority under the Tobacco Control Act to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine. On March 16, 2018, the FDA issued an Advance Notice of Proposed Rulemaking (“ANPRM”) to obtain information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes. The FDA is engaging in a required rule-making process to enact such new nicotine reduction regulations. It is uncertain how long the FDA rule-making process will take to complete.

We believe this regulatory environment represents a paradigm shift for the tobacco industry and will create opportunities for us in marketing our VLNC tobacco cigarettes under our proposed product name of VLN[®] and in licensing our proprietary technology and/or tobaccos to larger competitors. On July 16, 2018, we publicly submitted to the FDA our formal written response to the ANPRM in which we described how (i) the FDA’s proposed new rule is supported by rigorous independent, published science, (ii) the FDA’s stated goal to render cigarettes minimally or non-addictive is immediately feasible as evidenced by our production and delivery of more than 28 million VLNC research cigarettes since the year 2011, and (iii) the FDA’s proposed new rule is exceedingly practical and urgently needed in the interests of public health.

Modified Risk Cigarettes

The Tobacco Control Act establishes procedures for the FDA to regulate the labeling and marketing of Modified Risk Tobacco Products, which includes cigarettes marketed to (i) reduce harm or the risk of tobacco-related disease or (ii) reduce or eliminate exposure to a substance (“Modified Risk Cigarettes”). The Tobacco Control Act required the FDA to issue specific regulations and/or guidance regarding applications submitted to the FDA for the authorization to label and market Modified Risk Tobacco Products. On March 30, 2012, the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance*. On December 5, 2018, we submitted a new PMTA to the FDA and on December 27, 2018, we submitted a new MRTPA to the FDA, in each case for our VLNC cigarettes for which we are requesting a reduced exposure marketing authorization from the FDA to market our VLNC cigarettes as a Modified Risk Cigarette with product labeling that includes the proposed brand name of VLN[®] and states that the VLN[®] product has 95% less nicotine than conventional cigarettes. We believe that our VLN[®] cigarettes will qualify as Modified Risk Cigarettes. We believe that obtaining FDA authorization to promote our VLN[®] cigarettes as Modified Risk Cigarettes will create opportunities for us to market our own unique product and license our proprietary technology and/or our tobaccos to larger competitors.

On December 17, 2019, the FDA publicly announced that the FDA had authorized us to market in the U.S. our VLNC tobacco cigarettes under the product names of Moonlight[®] and Moonlight Menthol[®] that were the subject of our PMTA. Our Moonlight[®] and Moonlight Menthol[®] cigarettes are made with our proprietary VLNC tobacco and, as a result, contain very low levels of nicotine. Our Moonlight[®] and Moonlight Menthol[®] cigarettes were modeled after our VLNC *SPECTRUM*[®] research cigarettes. Our PMTA reference more than 50 independent studies conducted using our proprietary *SPECTRUM*[®] research cigarettes. In its public announcement relating to our PMTA, the FDA stated that following a rigorous science-based review of our PMTA, the FDA had determined that authorizing these reduced nicotine products for sale in the U.S. is appropriate for the protection of the public health because of, among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure and cigarette consumption. The FDA further stated that the FDA had determined that non-smokers, including youth, are also unlikely to start using these products, and those who experiment are less likely to become addicted than people who experiment with conventional cigarettes.

On February 14, 2020 TPSAC conducted a public hearing regarding our MRTPA for our VLNC tobacco cigarettes for which we are requesting a reduced exposure marketing authorization from the FDA to market our VLNC tobacco cigarettes in the U.S. as a Modified Risk Tobacco Product with product labeling that includes the proposed brand name of VLN[®] and states that the VLN[®] product has 95% less nicotine than conventional cigarettes. This meeting was the first time that TPSAC considered an MRTP application for a modified exposure claim and also TPSAC’s first discussion of an application for a combustible tobacco product. We 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 meeting materials, including briefing materials for the committee provided by us and the FDA, and presentation given by the different stakeholders are publicly available for review via FDA’s website. The public comment period on the applications remains open at this time. FDA continues to comprehensive evaluation of our applications.

We supply our proprietary cigarettes for use by independent researchers so studies can be conducted to obtain additional information on our products. We expect this information will assist us, along with our own funded studies, in obtaining the necessary FDA authorizations to market our VLNC tobacco cigarettes under our proposed product name of VLN[®] as a Modified Risk Cigarette.

Hemp

On December 20, 2018, the Agricultural Improvement Act of 2018, which is also known as the “2018 Farm Bill,” was enacted and, among other things, further legalized hemp under U.S. federal law, but with compliance still being required with all applicable state hemp laws. The 2018 Farm Bill includes certain benefits for the hemp industry in the United States, including: (i) the extension of the protections for hemp research and researchers and the conditions in which hemp research can be done, (ii) the protection of hemp farmers and hemp production under federal crop insurance programs, (iii) the permitting of the cultivation, interstate transportation and sale of hemp and hemp products in the U.S. in compliance with all other applicable federal and state laws, and (iv) the removal of hemp and hemp derived products from Schedule 1 of the Controlled Substances Act (“CSA”). However, the FDA has publicly stated that certain products derived from hemp, including cannabidiol (“CBD”), which is a cannabinoid that can be extracted from hemp, will be regulated by the FDA. Thus, participants in the hemp industry will need to comply with all applicable federal and state laws, rules and regulations in the cultivation, transportation and sale of hemp and hemp derived products.

As of January 1, 2020, (i) federal law and the laws of 47 states in the United States and the District of Columbia have legalized hemp, (ii) 33 states in the United States and the District of Columbia have laws and/or regulations that recognize, in one form or another, legitimate medical uses for cannabis/marijuana and consumer use of cannabis/marijuana in connection with medical treatment, and (iii) 11 states in the United States and the District of Columbia have legalized cannabis/marijuana for adult recreational use. Many other states are considering similar legislation. Conversely, under the federal CSA, the policies and regulations of the federal government and its agencies are that cannabis/marijuana has no medical benefit and a range of activities are prohibited, including cultivation, possession, personal use and interstate distribution of cannabis/marijuana. In the event the U.S. Department of Justice begins strict enforcement of the CSA in states that have laws legalizing medical and/or adult recreational cannabis/marijuana, there may be a direct and adverse impact to any future potential business or prospects that we may have in the cannabis/marijuana business. However, our current activities involve only work with legal hemp, which would continue since our hemp activities are permitted under applicable federal and state laws, rules, and regulations.

Competition

We are not currently aware of any competition to our VLNC tobaccos inside or outside of the United States. It is possible that our VLNC tobacco cigarettes may compete with FDA-approved smoking cessation aids. In the market for FDA-approved smoking cessation aids, our principal competitors would include Pfizer Inc., GlaxoSmithKline plc, Perrigo Company plc, Novartis International AG, and Nicovum AB, a subsidiary of Reynolds American Inc. The industry consists of major domestic and international companies, most of which have existing relationships in the markets into which we plan to sell, as well as financial, technical, marketing, sales, manufacturing, scaling capacity, distribution and other resources, and name recognition substantially greater than ours.

We are also not aware of any competition in the creation and provision of VLNC tobacco research cigarettes for use in independent clinical studies.

Cigarette and filtered cigar companies compete primarily on the basis of product quality, brand recognition, brand loyalty, taste, innovation, packaging, service, marketing, advertising, retail shelf space, and price. Cigarette sales can be significantly influenced by weak economic conditions, erosion of consumer confidence, competitors’ introduction of low-price products or innovative products, higher taxes, higher absolute prices and larger gaps between price categories, and product regulation that diminishes the ability to differentiate tobacco products. Domestic cigarette competitors included Philip Morris USA Inc., Reynolds American Inc., and Vector Group Ltd. International competitors included Philip Morris International Inc., British American Tobacco, JT International SA, Imperial Brands plc, and regional and local tobacco companies; and in some instances, government-owned tobacco enterprises such as the China National Tobacco Corporation.

Currently, competition in the hemp/cannabis space includes many small regional marketers/packagegers of CBD oil and CBD oil containing products.

Employees

As of February 15, 2020, we employed 67 people and we consider our employee relations to be good.

Corporate Information

We are a Nevada corporation and our corporate headquarters is located at 8560 Main Street, Suite 4, Williamsville, New York 14221. Our telephone number is (716) 270-1523. Our internet address is www.xxiiicentury.com. All of our filings with the Securities and Exchange Commission can be accessed free of charge through our website promptly after filing; however, in the event that the website is inaccessible, we will provide paper copies of our most recent Annual Report on Form 10-K, the most recent Quarterly Report on Form 10-Q, Current Reports filed or furnished on Form 8-K, and all related amendments, excluding exhibits, free of charge upon request. These filings are also accessible on the SEC's website at www.sec.gov. We do not incorporate the information on our website into this Annual Report on Form 10-K.

Item 1A. Risk Factors.

You should carefully consider the risk factors set forth below and in other reports that we file from time to time with the Securities and Exchange Commission and the other information in this Annual Report on Form 10-K. The matters discussed in the risk factors, and additional risks and uncertainties not currently known to us or that we currently deem immaterial, could have a material adverse effect on our business, financial condition, results of operation and future growth prospects and could cause the trading price of our common stock to decline.

Risks Related to Our Business and Operations

We have had a history of losses, and we may be unable to achieve and sustain profitability.

We have experienced net losses of approximately \$26.6 million, \$8.0 million and \$13.0 million during the years ended December 31, 2019, 2018, and 2017, respectively. While our current balance of cash and cash equivalents and short-term investment securities is adequate to sustain operations for a number of years, generating net income in the future will depend on our ability to successfully operate our cigarette manufacturing facility, sell and market our proprietary tobacco and hemp products, and generate royalty revenue from the licensing of our intellectual property. There is no guarantee that we will be able to achieve or sustain profitability in the future. An inability to successfully achieve profitability may decrease our long-term viability.

We have had a history of negative cash flow, and our ability to sustain positive cash flow is uncertain.

We have had a history of negative cash flow from operating activities, before cash used in investing activities and cash provided by financing activities, including approximately \$14.6 million of negative cash flow from operations during the year ended December 31, 2019. We believe our current position of cash and cash equivalents and short-term investment securities is adequate to sustain operations and to meet all current obligations as they come due for a number of years. Generation of positive cash flow from operations will depend on our ability to successfully implement the net income generating activities discussed in the previous risk factor discussion. An inability to successfully implement our net income producing initiatives may decrease our long-term viability.

If regulations by the FDA requiring the reduction of nicotine to minimally or non-addictive levels in all cigarettes sold in the U.S. are delayed or do not become implemented, then the demand for our proprietary Very Low Nicotine Content tobacco may not substantially increase in the U.S.

On July 28, 2017, the FDA publicly announced that it intends to implement new regulations that will mandate minimally or non-addictive levels of nicotine in all cigarettes sold in the U.S.

However, there can be no assurance that the FDA will implement such new regulations or, if implemented, when such regulations would take effect. In the event the FDA does not implement such new regulations or implementation is delayed, then the demand for our proprietary VLNC tobacco may not substantially increase in the U.S. and such action would have a material adverse effect on our business and operations.

If we fail to obtain FDA and foreign regulatory approvals for authorization to market our VLNC tobacco as a Modified Risk Cigarette, we will be unable to commercialize this potential product in and outside the U.S.

Although our PMTA for our VLNC tobacco cigarettes has been authorized by the FDA for marketing and sale in the United States, there can be no assurance that our MRTPA for our VLNC tobacco cigarettes will be authorized by the FDA and/or that our VLNC tobacco cigarettes will be approved by foreign regulators. In addition, there can be no assurance that all necessary approvals will be granted for our potential products or that review or actions will not involve delays caused by requests for additional information or testing that could adversely affect the time and cost to market and sell our potential products.

The development, testing, manufacturing, and marketing of our potential products are subject to extensive regulation by governmental authorities in the United States and throughout the world. In particular, the process of obtaining approvals by the FDA and other international FDA equivalent agencies in targeted countries is costly and time consuming, and the time required for such approvals is uncertain. Our MRTPA for our VLNC tobacco cigarettes must undergo an extensive regulatory approval process mandated by the FDA in the U.S. and any other approval processes required by FDA-equivalent agencies in foreign countries where we want to introduce our potential products.

The scope of review, including product testing and exposure studies, to be required by the FDA under the Tobacco Control Act in order for cigarettes to be marketed as Modified Risk Cigarettes has not yet been fully established, even though the FDA issued *Modified Risk Tobacco Product Applications Draft Guidance* on March 30, 2012.

The FDA could force the removal of our products from the U.S. market.

The FDA has broad authority over the regulation of tobacco products. The FDA could, among other things, force us to remove from the U.S. market our VLNC tobacco cigarettes even after the FDA authorization on December 17, 2019 of our PMTA or the potential future authorization of our MRTPA for us to market in the U.S. our VLNC tobacco cigarettes, as well as the FDA could levy fines or change their regulations on advertising. Any adverse action by the FDA could have a material adverse impact on our business.

Negative press from being in the hemp/cannabis space could have a material adverse effect on our business, financial condition, and results of operations.

The hemp plant and the marijuana plant are both part of the same *cannabis* genus of plant, except that hemp, by definition, has not more than 0.3% THC content and is legal under the federal 2018 Farm Bill and certain state laws, but the same plant with a higher THC content is defined as marijuana, which is legal under certain state laws, is not legal under federal law. The similarities between these plants can cause confusion, and our activities with legal hemp may be incorrectly perceived as us being involved in federally illegal marijuana. Also, despite growing support for the marijuana industry and legalization of marijuana in certain U.S. states, many individuals and businesses remain opposed to the marijuana industry. Any negative press resulting from the incorrect perception that we have entered into the marijuana space could result in a loss of current or future business. It could also adversely affect the public's perception of us and lead to reluctance by new parties to do business with us or to own our common stock. We cannot assure you that additional business partners, including but not limited to financial institutions, banking institutions and customers, will not attempt to end or curtail their relationships with us. Any such negative press or cessation of business could have a material adverse effect on our business, financial condition, and results of operations.

Any business-related cannabinoid production is dependent on laws pertaining to the hemp/cannabis industry.

On December 20, 2018, the Agricultural Improvement Act of 2018, which is also known as the "2018 Farm Bill," was enacted and legalized hemp and hemp products under U.S. federal law, but with compliance still being required with all applicable state hemp laws and all regulations developed by the United States Department of Agriculture ("USDA"). In addition, the FDA is regulating products derived from hemp, including cannabidiol ("CBD"), for compliance under the Federal Food, Drug and Cosmetic Act and has issued several warning letters to firms marketing CBD products to treat disease or for other therapeutic uses. Under the Federal Food, Drug and Cosmetic Act, any product intended to affect the structure or function of the body of humans or animals is considered a drug that must receive premarket approval by the FDA through its new drug application process. Thus, participants in the hemp industry will need to comply with all applicable federal and state laws, rules and regulations in the cultivation, transportation, and sale of hemp and hemp derived products, including the Federal Food, Drug and Cosmetic Act.

As of January 1, 2020, (i) federal law and the laws of 47 states in the United States and the District of Columbia have legalized hemp, (ii) 33 states and the District of Columbia allow their citizens to use medical marijuana and, (iii) 11 states and the District of Columbia have legalized marijuana for adult recreational use. Many other states are considering similar legislation. Conversely, under the federal Controlled Substance Act (the "CSA"), the policies and regulations of the federal government and its agencies are that marijuana has no medical benefit and a range of activities are prohibited, including cultivation, possession, personal use, and interstate distribution of marijuana. In the event the U.S. Department of Justice begins strict enforcement of the CSA in states that have laws legalizing medical and/or adult recreational marijuana, there may be a direct and adverse impact to any future business or prospects that we may have in the marijuana business. Even in those jurisdictions in which the manufacture and use of medical marijuana has been legalized at the state level, the possession, use, and cultivation of marijuana all remain violations of federal law that are punishable by imprisonment and substantial fines. Moreover, individuals and entities may violate federal law if they intentionally aid and abet another in violating these federal controlled substance laws or conspire with another to violate them.

We currently conduct sponsored research on hemp in Oregon, Maryland and The Netherlands with third-parties that possess all necessary permits and licenses to engage legally in such activities. We have conducted hemp research in Virginia and Canada with third-parties possessing all necessary permits and licenses to engage legally in such activities. In order to carry out research in other countries, similar licenses are required to be issued by the relevant authority in each country. We also conduct hemp research in our laboratories in New York under a license granted to us by the State of New York.

Local, state, federal, and international hemp and marijuana laws and regulations are broad in scope and subject to evolving interpretations, which could require us to incur substantial costs associated with compliance requirements. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our operations. In addition, it is possible that regulations may be enacted in the future that will be directly applicable to our proposed business regarding cannabinoid production. It is also possible that the federal government will begin strictly enforcing existing laws, which may limit the legal uses of the hemp plant and its derivatives and extracts, such as cannabinoids. However, our work in hemp would continue since hemp research, development, and commercialization activities are permitted under applicable federal and state laws, rules, and regulations. We cannot predict the nature of any future laws, regulations, interpretations, or applications, nor can we determine what effect additional governmental regulations or administrative policies and procedures, when and if promulgated, could have on our activities in the legal hemp industry.

We expect to continue to acquire or invest in other companies, which may divert our management's attention, result in additional dilution to our stockholders, and consume resources that are necessary to sustain our business.

We recently made an investment in Panacea, a vertically-integrated developer, producer and seller of legal, hemp-derived, CBD products, with extraction, distillation, testing and manufacturing operations located in a 51,000 square foot facility in Golden, Colorado. We expect to continue to acquire or invest in complementary solutions, services, technologies, or businesses in the future. We may also enter into relationships with other businesses to expand our intellectual property portfolio, which could involve preferred or exclusive licenses or investments in other companies. Negotiating these transactions can be time-consuming, difficult and expensive, and our ability to complete these transactions may often be subject to conditions or approvals that are beyond our control. Consequently, these transactions, even if undertaken and announced, may not close.

Acquisitions may also disrupt our business, divert our resources, and require significant management attention that would otherwise be available for the development of our business. Moreover, the anticipated benefits of any acquisition, investment, or business relationship may not be realized or we may be exposed to unknown liabilities, including litigation against the companies that we may acquire. In connection with any such transaction, we may:

- issue additional equity securities that would dilute our stockholders;
- use cash that we may need in the future to operate our business;
- incur debt on terms unfavorable to us, that we are unable to repay, or that may place burdensome restrictions on our operations;
- incur large charges or substantial liabilities; or
- become subject to adverse tax consequences or substantial depreciation, deferred compensation, or other acquisition-related accounting charges.

Any of these risks could harm our business.

Integration of an acquired company's operations may present challenges.

The integration of an acquired company requires, among other things, coordination of administrative, sales and marketing, accounting and finance functions, and expansion of information and management systems. Integration may prove to be difficult due to the necessity of coordinating geographically separate organizations and integrating personnel with disparate business backgrounds and accustomed to different corporate cultures. We may not be able to retain key employees of an acquired company. Additionally, the process of integrating a company may require a disproportionate amount of time and attention of our management and financial and other resources. Any difficulties or problems encountered in an integration could have a material adverse effect on our business.

In addition, we may only be able to conduct limited due diligence on an acquired company's operations. Following an acquisition, we may be subject to liabilities arising from an acquired company's past or present operations, including liabilities related to data security, encryption and privacy of customer data, and these liabilities may be greater than the warranty and indemnity limitations that we negotiate. Any liability that is greater than these warranty and indemnity limitations could have a negative impact on our financial condition.

Even if successfully integrated, there can be no assurance that our operating performance after an acquisition will be successful or will fulfill management's objectives.

We intend to distribute and sell our potential products outside of the U.S., which will subject us to other regulatory risks.

In addition to seeking authorization from the FDA to market our VLNC tobacco cigarettes as a Modified Risk Cigarette in the U.S., we intend to seek governmental approvals required to market our VLNC tobacco cigarettes and our other products in other countries. Marketing of our products is not permitted in certain countries until we have obtained required approvals or exemptions in these individual countries. The regulatory review process varies from country to country, and approval by foreign governmental authorities is unpredictable, uncertain, and generally expensive. Our ability to market our potential products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances. We anticipate commencing the applications required in some or all of these countries following authorization by the FDA; however, we may decide to file applications in advance of the FDA authorization if we determine such filings to be both time and cost effective. If we export any of our potential products, or products that have not yet been cleared for commercial distribution in the U.S., then such products may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals could impair our ability to generate revenue from international sources.

Business interruptions, whether caused by natural disaster, terrorism, economic downturns, global pandemics or other events, could negatively impact our business.

A natural disaster (such as an earthquake, hurricane, fire, or flood) or an act of terrorism could cause substantial delays in our operations, damage or destroy our equipment or facilities, and cause us to incur additional expenses and lose revenue. The insurance we maintain against natural disasters may not be adequate to cover our losses in any particular case, which would require us to expend significant resources to replace any destroyed assets, thereby materially and adversely affecting our financial condition and prospects. Other global incidents could have a similar effect of disrupting our business to the extent they reach and impact the areas in which we operate, the availability of inventory we need, the customers we serve, the partners on whom we rely for products or services or the employees who operate our businesses. For example, the outbreak of the coronavirus currently being experienced globally could disrupt our supply chain for tobacco, as well as negatively impact employee productivity, including affecting the availability of employees reporting for work. Further, the coronavirus outbreak has affected, and may continue to affect, the economies and financial markets of many countries, which may result in an economic downturn.

Our studies and testing of any of our potential products may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional studies and/or testing for these potential products or cease our studies and testing.

We do not know whether further studies and testing of our potential products will demonstrate safety and efficacy sufficient to result in marketable products. We may not be able to obtain approval or marketing authorization for these potential products or our anticipated time of bringing these potential products to the market may be substantially delayed. We may also experience significant additional development costs and be required to undertake additional studies and/or testing if we change our potential products. Any such delays or costs could have a material adverse effect on our business.

Our working capital requirements involve estimates based on demand expectations and may increase beyond those currently anticipated, which could harm our operating results and financial condition.

We have no experience in selling Modified Risk Cigarettes on a commercial basis. As a result, we intend to base our funding and inventory decisions on estimates of future demand. If demand for our products does not increase as quickly as we have estimated, our inventory and expenses could rise, and our business and operating results could suffer. Alternatively, if we experience sales in excess of our estimates, our working capital needs may be higher than those currently anticipated. Our ability to meet any demand for our products may depend on our ability to arrange for additional financing for any ongoing working capital shortages, since it is likely that cash flow from sales will lag behind our investment requirements.

We may require additional capital before we can complete the FDA authorization process for our Modified Risk Tobacco Product Application (“MRTPA”).

We may require additional capital in the future before we can complete the FDA authorization process for our MRTPA. The cost of completing the FDA authorization process for our MRTPA is difficult to estimate since it is currently unknown exactly what the FDA will require. If we raise additional funds through the issuance of equity securities to complete the FDA authorization process for our MRTPA, our stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. We could also wait for our own revenues and profits to be sufficient for us to provide such funding, which could delay our completion of the FDA authorization process for our MRTPA. We also could elect to seek funds through arrangements with collaborators or licensees. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our potential products or grant licenses on terms that are not favorable to us.

If we cannot raise additional capital on acceptable terms, we may not be able to, among other things:

- undertake the steps necessary to seek FDA authorization of our MRTPA;
- develop or enhance our potential products or introduce new products;
- expand our development, sales and marketing, and general and administrative activities;
- attract tobacco growers, customers, or manufacturing and distribution partners;
- acquire complementary technologies, products, or businesses;
- expand our operations in the United States or internationally;
- hire, train, and retain employees; or
- respond to competitive pressures or unanticipated working capital requirements.

We have no experience in managing growth. If we fail to manage our growth effectively, we may be unable to execute our business plan or to address competitive challenges adequately.

From 2013 to February 15, 2020, we grew from nine (9) employees to sixty-seven (67) employees. Any growth in our business will place a significant strain on our managerial, administrative, operational, financial, information technology and other resources. We intend to further expand our overall business, customer base, employees and operations, which will require substantial management effort and significant additional investment in our infrastructure. We will be required to continue to improve our operational, financial and management controls and our reporting procedures and we may not be able to do so effectively. As such, we may be unable to manage our growth effectively.

Our manufacturing facility is subject to FDA regulations.

Manufacturers of tobacco products must comply with FDA regulations which require, among other things, compliance with the FDA's evolving regulations on Current Good Manufacturing Practices ("cGMP(s)"), which are enforced by the FDA through its facilities inspection program. The manufacture of products is subject to strict quality control, testing and record keeping requirements, and continuing obligations regarding the submission of safety reports and other post-market information. We cannot guarantee that our current manufacturing facility will pass FDA inspections and/or similar inspections in foreign countries to produce our tobacco products, or that future changes to cGMP manufacturing standards will not also negatively affect the cost or sustainability of our manufacturing facility.

The loss of a significant customer for whom we manufacture tobacco products could have an adverse impact on our results of operation.

Currently, a significant portion of our revenues (and corresponding accounts receivable) from manufacturing tobacco products are derived from our three largest customers, with whom we do not have an agreement requiring them to purchase a minimum amount of products from us or guaranteeing any minimum future purchase amounts from us. Such customers may, at any time, delay or decrease their level of purchases from us or cease doing business with us altogether. Since many of our manufacturing costs are fixed, if sales to such customers cease or are reduced, we may not obtain sufficient purchase orders from other customers necessary to offset any such losses or reductions, which could have a negative impact on our results of operations.

Federal, state and local governmental actions, including actions by the FDA, may have an adverse impact on us and/or our customers for whom we manufacture tobacco products.

We and our customers for whom we manufacture tobacco products face significant governmental regulation, including efforts aimed at reducing the incidence of tobacco use. Actions by the FDA and other federal, state or local governments or agencies may impact the adult tobacco consumer acceptability of or access to tobacco products (for example, through product standards proposed by the FDA for nicotine and flavors including menthol), delay or prevent the launch of new or modified tobacco products or products with claims of reduced risk, require the recall or other removal of tobacco products from the marketplace, impose additional manufacturing, labeling or packing requirements, interrupt manufacturing or otherwise significantly increase the cost of doing business. Any one or more of these actions may have a material adverse impact on us or the business of our customers for whom we make tobacco products, which could have a negative impact on our results of operations.

Our principal competitors in the modified risk tobacco products market have, and any future competitors may have, greater financial and marketing resources than we do, and they may therefore develop products or other technologies similar or superior to ours, or otherwise compete more successfully than we do.

We have no experience in selling modified risk tobacco products. As of December 31, 2019, the only company that has received authorization from the FDA to market modified risk tobacco products in the United States is Swedish Match, which has significantly greater resources than us. The industry consists of major domestic and international companies, most of which have existing relationships in the markets in which we plan to sell, as well as financial, technical, marketing, sales, manufacturing, scaling capacity, distribution and other resources and name recognition substantially greater than ours. In addition, we expect new competitors will enter the markets for our products in the future. Potential customers may choose to do business with our more established competitors because of their perception that our competitors are more stable, are more likely to complete various projects, can scale operations more quickly, have greater manufacturing capacity, are more likely to continue as a going concern, and lend greater credibility to any joint venture. If we are unable to compete successfully against manufacturers of other modified risk tobacco products, our business could suffer, and we could lose or be unable to obtain market share.

Our competitors may develop products that are less expensive, safer or otherwise more appealing, which may diminish or eliminate the commercial success of any potential product that we may commercialize.

If our competitors market products that are less expensive, safer or otherwise more appealing than our potential products, or that reach the market before our potential products, we may not achieve commercial success. The market may choose to continue utilizing existing products for any number of reasons, including familiarity with or pricing of these existing products. The failure of our PMTA product or our MRTPA product to compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition, results of operations, and cash flows. Our competitors may:

- develop and market products that are less expensive, safer, or otherwise more appealing than our products;
- commercialize competing products before we or our partners can launch our products; and
- initiate or withstand substantial price competition more successfully than we can.

If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages that we believe we derive from our research approach and proprietary technologies. Our competitors may:

- operate larger research and development programs or have substantially greater financial resources than we do;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

Government mandated prices or taxes, production control programs, shifts in crops driven by economic conditions, and adverse weather patterns may increase the cost or reduce the quality of the tobacco and other agricultural products used to manufacture our products.

We depend on independent tobacco farmers to grow our specialty proprietary tobaccos with specific nicotine contents for our potential products. As with other agricultural commodities, the price of tobacco leaf can be influenced by imbalances in supply and demand, and crop quality can be influenced by variations in weather patterns, diseases, and pests. We must also compete with other tobacco companies for contract production with independent tobacco farmers. Tobacco production in certain countries is subject to a variety of controls, including government mandated prices and production control programs. Changes in the patterns of demand for agricultural products could cause farmers to plant less tobacco. Any significant change in tobacco leaf prices or taxes, quality and quantity could affect our profitability and our business.

Product liability claims, product recalls, or other claims could cause us to incur losses or damage our reputation.

The risk of product liability claims or product recalls, and associated adverse publicity, is inherent in the development, manufacturing, marketing, and sale of modified risk tobacco products. Any product recall or lawsuit seeking significant monetary damages may have a material adverse effect on our business and financial condition. A successful product liability claim against us could require us to pay a substantial monetary award. Though we currently have no pending product liability claims against us, we cannot assure you that such claims will not be made in the future.

The failure of our information systems to function as intended or their penetration by outside parties with the intent to corrupt them could result in business disruption, litigation and regulatory action, and loss of revenue, assets, or personal or confidential data (Cybersecurity).

We use information systems to help manage business processes, collect and interpret business data and communicate internally and externally with employees, suppliers, customers and others. Some of these information systems are managed by third-party service providers. We have backup systems and business continuity plans in place, and we take care to protect our systems and data from unauthorized access. Any cybersecurity breaches would be reported to the Board of Directors and appropriate actions taken. On a quarterly basis, during our Board meetings, we review the status of events or lack thereof. A failure of our systems to function as intended, or penetration of our systems by outside parties intent on extracting or corrupting information or otherwise disrupting business processes, could place us at a competitive disadvantage, result in a loss of revenue, assets or personal or other sensitive data, litigation and regulatory action, cause damage to our reputation and that of our brands and result in significant remediation and other costs.

Risks Related to the Tobacco Industry

The third-party tobacco products made in our manufacturing business face significant governmental action aimed at increasing regulatory requirements with the goal of significantly restricting the use of tobacco products.

As of December 31, 2019, most of the revenues of our manufacturing business are from the production of tobacco cigarettes and filtered cigars made for third-party brand owners of such products. Cigarette and filtered cigar companies face significant governmental action, especially in the United States pursuant to the Tobacco Control Act, including but not limited to efforts aimed at reducing the incidence of tobacco use, restricting marketing and advertising, imposing regulations on packaging, mandating warnings and disclosure of flavors or other ingredients, prohibiting the sale of tobacco products with certain flavors or other characteristics, limiting or prohibiting the sale of tobacco products by certain retail establishments and the sale of tobacco products in certain packaging sizes, and seeking to hold retailers and distributors responsible for the adverse health effects associated with both smoking and exposure to environmental tobacco smoke. Governmental actions, combined with the diminishing social acceptance of smoking and private actions to restrict smoking, have resulted in reduced industry volume in the United States and in certain other countries, and we expect that these factors will continue to reduce consumption levels in these markets.

Significant regulatory developments will take place over the next few years in many markets, driven principally by the World Health Organization's Framework Convention on Tobacco Control ("FCTC"). The FCTC is the first international public health treaty on tobacco, and its objective is to establish a global agenda for tobacco regulation with the purpose of reducing initiation of tobacco use and encouraging cessation. In addition, the FCTC has led to increased efforts by tobacco control advocates and public health organizations to reduce the appeal of tobacco products. Partly because of some or a combination of these efforts, unit sales of tobacco products in certain markets, principally Western Europe and Japan, have been in general decline and we expect this trend to continue. Our operating results could be significantly affected by any significant increase in the cost of complying with new regulatory requirements.

If the FDA's proposed rule regarding graphic health warnings on cigarette packaging and in cigarette advertising is finalized, the final rule is likely to have a negative impact on sales of our third-party customers' products and potential Company products.

On August 16, 2019, as required by the Federal Cigarette Labeling and Advertising Act, as amended by the Family Smoking Prevention and Tobacco Control Act, the FDA issued a proposed rule to modify the required warnings that appear on cigarette packages and in cigarette advertisements. The FDA proposes to require tobacco product manufacturers to display one of thirteen pairs of text warnings and photorealistic images depicting negative health consequences of smoking. If finalized, the rule would require, within 15 months of finalization, the graphic health warnings to appear directly on the cigarette package and be directly visible beneath the cellophane wrapping and comprise the top 50 percent of the front and rear panels of cigarette packages. FDA first promulgated a final rule in September 2012, which would have imposed graphic health warning requirements to those proposed in the FDA's August 2019 proposed rule. However, a federal appellate court vacated the September 2012 rules after holding that the rule was unconstitutional. If the FDA successfully implements these revised regulations announced in its August 2019 proposed rule, and any reviewing federal court does not strike them down on constitutional or other grounds, then all cigarettes manufactured for sale or distribution in the United States will need to include these new graphic health warnings on their packages consistent with the effective date(s) included in such regulations. Any resulting reduction in the number of smokers will probably reduce the demand for the products manufactured by our factory for our potential Company products and for third-party brand owners of such products.

We may become subject to litigation related to cigarette smoking and exposure to environmental tobacco smoke, or ETS, which could severely impair our results of operations and liquidity.

Although we are not currently subject to legal proceedings related to cigarette smoking or ETS, we may become subject to litigation related to the sale of our Modified Risk Cigarettes. Legal proceedings covering a wide range of matters related to tobacco use are pending or threatened in various U.S. and foreign jurisdictions. Various types of claims are raised in these proceedings, including product liability, consumer protection, antitrust, tax, contraband shipments, patent infringement, employment matters, claims for contribution, and claims of competitors and distributors.

Litigation is subject to uncertainty and it is possible that there could be adverse developments in pending cases. An unfavorable outcome or settlement of pending tobacco related litigation could encourage the commencement of additional litigation. The variability in pleadings, together with the actual experience of management in litigating claims, demonstrates that the monetary relief that may be specified in a lawsuit bears little relevance to the ultimate outcome.

Damages claimed in some tobacco-related litigation are significant and, in certain cases, range into the billions of dollars. We anticipate that new cases will continue to be filed. The FCTC encourages litigation against tobacco product manufacturers. It is possible that our results of operations, cash flows, or financial position could be materially affected by an unfavorable outcome or settlement of litigation.

Cigarettes are subject to substantial taxes. Significant increases in cigarette-related taxes have been proposed or enacted and are likely to continue to be proposed or enacted in numerous jurisdictions. These tax increases may affect the sales of our potential Company products and our third-parties customers' tobacco products manufactured at our factory, which could result in decreased sales and profitability of our manufacturing business.

Tax regimes, including excise taxes, sales taxes, and import duties, can disproportionately affect the retail price of manufactured cigarettes versus other tobacco products, or disproportionately affect the relative retail price of our Modified Risk Cigarettes versus lower-priced cigarette brands manufactured by our competitors. Increases in cigarette taxes are expected to continue to have an adverse impact on sales of cigarettes resulting in (i) lower consumption levels, (ii) a shift in sales from manufactured cigarettes to other tobacco products or to lower-price cigarette categories, (iii) a shift from local sales to legal cross-border purchases of lower price products, and (iv) illicit products such as contraband and counterfeit.

We may become subject to governmental investigations on a range of matters.

Tobacco companies are often subject to investigations, including allegations of contraband shipments of cigarettes, allegations of unlawful pricing activities within certain markets, allegations of underpayment of custom duties and/or excise taxes, and allegations of false and misleading usage of descriptors such as "lights" and "ultra-lights." We cannot predict the outcome of any investigations to which we may become subject, but we may be materially affected by an unfavorable outcome of potential future investigations.

Risks Related to Intellectual Property

Our proprietary rights may expire or may not otherwise adequately protect our intellectual property, products and potential products, and if we cannot obtain adequate protection of our intellectual property, products and potential products, we may not be able to successfully market our products and potential products.

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our technologies, products, and potential products. We will only be able to protect our technologies, products, and potential products from unauthorized use by third parties to the extent that valid and enforceable patents cover them, or to the extent that other market exclusionary rights apply.

The patent positions of life sciences companies, like ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. The general patent environment outside the United States also involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may be allowed or that the scope of these patent rights could provide a sufficient degree of future protection that could permit us to gain or keep our competitive advantage with respect to these products and technology. Additionally, life science companies like ours are often dependent on creating a pipeline of products. We may not be able to develop additional potential products or proprietary technologies that produce commercially viable products or that are themselves patentable.

Although there are currently no challenges to any portion of our intellectual property, our issued patents may be subject to challenge and potential invalidation by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States, or in other countries, may diminish the value of our intellectual property. In addition, others may independently develop similar or alternative products and technologies that may be outside the scope of our intellectual property. Should third parties obtain patent rights to similar products or technology, this may have an adverse effect on our business.

The expiration of a portion of the QPT patent family in 2018 may provide third parties with the freedom to target the QPT gene in the tobacco plant, which may give third-parties the freedom to target the QPT gene in experiments to try to reduce nicotine levels in tobacco plants to levels that may satisfy the planned new nicotine reduction regulations coming from the FDA. There can be no assurance about whether any third-parties will or will not be successful in such efforts, how long or short in time such efforts will entail and/or if such efforts will or will not infringe other genes and other intellectual property on which we have continuing patent protection that would need to be used, in combination with QPT, to result in VLNC tobacco. If our competitors are able to successfully reduce nicotine levels in tobacco plants without violating our patent protections, our ability to license our technology would be negatively impacted and we would likely face increased competition.

We also rely on trade secrets to protect our technology, products, and potential products, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets, however, are difficult to protect. While we believe that we use reasonable efforts to protect our trade secrets, our own, our licensees' or our strategic partners' employees, consultants, contractors or advisors may unintentionally or willfully disclose our information to competitors. We seek to protect this information, in part, through the use of non-disclosure and confidentiality agreements with employees, consultants, advisors, and others. These agreements may be breached, and we may not have adequate remedies for a breach. In addition, we cannot ensure that those agreements will provide adequate protection for our trade secrets, know-how, or other proprietary information, or prevent their unauthorized use or disclosure.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our products and potential products, disputes may arise as to the proprietary rights of the information, which may not be resolved in our favor. Key employees are required to assign all intellectual property rights in their discoveries to us. However, these key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods, or technologies. If we were to prosecute a claim that a third party had illegally obtained and was using our trade secrets, it could be expensive and time consuming and the outcome could be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any contractual claim to this information, and our business could be harmed.

The ability to commercialize our potential products will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business.

The ability to commercialize our potential products will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third-party intellectual property rights in our field are complicated, and third-party intellectual property rights in these fields are continuously evolving. While we have conducted searches for such third-party intellectual property rights, we have not performed specific searches for third-party intellectual property rights that may raise freedom-to-operate issues, and we have not obtained legal opinions regarding commercialization of our potential products. As such, there may be existing patents that may affect our ability to commercialize our potential products.

In addition, because patent applications are published up to 18 months after their filing, and because patent applications can take several years to issue, there may be currently pending third-party patent applications and freedom-to-operate issues that are unknown to us, which may later result in issued patents.

If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process, and can divert management's attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- a court order prohibiting us from commercializing our potential products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our potential products to market.

Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

Our patent applications may not result in issued patents, which may have a material adverse effect on our ability to prevent others from commercially exploiting products similar to ours.

We own or exclusively control many issued patents and pending patent applications. We cannot be certain that these patent applications will issue, in whole or in part, as patents. Patent applications in the United States are maintained in secrecy until the patents are published or are issued. Since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we are the first creator of inventions covered by pending patent applications or the first to file patent applications on these inventions. We also cannot be certain that our pending patent applications will result in issued patents or that any of our issued patents will afford protection against a competitor. In addition, patent applications filed in foreign countries are subject to laws, rules and procedures that differ from those of the United States, and thus we cannot be certain that foreign patent applications related to U.S. patents will be issued. Furthermore, if these patent applications issue, some foreign countries provide significantly less effective patent enforcement than in the United States.

The status of patents involves complex legal and factual questions and the breadth of claims allowed is uncertain. Accordingly, we cannot be certain that the patent applications that we or our licensors file will result in patents being issued, or that our patents and any patents that may be issued to us in the near future will afford protection against competitors with similar technology. In addition, patents issued to us may be infringed upon or designed around by others and others may obtain patents that we need to license or design around, either of which would increase costs and may adversely affect our operations.

We license certain patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects could be harmed.

We license rights to third-party intellectual property that is necessary or useful for our business, and we may enter into additional licensing agreements in the future. Our success could depend in part on the ability of some of our licensors to obtain, maintain, and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued with respect to these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we could. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Our worldwide exclusive licenses relating to tobacco from NCSU involve multiple patent families. The exclusive rights under the NCSU agreements expire on the date on which the last patent or registered plant variety covered by the subject license expires in the country or countries where such patents or registered plant varieties are in effect. The NCSU licenses relate predominately to issued patents, and our exclusive rights in the NCSU licenses are expected to expire in 2036.

Our worldwide sublicense from Anandia, a plant biotechnology company based in Vancouver, Canada, grants us exclusive rights in the United States and co-exclusive rights with Anandia everywhere else in the world (except not in Canada where Anandia retains exclusive rights) to certain patents and patent applications relating to certain genes in the hemp/cannabis plant that are required for the production of cannabinoids, the “active ingredients” in the cannabis plant. The Anandia sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustained, and you may not be able to resell your shares at or above the price at which you purchased them.

An active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, shares of common stock may not be able to be resold at or above the purchase price of such shares. Although there can be no assurances, we expect that our common stock will continue to be quoted on the New York Stock Exchange American market (“NYSE American”). However, even if our common stock continues to be quoted on the NYSE American, there is no assurance that an active market for our common stock will continue in the foreseeable future. There also can be no assurance that we can maintain such listing on the NYSE American. If we are ever no longer listed on the NYSE American or other national stock exchange in the future, then it would be more difficult to dispose of shares or to obtain accurate quotations as to the market value of our common stock compared to securities of companies whose shares are traded on national stock exchanges.

Our stock price may be highly volatile and could decline in value.

Our common stock is currently traded on the NYSE American and the market price for our common stock has been volatile. Further, the market prices for securities in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- failure or discontinuation of any of our research programs;
- delays in establishing new strategic relationships;
- delays in the development of our potential products and commercialization of our potential products;
- market conditions in our sector and issuance of new or changed securities analysts’ reports or recommendations;
- general economic conditions, including adverse changes in the global financial markets;
- actual and anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing or distributing our products or potential products;
- market acceptance of our products or potential products;

- FDA or other United States or foreign regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our products or potential products;
- negative press or publicity regarding us or our common stock;
- the announcement of litigation against us or the results of on-going litigation;
- additions or departures of key personnel;
- third-party sales of large blocks of our common stock or third party short-selling activity;
- sales of our common stock by our executive officers, directors, or significant stockholders; and
- equity sales by us of our common stock or securities convertible into common stock to fund our operations.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock, such as the current class action and derivative lawsuits. Such lawsuits and any future related lawsuits could cause us to incur substantial costs defending the lawsuit and can also divert the time and attention of our management, which would have a negative adverse impact on our business. See the risk factor below entitled: “We are named defendant in certain litigation matters, including federal securities class action lawsuits and derivative complaints; if we are unable to resolve these matters favorably, then our business, operating results and financial condition may be adversely affected.”

We are named defendant in certain litigation matters, including federal securities class action lawsuits and derivative complaints; if we are unable to resolve these matters favorably, then our business, operating results and financial condition may be adversely affected.

We are currently involved in certain litigation matters, including securities class action and derivative litigation. See "Item 3 – Legal Proceedings" included in this Annual Report on Form 10-K. We cannot at this time predict the outcome of these matters or any future litigations matters (whether related or unrelated) or reasonably determine the probability of a material adverse result or reasonably estimate range of potential exposure, if any, that these matters or any future matters might have on us, our business, our financial condition or our results of operations, although such effects, including the cost to defend, any judgements or indemnification obligations, among others, could be materially adverse to us. In addition, in the future, we may need to record litigation reserves with respect to these matters. Further, regardless of how these matters proceed, it could divert our management’s attention and other resources away from our business.

Future sales of our common stock will result in dilution to our common stockholders.

Sales of a substantial number of shares of our common stock in the public market may depress the prevailing market price for our common stock and could impair our ability to raise capital through the future sale of our equity securities. Additionally, if the holders of outstanding options or warrants exercise or convert those shares, as applicable, our common stockholders will incur dilution in their relative percentage ownership. The prospect of this possible dilution may also impact the price of our common stock.

We do not expect to declare any dividends on our common stock in the foreseeable future.

We have not paid cash dividends to date on our common stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our business, and we do not anticipate paying any cash dividends on our common stock for the foreseeable future. Additionally, the terms of any future debt facilities may preclude us from paying dividends on the common stock. As a result, capital appreciation, if any, of our common stock could be the sole source of gain for the foreseeable future.

Anti-takeover provisions contained in our articles of incorporation and bylaws, as well as provisions of Nevada law, could impair a takeover attempt.

Our amended and restated articles of incorporation and bylaws currently contain provisions that, together with Nevada law, could have the effect of rendering more difficult or discouraging an acquisition deemed undesirable by our board of directors. Our corporate governance documents presently include the following provisions:

- providing for a “staggered” board of directors in which only one-third (1/3) of the directors can be elected in any year;
- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend, and other rights superior to our common stock; and
- limiting the liability of, and providing indemnifications to, our directors and officers.

These provisions, alone or together, could delay hostile takeovers and changes in control of our Company or changes in our management.

As a Nevada corporation, we also may become subject to the provisions of Nevada Revised Statutes Sections 78.378 through 78.3793, which prohibit an acquirer, under certain circumstances, from voting shares of a corporation’s stock after crossing specific threshold ownership percentages, unless the acquirer obtains the approval of the stockholders of the issuer corporation. The first such threshold is the acquisition of at least one-fifth, but less than one-third of the outstanding voting power of the issuer. We may become subject to the above referenced Statutes if we have 200 or more stockholders of record, at least 100 of whom are residents of the State of Nevada and do business in the State of Nevada directly or through an affiliated corporation.

As a Nevada corporation, we are subject to the provisions of Nevada Revised Statutes Sections 78.411 through 78.444, which prohibit an “interested stockholder” from entering into a combination with the corporation, unless certain conditions are met. An “interested stockholder” is a person who, together with affiliates and associates, beneficially owns (or within the prior two years did own) 10 percent or more of the corporation’s voting stock.

Any provision of our amended and restated articles of incorporation, our bylaws or Nevada law that has the effect of delaying or deterring a change in control of our Company could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Item 1B Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal administrative offices are located at 8560 Main Street, Suite 4, Williamsville, New York 14221. On October 4, 2017, we entered a lease for such office space in Williamsville, New York with an initial three-year term and with a monthly lease payment of \$6,375. The office space lease contains three (3) additional extensions; with each lease extension being for an additional one (1) year in duration, exercisable at our option. Future minimum annual lease payments under the lease will be approximately \$76,000 and \$80,000 for each of the years ended December 31, 2020, and 2021, respectively.

On January 15, 2020 the Company entered a new lease agreement for its current laboratory space in Buffalo, New York. The lease commenced on February 1, 2020 with an initial one-year term, a monthly lease payment of \$8,408 and an option to renew for an additional 12 months with a 3% increase in the monthly lease payments. The lease expense for the laboratory space was approximately \$68,700, \$62,600 and \$30,483 for the years ended December 31, 2019, 2018, and 2017, respectively. Future minimum annual lease payments under the laboratory space lease will be approximately \$100,000, \$104,000 and \$8,700 for the years ended December 31, 2020, 2021 and 2022, respectively.

We lease a manufacturing facility and warehouse located in North Carolina on a triple net lease basis. The manufacturing facility lease commenced on January 14, 2014 and had an initial term of twelve (12) months. The manufacturing facility lease contains four (4) additional extensions; with one lease extension being for an additional one (1) year and with the other three (3) lease extensions each being for an additional two (2) years in duration, exercisable at our option. We are currently in the third two-year lease extension term that will expire on October 31, 2020. The lease expense for our manufacturing facility for the years ended December 31, 2019, 2018, and 2017 amounted to approximately \$169,000, \$169,000 and \$156,000, respectively. The future minimum annual lease payments if we exercise each of the additional extensions are approximately as follows:

Year ended December 31, 2020 -	\$	169,000
Year ended December 31, 2021 -	\$	141,000

On August 14, 2017, we entered into a lease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment, to store our proprietary tobacco leaf and to store inventory used in our contract manufacturing business. On August 14, 2019, we entered into a second amendment to the lease. The amended lease calls for a monthly payment of \$4,665, on a month to month basis with a 30 day written termination requirement. Future minimum annual lease payments will be approximately \$56,000 per year for each subsequent year the warehouse space is leased by us.

Item 3. Legal Proceedings.

See Note 10 - Commitments and Contingencies – Litigation - to our consolidated financial statements included in this Annual Report for information concerning our on-going litigation. In addition to the lawsuits described in Note 10 to our consolidated financial statements, from time to time we may be involved in claims arising in the ordinary course of business. To our knowledge other than the cases described in Note 10 to our consolidated financial statements, no material legal proceedings, governmental actions, investigations or claims are currently pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

Item 4. Mine Safety Disclosures.

Not applicable

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is listed on the NYSE American under the symbol “XXII.” As of December 31, 2019, there were 89 holders of record of shares of our common stock.

Dividend Policy

We have not previously and do not plan to declare or pay any dividends on our common stock. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including current financial condition, operating results and current and anticipated cash needs.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Shares authorized for issuance under equity compensation plans

On April 12, 2014, the shareholders of the Company approved the 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (the “OIP”) and the authorization of 5,000,000 shares thereunder. On April 29, 2017, the stockholders approved an amendment to the OIP to increase the number of shares available for issuance by an additional 5,000,000 shares and on May 3, 2019, the stockholders approved an additional amendment to the OIP to increase the number of shares available for issuance by an additional 5,000,000 shares. The OIP allows for the granting of equity and cash incentive awards to eligible individuals over the life of the OIP. The OIP has a term of ten years and is administered by the Compensation Committee of the Company’s Board of Directors to determine the various types of incentive awards that may be granted to recipients under this plan and the number of shares of common stock to underlie each such award under the OIP. As of December 31, 2019, the Company had available 6,307,115 shares remaining for future awards under the OIP.

The following table summarizes the number of shares of common stock to be issued upon exercise of outstanding and restricted stock units, the weighted-average exercise price of such stock options and the number of securities available to be issued under the OIP as of December 31, 2019:

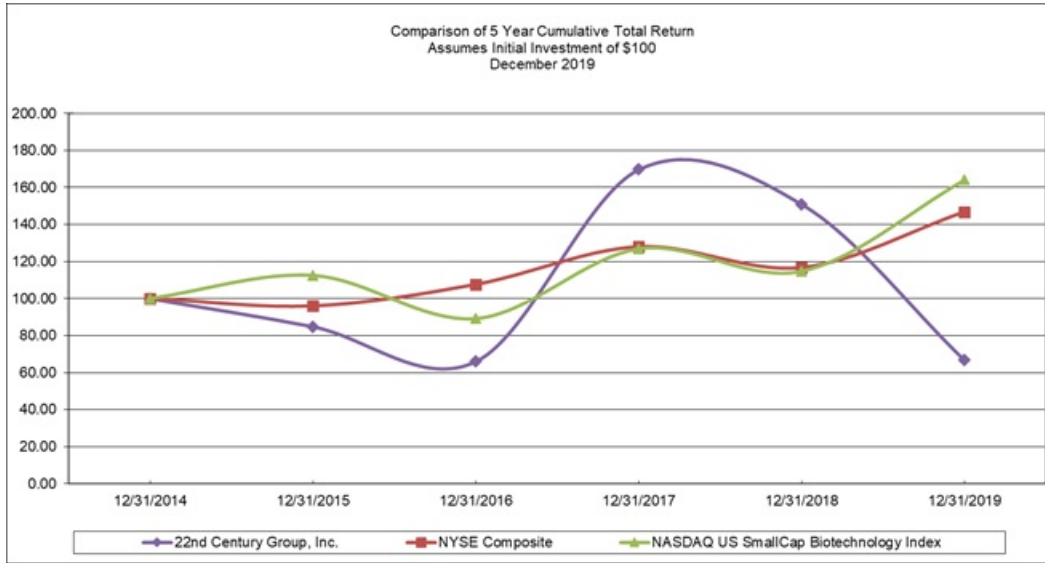
	Number of securities to be issued upon exercise of outstanding options, and restricted stock units, (a)	Weighted average exercise price of outstanding options (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	8,088,172	\$ 1.49	6,307,115
Equity compensation plans not approved by security holders	-	N/A	-
Total	8,088,172		6,307,115⁽¹⁾

(1) Consists of shares available for award under the OIP.

Stock Performance Graph

The following information in this Item of the Annual Report on Form 10-K is not deemed to be “soliciting material” or to be “filed” with the Securities and Exchange Commission or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or to the liabilities of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference to any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that we specifically incorporate such information into such filing.

The performance graph shown below compares the cumulative total shareholder return on the Company’s common stock, based on the market price of the common stock, with the total return of the NYSE American Composite Index and the NASDAQ US Small Cap Biotechnology Index for the period covering December 31, 2014 through December 31, 2019. The comparison of total return assumes that a fixed investment of \$100 was invested on December 31, 2014 in the Company’s common stock and in each of the foregoing indices and further assumes the reinvestment of dividends. The stock price performance shown on the graph is not necessarily indicative of future price performance.



Item 6. Selected Financial Data.

The selected consolidated financial data for each of the five years in the period ending December 31, 2019 are derived from our audited financial statements. The selected consolidated financial data should be read in conjunction with our audited consolidated financial statements and the notes thereto contained in Item 8, and Management's Discussion and Analysis of Financial Condition and Results of Operations and Comprehensive Loss, as set forth in Item 7 of this Annual Report on Form 10-K.

	Years Ended December 31 ,				
	2019	2018	2017	2016	2015
Consolidated Statements of Operations and Comprehensive Loss data:					
Revenue	\$ 25,832,530	\$ 26,426,347	\$ 16,600,244	\$ 12,279,979	\$ 8,521,998
Gross profit (loss)	\$ 14,455	\$ 898,987	\$ (707,912)	\$ (429,699)	\$ (580,562)
Operating expenses (1)	\$ 21,013,564	\$ 23,575,279	\$ 11,644,955	\$ 10,115,968	\$ 10,689,010
Equity based compensation included in operating expenses	\$ 3,539,744	\$ 3,187,331	\$ 941,650	\$ 911,382	\$ 3,585,540
Operating loss	\$ (23,566,461)	\$ (24,018,627)	\$ (13,299,864)	\$ (11,387,847)	\$ (12,043,883)
Warrant liability gain (loss) - net	\$ -	\$ 48,711	\$ (157,809)	\$ 29,615	\$ 144,550
Net loss	\$ (26,558,544)	\$ (7,966,911)	\$ (13,029,117)	\$ (11,581,430)	\$ (11,031,931)
Loss per common share - basic and diluted	\$ (0.21)	\$ (0.06)	\$ (0.13)	\$ (0.15)	\$ (0.16)
Common shares used in basic earnings per share calculation	125,882,717	124,298,981	101,161,380	79,842,773	68,143,284
Consolidated Balance Sheet data:					
Working capital	\$ 36,963,118	\$ 56,023,982	\$ 63,308,249	\$ 13,548,118	\$ 3,991,828
Total assets	\$ 68,951,365	\$ 77,302,136	\$ 79,739,406	\$ 27,642,357	\$ 18,370,512
Total debt	\$ 1,474,865	\$ 1,537,365	\$ -	\$ 307,938	\$ 616,520
Total shareholders' equity	\$ 62,050,822	\$ 71,280,735	\$ 75,426,200	\$ 24,334,359	\$ 11,728,500
Other data:					
Net cash used in operating activities	\$ (14,587,364)	\$ (17,844,266)	\$ (12,068,383)	\$ (9,887,580)	\$ (7,321,811)
Net cash provided by (used in) investing activities (2)	\$ 4,551,933	\$ 15,145,044	\$ (60,586,245)	\$ (553,770)	\$ (450,661)
Net cash (used in) provided by financing activities	\$ 9,915,617	\$ (355,387)	\$ 62,845,974	\$ 20,149,241	\$ 5,130,082
Acquisition of patents and trademarks (3)	\$ 825,567	\$ 656,985	\$ 450,208	\$ 356,541	\$ 413,180
Depreciation	\$ 589,310	\$ 522,695	\$ 353,435	\$ 326,124	\$ 319,699
Amortization (4)	\$ 835,693	\$ 819,640	\$ 593,562	\$ 516,056	\$ 454,612

(1) Operating expenses include costs for research and development, sales, general and administrative, and exclude impairment, depreciation and amortization expense. Operating expenses for the years ended December 31, 2019 and 2018 include expenses relating to our MRTPA of approximately \$1,675,000 and \$9,800,000, respectively.

(2) Includes \$58,979,131 used to purchase short-term investment securities during the year ended December 31, 2017.

(3) Includes cash paid for patent and trademark costs during the applicable year.

(4) Includes the amortization of patent costs and license fees.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This discussion should be read in conjunction with the other sections of this Form 10-K, including "Risk Factors," and the Financial Statements and notes thereto. This section of the Form 10-K generally discusses 2019 and 2018 items and year-to-year comparisons of 2019 to 2018. Discussions of 2017 items and year-to-year comparisons of 2018 and 2017 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 on our Annual Report on Form 10-K for the year ended December 31, 2018. The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this Annual Report on Form 10-K. See "Forward-Looking Statements." Our actual results may differ materially. For purposes of this Management's Discussion and Analysis of Financial Condition and Results of Operations, references to the "Company," "we," "us" or "our" refer to the operations of 22nd Century Group, Inc. and its direct and indirect subsidiaries for the periods described herein.

Business Overview

We are a plant biotechnology company focused on (i) developing reduced risk tobacco cigarettes produced from modifying the nicotine content in tobacco plants through genetic engineering and modern plant breeding, and (ii) research and development of unique hemp/cannabis plants through genetic engineering and modern plant breeding to alter levels of cannabinoids to be used for potential new medicines and to improve other agronomic traits for improved agricultural applications. Our mission in tobacco is to reduce the harm caused by smoking by introducing adult smokers to our proprietary, Very Low Nicotine Content ("VLNC") tobacco and cigarettes. Our mission in hemp/cannabis is to develop proprietary varieties of hemp with valuable cannabinoid profiles and other superior agronomic traits. We have a significant intellectual property portfolio of issued patents and patent applications relating to the tobacco and hemp/cannabis plants.

We currently are primarily involved in the following activities:

- Continuing to work with the FDA on our Modified Risk Tobacco Product application ("MRTPA") that we have submitted to the FDA to obtain a reduced exposure marketing authorization for our Very Low Nicotine Content ("VLNC") cigarettes to be marketed in the United States under the proposed brand name of VLN[®] as containing 95% less nicotine than conventional tobacco cigarettes, and other related claims as may be approved by the FDA;
- Facilitating the implementation of the plan by the FDA to require that all combustible cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine;
- Seeking licensing agreements and strategic partnerships to commercialize our VLNC tobacco technology and/or our VLNC proprietary tobaccos in the U.S. and internationally;
- Continuing to produce *SPECTRUM*[®] research cigarettes for the National Institute on Drug Abuse ("NIDA"), which is part of the National Institutes of Health ("NIH"), for use in independent clinical studies;
- Continuing to expand our legal hemp/cannabis activities and development of unique plant varieties of hemp, including (i) hemp plants with other desirable agronomic traits in addition to low to no amounts of THC for the legal hemp industry, and (ii) hemp plants with high levels of CBD and other non-THC cannabinoids for the legal medical cannabinoid markets;
- Continuing to explore opportunities to create shareholder value through partnerships, investments and other strategic relationships across the entire hemp/cannabis value chain, including branded consumer products; and
- Continuing to seek additional customers to increase our contract manufacturing business for third-party branded tobacco products.

Recent Developments

For the fourth quarter of 2019, our accomplishments and notable events include:

On November 25, 2019, we entered into Warrant Exercise Agreements (the "Exercise Agreements") with all of the holders (the "Exercising Holders") of our outstanding warrants to purchase up to 11,293,211 shares of common stock with an exercise price of \$2.15 per share (the "Original Warrants") whereby we and the Exercising Holders agreed that the Exercising Holders would exercise for cash all of the Original Warrants at a reduced exercise price of \$1.00 per share, generating gross proceeds of approximately \$11.3 million. In consideration for the Exercising Holders exercising their Original Warrants for cash, we issued to each Exercising Holder a new warrant (each, a "New Warrant") to purchase shares of common stock equal to the number of shares of common stock underlying the Original Warrants. The terms of the New Warrants are substantially similar to the terms of the Original Warrants, except that the New Warrants are (i) exercisable from first issuance of the New Warrants for a period of five years and (ii) have an exercise price equal to \$1.11 per share.

On December 3, 2019, we announced that we had conducted an initial closing of an investment in Panacea, a vertically-integrated developer, producer and seller of legal, hemp-derived, CBD products, with extraction, distillation, testing and manufacturing operations located in a 51,000 square foot facility in Golden, Colorado. In that public announcement, we stated that our 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 our common stock in exchange for Panacea-issued debt and Panacea preferred stock. We also received a warrant from Panacea to purchase additional shares of preferred stock of Panacea, which upon full exercise will provide us with a controlling equity position in Panacea. To date, the Company has issued a \$7 million convertible note receivable, purchased 3,733,334 shares of Series B Preferred Shares at a cost of \$5 million, issued 1,297,017 shares of 22nd Century common stock to Panacea, and received a warrant to purchase additional Series B Preferred Shares at \$2.344.

On December 17, 2019, the FDA publicly announced that the FDA had authorized us to market in the U.S. our VLNC tobacco cigarettes under the product names of Moonlight[®] and Moonlight Menthol[®] that were the subject of our Premarket Tobacco product application (“PMTA”). Our Moonlight[®] and Moonlight Menthol[®] cigarettes are made with our proprietary VLNC tobacco and, as a result, contain very low levels of nicotine. Our Moonlight[®] and Moonlight Menthol[®] cigarettes were modeled after our VLNC SPECTRUM[®] research cigarettes. Our PMTA references more than 50 independent studies conducted using our proprietary SPECTRUM[®] research cigarettes. In its public announcement relating to our PMTA, the FDA stated that following a rigorous science-based review of our PMTA, the FDA had determined that authorizing these reduced nicotine products for sale in the U.S. is appropriate for the protection of the public health because of, among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure and cigarette consumption. The FDA further stated that the FDA had determined that non-smokers, including youth, are also unlikely to start using these products, and those who experiment are less likely to become addicted than people who experiment with conventional cigarettes.

On February 14, 2020, the FDA’s Tobacco Products Scientific Advisory Committee (“TPSAC”) conducted a public hearing regarding our MRTPA for our VLNC tobacco cigarettes for which we are requesting a reduced exposure marketing authorization from the FDA to market our VLNC tobacco cigarettes in the U.S. as a Modified Risk Tobacco Product with product labeling that includes the proposed brand name of VLN[®] and states that the VLN[®] product has 95% less nicotine than conventional cigarettes. Our MRTPA requests FDA authorization for us to state on packaging and advertising that, among other things, the proposed VLN[®] cigarettes contain “95% Less Nicotine.” In contrast, an analysis of the top 100 leading cigarette styles in the United States showed that conventional and highly addictive cigarettes currently sold in the United States contain an average of 19.4mg of nicotine per gram of tobacco (with an actual nicotine range of 14.7mg to 33.2mg per gram of tobacco). The MRTPA states that 22nd Century’s proposed VLN[®] cigarettes are the same as the lowest nicotine content style of the Company’s SPECTRUM[®] research cigarettes. Our SPECTRUM[®] research cigarettes were developed in collaboration with the FDA and other U.S. federal government agencies to provide independent scientists with the products necessary to investigate the public health benefits of reduced-nicotine content cigarettes. Our MRTPA references more than 50 independent studies that utilized SPECTRUM[®] research cigarettes.

This meeting was the first time that TPSAC considered an MRTP application for a modified exposure claim and also TPSAC’s first discussion of an application for a combustible tobacco product. We 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 meeting materials, including briefing materials for the committee provided by us and the FDA, and presentation given by the different stakeholders are publicly available for review via FDA’s website. The public comment period on the applications remains open at this time. FDA continues to comprehensive evaluation of our applications.

Results of Operations

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018.

Revenue - Sale of products, net

We realized net revenue from the sale of products in the amount of \$25,832,530 during the year ended December 31, 2019, as compared to net revenues of \$26,426,347 during the year ended December 31, 2018, a decrease of \$593,817, or 2%. This decrease in net revenue was primarily the result of the sale of *SPECTRUM*[®] research cigarettes during the fourth quarter of 2018 in the amount of \$607,000. There were no sales of *SPECTRUM*[®] research cigarettes during 2019.

Costs of goods sold - Products

During the year ended December 31, 2019, cost of goods sold were \$25,818,075, or 100.0% of net sales revenue, resulting in a gross profit on sales of products in the amount of \$14,455. During the year ended December 31, 2018, cost of goods sold were \$25,527,360, or 97%, of net sales revenue, resulting in a gross profit on sales of products in the amount of \$898,987. The \$884,532 decline in gross profit for the year ended December 31, 2019 from the year ended December 31, 2018 consisted primarily of an increase in fees due to the FDA on filtered cigars and the absence in 2019 of sales of *SPECTRUM*[®] research cigarettes. Additionally, included in the cost of goods sold during 2019 was a net write off of obsolete finished goods and raw materials inventory in the approximate amount of \$54,000, resulting in a corresponding increase in the cost of goods sold.

Research and development expense

Research and development expenses were \$8,057,147 for the year ended December 31, 2019, a decrease of \$6,932,599, or 46%, from \$14,989,746 for the year ended December 31, 2018. This decrease was primarily the result of a decrease in expenses relating to our MRTPA with the FDA for our VLNC cigarettes of approximately \$8,125,000, a decrease in equity-based compensation of approximately \$1,472,000 (2018 included approximately \$1,230,000 in equity-based compensation recognized due to the death of our Senior Vice President of Science and Regulatory Affairs in the second quarter of 2018), partially offset by an increase in sponsored research costs of approximately \$1,310,000, an increase in consulting fees of approximately \$139,000, an increase in the net write off of our tobacco leaf inventory of approximately \$985,000, an increase in severance expense of approximately \$160,000, and approximately \$125,000 in additional royalty expenses during the year ended December 31, 2019, as compared to the year ended December 31, 2018.

Sales, general and administrative expense

Sales, general and administrative expense was \$12,956,417 for the year ended December 31, 2019, an increase of \$4,370,884, or 51%, from \$8,585,533 for the year ended December 31, 2018. The increase was primarily due to an increase in equity-based compensation of approximately \$1,825,000, an increase in payroll and payroll related benefits of approximately \$2,031,000 (including approximately \$720,000 in one-time severance costs), an increase in legal and other professional expenses of approximately \$452,000, an increase in business insurance expenses of approximately \$190,000, an increase in consulting fees of approximately \$100,000, an increase in repairs & maintenance expense of approximately \$80,000, an increase in Board of Director related expenses of \$72,500, and an increase in travel and entertainment expenses of approximately \$70,000, partially offset by a decrease in expenses relating to investor relations of approximately \$455,000 during the year ended December 31, 2019 as compared to the year ended December 31, 2018.

Impairment

The non-cash impairment charge for the year ended December 31, 2019 amounted to \$1,142,349 and related to the portion of our intellectual property portfolio relating to increased nicotine in tobacco, potentially reduced exposure products involving higher nicotine products, older scientific methods of working with genes in tobacco plants, methods of utilizing the biomass of tobacco plants, and trademarks that do not fit within the types of products that we desire to commercialize in the future. We incurred no impairment for the year ended December 31, 2018.

Depreciation expense

Depreciation expense for the year ended December 31, 2019 amounted to \$589,310, an increase of \$66,615, or 12.7%, from \$522,695 for the year ended December 31, 2018. The increase was primarily due to depreciable acquisitions of machinery and equipment during the years ended December 31, 2019 and 2018 in the approximate amount of \$527,000 and \$449,000, respectively, primarily consisting of equipment additions in our NASCO factory operations in North Carolina, equipment additions in our laboratory facility in Buffalo, New York, and leasehold improvements to our corporate office in Williamsville, New York.

Amortization expense

Amortization expense, relating to amortization taken on capitalized patent costs and license fees, for the year ended December 31, 2019 amounted to \$835,693, an increase of \$16,053, or 2.0%, from \$819,640 for the year ended December 31, 2018. The increase is primarily due to amortization on additional patent costs incurred during the years ended December 31, 2018, and 2019 in the amounts of \$751,492 and \$1,233,806. This was partially offset by lower amortization expense on a lower patent asset base, following impairment charges of \$1,142,349 during the third quarter of 2019.

Unrealized (loss) gain on investments

In January of 2018, Anandia closed a private placement of common stock reducing our equity investment in Anandia to 14.8%. On August 8, 2018, all of Anandia's outstanding common stock was acquired by Aurora Cannabis, Inc. ("Aurora") (TSX: ACB.TO), in exchange for (i) free trading shares of Aurora common stock, and (ii) warrants with a five-year term to purchase one-half of a share of Aurora common stock for each whole share of Aurora common stock received as part of the transaction (the "Anandia transaction"). As a result of the Anandia transaction, we received 1,947,943 shares of Aurora common stock and warrants to purchase 973,971 shares of Aurora common stock that had a fair value of \$9,221,594 and \$2,807,958, respectively.

The warrants to purchase 973,971 shares of Aurora common stock, described above and in Note 8 to our financial statements, are considered an equity security, and are recorded at fair value. The Company recorded the fair value of the stock warrants of \$673,010 at December 31, 2019, using the Black-Scholes pricing model, and recorded an unrealized loss on the warrants in the amount of \$2,419,348 for the year ended December 31, 2019. For the year ended December 31, 2018, we recorded the fair value of these warrants of \$3,092,358 and recorded an unrealized gain of \$284,400. The decrease in the fair value of the stock warrants is primarily related to the decrease in the stock price of Aurora.

Realized gain on investments

There were no realized gains on investments during 2019.

As a result of the Anandia transaction described above, we recorded a realized gain on the transaction in the amount of \$4,515,971 during the third quarter of 2018. Additionally, the unrealized gain on our investment in Anandia in the amount of \$6,147,088 from the first quarter of 2018 became a realized gain at time the security was sold. Subsequent to the Anandia transaction, we sold all our Aurora common stock resulting in net sales proceeds \$13,051,503 and realized a gain on the sale of \$3,829,909. The realized gain from the Anandia transaction, the gain from ASU 2016-01, and the sale of the Aurora common shares resulted in an aggregate realized gain of \$14,492,968 for the year ended December 31, 2018.

Realized gain (loss) on short-term investment securities

The realized gain on short-term investment securities for the year ended December 31, 2019 was \$220,872, an increase of \$275,323 from a loss of \$54,451 for the year ended December 31, 2018. The realized gain on short-term investment securities was the result of the maturity of various debt instruments held in the short-term investment account. Investments in the short-term investment account are managed in accordance with our investment policy.

Litigation settlement expense

We incurred an expense relating to the settlement agreement in the Crede litigation in the amount of \$1,890,900 for the year ended December 31, 2019. We had no litigation settlement expenses for the year ended December 31, 2018.

Gain on the sale of machinery and equipment

During the year ended December 31, 2019, we sold a piece of machinery and equipment no longer required in our factory operations in North Carolina and recorded a gain on the sale in the amount of \$87,351. We had no sales of machinery and equipment during the year ended 2018.

Warrant liability gain (loss), net

There were no warrants with anti-dilution features outstanding during 2019 and, therefore, no warrant liability gain (loss) was recorded in 2019 compared to a \$48,711 gain for the year ended December 31, 2018.

Dividend income

We received no dividend income for the year ended December 31, 2019, a decrease of \$221,991 from the year ended December 31, 2018. During the period of 2018 that we owned common stock in Aurora, Aurora spun off a subsidiary into a separate publicly traded Canadian company. Non-Canadian shareholders received a one-time cash dividend and as a result of this transaction we received a cash dividend in the amount of \$221,991

Interest income, net

Interest income, net for the year ended December 31, 2019 was \$1,066,324, a decrease of \$2,712 from interest income of \$1,069,036 for the year ended December 31, 2018. The decrease in net interest income (interest income less investment fees) was the result of lower interest-bearing balances largely offset with the addition of approximately \$76,000 interest income earned on the convertible note receivable from Panacea during 2019 as compared to 2018.

Interest expense

Interest expense was \$56,382 and \$10,939 for the years ended December 31, 2019 and 2018, respectively. The interest expense for the year ended December 31, 2019 was primarily derived from interest accreted on notes payable to NCSU and the University of Kentucky, and interest accretion on accrued severance.

Net loss

We had a net loss for the year ended December 31, 2019 of \$26,558,544 as compared to a net loss of \$7,966,911 for the year ended December 31, 2018, an increase in the net loss of \$18,591,633, or 233%. This increase in the net loss was primarily the result of a decrease in the one-time realized gain on investments relating to the Anandia/Aurora transactions during 2018 of approximately \$14,493,000, a decrease in the unrealized gain (loss) on the Aurora stock warrants of approximately \$2,704,000, a one-time litigation settlement expense of approximately \$1,891,000, and a reduction in gross profit of approximately \$885,000, partially offset by a decrease in operating expenses of approximately \$1,337,000, and an increase in net other income (expense) items of approximately \$44,000.

Other comprehensive income

We maintain an account for short-term investment securities that are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as Other comprehensive income or loss. We recorded an unrealized gain on short-term investment securities in the amount of \$206,583 and recorded a reclassification of gains to net loss in the amount of \$220,872 resulting in an other comprehensive loss of \$14,289 for the year ended December 31, 2019, compared to an other comprehensive gain of \$21,363 for the year ended December 31, 2018.

Liquidity and Capital Resources

Working Capital

As of December 31, 2019, we had positive working capital of approximately \$37.0 million compared to positive working capital of approximately \$56.0 million at December 31, 2018, a decrease of approximately \$19.0 million. This decrease in working capital is due a decrease in current assets of approximately \$18.5 million, which is primarily due to a decrease in cash and cash equivalents and short-term investment securities of approximately \$17.4 million, slightly offset by a decrease in current liabilities of approximately \$0.6 million. We used approximately \$14.6 million in operating activities during the year ended December 31, 2019.

We must successfully execute our business plan to increase revenue in order to achieve positive cash flows from operations to sustain adequate liquidity without requiring additional funds from capital raises and other external sources to meet minimum operating requirements.

Cash demands on operations

We had cash and cash equivalents and short-term investment securities at December 31, 2019 of \$38,962,185. We believe this amount of cash and cash equivalents and short-term investment securities will be adequate to sustain normal operations and meet all current obligations as they come due for a number of years. During the year ended December 31, 2019, we experienced an operating loss of \$23,566,461 (including approximately \$1,675,000 in expenses relating to our MRTPA) and used cash in operations of \$14,587,364. Excluding discretionary expenses relating to R&D, patent and trademark costs, contract growing of our proprietary tobacco, modified risk tobacco products and certain nonrecurring expenses relating to factory capital expenses, and investor relations and marketing costs, our monthly cash expenditures are approximately \$1,000,000. There may be additional future costs relating to our MRTPA should the FDA require additional studies.

Net cash used in operating activities

In the year ended December 31, 2019, \$14,587,364 of cash was used in operating activities as compared to \$17,844,266 of cash used in operating activities in the year ended December 31, 2018; a decrease of \$3,256,901. The decrease in use of cash in operations was primarily due to the decrease in the cash portion of the net loss in the amount of \$3,947,681, partially offset by an increase in cash used from working capital components related to operations in the amount of \$690,780, for the year ended December 31, 2019 as compared to the year ended December 31, 2018.

Net cash provided by (used in) investing activities

In the year ended December 31, 2019, net cash provided by investing activities was \$4,551,933 as compared to \$15,145,044 of cash provided by investing activities during the year ended December 31, 2018. During the year ended December 31, 2019 the cash provided by investing activities consisted of net cash provided by transactions relating to our short-term investment account in the amount of \$17,478,448, and proceeds from the sale of machinery and equipment in the amount of \$166,150, partially offset by cash used in the acquisition of patents and trademarks, machinery and equipment and a cigarette predicate license agreement in the amount of \$1,092,665 and by the equity and debt investment in Panacea of \$12,000,000. During the year ended December 31, 2018 the cash provided by investing activities consisted of net cash provided from our sale of the common stock of Aurora in the amount of \$13,051,503 and net cash provided by transactions relating to our short-term investment account in the amount of \$3,199,165, partially offset by cash used in the acquisition of patents and trademarks and machinery and equipment in the amount of \$1,105,624.

Net cash provided by (used in) financing activities

During the year ended December 31, 2019, we realized \$9,915,617 in proceeds from our financing activities resulting from net proceeds from the exercise of warrants in the amount of \$10,615,617, partially offset by payments on notes payable in the amount of \$700,000.

During the year ended December 31, 2018, we used \$355,387 in our financing activities as a result of payments on notes payable in the amount of \$800,000, offset by net cash proceeds received from the exercise of stock options in the amount of \$444,613.

Contractual Obligations

The following table summarizes by category our expected future cash outflows associated with contractual obligations in effect at December 31, 2019:

	Payments Due by Period				
	Total	Year Ended December 31, 2020	Years Ended December 31, 2021 & 2022	Years Ended December 31, 2023 & 2024	More Than Five Years
Notes payable	\$ 900,000	\$ 900,000	\$ -	\$ -	\$ -
Operating lease obligations (1)	905,917	359,326	458,088	88,558	-
Consulting agreements	105,000	105,000	-	-	-
License fees	2,290,000	290,000	620,000	220,000	1,160,000
Sponsored research	<u>5,095,000</u>	<u>1,200,000</u>	<u>2,400,000</u>	<u>1,495,000</u>	<u>-</u>
Total	<u>\$ 9,295,917</u>	<u>\$ 2,854,326</u>	<u>\$ 3,478,033</u>	<u>\$ 1,803,558</u>	<u>\$ 1,160,000</u>

(1) Include potential lease obligations due upon exercise of various lease option renewals.

Critical Accounting Policies and Estimates

Accounting principles generally accepted in the United States of America, or U.S. GAAP, require estimates and assumptions to be made that affect the reported amounts in our consolidated financial statements and accompanying notes. Some of these estimates require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations.

Short-term Investment Securities

Our short-term investment securities are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. Our short-term investment securities are carried at fair value within current assets on the Company's Consolidated Balance Sheets, with fair value based on either quoted market prices or pricing models maximizing the use of observable inputs for similar securities. We view our available-for-sale securities as available for use in current operations regardless of the stated maturity date of the security. Our investment policy states that all investment securities must have a maximum maturity of twenty-four (24) months or less and the maximum weighted maturity of the investment securities must not exceed twelve (12) months. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as other comprehensive income or loss on our Consolidated Statements of Operations and Comprehensive Loss. Realized gains and losses on short-term investment securities are recorded in the other income (expense) portion of our Consolidated Statements of Operations and Comprehensive Loss. Interest earned, net of investment fees, on the short-term investment securities are included in interest income.

Inventory

Inventories are valued at the lower of cost or net realizable value. Cost is determined using an average cost method for tobacco leaf inventory and raw materials inventory and standard cost is primarily used for finished goods inventory. Inventories are evaluated to determine whether any amounts are not recoverable based on slow moving or obsolete condition and are written off or reserved as appropriate.

Right-of-use assets

On January 1, 2019, the Company adopted ASU 2016-02, Subtopic ASC 842, Leases (the “new guidance”). Under the new guidance, the Company was required to evaluate its leases and record a Right-of-use (“ROU”) asset and a corresponding lease obligation for leases that qualified as either finance or operating leases. Prior to the adoption of the new guidance, the Company had various operating leases for real estate. The Company elected to use the practical expedient which allowed the Company to carry forward the historical lease classifications of the existing leases. The Company determined that its leases contained (1) no variable lease expenses, (2) no termination options, (3) no residual lease guarantees, and (4) no material restrictions or covenants. The new guidance calls for the lease obligations to be recorded at the present value of the remaining lease payments under the leases and the ROU assets are recorded as the sum of the present value of the lease obligations plus any initial direct costs minus lease incentives plus prepaid lease payments. All remaining renewal options have been included in the computation of the ROU assets and lease obligations. The Company determined that two real estate leases qualified as operating leases under the new guidance.

Revenue Recognition

On January 1, 2018, we adopted ASC 606, Revenue from Contracts with Customers and all related amendments (the “new revenue standard”) for all contracts using the modified retrospective method. Under the modified retrospective method, we were required to record a cumulative-effect adjustment to the opening balance of retained earnings on January 1, 2018. We determined that the adoption of the new revenue standard did not require a cumulative-effect adjustment. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

We recognize revenue when it satisfies a performance obligation by transferring control of the product to a customer. Our customer contracts consist of obligations to manufacture the customer’s branded filtered cigars and cigarettes. For certain contracts, the performance obligation is satisfied over time as we determine, due to contract restrictions, it does not have an alternative use of the product, and it has an enforceable right to payment as the product is manufactured. We recognize revenue under those contracts at the unit price stated in the contract based on the units manufactured. The manufacturing process is completed on a daily basis and, therefore, there were no performance obligations partially satisfied at December 31, 2018. For contracts where the performance obligation is satisfied at a point in time, we recognize revenue when the product is transferred to the customer. Revenue from the sale of our products is recognized net of cash discounts, sales returns and allowances. There was no allowance for discounts or returns and allowances at December 31, 2019 and 2018.

The Company provides assurance to customers that the product complies with the agreed-upon contract specifications. Shipping and handling activities associated with outbound freight after control of the product has transferred to a customer are considered a fulfillment activity. The related shipping and handling expenses are included in cost of goods sold.

We generally require a down payment from its customers prior to commencement of manufacturing the product. Amounts received in advance of satisfying the performance obligations are recorded as deferred revenue. Customer payment terms vary depending on the terms of each customer contract, but payment is generally due prior to product shipment or within extended credit terms up to twenty-one (21) days after shipment; therefore, the Company’s contracts with customers do not include a significant financing component.

Impairment of Long-Lived Assets

We review the carrying value of our amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable. We also assess recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset’s carrying value and its fair value. Non-amortizing intangibles (e.g. trademarks) are reviewed annually for impairment. During the year ended December 31, 2019, the Company decided on a going-forward basis that it will be concentrating its business and scientific resources, personnel and efforts on the portion of our intellectual property portfolio (patents, patent applications and trademarks) that relate to very low nicotine tobacco plants and potential products, as well as unique hemp/cannabis plants and potential products, in order to more strategically pursue our objectives. Accordingly, we recorded a non-cash impairment charge of \$1,142,349 (cost of \$2,092,485 less accumulated amortization of \$950,136) relating to patent and trademark costs not associated with these strategic objectives. This impairment charge is included as a separate line item in operating expenses on the Company’s Consolidated Statements of Operations and Comprehensive (Loss) Income.

Amortization Estimates of Intangible Assets

We generally determine amortization based on the estimated useful lives of the assets and record amortization expense on a straight-line method over such lives. The remaining life of the primary patent in each patent family is generally used to determine the estimated useful life of the related patent costs.

Fair Value of Financial Instruments

The Company’s financial instruments include cash and cash equivalents, short-term investment securities, accounts receivable, investments, a convertible note receivable, accounts payable, accrued expenses, and notes payable. Other than for cash equivalents, short-term investment securities, investments, and convertible note receivable, fair value is assumed to approximate carrying values for these financial instruments, since they are short term in nature, they are receivable or payable on demand, or had stated interest rates that approximate the interest rates available to the Company as of the reporting date. The determination of the fair value of cash equivalents, short-term investment securities, investments (stock warrants and equity investment), and convertible note receivable are discussed in Note 5.

Investments

The Company accounts for investments in equity securities of other entities under the equity method of accounting if the Company’s investment in the stock of the other entity provides the Company with the ability to have significant influence over the operating and financial policies of the investee. If the Company does not have significant influence over the operating or financial policies of the entity, and such equity investment does not have a readily determinable market value, then the Company accounts for such equity investments in accordance with FASB ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which the Company adopted in the first quarter of 2018 with respect to the Company’s investments. Under ASU 2016-01 equity securities are recorded at fair value, with changes in fair value recorded through the statement of operations. Equity securities without a readily determinable market value are carried at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same issuer. The Company considers debt instruments as available-for-sale securities, and accordingly, all unrealized gains and losses incurred on the short-term investment securities (the adjustment to fair value) are recorded in other comprehensive income or loss on the Company’s Consolidated Statements of Operations and Comprehensive Loss.

The Company has an investment in Aurora stock warrants that are considered equity securities under ASC 321 – Investments – Equity Securities and a derivative instrument under ASC 815 – Derivatives and Hedging. The stock warrants are not designated as a hedging instrument, and in accordance with ASC 815, the Company's investment in stock warrants are recorded at fair value with changes in fair value recorded in the Company's Consolidated Statements of Operations and Comprehensive Loss. The Company also has Panacea stock warrants that are not considered a derivative under ASC 815. As such, the Panacea stock warrants are considered an equity investment with no readily determinable market value and are carried at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same issuer.

During the fourth quarter of 2019, the Company made an investment in Panacea consisting of preferred shares that are not considered in-substance common stock, a stock warrant and a convertible note receivable. The convertible note receivable was recorded at a discount with the note discount amortized into interest income over the term of the note. This transaction, along with the related valuation techniques are more fully described in Note 4.

Stock Based Compensation

We use a fair-value based method to determine compensation for all arrangements under which Company employees and others receive shares, options or warrants to purchase shares of our common stock. Equity based compensation expense is recorded over the requisite service period based on estimates of probability and time of achieving milestones and vesting. For accounting purposes, the shares will be considered issued and outstanding upon vesting.

Income taxes

We recognize deferred tax assets and liabilities for any basis differences in our assets and liabilities between tax and U.S. GAAP reporting, and for operating loss and credit carry-forwards. In light of our history of cumulative net operating losses and the uncertainty of their future utilization, we have established a valuation allowance to fully offset our net deferred tax assets as of December 31, 2019 and 2018.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. Derivative financial instruments are initially recorded at fair market value and then are revalued at each reporting date, with changes in fair value reported in the Consolidated Statements of Operations and Comprehensive Loss.

The classification of derivative instruments is evaluated at the end of each reporting period. Derivative instruments are classified in the consolidated balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the consolidated balance sheet date.

Inflation

Inflation did not have a material effect on our operating results for the years ended December 31, 2019 and 2018.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by Item 303(a)(4) of Regulation S-K.

Item 8. Financial Statements and Supplementary Data.

The required financial statements and the notes thereto are contained in a separate section of this Form 10-K beginning with the page following Item 15 (Exhibits and Financial Statement Schedules, including Selected Quarterly Financial Data).

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our president (principal executive officer) and chief financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based on this evaluation, our president and chief financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K to ensure information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms. These disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit is accumulated and communicated to management, including our president and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our president and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control - Integrated Framework (2013)*, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Freed Maxick CPAs, P.C., an independent registered public accounting firm, has audited the consolidated financial statements included in this Annual Report on Form 10-K and, as part of their audit, has issued a report, included herein, on the effectiveness of our internal control over financial reporting.

Our system of internal control over financial reporting was designed to provide reasonable assurance regarding the preparation and fair presentation of published financial statements in accordance with accounting principles generally accepted in the United States. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Controls over Financial Reporting

There was no change in the Company's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors
22nd Century Group, Inc.

Opinion on the Internal Control Over Financial Reporting

We have audited 22nd Century Group Inc. and Subsidiaries (the Company) internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows of the Company for each of the three years in the period ended December 31, 2019 of the Company and our report dated March 11, 2020 expressed an unqualified opinion.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting in the accompanying "Management's Annual Report on Internal Controls Over Financial Reporting".

Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Freed Maxick CPAs, P.C.

Buffalo, New York
March 11, 2020

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information concerning our executive officers, directors and corporate governance is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2020 Annual Meeting of Stockholders.

Set forth below is information regarding our directors, executive officers and key personnel as of March 11, 2020:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Michael Zercher	49	President and Chief Operating Officer
Andrea Jentsch	49	Chief Financial Officer & Treasurer
James W. Cornell	63	Director*
Richard M. Sanders	67	Director**
Nora B. Sullivan	62	Director***
Clifford B. Fleet	49	Director****
Roger D. O'Brien	72	Director*****

* Mr. Cornell is currently the President and Chief Executive Officer of Praxiis, LLC, an enterprise that provides support for clients in organizational change, leadership development and transactional advisory services. Mr. Cornell is also the current Manager of Larkin Center Management, LLC, a real estate development company, and has served in this capacity since October 2010.

** Since August 2009, Mr. Sanders has served as a General Partner of Phase One Ventures, LLC, a venture capital firm which focuses on nanotechnology and biotechnology start-up opportunities in New Mexico and surrounding states.

*** Since May 18, 2015, Ms. Sullivan is President of Sullivan Capital Partners, LLC, a financial services company providing investment banking and consulting services to businesses seeking growth through acquisitions or strategic partnerships. Ms Sullivan focuses on due diligence, deal structure, strategic planning and governance matters.

**** Mr. Fleet previously served as the President and Chief Executive Officer of the Company from August 3, 2019 until December 13, 2019. Mr. Fleet also served as a strategic advisor consultant to the Company from December 2018 to August 3, 2019. Since December 31, 2019, Mr. Fleet has served as the President and Chief Executive Officer of the Colonial Williamsburg Foundation. Prior to August 2019, Mr. Fleet served as a Managing Partner at SIR, a strategic management consultancy based in Richmond, Virginia since his retirement in 2017 from Philip Morris USA.

***** Since 2000 Mr. O'Brien has been the President of O'Brien Associates, LLC, a general management consulting firm providing advisory and implementation services to companies in a variety of competitive industries, with special focus on general management, technology commercialization, organizational development and strategy.

Code of Ethics

In 2006, we adopted a Code of Ethics that applies to all our employees. A copy of our Code of Ethics is available on our website <http://www.xxicentury.com> and will be provided to any person requesting same without charge. To request a copy of our Code of Ethics, please make a written request to our General Counsel, c/o 22nd Century Group, Inc., 8560 Main Street, Suite 4, Williamsville, New York 14221. Future material amendments or waivers relating to the Code of Ethics will be disclosed on our website within four business days following the date of such amendment or waiver.

Item 11. Executive Compensation.

Information is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2020 Annual Meeting of Stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2020 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2020 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services.

Information is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K with respect to its 2020 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

- (a) Financial Statements
- (b) Financial Statement Schedules

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
Consolidated Financial Statements:	
<u>Consolidated Balance Sheets</u>	<u>F-3</u>
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	<u>F-4</u>
<u>Consolidated Statements of Changes in Shareholders' Equity</u>	<u>F-5</u>
<u>Consolidated Statements of Cash Flows</u>	<u>F-6</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-7 - F-29</u>

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors
22nd Century Group, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 22nd Century Group, Inc. and Subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and the schedule in item 15 (b) (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal controls over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework* issued by Committee of Sponsoring Organizations of the Treadway Committee in 2013, and our report dated March 11, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Freed Maxick, CPAs, P.C.

We have served as the Company's auditor since 2011.

Buffalo, New York
March 11, 2020

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31,

	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 485,111	\$ 604,925
Short-term investment securities	38,477,074	55,748,939
Accounts receivable	866,860	871,293
Inventory, net	2,266,304	3,043,949
Prepaid expenses and other assets	648,149	928,420
Total current assets	<u>42,743,498</u>	<u>61,197,526</u>
Property, plant and equipment:		
Machinery and equipment, net	3,119,970	3,260,748
Operating leases right-of-use assets, net	601,979	-
	<u>3,721,949</u>	<u>3,260,748</u>
Other assets:		
Intangible assets, net	8,493,913	9,751,504
Investments	8,402,527	3,092,358
Convertible note receivable, net	5,589,478	-
Total other assets	<u>22,485,918</u>	<u>12,843,862</u>
Total assets	<u>\$ 68,951,365</u>	<u>\$ 77,302,136</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 580,709	\$ 689,148
Operating lease obligations	219,814	-
Accounts payable	1,997,820	2,574,840
Accrued expenses	2,618,577	1,826,481
Accrued severance	358,610	-
Deferred income	4,850	83,075
Total current liabilities	<u>5,780,380</u>	<u>5,173,544</u>
Long-term liabilities:		
Notes Payable	292,177	848,217
Operating lease obligations	382,165	-
Accrued severance	445,821	-
Total liabilities	<u>6,900,543</u>	<u>6,021,761</u>
Commitments and contingencies (Note 10)	-	-
Shareholders' equity		
10,000,000 preferred shares, \$.00001 par value		
300,000,000 common shares, \$.00001 par value		
Capital stock issued and outstanding:		
138,362,809 common shares (124,642,593 at December 31, 2018)	1,384	1,246
Capital in excess of par	187,735,391	170,392,249
Accumulated other comprehensive income	7,074	21,363
Accumulated deficit	(125,693,027)	(99,134,483)
Total shareholders' equity	<u>62,050,822</u>	<u>71,280,375</u>
Total liabilities and shareholders' equity	<u>\$ 68,951,365</u>	<u>\$ 77,302,136</u>

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
Year Ended December 31,

	2019	2018	2017
Revenue:			
Sale of products, net	\$ 25,832,530	\$ 26,426,347	\$ 16,600,244
Cost of goods sold (exclusive of depreciation shown separately below):			
Products	25,818,075	25,527,360	17,308,156
Gross profit (loss)	14,455	898,987	(707,912)
Operating expenses:			
Research and development (including equity-based compensation of \$373,762; \$1,846,116 and \$182,854, respectively)	8,057,147	14,989,746	3,366,468
Sales, general and administrative (including equity-based compensation of \$3,165,983; \$1,341,215 and \$758,796, respectively)	12,956,417	8,585,533	8,278,487
Impairment	1,142,349	-	-
Depreciation	589,310	522,695	353,435
Amortization	835,693	819,640	593,562
	<u>23,580,916</u>	<u>24,917,614</u>	<u>12,591,952</u>
Operating loss	(23,566,461)	(24,018,627)	(13,299,864)
Operating income (expense):			
Unrealized (loss) gain on investments	(2,419,348)	284,400	342,562
Realized gain on investments	-	14,492,968	-
Realized gain (loss) on short-term investment securities	220,872	(54,451)	-
Litigation expense	(1,890,900)	-	-
Gain on the sale of machinery and equipment	87,351	-	-
Warrant liability gain (loss), net	-	48,711	(157,809)
Dividend income	-	221,991	-
Interest income, net	1,066,324	1,069,036	115,098
Interest expense	(56,382)	(10,939)	(29,104)
	<u>(2,992,083)</u>	<u>16,051,716</u>	<u>270,747</u>
Loss before income taxes	(26,558,544)	(7,966,911)	(13,029,117)
Income taxes	-	-	-
Net loss	\$ (26,558,544)	\$ (7,966,911)	\$ (13,029,117)
Other comprehensive income (loss):			
Unrealized gain (loss) on short-term investment securities	206,583	(21,653)	-
Reclassification of (gains) losses to net loss	(220,872)	43,016	-
	<u>(14,289)</u>	<u>21,363</u>	<u>-</u>
Comprehensive loss	<u>\$ (26,572,833)</u>	<u>\$ (7,945,548)</u>	<u>\$ (13,029,117)</u>
Net loss per common share - basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.06)</u>	<u>\$ (0.13)</u>
Common shares used in basic and diluted earnings per share calculation	<u>125,882,717</u>	<u>124,298,981</u>	<u>101,161,380</u>

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Years Ended December 31, 2019, 2018 and 2017

	Common Shares Outstanding	Par Value of Common Shares	Capital in Excess of Par Value	Accumulated Other Comprehensive Income	Accumulated Deficit	Shareholders' Equity
Balance at December 31, 2016	90,698,113	\$ 907	\$ 102,471,907	\$ -	\$ (78,138,455)	\$ 24,334,359
Equity-based compensation	-	-	941,650	-	-	941,650
Stock issued in connection with warrant exercises	12,249,327	122	12,446,986	-	-	12,447,108
Stock issued in connection with option exercises	51,927	1	(1)	-	-	-
Stock issued in October 2017 registered direct offering, net	20,570,000	206	50,731,994	-	-	50,732,200
Net loss	-	-	-	-	(13,029,117)	(13,029,117)
Balance at December 31, 2017	123,569,367	1,236	166,592,536	-	(91,167,572)	75,426,200
Stock issued in connection with warrant exercises	490,012	5	(5)	-	-	-
Stock issued in connection with option exercises	583,214	5	444,608	-	-	444,613
Equity-based compensation	-	-	3,187,331	-	-	3,187,331
Reclassification of warrant liability to capital in excess of par	-	-	167,779	-	-	167,779
Unrealized loss on short-term investment	-	-	-	(21,653)	-	(21,653)
Reclassification of losses to net loss	-	-	-	43,016	-	43,016.00
Net loss	-	-	-	-	(7,966,911)	(7,966,911)
Balance at December 31, 2018	124,642,593	1,246	170,392,249	21,363	(99,134,483)	71,280,375
Stock issued in connection with warrant exercises	11,293,211	113	10,615,505	-	-	10,615,618
Stock issued in connection with option exercises	39,988	1	(1)	-	-	-
Equity-based compensation	100,000	1	3,539,744	-	-	3,539,745
Stock issued in connection with litigation expense	990,000	10	1,890,890	-	-	1,890,900
Stock issued in connection with Panacea investment	1,297,017	13	1,297,004	-	-	1,297,017
Unrealized gain on short-term investment	-	-	-	206,583	-	206,583
Reclassification of gains to net loss	-	-	-	(220,872)	-	(220,872)
Net loss	-	-	-	-	(26,558,544)	(26,558,544)
Balance at December 31, 2019	138,362,809	\$ 1,384	\$ 187,735,391	\$ 7,074	\$ (125,693,027)	\$ 62,050,822

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31,

	2019	2018	2017
Cash flows from operating activities:			
Net loss	\$ (26,558,544)	\$ (7,966,911)	\$ (13,029,117)
Adjustments to reconcile net loss to cash used in operating activities:			
Impairment of intangible assets	1,142,349	-	-
Amortization and depreciation	1,186,343	1,199,794	848,974
Amortization of license fees	238,661	142,541	98,022
Lease expense	212,297	-	-
Severance expense	880,838	-	-
Unrealized loss (gain) on investments	2,419,348	(284,400)	(342,562)
Realized gain on the sale of investments	-	(14,492,968)	-
Realized (gain) loss on short-term investment securities	(220,872)	54,451	-
Litigation expense	1,890,900	-	-
Gain on the sale of machinery and equipment	(87,351)	-	-
Warrant liability (gain) loss	-	(48,711)	157,809
Accretion of interest on note payable and accrued severance	47,775	10,939	29,104
Accretion of interest income on convertible note receivable	(21,978)	-	-
Equity-based employee compensation expense	3,539,745	3,187,331	941,650
Inventory write-off	985,238	-	-
Decrease in allowance for doubtful accounts	-	-	(10,000)
(Decrease) increase in inventory reserve	-	(95,000)	(60,623)
(Increase) decrease in assets:			
Accounts receivable	4,433	85,773	(906,074)
Inventory	(207,593)	333,588	(129,228)
Prepaid expenses and other assets	280,271	(181,615)	(551,236)
Increase (decrease) in liabilities:			
Operating lease obligation	(212,297)	-	-
Accounts payable	(732,135)	323,070	473,804
Accrued expenses	792,095	(166,873)	586,109
Accrued severance	(88,661)	-	(203,365)
Deferred revenue	(78,226)	54,725	28,350
Net cash used in operating activities	(14,587,364)	(17,844,266)	(12,068,383)
Cash flows from investing activities:			
Acquisition of patents and trademarks	(515,335)	(656,985)	(450,208)
Acquisition of machinery and equipment	(527,330)	(448,639)	(1,156,906)
Acquisition of license	(50,000)	-	-
Proceeds from the sale of machinery and equipment	166,150	-	-
Investment in Panacea	(12,000,000)	-	-
Proceeds from the sale of investments	-	13,051,503	-
Sales and maturities of short-term investment securities	(1,841,821)	37,415,159	-
Purchase of short-term investment securities	19,320,269	(34,215,994)	(58,979,131)
Net cash provided by (used in) investing activities	4,551,933	15,145,044	(60,586,245)
Cash flows from financing activities:			
Payment on notes payable	(700,000)	(800,000)	(333,334)
Proceeds from exercise of stock options	-	444,613	-
Net proceeds from exercise of stock warrants	10,615,617	-	12,447,108
Net proceeds from October 2017 registered direct offering	-	-	50,732,200
Net cash provided by (used in) financing activities	9,915,617	(355,387)	62,845,974
Net decrease in cash	(119,814)	(3,054,609)	(9,808,654)
Cash and cash equivalents - January 1,	604,925	3,659,534	13,468,188
Cash and cash equivalents - December 31,	\$ 485,111	\$ 604,925	\$ 3,659,534
Supplemental disclosures of cash flow information:			
Net cash paid for:			
Cash paid during the period for interest	\$ 3,338	\$ -	\$ 29,104
Cash paid during the period for income taxes	\$ -	\$ -	\$ -
Non-cash transactions:			
Patent and trademark additions included in accounts payable	\$ 155,116	\$ 152,322	\$ 188,818
Machinery and equipment additions included in accounts payable	\$ -	\$ 18,757	\$ 77,913
Unrealized (gain) loss on short-term investment securities	\$ (206,583)	\$ 27,042	\$ -
Licenses acquired with notes payable	\$ -	\$ 2,326,427	\$ -
Reclassification of warrant liability to capital in excess of par	\$ -	\$ 167,779	\$ -
Stock issued in connection with equity investment	\$ 1,297,017	\$ -	\$ -

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019

NOTE 1. - NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation - The accompanying consolidated financial statements include the accounts of 22nd Century Group, Inc. ("22nd Century Group"), its three wholly-owned subsidiaries, 22nd Century Limited, LLC ("22nd Century Ltd"), NASCO Products, LLC ("NASCO"), and Botanical Genetics, LLC ("Botanical Genetics"), and two wholly-owned subsidiaries of 22nd Century Ltd, Goodrich Tobacco Company, LLC ("Goodrich Tobacco") and Heracles Pharmaceuticals, LLC ("Heracles Pharma", formerly known as Hercules Pharmaceuticals, LLC) (collectively, the "Company"). All intercompany accounts and transactions have been eliminated.

Nature of Business - 22nd Century Ltd is a plant biotechnology company specializing in technology that allows (i) for the level of nicotine and other nicotinic alkaloids in tobacco plants to be altered through genetic engineering and modern plant breeding and (ii) the levels of cannabinoids in hemp plants to be decreased or increased through genetic engineering and modern plant breeding. Goodrich Tobacco and Heracles Pharma are business units for the Company's (i) potential modified risk tobacco products and (ii) smoking cessation product, respectively. NASCO is a federally licensed tobacco products manufacturer, a subsequent participating member under the tobacco Master Settlement Agreement ("MSA") between the tobacco industry and the settling states under the MSA and operates the Company's tobacco products manufacturing business in North Carolina. Botanical Genetics is a wholly-owned subsidiary of 22nd Century Group and was incorporated to facilitate the original investment in Anandia, Inc., and performs research and development related to the Company's hemp business.

Reclassifications - Certain items in the 2018 and 2017 financial statements have been reclassified to conform to the 2019 classification. During the third quarter of 2019, the Company combined sales and marketing expenses with general and administrative expenses to create a single line item in the operating expense section of the Company's Consolidated Statements of Operations and Comprehensive Loss titled sales, general and administrative expenses. The comparative classifications for 2018 and 2017 have been reclassified to conform to the new presentation.

Preferred stock authorized - The Company is authorized to issue "blank check" preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock.

Concentration of Credit Risk - Financial instruments that potentially subject the Company to concentration of credit risk consist of cash accounts in financial institutions. Although the cash accounts exceed the federally insured deposit amount, management does not anticipate nonperformance by the financial institutions. Management reviews the financial viability of these institutions on a periodic basis.

Cash and cash equivalents - The Company considers all highly liquid investments with maturities of three months or less at the date of acquisition to be cash equivalents. However, the Company has elected to classify money market mutual funds related to its short-term investment portfolio as short-term investment securities.

Short-term investment securities - The Company's short-term investment securities are classified as available-for-sale securities and consist of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, and commercial paper with maturities greater than three months at the time of acquisition. The Company's short-term investment securities are carried at fair value within current assets on the Company's Consolidated Balance Sheets. The Company views its available-for-sale securities as available for use in current operations regardless of the stated maturity date of the security. The Company's investment policy states that all investment securities must have a maximum maturity of twenty-four (24) months or less and the maximum weighted maturity of the investment securities must not exceed twelve (12) months. All the Company's short-term investment securities are fixed-income debt instruments, and accordingly, all unrealized gains and losses incurred on the short-term investment securities (the adjustment to fair value) are recorded in other comprehensive income or loss on the Company's Consolidated Statements of Operations and Comprehensive Loss. Realized gains and losses on short-term investment securities are recorded in the other income (expense) portion of the Company's Consolidated Statements of Operations and Comprehensive Loss. Interest income is recorded on the accrual basis and presented net of investment related fees.

Accounts receivable - The Company periodically reviews aged account balances for collectability. The Company concluded that an allowance for doubtful accounts was not required at both December 31, 2019 and December 31, 2018.

Inventory - Inventories are valued at the lower of historical cost or net realizable value. Cost is determined using an average cost method for tobacco leaf inventory and raw materials inventory and standard cost is primarily used for finished goods inventory. Inventories are evaluated to determine whether any amounts are not recoverable based on slow moving or obsolete condition and are written off or reserved as appropriate. For the year ended December 31, 2019, the Company wrote off tobacco leaf inventory with a cost of \$985,238 and this cost is included in research and development expenses on the Company's Consolidated Statement of Operations and Comprehensive Loss. Inventories at December 31, 2019 and 2018 consisted of the following:

	December 31, 2019	December 31, 2018
Inventory - tobacco leaf	\$ 1,178,147	\$ 1,556,581
Inventory - finished goods		
Cigarettes and filtered cigars	106,264	156,702
Inventory - raw materials		
Cigarette and filtered cigar components	1,081,893	1,430,666
	2,366,304	3,143,949
Less: inventory reserve	100,000	100,000
	<u>\$ 2,266,304</u>	<u>\$ 3,043,949</u>

Machinery and equipment - Machinery and equipment are recorded at their acquisition cost and depreciated on a straight-line basis over their estimated useful lives ranging from 3 to 10 years. Depreciation commences when the asset is placed in service.

Right-of-use assets - On January 1, 2019, the Company adopted ASU 2016-02, Subtopic ASC 842, Leases, and as a result has recorded Right-to-use assets and corresponding Lease obligations as more fully discussed in Note 3.

Intangible Assets - Intangible assets are recorded at cost and consist primarily of (1) expenditures incurred with third-parties related to the processing of patent claims and trademarks with government authorities, as well as costs to acquire patent rights from third-parties, (2) license fees paid for third-party intellectual property, (3) costs to become a signatory under the tobacco MSA, and (4) license fees paid to acquire a predicate cigarette brand. The amounts capitalized relate to intellectual property that the Company owns or to which it has exclusive rights. The Company's intellectual property capitalized costs are amortized using the straight-line method over the remaining statutory life of the granted patent assets in each of the Company's patent families, which have estimated expiration dates ranging from 2019 to 2036. Periodic maintenance or renewal fees are expensed as incurred. Annual minimum license fees are charged to expense. License fees paid for third-party intellectual property are amortized on a straight-line basis over the last to expire patents, which patent expiration dates are expected to range from 2019 through 2036. The Company believes costs associated with becoming a signatory to the MSA and acquiring a predicate cigarette brand have an indefinite life and as such, no amortization is taken.

Total intangible assets at December 31, 2019 and 2018 consisted of the following:

	December 31, 2019	December 31, 2018
Intangible assets, net		
Patent and trademark costs	\$ 5,712,415	\$ 7,136,774
Less: accumulated amortization and impairment	2,839,135	3,194,565
Patent and trademark costs, net	2,873,279	3,942,209
License fees, net	3,776,427	3,776,427
Less: accumulated amortization	707,793	469,132
License fees, net	3,068,634	3,307,295
MSA signatory costs	2,202,000	2,202,000
License fee for predicate cigarette brand	350,000	300,000
	<u>\$ 8,493,913</u>	<u>\$ 9,751,504</u>

Amortization expense relating to the above intangible assets for the years ended December 31, 2019, 2018, and 2017 amounted to \$835,693, \$819,640 and \$539,562, respectively.

The estimated annual average amortization expense for the next five years is approximately \$401,500 for patent costs and \$239,100 for license fees.

Impairment of Long-Lived Assets - The Company reviews the carrying value of its amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable. The Company assesses recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value.

During the year ended December 31, 2019, the Company decided on a going-forward basis that it will be concentrating its business and scientific resources, personnel and efforts on the portion of our intellectual property portfolio (patents, patent applications and trademarks) that relate to very low nicotine tobacco plants and potential products, as well as unique hemp/cannabis plants and potential products, in order to more strategically pursue our objectives. Accordingly, we recorded a non-cash impairment charge of \$1,142,349 (cost of \$2,092,485 less accumulated amortization of \$950,136) relating to patent and trademark costs not associated with these strategic objectives. This impairment charge is included as a separate line item in operating expenses on the Company's Consolidated Statements of Operations and Comprehensive Loss. There was no impairment loss recorded during the years ended December 31, 2018, and 2017.

Income Taxes - The Company recognizes deferred tax assets and liabilities for any basis differences in its assets and liabilities between tax and U.S. GAAP reporting, and for operating loss and credit carry-forwards.

As a result of the Company's history of cumulative net operating losses and the uncertainty of their future utilization, the Company has established a valuation allowance to fully offset its net deferred tax assets as of December 31, 2019 and 2018. Additionally, because the Company has a full valuation allowance offsetting its deferred tax assets and as a result has an effective tax rate of zero, the Company has elected to present other comprehensive income items relating to net unrealized gains on short-term investment securities gross and not net of taxes.

The Company's federal and state tax returns for the years ended December 31, 2016 through December 31, 2018 are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2019.

The Tax Cuts and Jobs Act of 2017 (the "TCJA") was signed into law on December 22, 2017. The TCJA includes significant changes to the U.S. corporate income tax system, including a Federal corporate rate reduction from 35% to 21%. In accordance with a question and answer document issued by the Financial Accounting Standards Board ("FASB") staff on January 18, 2018, the Company is applying the guidance in Securities and Exchange Commission Staff Accounting Bulletin ("SAB") 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, which provides guidance on applying FASB Accounting Standards Codification ("ASC") 740, Income Taxes, if the accounting for certain income tax effects of the TCJA are incomplete by the time the financial statements are issued for a reporting period. Specifically, SAB 118 permits companies to use reasonable estimates and provisional amounts for some line items for taxes when preparing year-end 2018 and 2017 financial statements. The Company has completed the accounting under the TCJA, and accordingly, has reported the effects in the Company's consolidated financial statements for the years ended December 31, 2019, 2018, and 2017. Additional disclosures required by SAB 118 are included in Note 13.

Stock Based Compensation - The Company uses a fair-value based method to determine compensation for all arrangements under which Company employees and others receive shares, restricted stock units or options to purchase common shares of the Company. Stock based compensation expense is recorded over the requisite service period based on estimates of probability and time of achieving milestones and vesting. For accounting purposes, the shares will be considered issued and outstanding upon vesting or risks of forfeiture expiring.

Revenue Recognition - On January 1, 2018, the Company adopted ASC 606, Revenue from Contracts with Customers and all related amendments (the "new revenue standard") for all contracts using the modified retrospective method. Under the modified retrospective method, the Company was required to record a cumulative-effect adjustment to the opening balance of retained earnings on January 1, 2018. The Company has determined that the adoption of the new revenue standard did not require a cumulative-effect adjustment. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the product to a customer. The Company's customer contracts consist of obligations to manufacture the customer's branded filtered cigars and cigarettes. For certain contracts, the performance obligation is satisfied over time as the Company determines, due to contract restrictions, it does not have an alternative use of the product, and it has an enforceable right to payment as the product is manufactured. The Company recognizes revenue under those contracts at the unit price stated in the contract based on the units manufactured. The manufacturing process is completed on a daily basis and, therefore, there were no performance obligations partially satisfied at December 31, 2019 and 2018. For contracts where the performance obligation is satisfied at a point in time, the Company recognizes revenue when the product is transferred to the customer. Revenue from the sale of the Company's products is recognized net of cash discounts, sales returns and allowances. There was no allowance for discounts or returns and allowances at December 31, 2019 and 2018.

The Company provides assurance to customers that the product complies with agreed-upon contractual specifications. Shipping and handling activities associated with the outbound freight after control of the product has transferred to a customer are considered a fulfillment activity. The related shipping and handling expenses are included in cost of goods sold.

The Company generally requires a down payment from its customers prior to commencement of manufacturing the product. Amounts received in advance of satisfying the performance obligations are recorded as deferred revenue. Customer payment terms vary depending on the terms of each customer contract, but payment is generally due prior to product shipment or within extended credit terms up to twenty-one (21) days after shipment; therefore The Company's contracts with customers do not include a significant financing component.

The Company's net sales revenue is derived from customers located primarily in the United and is disaggregated by the timing of revenue recognition. For the years ended December 31, 2019 and 2018, net sales revenue from products transferred over time amounted to approximately \$16,466,000 and \$16,785,000, respectively, and net sales revenue from products transferred at a point in time amounted to approximately \$9,367,000 and \$9,641,000, respectively.

The Company had certain customers whose revenue individually represented 10% or more the Company's total revenue and whose accounts receivable balances individually represented 10% or more the Company's total accounts receivable. For the years ended December 31, 2019, and 2018, three customers accounted for over 92.7% and 92.0% of our revenue and approximately 98.5% and 85.6%, respectively, of accounts receivable.

Derivatives - The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. Derivative financial instruments are initially recorded at fair market value and then are revalued at each reporting date, with changes in fair value reported in the Consolidated Statements of Operations and Comprehensive Loss. The classification of derivative instruments is evaluated at the end of each reporting period. Derivative instruments are classified on the balance sheet as current or non-current based on if the net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

Research and Development - Research and development costs are expensed as incurred.

Loss Per Common Share - Basic loss per common share is computed using the weighted-average number of common shares outstanding. Diluted loss per share is computed assuming conversion of all potentially dilutive securities. Potential common shares outstanding are excluded from the computation if their effect is anti-dilutive.

Use of Estimates - The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

Fair Value of Financial Instruments - The Company's financial instruments include cash and cash equivalents, short-term investment securities, accounts receivable, investments, a convertible note receivable, accounts payable, accrued expenses, and notes payable. Other than for cash equivalents, short-term investment securities, investments, and convertible note receivable, fair value is assumed to approximate carrying values for these financial instruments, since they are short term in nature, they are receivable or payable on demand, or had stated interest rates that approximate the interest rates available to the Company as of the reporting date. The determination of the fair value of cash equivalents, short-term investment securities, investments (stock warrants and equity investment), and convertible note receivable are discussed in Note 5.

Investments -

The Company accounts for investments in equity securities of other entities under the equity method of accounting if the Company's investment in the stock of the other entity provides the Company with the ability to have significant influence over the operating and financial policies of the investee. If the Company does not have significant influence over the operating or financial policies of the entity, and such equity investment does not have a readily determinable market value, then the Company accounts for such equity investments in accordance with FASB ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which the Company adopted in the first quarter of 2018 with respect to the Company's investments. Under ASU 2016-01 equity securities are recorded at fair value, with changes in fair value recorded through the statement of operations. Equity securities without a readily determinable market value are carried at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same issuer. The Company considers debt instruments as available-for-sale securities, and accordingly, all unrealized gains and losses incurred on the short-term investment securities (the adjustment to fair value) are recorded in other comprehensive income or loss on the Company's Consolidated Statements of Operations and Comprehensive Loss.

The Company has an investment in Aurora stock warrants that are considered equity securities under ASC 321 – Investments – Equity Securities and a derivative instrument under ASC 815 – Derivatives and Hedging. The stock warrants are not designated as a hedging instrument, and in accordance with ASC 815, the Company's investment in stock warrants are recorded at fair value with changes in fair value recorded in the Company's Consolidated Statements of Operations and Comprehensive Loss. The Company also has Panacea stock warrants that are not considered a derivative under ASC 815. As such, the Panacea stock warrants are considered an equity investment with no readily determinable market value and are carried at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same issuer.

During the fourth quarter of 2019, the Company made an investment in Panacea consisting of preferred shares that are not considered in-substance common stock, a stock warrant and a convertible note receivable. The convertible note receivable was recorded at a discount with the note discount amortized into interest income over the term of the note. This transaction, along with the related valuation techniques are more fully described in Note 4.

Accounting Pronouncement -

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments." The standard replaces the incurred loss model with the current expected credit loss (CECL) model to estimate credit losses for financial assets measured at amortized cost and certain off-balance sheet credit exposures. The CECL model requires companies to estimate credit losses expected over the life of the financial assets based on historical experience, current conditions and reasonable and supportable forecasts. The provisions of the ASU are effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The ASU requires retrospective approach by recording a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. The Company will adopt ASU 2016-13 on January 1, 2023 and is evaluating the expected impacts.

NOTE 2. - MACHINERY AND EQUIPMENT

Machinery and equipment at December 31, 2019 and December 31, 2018 consisted of the following:

	Useful Life	December 31, 2019	December 31, 2018
Cigarette manufacturing equipment	3 - 10 years	\$ 4,869,808	\$ 4,608,267
Office furniture, fixtures and equipment	5 years	152,454	135,909
Laboratory equipment	5 years	124,627	104,709
Leasehold improvements	6 years	256,604	169,362
		5,403,493	5,018,247
Less: accumulated depreciation		2,283,523	1,757,499
Machinery and equipment, net		\$ 3,119,970	\$ 3,260,748

Depreciation expense was \$589,310, \$522,695 and \$353,435 for the years ended December 31, 2019, 2018, and 2017, respectively.

NOTE 3. - RIGHT-OF-USE ASSETS, LEASE OBLIGATIONS, AND OTHER LEASES

On January 1, 2019, the Company adopted ASU 2016-02, Subtopic ASC 842, Leases (the "new guidance"). Under the new guidance, the Company was required to evaluate its leases and record a Right-of-use ("ROU") asset and a corresponding lease obligation for leases that qualified as either finance or operating leases. Prior to the adoption of the new guidance, the Company had various operating leases for real estate. The Company elected to use the practical expedient which allowed the Company to carry forward the historical lease classifications of the existing leases. The Company determined that its leases contained (1) no variable lease expenses, (2) no termination options, (3) no residual lease guarantees, and (4) no material restrictions or covenants. The new guidance calls for the lease obligations to be recorded at the present value of the remaining lease payments under the leases and the ROU assets are recorded as the sum of the present value of the lease obligations plus any initial direct costs minus lease incentives plus prepaid lease payments. All remaining renewal options have been included in the computation of the ROU assets and lease obligations. The present value of the remaining lease payments was computed using a discount rate of 5.14%. The Company determined that two real estate leases qualified as operating leases under the new guidance as discussed below.

Further, FASB issued ASU 2018-11, Re-Leases Targeted Improvements to ASC 842, to provide entities with relief from the costs of implementing certain aspects of the new guidance. Under ASU 2018-11, entities may elect not to recast comparative periods when transitioning to the new guidance. The Company has adopted ASU 2018-11, and accordingly, will (1) apply ASC 840 Lease Accounting (the "old guidance") in comparative periods, (2) provide disclosures for all comparative periods presented in accordance with the old guidance, and (3) recognize the effects of applying the new guidance as a cumulative-effects adjustment to retained earnings as of January 1, 2019. No cumulative-effects adjustment was made as the Company determined it to be immaterial.

The Company leases a manufacturing facility and warehouse located in North Carolina on a triple net lease basis with a monthly lease payment of \$14,094. As of January 1, 2019, the lease had a remaining term of thirty-four (34) months including all renewal options. Under the new guidance, the Company recorded a ROU asset and a corresponding lease obligation in the amount of \$446,950 on January 1, 2019 and recorded a lease expense for the year ended December 31, 2019 of approximately \$168,100.

On October 4, 2017, the Company entered a lease for office space at a location in Williamsville, New York with an initial monthly lease payment of \$6,375 per month for the first three years of the lease. The monthly lease payment increases by 5% annually for the remainder of the lease. As of January 1, 2019, the lease had a remaining term of sixty-two (62) months including all renewal options. Under the new guidance, the Company recorded a ROU asset and a corresponding lease obligation in the amount of \$367,325 on January 1, 2019 and recorded a lease expense for the year ended December 31, 2019 of approximately \$76,500.

As of December 31, 2019, the ROU assets and corresponding operating lease obligations had a balance of \$601,979, with \$219,814, and \$382,165 of the operating lease obligation shown as current and long-term, respectively.

In addition, the Company has two leases that did not qualify as operating or financing leases under the new guidance as discussed below.

On August 14, 2017, the Company entered into a lease for warehouse space in North Carolina to store and operate tobacco leaf processing equipment, to store the Company's proprietary tobacco leaf and to store inventory used in the Company's contract manufacturing business. On August 14, 2019 the Company signed an amended month to month lease agreement. The lease calls for a monthly payment of \$4,665 and expires on August 14, 2020.

On May 1, 2016, the Company entered a sublease for laboratory space in Buffalo, New York. During the years ended December 31, 2017, 2018, and 2019 the Company entered various sublease amendments that changed the subleased laboratory space and increased the monthly sublease payments and extended the sublease periods until February 2020. On January 15, 2020 the Company entered a new lease agreement with the landlord. The lease commences on February 1, 2020 with an initial one-year term, a monthly lease payment of \$8,408 and an option to renew for an additional 12 months with a 3% increase in the monthly lease payments. The lease expense for the laboratory space was approximately \$68,700, \$62,600 and \$30,483 for the years ended December 31, 2019, 2018, and 2017, respectively. Future minimum annual lease payments under the laboratory space lease will be approximately \$100,000, \$104,000, and \$8,700 for the years ended December 31, 2020, 2021, and 2022, respectively.

NOTE 4. - INVESTMENTS

Investments at December 31, 2019 and 2018 are \$8,402,527 and \$3,092,358, respectively. The investments at December 31, 2019 consist of the fair value of the Aurora stock warrants of \$673,010, the fair value of the Panacea preferred stock of \$4,864,517 and the cost of the Panacea stock warrants of \$2,865,000. The Company also has a convertible note receivable from Panacea in the amount of \$5,589,478 at December 31, 2019. The investment at December 31, 2018 consists of the fair value of the Aurora stock warrants. These investments are described in more detail below.

Investment in Panacea

On December 3, 2019, the Company entered into an agreement to obtain a 15.8% ownership in Panacea as part of its strategy to expand its operations to the legal, hemp/cannabis, consumer packaged goods space. Panacea offers a line of legal, THC-free, hemp-derived cannabinoid products for humans and animals, including fast-acting sublingual tablets, soft gels, gummies, tinctures, cosmetics and other topicals. The transaction gives the Company 33% voting interest in the board of directors of Panacea. Pursuant to the agreement, the Company received 3,733,334 shares of preferred stock with an embedded put right, warrants to purchase additional preferred stock, and a \$7,000,000 note receivable bearing interest at 10% that is convertible to 3,733,334 preferred shares. The Company paid Panacea \$12,000,000 in cash and issued 1,297,017 shares of 22nd Century common stock with a fair value of \$1,297,017. The agreement with Panacea also requires the Company to purchase 5,333,334 shares of puttable preferred stock at \$1.875 when Panacea achieves a certain twelve-month sales target that is payable in \$8,500,000 of cash and the remainder in 22nd Century Group common stock.

The financial instruments acquired are as follows:

The warrant allows the Company to purchase additional shares of preferred stock sufficient to obtain a 51% controlling interest in Panacea. The warrant can be

exercised any time after December 3, 2024, or earlier if Panacea achieves certain sales targets for two consecutive years at an exercise price of \$2.344 per share. Upon the exercise of the warrant, the other stockholders of Panacea have the option to put their remaining stock in Panacea to the Company at \$2.344 per share, which shall be payable in cash and/or 22nd Century common stock at the Company's discretion.

The preferred stock in Panacea accrues cumulative preferred dividends at 10% of face value of \$7,000,000 compounded annually payable upon a liquidation event, conversion or redemption. The preferred stock also includes an embedded put right that expires at the earlier date of December 3, 2024 or when the warrants are exercised. The put allows the Company to require Panacea to redeem its 3,733,334 preferred stock at its original issue price of \$1.875 per preferred share plus any unpaid cumulative preferred dividends. The put option is not considered a derivative instrument for accounting purposes.

Note receivable from Panacea with a par value of \$7,000,000 bears interest at 10% payable monthly, with final principal payment due on December 3, 2024. The note receivable has an embedded conversion option that allows the Company to convert the note to 3,733,333 additional shares of preferred stock. The embedded conversion option is not considered a derivative instrument for accounting purposes.

The Company allocated the purchase price of its investment in Panacea as follows:

Convertible note receivable	\$	5,567,500
Preferred stock	\$	4,864,517
Preferred stock warrants	\$	2,865,000
	\$	<u>13,297,017</u>

To allocate the cost of its investment in Panacea, the Company determined the fair value of the warrants of \$2,865,000 based on the following assumptions: volatility of 70%, discount of 25% for lack of marketability and risk-free rate of 2% and is classified as level 3 of the fair value hierarchy at the time of its acquisition. The value of the warrants was allocated to the preferred stock and the note receivable equally as a discount to the acquisition price. The discount on the preferred shares was determined to be for lack of control and the discount on the note receivable was determined to be related to issuing the note at an interest rate below market rates for similar instruments. The discount on the convertible note receivable amounted to \$1,432,500 and is being amortized into interest income over the term of the note. The amortization of the discount amounted to \$21,978 for the year ended December 31, 2019, leaving convertible note receivable with a balance of \$5,589,478 at December 31, 2019. There were no adjustments recorded to the fair value of the convertible note receivable for the year ended December 31, 2019.

The Company accounts for its warrant to purchase additional preferred stock of Panacea using the practical expedient for equity securities without readily determinable fair values at its cost minus an impairment charge, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. There were no adjustments recorded to the original cost basis, for the year ended December 31, 2019. The note receivable and the preferred stock in Panacea are considered an available for sale security debt securities and are recorded at fair value.

Investment in Anandia

The Company (through its wholly-owned subsidiary, Botanical Genetics) held an equity investment in Anandia, a Canadian plant biotechnology company. On August 8, 2018, all of Anandia's outstanding common stock was acquired by Aurora Cannabis, Inc. ("Aurora"), a Canadian company (NYSE: ACB and TSX: ACB), and as a result the Company received in exchange for its Anandia equity: (i) 1,947,943 free trading shares of Aurora common stock, and (ii) stock warrants to purchase 973,971 shares of Aurora common stock (the "Anandia transaction"). The Company sold all the shares of Aurora common stock during the third quarter of 2018 but retains ownership of the stock warrant to purchase 973,971 shares of Aurora common stock as of December 31, 2019. The stock warrants have a five-year contractual term, an exercise price of \$9.37 per share (Canadian Dollars; approximately \$7.21 per share U.S. Dollars at December 31, 2019), is currently exercisable, is considered an equity security, and is recorded at fair value (Level 3 of the valuation hierarchy). The Company recorded the fair value of the Aurora common stock warrant of \$673,010 and \$3,092,358 at December 31, 2019 and December 31, 2018, respectively, using the Black-Scholes pricing model and was classified within Other assets on the Company's Consolidated Balance Sheets. The Company recorded an unrealized (loss) gain, the adjustment to fair value, in the amount of (\$2,419,348) and \$284,400 for the years ended December 31, 2019 and 2018, respectively.

Effective January 1, 2018, the Company adopted Financial Accounting Standards Board ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. This guidance changed how entities account for equity investments that do not result in consolidation and are not accounted for under the equity method of accounting. Under ASU 2016-01, the Company was required to measure its investment in Anandia at fair value at the end of each reporting period and recognize changes in fair value in net income. As allowed by ASU 2016-01, since the Company's investment in Anandia did not have readily determinable fair value, the Company elected to account for its investment at cost. The cost basis is required to be adjusted in the event of impairment, if any, and for any observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Accordingly, and as a result of, an equity issuance in January of 2018 by Anandia that was considered an orderly transaction, the Company recorded an unrealized gain on its investment in Anandia in the amount of \$6,147,088 during the first quarter of 2018. There were no further changes in the fair value of the Company's equity investment in Anandia through the acquisition of Anandia by Aurora on August 8, 2018, as discussed above.

As a result of the Anandia transaction, the Company received 1,947,943 shares of Aurora common stock and warrants to purchase 973,971 shares of Aurora common stock that had a fair value of \$9,221,594 and \$2,807,958, respectively. The Company recorded a realized gain on the transaction in the amount of \$4,515,971 during the third quarter of 2018. Additionally, the unrealized gain on the Company's investment in Anandia in the amount of \$6,147,088 under ASU 2016-01 from the first quarter of 2018 became a realized gain at time of the Anandia transaction (see the paragraph below for additional details). Subsequent to the transaction, the Company sold all of its Aurora common stock resulting in net sales proceeds to the Company of \$13,051,503 and realized a gain on the sale of \$3,829,909 during the year ended December 31, 2018. The Anandia transaction, the gain from ASU 2016-01, and the sale of the Aurora common shares resulted in an aggregate realized gain of \$14,492,968 for the year ended December 31, 2018.

The Company's investment in Anandia was recorded using the equity method of accounting until the first quarter of 2017, when a dilutive event occurred bringing the Company's investment percentage in Anandia below 20%. Accordingly, the Company discontinued applying the equity method of accounting for its investment in Anandia and began accounting for its investment in Anandia under the cost method of accounting. The Company's unrealized gain (loss) on the investment in Anandia was \$346,180 for the year ended December 31, 2017. There was no unrealized gain (loss) for the year ended December 31, 2018. At December 31, 2017, the Company's investment balance in Anandia was \$1,366,493, and was classified within Other assets on the accompanying Consolidated Balance Sheets.

NOTE 5. – FAIR VALUE MEASUREMENTS AND SHORT-TERM INVESTMENTS

FASB ASC 820 - "Fair Value Measurements and Disclosures" establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and
- Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value.

A financial asset's or a financial liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table presents information about our assets and liabilities measured at fair value at December 31, 2019 and 2018, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	Asset and Liabilities at Fair Value			
	As of December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets				
Short-term investment securities:				
Money market funds	\$ 12,145,726	\$ -	\$ -	\$ 12,145,726
Corporate bonds	-	26,331,348	-	26,331,348
Total short-term investment securities	<u>\$ 12,145,726</u>	<u>\$ 26,331,348</u>	<u>\$ -</u>	<u>\$ 38,477,074</u>
Investments :				
Stock warrants	\$ -	\$ -	\$ 673,010	\$ 673,010
Convertible note receivable	-	-	5,589,478	5,589,478
Preferred stock in Panacea	-	-	4,864,517	4,864,517
Total Investment	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 11,270,005</u>	<u>\$ 11,270,005</u>
	Asset and Liabilities at Fair Value			
	As of December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets				
Short-term investment securities:				
Money market funds	\$ 10,083,972	\$ -	\$ -	\$ 10,083,972
Corporate bonds	-	38,579,055	-	38,579,055
U.S. treasury securities	-	2,970,900	-	2,970,900
U.S. government agency bonds	-	4,115,012	-	4,115,012
Total short-term investment securities	<u>\$ 10,083,972</u>	<u>\$ 45,664,967</u>	<u>\$ -</u>	<u>\$ 55,748,939</u>
Investments:				
Stock warrants	\$ -	\$ -	\$ 3,092,358	\$ 3,092,358

Money market mutual funds are valued at their daily closing price as reported by the fund. Money market mutual funds held by the Company are open-end mutual funds that are registered with the SEC that generally transact at a stable \$1.00 Net Asset Value (“NAV”) representing its estimated fair value. On a daily basis the fund’s NAV is determined by the fund based on the amortized cost of the funds underlying investments.

U.S. government agency bonds, U.S. treasury securities, and corporate bonds are valued using pricing models maximizing the use of observable inputs for similar securities.

The investment in stock warrants that are accounted for under ASC 815 are measured at fair value using the Black-Scholes pricing model and are classified within Level 3 of the valuation hierarchy. The unobservable input is an estimated volatility factor of 83% at December 31, 2019. A 20% increase or decrease in the volatility factor used at December 31, 2019 would have the impact of increasing or decreasing the fair value measurement of the stock warrants by approximately \$260,000. The stock warrants (the Panacea warrants) are not recorded under ASC 815 and are not adjusted to fair value at each reporting date due to the practical expedient under ASU 2016-01.

The convertible note receivable is with a private company (Panacea) that is not traded in active markets. Since observable price quotations were not available, fair value was estimated based on cost less an appropriate discount, and the fair value is evaluated based on Panacea’s financial performance and credit worthiness, and changes in market interest rates. The discount is amortized into interest income over the life of the convertible note receivable and amounted to \$21,978 for the year ended December 31, 2019. As a result of the put option included in the Panacea preferred shares, they are not considered equity instruments. Fair value is determined similarly to the convertible note.

The following table sets forth a summary of the changes in fair value of the Company’s Level 3 investments for the year ended December 31, 2019

Fair value at December 31, 2017	\$ -
Fair value of stock warrants acquired on August 8, 2018	2,807,958
Unrealized gain as a result of change in fair value	284,400
Fair value at December 31, 2018	3,092,358
Unrealized loss as a result of change in fair value	(2,419,348)
Accretion of interest income on convertible note receivable	21,978
Panacea convertible note receivable	5,567,500
Preferred stock in Panacea	4,864,517
Fair value at December 31, 2019	<u>\$ 11,127,005</u>

The warrant liability was measured at fair value using certain estimated factors such as volatility and probability which are classified within Level 3 of the valuation hierarchy. Significant unobservable inputs that are used in the fair value measurement of the Company’s derivative warrant liabilities including the volatility factor. Significant increases or decreases in the volatility factor would have resulted in a significantly higher or lower fair value measurement. The Company’s warrants associated with the warrant liability were exercised in July 2018 and the remaining outstanding warrants at December 31, 2018 do not include anti-dilution features and therefore are not considered derivative instruments and do not have an associated warrant liability.

The following table sets forth a summary of the Company’s available-for-sale securities from amortized cost basis to fair value at December 31, 2019 and 2018:

	Available-for-sale Securities - December 31, 2019			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$ 26,324,274	\$ 64,408	\$ (57,334)	\$ 26,331,348
Convertible Note Receivable	5,589,478	-	-	5,589,478
Preferred stock in Panacea	4,864,517	-	-	4,864,517
Totals	<u>\$ 36,778,269</u>	<u>\$ 64,408</u>	<u>\$ (57,334)</u>	<u>\$ 36,785,343</u>

	Available-for-Sale Securities – December 31, 2018			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$ 38,579,541	\$ 48,796	\$ (49,282)	\$ 38,579,055
U.S. treasury securities	2,959,063	11,837	-	2,970,900
U.S. government agency bonds	4,099,321	15,691	-	4,115,012
Totals	<u>\$ 45,637,925</u>	<u>\$ 76,324</u>	<u>\$ (49,282)</u>	<u>\$ 45,664,967</u>

The following table sets forth a summary of the Company's available-for-sale securities in its short-term investment account for amortized cost basis and fair value by contractual maturity at December 31, 2019 and 2018:

	Available-for-Sale Securities		Available-for-Sale Securities	
	December 31, 2019		December 31, 2018	
	Amortized Cost Basis	Fair Value	Amortized Cost Basis	Fair Value
Due in one year or less	\$ 16,823,028	\$ 16,851,008	\$ 43,050,306	\$ 43,082,677
Due after one year through five years	9,501,246	9,480,340	2,587,619	2,582,290
Due in five years	10,453,995	10,453,995	-	-
	<u>\$ 36,778,269</u>	<u>\$ 36,785,343</u>	<u>\$ 45,637,925</u>	<u>\$ 45,664,967</u>

NOTE 6. – NOTE PAYABLES FOR LICENSE FEES

On June 22, 2018, the Company entered into the Second Amendment to the License Agreement (the "Second Amendment") with North Carolina State University ("NCSU") that amended an original License Agreement between the Company and NCSU, dated December 8, 2015, and the First Amendment, dated February 14, 2018, to the original License Agreement. Under the terms of the Second Amendment, the Company is obligated to pay NCSU milestone payments totaling \$1,200,000, of which amount \$500,000 was payable upon execution of the Second Amendment, \$400,000 was payable on the first anniversary of the execution of the Second Amendment, and \$300,000 will be payable on the second anniversary of the execution of the Second Amendment. The Company has recorded the present value of the obligations under the Second Amendment as a note payable that originally amounted to \$1,175,226.

The cost of the acquired license amounted to \$1,175,226 and is included in Intangible assets, net on the Company's Consolidated Balance Sheets, and will be amortized on a straight-line basis over the last-to-expire patent, which is expected to be in 2036.

On October 22, 2018, the Company entered into a License Agreement with the University of Kentucky. Under the terms of the License Agreement, the Company is obligated to pay the University of Kentucky milestone payments totaling \$1,200,000, of which amount \$300,000 was payable upon execution, and \$300,000 will be payable annually over the next three years on the anniversary of the execution of the License Agreement. The Company has recorded the present value of the obligations under the License Agreement as a note payable that originally amounted to \$1,151,201. The cost of the of acquired licenses amounted to \$1,151,201 and is included in Intangible assets, net on the Company's Consolidated Balance Sheets, and will be amortized on a straight-line basis over the last-to- expire patent, which is expected to be in 2033.

After the accretion of interest during the year ended December 31, 2019 in the amount of \$35,521 the balance remaining on these two notes payable as of December 31, 2019 amounted to \$872,886, with \$580,709 and \$292,177 reported as current and long-term, respectively, on the Company's Consolidated Balance Sheets (notes payable balance of \$1,537,365 as of December 31, 2018, with \$689,148 and \$848,217 reported as current and long-term, respectively).

NOTE 7. - SEVERANCE LIABILITY

The Company recorded an accrual for employee severance during the third quarter of 2019 in the initial amount of \$720,838 in accordance with FASB ASC 712 - "Compensation – Nonretirement Postemployment Benefits." The severance accrual relates to the resignation of the Company's former President and Chief Executive Officer (the "former CEO") effective July 26, 2019. Concurrent with the former CEO's resignation, the Company entered into a Consulting Agreement (the "Agreement") with the former CEO. The Agreement calls for the Company to pay a monthly consulting fee to the former CEO in the amount of \$16,667 plus health insurance benefits for a period of forty-two months. The Company concluded that the terms of the Agreement met the severance criteria in ASC 712 and accordingly, a severance accrual was recorded. The Company computed the present value of the payments called for under the Agreement and recorded an initial severance liability in the amount of \$720,838. As a result of broad-based actions to reduce expenses in the fourth quarter the Company initiated a reduction in its workforce. An additional severance accrual in the amount of \$160,000 was recorded as of December 31, 2019. After payments under the Agreement and the accretion of interest during 2019, the accrued severance balance remaining at December 31, 2019 was \$804,431 with \$358,610 and \$445,821, respectively, shown as current and long-term accrued severance on the Company's Consolidated Balance Sheets.

NOTE 8. - WARRANTS FOR COMMON STOCK

At December 31, 2019, the Company had outstanding warrants to purchase 11,293,211 shares of common stock of the Company that were issued in conjunction with the November 2019 warrant exchange agreement with an exercise price of \$1.11 per share and an expiration date of November 25, 2024.

On November 25, 2019, the Company entered into Warrant Exercise Agreements (the "2019 Exercise Agreements") with all of the holders (the "Holders") of its outstanding warrants to purchase up to 11,293,211 shares of common stock of the Company with an exercise price of \$2.15 per share (the "Warrants") whereby the Holders and the Company agreed that the Holders would immediately exercise for cash 7,350,000 of the Warrants at a reduced exercise price of \$1.00 per share, generating proceeds to the Company before expenses of approximately \$7.4 million. In addition, the Holders agreed to exercise the remaining 3,943,211 Warrants for cash on or prior to January 27, 2020 provided that the Holders are in compliance with the beneficial ownership limitation provisions contained in the Warrants. The Holders exercised all of the Warrants for cash during December 2019 and the Company received net proceeds of approximately \$10.6 million from the exercise of all of the Warrants, after deducting expenses associated with the transaction.

In consideration for the Holders exercising their Warrants for cash, the Company issued to each Holder a new warrant (each, a "2019 Warrant") to purchase shares of common stock equal to the number of shares of common stock underlying the Warrants that shall be exercisable to the extent such Holder exercises for cash such Holder's Warrants pursuant to the 2019 Exercise Agreements. The terms of the 2019 Warrants are substantially similar to the terms of the Warrants, except that the 2019 Warrants are (i) exercisable from first issuance of the 2019 Warrants for a period of five years and (ii) had an initial exercise price equal to \$1.25 per share. On December 22, 2019, the Company entered into a Warrant Amendment Agreement with the holders of the Warrants (the "Amendment") whereby the Company agreed to amend the Warrants to (i) reduce the exercise price of the Warrants to \$1.11 and (ii) to add a call provision whereby the Company may call the Warrants with prior notice to the holders for \$0.001 per Warrant (during which time the holders may exercise the Warrants) provided that the Company's volume weighted average stock price exceeds \$3.00 per share for ten consecutive trading days and certain other conditions are satisfied.

On June 19, 2017, the Company entered into Warrant Exercise Agreements (the "2017 Exercise Agreements") with all the holders (the "2016 Holders") of outstanding warrants to purchase up to 7,043,211 shares of common stock of the Company at \$1.00 per share and warrants to purchase up to 4,250,000 shares of common stock of the Company at \$1.45 per share (collectively, the "2016 Warrants"). The Company and the 2016 Holders agreed that the 2016 Holders would, subject to beneficial ownership limitations on exercise contained in the 2016 Warrants, exercise all the 2016 Warrants for cash. During the second and third quarters of 2017, the 2016 Holders exercised 7,043,211 2016 Warrants at \$1.00 per share and 4,250,000 2016 Warrants at \$1.45 per share, resulting in net proceeds to the Company in the amount of \$12,336,858, after deducting expenses associated with the transaction.

In consideration for the 2016 Holders exercising their 2016 Warrants for cash, the Company issued to each 2016 Holder a new warrant (the "New Warrants") to purchase shares of common stock of the Company equal to the number of shares of common stock received by each 2016 Holder upon the cash exercise of the 2016 Holder's 2016 Warrants. The terms of the New Warrants are substantially similar to the terms of the 2016 Warrants exercised, except the New Warrants (i) have an exercise price equal to \$2.15 per share and (ii) are exercisable six months from the date of issuance of the New Warrants for a period of five (5) years. Accordingly, the Company issued an aggregate of 11,293,211 New Warrants to the 2016 Holders, upon exercise of the 2016 Holder's 2016 Warrants as described above. These New Warrants were all exercised pursuant to the 2019 Exercise Agreements, described above, and are no longer outstanding.

During the year ended December 31, 2018, warrant holders exercised 794,869 warrants on a cashless basis, resulting in the issuance of 490,012 shares.

The Company estimates the value of warrant liability upon issuance of warrants that are considered derivative instruments and at each balance sheet date using the binomial lattice model to allocate total enterprise value to the warrants and other securities in the Company's capital structure. Volatility was estimated based on historical observed equity volatilities and implied (forward) or expected volatilities for a sample group of guideline companies and consideration of recent market trends. The Company's outstanding warrants at December 31, 2019 and 2018 do not include anti-dilution features and therefore are not considered derivative instruments and do not have an associated warrant liability. All warrants considered derivative instruments with an associated warrant liability were exercised during 2018.

The following table is a roll-forward summary of the warrant liability since December 31, 2017:

Fair value at December 31, 2017	\$ 216,490
Gain as a result of change in fair value	(48,711)
Reclassification of warrant liability to capital in excess of par	(167,779)
Fair value at December 31, 2018	-
Fair value at December 31, 2019	\$ -

The aggregate net gain (loss) as a result of the Company's warrant liability for the years ended December 31, 2019, 2018, and 2017 amounted to \$0, \$48,711 and (\$157,809), respectively, and are included in Other income (expense) under Warrant liability gain (loss), net in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

The following table summarizes the Company's warrant activity since December 31, 2016:

	Number of Warrants
Warrants outstanding at December 31, 2016	13,781,921
Warrants exercised during 2017	(1,470,027)
Warrants expired during 2017	(223,814)
Warrants exercised pursuant to June 2017 warrant exercise agreements	(11,293,211)
Warrants issued pursuant to June 2017 warrant exercise agreements	11,293,211
Warrants outstanding at December 31, 2017	12,088,080
Warrants exercised during 2018	(794,869)
Warrants outstanding at December 31, 2018	11,293,211
Warrants exercised during 2019 pursuant to November 2019 warrant exercise agreement	(11,293,211)
Warrants issued during 2019 pursuant to November 2019 warrant exercise agreement	11,293,211
Warrants outstanding at December 31, 2019	11,293,211

NOTE 9. - RETIREMENT PLAN

The Company sponsors a defined contribution plan under IRC Section 401(k). The plan covers all employees who meet the minimum eligibility requirements. Under the 401(k) plan eligible employees are allowed to make voluntary deferred salary contribution to the plan, subject to statutory limits. The Company has elected to make Safe Harbor Non-Elective Contributions to the plan for eligible employees in the amount of three percent (3%) of the employee's compensation. Total employer contributions to the plan for the years ended December 31, 2019, 2018, and 2017 amounted to \$156,908, \$141,083 and \$98,368, respectively.

NOTE 10. - COMMITMENTS AND CONTINGENCIES

License agreements and sponsored research— The Company has entered into various license agreements and sponsored research and development agreements. The costs associated with the following three agreements were initially recorded as a Prepaid expense on the Company's Consolidated Balance Sheets and subsequently expensed on a straight-line basis over the applicable period and included in Research and development costs on the Company's Consolidated Statements of Operations and Comprehensive Loss. The amounts expensed during the years ended December 31, 2019, 2018, and 2017 amounted to \$265,452, \$394,249, and \$232,140, respectively.

Under its exclusive worldwide license agreement with North Carolina State University ("NCSU"), the Company is required to pay minimum annual royalty payments, which are credited against running royalties on sales of licensed products. The minimum annual royalty is \$225,000. The license agreement continues through the life of the last-to-expire patent, which is expected to be 2022. The license agreement also requires a milestone payment of \$150,000 upon FDA approval or clearance of a product that uses the NCSU licensed technology. The Company expensed license fees of \$225,000 for each of the years ended December 31, 2019, 2018, and 2017. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. These costs vary from year to year and the Company has certain rights to direct the activities that result in these costs. During the years ended December 31, 2019, 2018, and 2017 the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$33,673, \$95,602, and \$71,596, respectively.

On December 8, 2015, the Company entered into an additional license agreement (the "License") with NCSU. Under the terms of the License, the Company paid NCSU a non-refundable, non-creditable lump sum license fee of \$150,000. Additionally, the License calls for the Company to pay NCSU a non-refundable, non-creditable minimum annual royalty beginning on December 31, 2018 in the amount of \$10,000. The minimum annual royalty payment increases to \$15,000 in 2019, \$25,000 in 2020 and 2021, and \$50,000 per year thereafter for the remaining term of the License. The Company expensed license fees of \$15,000, \$0, and \$0 for the years ended December 31, 2019, 2018, and 2017, respectively. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the years ended December 31, 2019, 2018, and 2017 the aggregate costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$11,740, \$113,578, and \$31,947, respectively. This License continues through the life of the last-to-expire patent, expected to be in 2036.

On February 10, 2014, the Company entered into a sponsored research and development agreement (the "Agreement") with NCSU. Under the terms of the Agreement, the Company paid NCSU \$162,408 over the two-year term of the Agreement, which grants certain licensed rights to the Company. The Company had extended the Agreement through January 31, 2017 at an additional cost of \$85,681. In February 2018, the Company finalized an additional extension to this Agreement through April 30, 2018 at a cost of \$88,344. In May 2018, the Company finalized an additional extension to this Agreement through April 30, 2019 at a total cost of \$121,357. The amounts expensed during the years ended December 31, 2019, 2018, and 2017 were \$40,452, \$169,249, and \$7,140, respectively.

Other license agreements - Additionally, the Company has entered into the following license agreements and the costs associated with these license agreements are included in Intangible assets, net in the Company's Consolidated Balance Sheets and the applicable license fees will be amortized over the term of the agreements based on their last-to-expire patent date. Amortization expense during the years ended December 31, 2019, 2018, and 2017 amounted to \$238,661, \$142,541, and \$98,022, respectively, and was included in Amortization expense on the Company's Consolidated Statements of Operations and Comprehensive Loss.

On October 22, 2018, the Company entered into a License Agreement (the "License") with the University of Kentucky. Under the terms of the License, the Company is obligated to pay the University of Kentucky a non-refundable, non-creditable license fee of \$1,200,000. The license fee is payable in accordance with a note payable more fully described in Note 10. The present value of the payments in the amount of \$1,151,201 are included in Intangible assets, net on the Company's Consolidated Balance Sheets, and will be amortized on a straight-line basis over the last-to-expire patent, which is expected to be in 2033.

On June 22, 2018, the Company entered into the Second Amendment to the License Agreement (the "Second Amendment") with NCSU that amended an original License Agreement between the Company and NCSU, dated December 8, 2015. Under the terms of the Second Amendment, the Company is obligated to pay NCSU a non-refundable, non-creditable license fee of \$1,200,000. The license fee is payable in accordance with a note payable more fully described in Note 6. The present value of the payments in the amount of \$1,175,226 are included in Intangible assets, net on the Company's Consolidated Balance Sheets, and will be amortized on a straight-line basis over the last-to-expire patent, which is expected to be in 2036.

On August 22, 2014, the Company entered into a Commercial License Agreement with Precision PlantSciences, Inc. (the "Precision License"). The Precision License grants the Company a non-exclusive, but fully paid up right and license to use technology and materials owned by Precision PlantSciences for a license fee of \$1,250,000. The Precision License continues through the life of the last-to-expire patent, which is expected to be in 2028.

On August 27, 2014, the Company entered into an additional exclusive License Agreement (the "License Agreement") with NCSU. Under the License Agreement, the Company paid NCSU a non-refundable, non-creditable lump sum license fee of \$125,000, and the Company must pay to NCSU an additional non-refundable, non-creditable lump sum fee of \$75,000 upon issuance of a U.S. utility patent included in the patent rights. A patent was issued during the first quarter of 2017 under this clause, and accordingly, the \$75,000 was due and payable to NCSU. The \$75,000 cost was included in Research and development costs on the Company's Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2017. Additionally, under the License Agreement the Company paid NCSU a non-refundable, non-creditable license maintenance fee in the amount of \$15,000 during the year ended December 31, 2017. The Company is obligated to pay to NCSU an annual minimum royalty fee of \$20,000 in 2018, \$30,000 in 2019, and \$50,000 per year thereafter for the remaining term of the License Agreement. The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred. During the years ended December 31, 2019, 2018, and 2017, the aggregated costs incurred related to capitalized patent costs and patent maintenance expense amounted to \$49,714, \$24,016, and \$41,033, respectively. The License Agreement continues through the life of the last-to-expire patent, which is expected to be in 2034.

On September 15, 2014, the Company entered into a Sublicense Agreement with Anandia, Inc. (the "Anandia Sublicense"). Under the terms of the Anandia Sublicense, the Company was granted an exclusive sublicense in the United States and a co-exclusive sublicense in the remainder of the world, excluding Canada, to the licensed intellectual property. The Anandia Sublicense required an up-front fee of \$75,000, an annual license fee of \$10,000, the payment of patent filing and maintenance costs, a running royalty on future net sales of products made from such sublicensed intellectual property, and a sharing of future sublicensing consideration received from sublicensing to third-parties such sublicensed intellectual property. The Anandia Sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035. As discussed in Note 4, Anandia was purchased by Aurora on August 8, 2018 and has become a wholly owned subsidiary of Aurora. The Anandia Sublicense is still in effect.

Other research agreements - Further, the Company has entered into the following agreements relating to sponsored research. Costs associated with these agreements are expensed when incurred in Research and development costs on the Company's Consolidated Statements of Operations and Comprehensive Loss.

On September 28, 2015, the Company's wholly-owned subsidiary, Botanical Genetics, entered into a Sponsored Research Agreement (the "Agreement") with Anandia. Pursuant to the Agreement, Anandia conducted research on behalf of the Company relating to the hemp/cannabis plant. During the years ended December 31, 2019, 2018, and 2017 expenses related to the Agreement amounted to \$0, \$130,850, and \$654,250, respectively. Under the terms of the Agreement, the Company will have co-exclusive worldwide rights with Anandia to all the intellectual property resulting from the sponsored research between the Company and Anandia. The party that commercializes such intellectual property in the future will pay royalties in varying amounts to the other party, with the amount of such royalties being dependent upon the type of products that are commercialized in the future. If either party sublicenses such intellectual property to a third-party, then the Company and Anandia will share equally in such sublicensing consideration. As discussed in Note 4, Anandia was purchased by Aurora on August 8, 2018 and has become a wholly owned subsidiary of Aurora.

In December 2016, the Company entered into a new sponsored research agreement with UVA and an exclusive license agreement with the University of Virginia Patent Foundation d/b/a University of Virginia Licensing & Ventures Group ("UVA LVG") pursuant to which the Company will invest approximately \$1,000,000 over a three-year period with UVA to create unique industrial hemp plants with guaranteed levels of THC below the legal limits and optimize other desirable hemp plant characteristics to improve the plant's suitability for growing in Virginia and other legacy tobacco regions of the United States. This work with UVA will also involve the development and study of medically important cannabinoids to be extracted by UVA from the Company's hemp plants. UVA and the Company will conduct all activities in this scientific collaboration within the parameters of state and federal licenses and permits held by UVA for such work. The agreements with UVA and UVA LVG grant the Company exclusive rights to commercialize all results of the collaboration in consideration of royalty payments by the Company to UVA LVG. The Company incurred expenses under the agreement in the amount \$287,535, \$360,046, and \$296,710 for the years ended December 31, 2019, 2018, and 2017, respectively.

On May 1, 2018, the Company entered into a University Growing and Evaluation Agreement (the "Agreement") with the University of Kentucky Research Foundation ("UKRF") whereby UKRF will provide the Company with services relating to growing certain tobacco breeding lines of the Company. Under the Agreement, the Company is obligated to pay \$75,000 to UKRF in three installments of \$25,000 each through January 31, 2019. During the years ended December 31, 2019 and 2018 expenses related to the Agreement amounted to \$25,000 and \$50,000, respectively.

On February 1, 2019, the Company entered into a Master Collaboration and Research Agreement (the "Agreement") with a Natural Good Medicines, LLC ("NGM"), the owners of certain hemp and cannabis plant lines (the "NGM Material"). The Agreement calls for NGM to cultivate, grow and process a certain amount of the NGM Material with the financial support of the Company. NGM has granted the Company certain exclusive rights to the hemp and cannabis plant lines of NGM. Additionally, three (3) years from the effective date of the Agreement, NGM and the Company will mutually share in the proceeds from the sale of non-propagating parts of the NGM Material. The Company's total financial commitment under the Agreement is \$442,333, which has been included in Research and development expenses on the Company's Statements of Operations and Comprehensive (Loss) Income for the year ended December 31, 2019.

On April 3, 2019, the Company entered into a Framework Collaborative Research Agreement (the "Agreement") with KeyGene under which KeyGene has agreed to work exclusively with the Company with respect to the *Cannabis Sativa L.* plant and all uses thereof (the "Field"). The initial term is for five (5) years with an option for an additional two (2) years in consideration of the Company paying KeyGene an aggregate of Six Million United States Dollars (\$6,000,000) over the initial term of the Agreement. A minimum of \$1,200,000 will be paid annually during the initial term of the Agreement with a portion of such amount being paid based on KeyGene achieving certain milestone deliverables for the Company. The Company will exclusively own all results and all intellectual property relating to the results from this collaboration with KeyGene ("Results"). The Company will pay royalties in varying amounts to KeyGene relating to the Company's commercialization in the Field of certain Results. The Company has granted KeyGene a license to commercialize the Results outside of the Field and KeyGene will pay royalties in varying amounts to the Company relating to KeyGene's commercialization outside of the Field of the Results. The Agreement also includes customary termination provisions for both KeyGene and the Company as well as representations, warranties, and covenants by the parties that are customary for a transaction of this nature. During the year ended December 31, 2019, expenses related to the agreement amounted to approximately \$905,000.

Modified Risk Tobacco Product Application (“MRTP Application”)– In connection with the Company’s MRTP Application for its Very Low Nicotine Content (“VLNC”) cigarettes with the FDA, the Company has entered in various contracts with third-party service providers to fulfill various requirements of the MRTP Application. Such contracts include services for clinical trials, perception studies, legal guidance, product testing, and consulting expertise. During the years ended December 31, 2019 and 2018 the Company incurred expenses relating to these contracts in the approximate amount of \$1,675,000 and \$9,800,000, respectively. The Company will incur consulting and legal expenses as our MRTPA continues through the FDA review process. The Company cannot currently quantify the additional expenses that the Company will incur in the FDA review process because it will involve various factors that are within the discretion and control of the FDA.

Litigation - In accordance with applicable accounting guidance, the Company establishes an accrued liability for litigation and regulatory matters when those matters present loss contingencies that are both probable and estimable. In such cases, there may be an exposure to loss in excess of any amounts accrued. When a loss contingency is not both probable and estimable, the Company does not establish an accrued liability. As a litigation or regulatory matter develops, the Company, in conjunction with any outside counsel handling the matter, evaluates on an ongoing basis whether such matter presents a loss contingency that is probable and estimable. If, at the time of evaluation, the loss contingency related to a litigation or regulatory matter is not both probable and estimable, the matter will continue to be monitored for further developments that would make such loss contingency both probable and estimable. When a loss contingency related to a litigation or regulatory matter is deemed to be both probable and estimable, the Company will establish an accrued liability with respect to such loss contingency and record a corresponding amount of related expenses. The Company will then continue to monitor the matter for further developments that could affect the amount of any such accrued liability.

Crede Settlement

On June 19, 2019, the Company, Crede CG III, LTD. (“Crede”) and Terren Peizer (“Peizer”) participated in a settlement conference meeting as required by the United States District Court for the Southern District of New York (the “SDNY Court”) entitled Crede CG III, LTD. v. 22nd Century Group, Inc. Subsequently, the Company, Crede and Peizer entered into a settlement agreement that settled this case, with the effective date of the settlement agreement being on July 22, 2019. Under the terms of the settlement agreement: (i) the Company issued to Crede on July 25, 2019 an aggregate of Nine Hundred Ninety Thousand (990,000) shares of common stock of the Company in full satisfaction of the cashless exchange of the Tranche 1A warrant and in settlement of all disputes between Crede, Peizer and the Company; (ii) Crede granted a proxy to the Company for a period of five (5) years for the Company to vote all of the shares of common stock of the Company owned by Crede in favor of the recommendations by the Company’s Board of Directors (excluding any extraordinary transactions); (iii) Crede agreed to not purchase, borrow or short any securities of the Company; and (iv) the Company, Crede and Peizer agreed to mutual releases of all claims between the parties and the dismissal of all the litigation claims and counterclaims with prejudice.

The Company accrued an expense related to the settlement of this case during the second quarter of 2019 in the amount of \$1,890,900, which is equal to the fair value of the 990,000 shares of Company common stock on July 22, 2019. The accrual was reclassified to capital upon the issuance of the common stock during the third quarter of 2019.

Class Action Cases

On January 21, 2019, Matthew Jackson Bull, a resident of Denver, Colorado, filed a Complaint against the Company, the Company’s then Chief Executive Officer, Henry Sicignano III, and the Company’s then Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Matthew Bull, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer Case No. 1:19-cv-00409. The Complaint alleges that Plaintiff Mr. Bull purchased shares of the Company’s common stock. Mr. Bull sues individually and seeks to bring a class action for persons or entities who acquired the Company’s common stock between February 18, 2016 and October 25, 2018, and alleges in Count I that the Company’s Annual Reports on Form 10-K for the years 2015, 2016 and 2017 allegedly contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, and alleges in Count II that Messrs. Sicignano and Brodfuehrer are liable for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Complaint seeks declaratory relief, unspecified money damages, and attorney’s fees and costs.

On January 29, 2019, Ian M. Fitch, a resident of Essex County Massachusetts, filed a Complaint against the Company, the Company’s then Chief Executive Officer, Henry Sicignano III, and the Company’s then Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Ian Fitch, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, Case No. 2:19-cv-00553. The Complaint filing alleges that the Plaintiff Mr. Fitch purchased shares of the Company’s common stock. Mr. Fitch sues individually and seeks to bring a class action for persons or entities who acquired the Company’s common stock between February 18, 2016 and October 25, 2018, and alleges in Count I that the Company’s Annual Reports on Form 10-K for the years 2015, 2016 and 2017 allegedly contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, and alleges in Count II that Messrs. Sicignano and Brodfuehrer are liable for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Complaint seeks declaratory relief, unspecified money damages, and attorney’s fees and costs.

On March 25, 2019, Plaintiffs’ counsel in the *Fitch* litigation filed a motion in both the *Fitch* and *Bull* actions: (1) proposing Joseph Noto, Garden State Tire Corp, and Stephens Johnson for Mr. Fitch as purportedly representative plaintiffs, (2) moving to consolidate the *Fitch* litigation with the *Bull* litigation, and (3) seeking to be appointed as lead counsel in the consolidated action. Plaintiffs’ counsel in the *Bull* litigation filed and then withdrew a comparable motion seeking to consolidate the cases and be appointed as lead counsel.

On May 28, 2019, plaintiff in the *Fitch* case voluntarily dismissed that action. On August 1, 2019, the Court in the *Bull* case issued an order designating Joseph Noto, Garden State Tire Corp, and Stephens Johnson as lead plaintiffs.

On September 16, 2019, pursuant to a joint motion by the parties, the Court in the *Bull* case transferred the class action to federal district court in the Western District of New York, where it remains pending as Case No. 1:19-cv-01285.

On October 9, 2019, the Court in the *Bull* case, now pending in the federal district court in the Western District of New York, entered an order requiring Plaintiffs to file an amended complaint by November 19, 2019, for the Company and Messrs. Sicignano and Brodfuehrer to file any motion to dismiss the amended complaint by January 29, 2020, for Plaintiffs then to file their response to the motion to dismiss by March 30, 2020, and for the Company and Messrs. Sicignano and Brodfuehrer to file their final reply in support of their motion to dismiss by April 29, 2020.

Plaintiffs filed their Amended Complaint on November 19, 2019. The Amended Complaint alleges that the Plaintiffs purchased shares of the Company's common stock and sues individually and to bring a class action for all persons or entities who acquired the Company's common stock between February 18, 2016 and July 31, 2019. The Amended Complaint alleges three counts: Count I sues the Company and Messrs. Sicignano and Brodfuehrer and alleges that the Company's quarterly and annual reports, SEC filings, press releases and other public statements and documents contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5; Count II sues Messrs. Sicignano and Brodfuehrer pursuant to Section 10(b) of the Securities Exchange Act and Rule 10b5(a) and (c); and Count III sues Messrs. Sicignano and Brodfuehrer for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Amended Complaint seeks to certify a class, and unspecified compensatory and punitive damages, and attorney's fees and costs.

On January 29, 2020, the Company and Messrs. Sicignano and Brodfuehrer filed a Motion to Dismiss the Amended Complaint. Plaintiffs have until March 30, 2020 to file a response to the Motion to Dismiss.

We believe that the claims are frivolous, meritless and that the Company and Messrs. Sicignano and Brodfuehrer have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and Messrs. Sicignano and Brodfuehrer against such claims.

Shareholder Derivative Cases

On February 6, 2019, Melvyn Klein, a resident of Nassau County New York, filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the United States District Court for the Eastern District of New York entitled: Melvyn Klein, derivatively on behalf of 22nd Century Group v. Henry Sicignano, III, Richard M. Sanders, Joseph Alexander Dunn, Nora B. Sullivan, James W. Cornell, John T. Brodfuehrer and 22nd Century Group, Inc., Case No. 1:19-cv-00748. Mr. Klein brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties for allegedly allowing the Company to make false statements; (ii) the director defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iii) the defendants allegedly violated Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made; and (iv) the director defendants allegedly violated Section 14(a) of the Securities Exchange Act and Rule 14a-9 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made in the Company's proxy statement. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. On April 11, 2019, pursuant to a stipulation by the parties, the Court ordered this litigation stayed and transferred the stayed action to the Western District of New York. On April 19, 2019, the case was opened in the United States District Court for the Western District of New York, Case No. 1-19-cv-0513. On August 15, 2019, the case was consolidated with the Mathew case identified below and stayed. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims.

On February 11, 2019, Stephen Mathew filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the Supreme Court of the State of New York, County of Erie, entitled: Stephen Mathew, derivatively on behalf of 22nd Century Group, Inc. v. Henry Sicignano, III, John T. Brodfuehrer, Richard M. Sanders, Joseph Alexander Dunn, James W. Cornell, Nora B. Sullivan and 22nd Century Group, Inc., Index No. 801786/2019. Mr. Mathew brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties by allegedly allowing the Company to make false statements; (ii) the director defendants were allegedly unjustly enriched by allegedly benefitting from allegedly allowing the Company to make false statements; (iii) the defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iv) the individual defendants allegedly abused their ability to control and influence the Company; and (v) the individual defendants allegedly engaged in gross mismanagement. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. On April 12, 2019, the parties jointly filed a Stipulated Notice of Removal in United States District Court for the Western District of New York. On April 23, 2019, the parties jointly filed an Amended Stipulated Notice of Removal in the Western District of New York. On May 3, 2019, pursuant to a stipulation from the parties, the Court ordered this litigation stayed. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims.

On August 15, 2019, the Court consolidated the *Mathew* and *Klein* actions pursuant to a stipulation by the parties.

On June 10, 2019, Judy Rowley filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the Supreme Court of the State of New York, County of Erie, entitled: *Judy Rowley, derivatively on behalf of 22nd Century Group, Inc. v. Henry Sicignano, III, Richard M. Sanders, Joseph Alexander Dunn, Nora B. Sullivan, James W. Cornell, John T. Brodfuehrer, and 22nd Century Group, Inc., Index No. 807214/2019*. Ms. Rowley brings this action derivatively alleging that the director defendants supposedly breached their fiduciary duties by allegedly allowing the Company to make false statements. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims. On September 13, 2019, the Court ordered the litigation stayed pursuant to joint stipulation by the parties.

On January 15, 2020, Kevin Broccuto filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and certain members of the Company's prior Board of Directors in the District Court of the State of Nevada, County of Clark, entitled: *Kevin Broccuto, derivatively on behalf of 22nd Century Group, Inc. v. James W. Cornell, Richard M. Sanders, Nora B. Sullivan, Henry Sicignano, III, and John T. Brodfuehrer, Case No. A-20-808599*. Mr. Broccuto brings this action derivatively alleging three counts: Count I alleges that the defendants breached their fiduciary duties; Count II alleges they committed corporate waste; and Count III that they were unjustly enriched, by allegedly allowing the Company to make false statements. The Complaint seeks unspecified monetary damages, corrective corporate governance actions, disgorgement of alleged profits and imposition of constructive trusts, and attorney's fees and costs. The Company and the individual defendants have not yet filed a response to the Complaint. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims.

On February 11, 2020, Jerry Wayne filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and certain members of the Company's prior Board of Directors in the District Court of the State of Nevada, County of Clark, entitled: *Jerry Wayne, derivatively on behalf of 22nd Century Group, Inc. v. James W. Cornell, Richard M. Sanders, Nora B. Sullivan, Henry Sicignano, III, and John T. Brodfuehrer, Case No. A-20-808599*. Mr. Wayne brings this action derivatively alleging three counts: Count I alleges that the defendants breached their fiduciary duties; Count II alleges they committed corporate waste; and Count III that they were unjustly enriched, by allegedly allowing the Company to make false statements. The Complaint seeks unspecified monetary damages, corrective corporate governance actions, disgorgement of alleged profits and imposition of constructive trusts, and attorney's fees and costs. The Complaint also seeks to declare as unenforceable the Company's Bylaw requiring derivative lawsuits to be filed in Erie County, New York, where the Company is headquartered. The Company and the individual defendants have not yet filed a response to the Complaint. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims.

Shareholder Derivative Demand

On February 19, 2019, the Company received a demand letter from attorneys representing Van McClendon, a shareholder of the Company, in which Mr. McClendon demanded that the Company's Board of Directors take action to pursue certain purported causes of action on behalf of the Company to remedy alleged breaches of fiduciary duties by each of the members of the Company's Board of Directors, the Company's Chief Executive Officer, Henry Sicignano III, and the Company's Chief Financial Officer, John T. Brodfuehrer. On February 28, 2019, the Board appointed a Special Committee of independent directors and instructed the Committee to assess whether pursuing the claims detailed in the demand letter would be in the best interests of the Company. Subsequently, Mr. McClendon sold his shares and withdrew his demand. On May 7, 2019, after Mr. McClendon sold his shares, the Company received a similar demand letter from attorneys representing Jeremy Houck, a shareholder of the Company. Pursuant to the Board's instruction, the Special Committee completed an investigation of the claims detailed in Mr. Houck's demand letter. The Special Committee determined that pursuing such claims would not be in the best interest of the Company.

NOTE 11. - EARNINGS PER COMMON SHARE

The following table sets forth the computation of basic and diluted earnings per common share for the years ended December 31, 2019, 2018, and 2017:

	December 31, 2019	December 31, 2018	December 31, 2017
Net loss attributed to common shareholders	\$ (26,558,544)	\$ (7,966,911)	\$ (13,029,117)
Denominator for basic and diluted earnings per common share-weighted average shares adjusted for dilutive securities	125,882,717	124,298,981	101,161,380
Loss per common share - basic and diluted	\$ (0.21)	\$ (0.06)	\$ (0.13)

Securities outstanding that were excluded from the computation of earnings per share for the years ended December 31, 2019, 2018, and 2017 because they would have been anti-dilutive are as follows:

	December 31, 2019	December 31, 2018	December 31, 2017
Warrants	11,293,211	11,293,211	12,088,080
Options	7,837,172	8,672,082	8,156,691
Restricted stock units	951,000	--	-
	20,081,383	19,965,293	20,244,771

NOTE 12. - EQUITY BASED COMPENSATION

On April 12, 2014, the shareholders of the Company approved the 22nd Century Group, Inc. 2014 Omnibus Incentive Plan (the "OIP") and the authorization of 5,000,000 shares thereunder. On April 29, 2017, the stockholders approved an amendment to the OIP to increase the number of shares available for issuance by an additional 5,000,000 shares and on May 3, 2019, the stockholders approved an additional amendment to the OIP to increase the number of shares available for issuance by an additional 5,000,000 shares. The OIP allows for the granting of equity and cash incentive awards to eligible individuals over the life of the OIP. The OIP has a term of ten years and is administered by the Compensation Committee of the Company's Board of Directors to determine the various types of incentive awards that may be granted to recipients under this plan and the number of shares of common stock to underlie each such award under the OIP. As of December 31, 2019, the Company had available 6,307,115 shares remaining for future awards under the OIP.

During the year ended December 31, 2019, the Company issued awards for restricted stock units from the OIP for 1,301,000 shares to eligible individuals with such restricted stock unit awards having vesting periods from immediate vesting to three years. During the year ended December 31, 2019, the Company issued stock option awards from the OIP for 700,000 shares having vesting periods of five and one-half months to thirty-five months. Additionally, during the year ended December 31, 2019, (1) 100,000 restricted stock units vested and 250,000 restricted stock units were forfeited, and (2) 75,410 stock options were exercised on a cashless basis and 1,395,500 were forfeited.

During the year ended December 31, 2018, the Company issued stock option awards from the OIP for 1,631,841 shares, to eligible individuals. Stock options issued to acquire 1,231,841 shares of Company common stock have vesting periods ranging from one to three years from the date of the award, and stock options issued to acquire 400,000 shares of Company common stock are scheduled to vest upon the attainment of various milestones. Additionally, 300,000 stock options were cancelled due to the death of the Company's Senior Vice President of Science and Regulatory Affairs. All forfeited and cancelled restricted stock units and stock option were added back to the remaining shares available to be rewarded under the OIP. All stock option awards were valued using the Black-Scholes option-pricing model on the date of the award.

For the years ended December 31, 2019, 2018, and 2017, the Company recorded compensation expense related to stock option and restricted stock awards granted under the OIP of \$3,539,745, \$3,187,331 and \$941,650, respectively. During the third quarter of 2019, in connection with the Company's recent management changes, certain existing stock options were modified with respect to vesting and exercise dates. The modifications to the stock options, in accordance with ASC 718, resulted in compensation expense in 2019 of approximately \$741,000. The compensation expense for the year ended December 31, 2018 includes compensation expense in the amount of approximately \$1,227,000 recognized in the second quarter of 2018 when 900,000 stock options vested upon the death of the Company's Senior Vice President of Science and Regulatory Affairs on April 19, 2018.

As of December 31, 2019, unrecognized compensation expense related to non-vested stock options amounted to approximately \$2,153,200, which is expected to be recognized as follows: approximately \$1,011,500, \$450,200 and \$54,600 during 2020, 2021 and 2022, respectively. Approximately \$636,900 of the unrecognized compensation expense relates to previously issued stock options, with the vesting of such stock options being based on the achievement of a certain milestones.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were used for the years ended December 31, 2019, 2018, and 2017:

	2019	2018	2017
Risk-free interest rate (weighted average)	1.54%	2.77%	2.05%
Expected dividend yield	0%	0%	0%
Expected stock price volatility	70%	90%	90%
Expected life of options (weighted average)	5.15 years	5.61 years	5.56 years

The Company estimated the expected volatility of the Company's stock to be 70%. The expected term was estimated using the contract life of the option. The risk-free interest rate assumption was determined using yield of the equivalent U.S. Treasury bonds over the expected term. The Company has never paid any cash dividends and does not anticipate paying any cash dividends in the foreseeable future. Therefore, the Company assumed an expected dividend yield of zero.

A summary of all stock option activity since December 31, 2016 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2016	5,650,679	\$ 1.04		
Granted in 2017	2,692,000	\$ 1.76		
Exercised in 2017	(85,988)	\$ 0.79		
Expired in 2017	(100,000)	\$ 1.43		
Outstanding at December 31, 2017	8,156,691	\$ 1.28		
Granted in 2018	1,631,841	\$ 2.64		
Exercised in 2018	(612,259)	\$ 0.87		
Expired / cancelled in 2018	(504,191)	\$ 1.71		
Outstanding at December 31, 2018	8,672,082	\$ 1.54		
Granted in 2019	600,000	\$ 2.07		
Exercised in 2019	(75,410)	\$ 0.93		
Forfeited in 2019	(1,359,500)	\$ 2.09		
Outstanding at December 31, 2019	<u>7,837,172</u>	<u>\$ 1.49</u>	<u>5.4 years</u>	<u>\$ 761,699</u>
Exercisable at December 31, 2019	<u>6,182,688</u>	<u>\$ 1.39</u>	<u>5.1 years</u>	<u>\$ 575,233</u>

The weighted average grant date fair value of options issued during the years ended December 31, 2019 and 2018 was \$1.19 and \$1.81, respectively. The total fair value of options that vested during the years ended December 31, 2019 and 2018 amounted to \$2,634,010 and \$2,628,622, respectively. There were 75,410 options exercised on a cashless basis during the year ended December 31, 2019 resulting in the issuance of 39,988 shares of the Company stock. There were 612,259 options exercised on a cash and cashless basis during the year ended December 31, 2018 resulting in the issuance of 583,214 shares and proceeds of \$444,614 to the Company. Stock options to purchase 900,000 shares of the Company common stock were not exercised by a former employee's beneficiaries during the twelve-month period following his death and have subsequently been returned to the OIP.

NOTE 13. - INCOME TAXES

The Tax Cuts and Jobs Act ("TCJA") was signed into law on December 22, 2017. The TCJA includes significant changes to the U.S. corporate income tax system, including a Federal corporate rate reduction from 35% to 21%. The Company's income tax provision (benefit) reflects the effect of this change in Federal corporate tax rates, primarily from the re-measurement of the Company's deferred tax assets and liabilities, including prior net operating loss carry-forwards. The effect of the rate change attributable to the TCJA on the Company's effective tax rate was a decrease of approximately 46% in the net deferred tax assets before the valuation allowance.

The following is a summary of the components giving rise to the income tax provision (benefit) for the years ended December 31, 2019, 2018, and 2017:

	<u>2019</u>	<u>2018</u>	<u>2017</u>
Current:			
Federal	\$ -	\$ -	\$ -
State	-	-	-
Total current	-	-	-
Deferred:			
Federal	\$ (5,607,324)	(1,446,323)	1,263,677
State	55,210	(13,927)	214,628
Total deferred	(5,552,114)	(1,460,250)	1,478,305
Change in valuation allowance	5,552,114	1,460,250	(1,478,305)
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ --</u>

The provision (benefit) for income tax varies from that which would be expected based on applying the statutory federal rate to pre-tax accounting loss, including the effect of the change in the U.S. corporate income tax rates, as follows:

	<u>2019</u>	<u>2018</u>	<u>2017</u>
Statutory federal rate	(21.0)%	(21.0)%	(34.0)%
Other items	(0.1)	0.1	(2.4)
Litigation Settlement	1.5		
Derivative liability	-	(0.1)	0.4
Stock based compensation	1.8	2.5	2.0
Research and development credit carryforward	(3.3)	(1.2)	(1.8)
State tax provision, net of federal benefit	0.2	(0.1)	0.1
Equity investment	-	1.5	-
Federal tax rate change	-	-	46.1
Valuation allowance	20.9	18.3	(11.4)
Effective tax rate (benefit) provision	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

Individual components of deferred taxes consist of the following as of December 31:

	2019	2018	2017
Deferred tax assets:			
Net operating loss carry-forward	\$ 14,996,042	\$ 11,526,599	\$ 9,917,641
Inventory	52,030	21,000	48,011
Stock-based compensation	1,048,993	813,585	388,925
Start-up expenditures	220,640	242,704	279,709
Research and development credit carryforward	1,208,641	326,269	232,198
Loss on equity investment	-	760	11,760
Accrued bonus	199,707	100,896	-
Severance liability	134,414	-	-
Investment in Panacea	39,966	-	-
Operating lease obligations	127,385	-	-
Other	22,094	19,605	4,272
	<u>18,049,912</u>	<u>13,051,418</u>	<u>10,882,516</u>
Deferred tax liabilities:			
Machinery and equipment	(238,733)	(214,587)	(220,888)
Patents and trademarks	(350,798)	(562,140)	(558,760)
Gain on investment	(104,223)	(612,286)	-
Accrued expense	(51,069)	(70,933)	-
Operating lease right-of-use assets	(126,416)	-	-
Other intangible assets	(188,394)	(153,307)	(124,953)
	<u>(1,059,633)</u>	<u>(1,613,253)</u>	<u>(904,601)</u>
Valuation allowance	(16,990,279)	(11,438,165)	(9,977,915)
Net deferred taxes	\$ --	\$ --	\$ --

The Company generated net operating losses (“NOL”) of approximately \$16,800,000 and \$7,700,000 for the years ended December 31, 2019 and 2018, respectively, and these NOL carryforward losses do not expire. The Company had accumulated an NOL carryforward of approximately \$46,900,000 through December 31, 2017 and this NOL carryforward begins to expire in 2031. As of December 31, 2019, the Company has a research and development credit carryforward of approximately \$1,200,000 that begins to expire in 2031. Utilization of these carryforwards may be subject to an annual limitation in the case of equity ownership changes, as defined by law. Due to the uncertainty of the Company’s ability to generate sufficient taxable income in the future, the Company has recorded a valuation allowance to reduce the net deferred tax asset to zero. These carryforwards are included in the net deferred tax asset that has been fully offset by the valuation allowance.

ASC 740 provides guidance on the financial statement recognition and measurement for uncertain income tax positions that are taken or expected to be taken in a company’s income tax return. The Company has evaluated its tax positions and believes there are no uncertain tax positions as of December 31, 2019.

NOTE 14. - SELECTED QUARTERLY FINANCIAL DATA (unaudited)

Below is selected quarterly financial data for the years ended December 31, 2019 and 2018:

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Revenue, net	\$ 6,293,648	\$ 5,814,979	\$ 6,461,914	\$ 7,261,989
Gross (loss) profit	\$ (102,910)	\$ (86,300)	\$ (21,068)	\$ 224,733
Loss from operations	\$ (5,379,159)	\$ (5,028,839)	\$ (7,605,516)	\$ (5,552,947)
Net loss	\$ (2,072,713)	\$ (8,041,682)	\$ (10,245,717)	\$ (6,198,432)
Loss per common share – basic and diluted	\$ (0.02)	\$ (0.06)	\$ (0.08)	\$ (0.05)

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Revenue, net	\$ 6,116,309	\$ 6,914,913	\$ 6,260,518	\$ 7,134,967
Gross profit	\$ 71,578	\$ 161,714	\$ 150,949	\$ 514,746
Loss from operations	\$ (4,968,772)	\$ (7,040,512)	\$ (6,208,834)	\$ (5,800,509)
Net income (loss)	\$ 1,386,488	\$ (6,738,652)	\$ 6,304,654	\$ (8,919,401)
Income (loss) per common share - basic	\$ 0.01	\$ (0.05)	\$ 0.05	\$ (0.07)
Income (loss) per common share - diluted	\$ 0.01	\$ (0.05)	\$ 0.04	\$ (0.07)

Item 15(b). Financial Statement Schedules

Valuation and Qualifying Accounts

The following table summarizes the Company's valuation and qualifying accounts from December 31, 2016:

	Allowance for doubtful Accounts	Reserve for inventory valuation	Deferred tax valuation allowance
Qualifying account valuation at December 31, 2016	\$ 10,000	\$ 255,623	\$ 11,456,220
Additions charged to costs and expenses during 2017	-	95,000	-
Deductions during 2016	(10,000)	(155,623)	(1,478,305)
Qualifying account valuation at December 31, 2017	-	195,000	9,977,915
Additions charged to costs and expenses during 2018	-	-	1,460,250
Deductions during 2018	-	(95,000)	-
Qualifying account valuation at December 31, 2018	-	100,000	11,438,165
Additions charged to costs and expenses during 2019	-	1,038,269	5,552,114
Deductions during 2019	-	(1,038,269)	-
Qualifying account valuation at December 31, 2019	<u>\$ -</u>	<u>\$ 100,000</u>	<u>\$ 16,990,279</u>

Item 15(c). Exhibits

In reviewing the agreements included as exhibits to this report, please remember they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about the Company, its subsidiaries or other parties to the agreements. The agreements contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement and:

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;
- may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time. We acknowledge that, notwithstanding the inclusion of the foregoing cautionary statements, we are responsible for considering whether additional specific disclosures of material information regarding material contractual provisions are required to make the statements in this report not misleading. Additional information about the Company may be found elsewhere in this report and the Company's other public files, which are available without charge through the SEC's website at <http://www.sec.gov>.

Exhibit No.	Description
3.1	<u>Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K for the year ended September 30, 2010 filed with the Commission on December 1, 2010).</u>
3.1.1	<u>Amendment to Certificate of Incorporation of the Company (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement filed with the Commission on March 4, 2014).</u>
3.2	<u>Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Commission on January 30, 2014).</u>
3.2.1	<u>Amendment No. 1 to Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 of the Company's Form 8-K filed with the Commission on April 28, 2015).</u>
4.1	<u>Form of New Warrant Agreement (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Commission on November 25, 2019)</u>
4.2	<u>Description of Securities Registered Pursuant to Section 12</u>
10.1†	<u>2010 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.3 to the Company's Form S-8 filed with the Commission on March 30, 2011).</u>
10.2†	<u>Employment Agreement between the Company and Michael J. Zercher (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the Commission on September 13, 2019)</u>
10.3††	<u>License Agreement dated March 6, 2009 between North Carolina State University and 22nd Century Limited, LLC (incorporated by reference to Exhibit 10.21 to the Company's Form S-1 registration statement filed with the Commission on August 26, 2011).</u>
10.3.1	<u>Amendment dated August 9, 2012 to License Agreement dated March 6, 2009 between North Carolina State University and 22nd Century Limited, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on August 20, 2012).</u>
10.4	<u>Letter Agreement between the Company and North Carolina State University dated November 22, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the Commission on November 23, 2011).</u>
10.5†	<u>Employment Agreement between the Company and Andrea S. Jentsch (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Commission on January 3, 2020)</u>
10.6†	<u>Form of Restricted Stock Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).</u>
10.7†	<u>Form of Stock Option Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).</u>
10.8†	<u>Form of Restricted Stock Award Agreement under 22nd Century Group, Inc. 2014 Omnibus Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the Commission on April 14, 2014).</u>
10.9†	<u>Form of Stock Option Award Agreement under 22nd Century Group, Inc. 2014 Omnibus Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed with the Commission on April 14, 2014).</u>

<u>10.10††</u>	<u>Research Funding Agreement dated December 14, 2016 with The Rector and Visitors of the University of Virginia, a not-for-profit Virginia educational institutional of the Commonwealth of Virginia (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Commission on March 8, 2017).</u>
<u>10.11††</u>	<u>Exclusive License Agreement dated December 14, 2016 with the University of Virginia Patent Foundation d/b/a University of Virginia Licensing & Ventures Group, a Virginia non-profit corporation (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Commission on March 8, 2017).</u>
<u>10.12†</u>	<u>22nd Century Group, Inc. 2014 Omnibus Incentive Plan, as amended and restated (incorporated by reference from Appendix A to the Company's definitive proxy statement filed on March 17, 2017).</u>
<u>10.13+*</u>	<u>Form of Executive Restricted Stock Unit Award under 2014 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.15 of the Company's Annual Report on Form 10-K filed with the Commission on March 6, 2019).</u>
<u>10.14+*</u>	<u>Form of Director Restricted Stock Unit Award under 2014 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.16 of the Company's Annual Report on Form 10-K filed with the Commission on March 6, 2019).</u>
<u>10.15</u>	<u>Series B Preferred Stock Purchase Agreement, dated as of December 3, 2019, between Panacea Life Sciences., Inc and 22nd Century Group, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Commission on December 3, 2019).</u>
<u>10.16</u>	<u>Convertible Note of Panacea Life Sciences., Inc., dated December 3, 2019, issued to 22nd Century Group, Inc.(incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the Commission on December 3, 2019).</u>
<u>10.17</u>	<u>Warrant to purchase shares of Series B Preferred Stock of Panacea Life Sciences., Inc., dated December 3, 2019, issued to 22nd Century Group, Inc. (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the Commission on December 3, 2019).</u>
<u>10.18</u>	<u>Side Agreement, dated as of December 3, 2019, Panacea Life Sciences, Inc., [EMPLOYEE], [EMPLOYEE], [EMPLOYEE], [EMPLOYEE], Quintel-MC Incorporated, and 22nd Century Group, Inc. (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the Commission on December 3, 2019).</u>
<u>10.19†††</u>	<u>Framework Collaborative Research Agreement, dated as of April 3, 2019, between KeyGene N.V. and 22nd Century Group, Inc.(incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the Commission on May 7, 2019).</u>
<u>23.1*</u>	<u>Consent of Freed Maxick CPAs, P.C.</u>
<u>31.1*</u>	<u>Section 302 Certification.</u>
<u>31.2*</u>	<u>Section 302 Certification.</u>
<u>32.1*</u>	<u>Written Statement of Principal Executive Officer and Chief Financial Officer pursuant to 18.U.S.C §1350.</u>
101*	Interactive data files formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, and (iv) the Notes to the Consolidated Financial Statements.
101.INS XBRL	Instance Document*
101.SCH XBRL	Taxonomy Extension Schema Document*
101.CAL XBRL	Taxonomy Extension Calculation Linkbase Document*
101.DEF XBRL	Taxonomy Extension Definition Linkbase Document*
101.LAB XBRL	Taxonomy Extension Label Linkbase Document*
101.PRE XBRL	Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

† Management contract or compensatory plan, contract or arrangement.

†† Certain portions of the exhibit have been omitted pursuant to a confidential treatment order. An unredacted copy of the exhibit has been filed separately with the United States Securities and Exchange Commission pursuant to the request for confidential treatment.

††† Certain portions of the exhibit have been omitted pursuant Regulation S-K Item 601(b) because it is both (i) not material to investors and (ii) likely to cause competitive harm to the Company is publicly disclosed.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

22nd CENTURY GROUP, INC.

Date: March 11, 2020

By: /s/ Michael J. Zercher
Michael J. Zercher
President and Chief Operating Officer
(Principal Executive Officer)

Date: March 11, 2020

By: /s/ Andrea S. Jentsch
Andrea S. Jentsch
Chief Financial Officer
(Principal Accounting and Financial Officer)

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 11, 2020

By: /s/ Clifford B. Fleet.
Clifford B. Fleet
Director

Date: March 11, 2020

By: /s/ Richard M. Sanders
Richard M. Sanders
Director

Date: March 11, 2020

By: /s/ Nora B. Sullivan
Nora B. Sullivan
Director

Date: March 11, 2020

By: /s/ Roger D. O'Brien
Roger D. O'Brien
Director

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

As of December 31, 2019, 22nd Century Group, Inc. (“we” or “our”) had one class of securities, our common stock, par value \$0.00001 per share (“Common Stock”), registered under Section 12 of the Securities Exchange Act of 1934, as amended. The following description of our Common Stock is a summary and is subject to, and is qualified in its entirety by reference to, the provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, copies of which are incorporated by reference as Exhibits 3.1, 3.1.1, 3.2 and 3.2.1, respectively, to our Annual Report on Form 10-K for the year ended December 31, 2019 of which this Exhibit 4.2 is a part.

Our authorized capital stock consists of 300,000,000 shares of Common Stock, \$0.00001 par value per share, and 10,000,000 shares of preferred stock, \$0.00001 par value per share. As of December 31, 2019, 138,362,809 shares of Common Stock were issued and outstanding and no shares of preferred stock were issued and outstanding.

Our Common Stock is traded on the NYSE American under the symbol “XXII.” Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Holders of Common Stock are entitled to receive ratably such dividends, if any, as may be declared by the board of directors out of funds legally available therefore, subject to a preferential dividend right of outstanding preferred stock. Upon the liquidation, dissolution or our winding up, the holders of Common Stock are entitled to receive ratably our net assets available after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. The rights, preferences and privileges of holders of our Common Stock are subject to, and may be adversely affected by the rights of the holders any series of preferred stock that we may designate and issue in the future.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Numbers 333-173166, 333-195380, 333-217771, and 333-231262 on Form S-8 and in Registration Statement Numbers 333-221270, 333-215391, and 333-199273 on Form S-3 of 22nd Century Group, Inc. of our report, dated March 11, 2020, relating to our audits of the consolidated financial statements and the effectiveness of internal controls over financial reporting as of and for the years ended December 31, 2019, 2018, and 2017, appearing in this Annual Report on Form 10-K of 22nd Century Group, Inc.

/s/ Freed Maxick CPAs, P.C.

Buffalo, NY
March 11, 2020

CERTIFICATIONS

I, Michael J. Zercher, President and Chief Operating Officer of 22nd CENTURY GROUP, INC., certify that:

1. I have reviewed this annual report on Form 10-K of 22nd CENTURY GROUP, INC.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2020

/s/ Michael J. Zercher

Michael J. Zercher
President and Chief Operating Officer
(Principal Executive Officer)

CERTIFICATIONS

I, Andrea S. Jentsch, Chief Financial Officer of 22nd CENTURY GROUP, INC., certify that:

1. I have reviewed this annual report on Form 10-K of 22nd CENTURY GROUP, INC.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2020

/s/ Andrea S. Jentsch

Andrea S. Jentsch
Chief Financial Officer
(Principal Financial Officer)

Written Statement of the President and Chief Financial Officer Pursuant to 18 U.S.C. §1350

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned President and Chief Operating Officer of 22nd CENTURY GROUP, INC. (the "Company"), and I, the undersigned Chief Financial Officer of the Company, hereby certify, to the best of my knowledge, that the annual report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Date: March 11, 2020

/s/ Michael J. Zercher

Michael J. Zercher
President and Chief Operating Officer

Date: March 11, 2020

/s/ Andrea S. Jentsch

Andrea S. Jentsch
Chief Financial Officer

**22ND CENTURY
LEADERSHIP TEAM**

Michael J. Zercher
President & Chief
Operating Officer

Andrea Jentsch
Chief Financial Officer

John T. Brodfuehrer
Vice President,
Strategy

Lisa Parks
Vice President,
Acquisitions

John Pritchard
Vice President,
Regulatory Science

**Juan Sanchez Tamburrino,
Ph.D.**
Vice President,
Research and Development

**22ND CENTURY
BOARD OF DIRECTORS**

Nora B. Sullivan
Director & Chair of the Board
President, Sullivan Capital
Partners, LLC

James W. Cornell
Director
President & CEO, Praxiis

Clifford B. Fleet
Director
President and CEO,
Colonial Williamsburg
Foundation

Roger D. O'Brien
Director
Partner,
O'Brien Associates, LLC

Richard M. Sanders
Director
Partner,
Phase One Ventures, LLC

OTHER INFORMATION

**INVESTOR
INFORMATION**

Mei Kuo
Director, Communications
& Investor Relations

22nd Century Group, Inc.
8560 Main Street, Suite 4
Williamsville, NY 14221
716 270 1523
mkuo@xxiicentury.com

**INDEPENDENT REGISTERED
PUBLIC ACCOUNTING FIRM**

Freed Maxick

Liberty Building
424 Main Street, Suite 800
Buffalo, NY 14202
716 847 0069
www.freedmaxick.com

**TRANSFER
AGENT**

**Continental Stock
and Transfer Company**

1 State Street, 30th Floor
New York, NY 10004
www.continentalstock.com

22nd Century Group, Inc.

8560 Main Street, Suite 4

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