2021 Annual Report

22nd Century Group, Inc.

Letter to Shareholders

Dear Fellow Shareholders,

"Helps You Smoke Less." These four words from the U.S. Food and Drug Administration (FDA) on December 23rd, 2021, capped off an amazing year at 22nd Century Group and ushered in what may be the most disruptive new tobacco product of our generation – our VLN® reduced nicotine content combustible cigarettes.

VLN® is designed specifically to help smokers smoke fewer cigarettes. In doing so, we can fulfill our primary mission to reduce the harm associated with smoking.

Our VLN® authorization reflects years of scientific research, federally funded clinical studies and regulatory persistence to secure the first and only Modified Risk Tobacco Product (MRTP) authorization granted to a combustible cigarette. It also signifies a new starting line as we bring VLN® to the $800 billion global tobacco market – 85% of which is focused on combustible tobacco cigarettes.

With more than 34 million smokers in the U.S. and more than a billion smokers around the world, this tremendous global market is ripe for disruption. In the U.S., we know that more than three out of four adult smokers want to quit and 50% attempt to quit each year. Yet less than 10% of smokers are able to successfully quit. More and more, smokers are actively seeking alternatives to addictive, conventional cigarettes, most of which are other addictive nicotine delivery systems.

We offer adult smokers something different – a way to reduce their smoking; a way to reduce their nicotine consumption. We are encouraged by data from our own consumer perception studies showing that 60% of current adult smokers are likely to use VLN®, and from extensive federally funded studies showing that reduced nicotine cigarettes like VLN® are effective in helping smokers truly smoke less.

And now, for the first time, adult smokers will have the opportunity to make that choice. VLN® will be positioned as a premium product in the market, alongside top global brands. But right on the front of our pack will be a clear and compelling statement giving every adult smoker a reason to try our product: "Helps You Smoke Less."

We have kicked off our pilot launch in Chicago at more than 150 Circle K stores, making VLN® available to over 1.2 million smokers within the greater Chicago market. The pilot launch is intended to hone our VLN® marketing messaging and plan, setting the stage for the broader launch of the product. As the second-largest convenience store chain in North America, Circle K is an ideal launch partner. They bring more than 7,000 stores of distribution capability, international reach, and extensive customer engagement and data tracking capabilities.

But the positive winds don't stop with just our markets and our corporate resources. We believe the recent appointment of Dr. Robert Califf as FDA Commissioner and the FDA's continued focus on pursuing a menthol ban for cigarettes signals a favorable regulatory environment for 22nd Century's VLN® products. Dr. Califf is known to be a longtime proponent of innovative tobacco control programs and strong supporter of the Agency's Comprehensive Plan for Tobacco and Nicotine Regulation. The FDA's decision to move forward with the rulemaking process to ban menthol in cigarettes signifies the Agency's intent to take significant action toward dramatically reducing tobacco-related disease and death in the U.S. – and we are on the forefront of this effort.

We are also launching in our first international market, South Korea, where there is a strong public interest in alternative tobacco products and smoking reduction. We have shipped our first Korean labeled packs to our local partner and are actively looking at additional international markets in Asia and Europe where regulations facilitate bringing our VLN® to market. 22nd Century also continues to develop its next-generation VLN® 2.0 tobacco portfolio, including non-GMO technology that will allow us to rapidly introduce reduced nicotine traits into virtually any variety of tobacco.

As exciting as our tobacco advances are, they are just one aspect of our success in 2021. 22nd Century also made significant progress in our hemp/cannabis franchise, where we acquired a showcase farm facility in Needle Rock Farms, secured USDA Organic Certification, and recorded our first biomass and license revenue. Our focus on the upstream segments of the cannabinoid value chain in this $100 billion global market is paying off as we continue to prove out the unique capabilities of our proprietary hemp/cannabis plants. Our specific capabilities and intellectual property include alkaloid profiling/mapping, genetic engineering, and gene editing, breeding and cultivation, and ingredient extraction and purification. With these capabilities, we look to provide the hemp/cannabis industry with enabling IP and plant lines featuring optimized cannabinoid and terpene profiles as well as stable genetics for higher commercial yields. Following a successful 2021 demonstration, we are expanding our 2022 planting and all of our biomass is spoken for with off-take commitments from our partners.

Last August, we announced our entry into the $500 billion global specialty hops market as our third plant franchise, leveraging our extensive alkaloid plant technologies and capabilities in this close relative to hemp/cannabis. We have expanded our research agreement with KeyGene to identify specific traits which, if appropriately engineered, could benefit consumers of hop products in both the beer and nutraceuticals segment of the industry. We have also initiated business development efforts to further identify opportunities moving forward. As with our other franchises, the global hops market is currently reliant on expensive and risky traditional breeding techniques that can take a decade or more to show results. We believe that our approach is highly attractive to industry customers, as it can shorten this process to just a matter of a few years, bringing truly disruptive new plant technologies to market in a fraction of the time and cost.

The Company also strengthened its balance sheet during 2021, including a $40 million registered direct offering and $11 million in proceeds from the exercise of warrants. (We are warrant free.) We completed an uplisting to the Nasdaq Capital Market, which we believe will enhance 22nd Century's visibility to life science and agricultural technology-focused institutional investors and secured new research analyst coverage at several top firms in our industry.

As we look to the year ahead, we expect 2022 will be truly transformational as we complete our VLN® pilot in Chicago and move to full, nationwide market launch. We have expanded our planned hemp crop at Needle Rock Farms for 2022 and look forward to exciting developments in hops as we scale up our efforts in that franchise. In closing, I thank you for your continued support of 22nd Century and its initiatives and look forward to our continued progress in these exciting markets.

James. A. Mish
Chief Executive 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, 2021

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	**98-0468420**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)

500 Seneca Street, Suite 507, Buffalo, New York 14204
(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	NASDAQ Capital Market

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 Date 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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

The aggregate market value of the registrant's common stock as of June 30, 2021, the last day of the registrant's most recently completed second fiscal quarter, was $740 million based upon the closing price reported for such date on the NYSE American. On February 22, 2022, the registrant had 162,938,375 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2022 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, 2021.

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Cautionary Note Regarding Forward-Looking Statements and Risk Factor Summary

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 the following summary of risks related to our business:

- We have had a history of losses and negative cash flows, and we may be unable to achieve and sustain profitability and positive cash flows from operations.
- Our competitors generally have, and any future competitors may have, greater financial resources and name recognition 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.
- Our research and development process may not develop marketable products, which would result in loss of our investment into such process.
- We may 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 or result in losses.
- The coronavirus pandemic (COVID-19) or another pandemic may cause a variety of business disruptions and future business risks.
- 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 may be unsuccessful at commercializing our Very Low Nicotine Content "VLNC" tobacco as a Modified Exposure Cigarette.
- The manufacturing of tobacco products subjects us to significant governmental regulation and the failure to comply with such regulations could have a material adverse effect on our business and subject us to substantial fines or other regulatory actions.
- We may become subject to litigation related to cigarette smoking and/or exposure to environmental tobacco smoke, or ETS, which could severely impair our results of operations and liquidity.
- The loss of a significant customer for whom we manufacture tobacco products could have an adverse impact on our results of operation.
- Product liability claims, product recalls, or other claims could cause us to incur losses or damage our reputation.
- The FDA could force the removal of our products from the U.S. market.
- Negative press from being in the hemp/cannabis space 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.

- Certain of our proprietary rights have expired or 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.

- 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.

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

- We are a 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.

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

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

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.

Overview

22nd Century Group, Inc. is a leading agricultural biotechnology and intellectual property company focused on tobacco harm reduction, reduced nicotine tobacco and improving health and wellness through plant science. In tobacco, hemp/cannabis, and hop plants, we use modern plant breeding technologies, including genetic engineering, gene-editing, and molecular breeding to deliver solutions for the life science and consumer products industries by creating new, proprietary plants with optimized alkaloid and flavonoid profiles as well as improved yields and valuable agronomic traits. 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 cigarette products. Our mission in hemp/cannabis is to develop proprietary varieties of hemp with valuable cannabinoid and terpene profiles and other superior agronomic traits, with potential applications in life sciences and consumer products. Our mission in hops is to leverage our experience with tobacco and hemp/cannabis, a close hop relative, and accelerate the development of proprietary specialty hop varieties or valuable traits, with potential applications in life sciences and consumer products. We have a significant intellectual property portfolio of issued patents and patent applications relating to both tobacco and hemp/cannabis plants and have further resources directed towards creating and securing additional intellectual property pertaining to all three franchises.

Tobacco

As stated, our mission in tobacco is to reduce the harm caused by smoking by introducing adult smokers to our proprietary, VLNC tobacco and cigarettes, which contain 95% less nicotine than conventional tobacco and cigarettes. The Food and Drug Administration ("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 for the U.S. Centers for Disease Control and Prevention ("CDC") states that tobacco use causes more than 480,000 deaths per year and costs the United States economy nearly $300 billion annually in lost productivity and direct heath care costs. 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.

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, 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 31.6 million variable nicotine research cigarettes for use in numerous independent clinical studies with agencies of the United States federal government. These independent clinical studies are estimated to have been performed at a cost of more than $125 million. The results of these independent clinical studies have been published in peer-reviewed publications (including the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and many others). These studies indicate that use of our VLNC tobaccos have been associated with reductions in smoking, nicotine exposure and nicotine dependence with little to no evidence of compensatory smoking and without serious adverse events. A list of completed and published clinical studies using cigarettes made with our VLNC tobaccos is shown on our website at https://www.xxiicentury.com/vln-clinical-studies/published-clinical-studies-on-very-low-nicotine-content-vlnc-cigarettes. A list of on-going clinical studies using our SPECTRUM® research cigarettes is shown on our website at https://www.xxiicentury.com/vln-clinical-studies/on-going-clinical-studies-on-very-low-nicotine-content-vlnc-cigarettes. We do not incorporate third party studies or the information on our website into this Annual Report on Form 10-K.

The results of these numerous completed 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. This was stated on March 19, 2018, where 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 all cigarettes minimally or

non-addictive is immediately feasible as evidenced by our production and delivery of millions of 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. On December 23, 2021 we were granted authorization to market our VLN® cigarettes under a Modified Risk Tobacco Product, modified exposure designation. We subsequently began efforts to offer our proprietary VLNC cigarettes for domestic sale under the brand name of VLN® within 90 days of the receipt of the Modified Risk Tobacco Product ("MRTP") marketing order. We also plan to offer VLN® for international sale and for licensing by third parties. Additional information regarding our regulatory activities with the FDA is described below.

Proposed Government Mandates Limiting the Nicotine in Cigarettes.

In a June 16, 2010 press release, Dr. David Kessler, a 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. 22nd Century's reduced nicotine cigarettes contain between 0.3-0.7 mg/g nicotine.

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, and (iii) increase the rate of quitting and reduce the number of smokers who relapse. 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, then 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 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's Center for Tobacco Products ("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. 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. 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 April 2021, the New Zealand government announced a six-week consultation (15 April – 5pm, May 31, 2021) on Proposals for a Smokefree Aotearoa 2025 Action Plan. This consultation included proposals to reduce nicotine in smoked tobacco products to very low levels. The Company returned a detailed, comprehensive submission to the New Zealand Ministry of Health in full support of the Smokefree proposals [Response Identifier 1048733132, publicly available]. The final Smokefree Aotearoa 2025 Action Plan was launched on December 9, 2021[https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/smokefree-aotearoa-2025-action-plan]. The New Zealand government has committed to introducing an amendment Bill in 2022 to allow only very low nicotine levels in smoked tobacco products for manufacture, importation, distribution and sale and introduce product assurance systems to support compliance with these requirements.

We believe that our VLNC tobacco technology and our production and delivery of millions of proprietary variable nicotine research cigarettes since 2011 reflects that the FDA's plan to dramatically reduce nicotine in cigarettes is technically achievable. In the United States, we are focused on working with the FDA on its nicotine reduction mandate. 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.

Modified Risk Tobacco Products

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. 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 Exposure Cigarettes").

On December 5, 2018, we submitted to the FDA a new Premarket Tobacco Application ("PMTA") and on December 27, 2018 we submitted to the FDA a new MRTP application, in each case for our VLNC tobacco cigarettes. Through our applications, we requested a reduced exposure marketing authorization from the FDA to market these products as Modified Exposure Cigarettes with product labeling that includes the brand name of VLN® and states that VLN® has 95% less nicotine than conventional cigarettes.

On December 17, 2019, the FDA authorized us to market in the U.S. our VLNC tobacco cigarettes that were the subject of our PMTA. While the PMTA authorized us to market the products in the U.S. it did not allow us to make product claims which would indicate that the product contained 95% less nicotine. Such claims would fall under receiving an order from the FDA which is designated as the MRTP. We made the decision to delay the introduction of our VLNC cigarette products to the market until we received the MRTP order.

On February 14, 2020, the FDA's Tobacco Products Scientific Advisory Committee ("TPSAC") conducted its public hearing regarding our MRTP application 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.

On December 23, 2021, we secured the world's first and only MRTP designation for a combustible cigarette for VLN® King and VLN® Menthol King 95% reduced nicotine content cigarettes. The FDA authorized the marketing of VLN® with the following claims, "*95% less nicotine*", "*Helps reduce your nicotine consumption*", and "*Greatly reduces your nicotine consumption*,". The FDA also proactively added "*Helps You Smoke Less*" evidence-based headline claim to our requested claims.

In 2019 and 2021, we contracted with farmers to grow considerable quantities of VLNC tobacco in anticipation of FDA authorization of its MRTP and subsequent commercial launch of VLN® cigarettes. In January 2022, at our manufacturing facility in North Carolina, we produced the first cartons of our VLN® reduced nicotine cigarettes, destined for commercial sale as a part of our pilot launch. Our marketing team has prepared a comprehensive launch plan for VLN® cigarettes starting with a pilot launch and progressing to a national roll-out. In March 2022, pending state regulatory authorizations, we plan to launch VLN® cigarettes in the U.S. market. We believe that the commercialization of VLN® cigarettes will create further opportunities for us to license our proprietary technology tobaccos and the VLN® brand.

VLN® Commercialization Plan

As stated above, our comprehensive launch plan for VLN® cigarettes starts with a pilot launch and progresses to a national roll-out. The initial pilot program will launch in March 2022 and run for 3 to 6 months. We are also in advanced discussions with multiple additional regional and national retail partners to carry VLN® and participate in our retail program as we scale nationally.

Hemp/Cannabis

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").

As of February 1, 2022, (i) federal law and the laws of 47 states in the United States and the District of Columbia have legalized hemp, (ii) 37 states in the United States, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands have enacted 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) 18 states in the United States, the District of Columbia, Guam, and the Northern Mariana Islands 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 hemp, we are developing proprietary hemp varieties with increased levels of certain cannabinoids and other desirable agronomic traits with the goal of generating new and valuable intellectual property and plant lines. Our activities in the United States involve only work with legal hemp in full compliance with U.S. federal and state laws. The hemp and the marijuana plants are both part of the same *cannabis* genus, except that hemp does not have more than 0.3% dry weight content of delta-9-tetrahydrocannabinol ("THC"). While the 2018 Farm Bill legalized hemp and cannabinoids extracted from hemp in the U.S., such extracts remain subject to state laws and regulation by other U.S. federal agencies such as the FDA, U.S. Drug Enforcement Administration ("DEA"), 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 which is 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/cannabis. This is not the case. In the United States, we work only with legal hemp in full compliance with federal and state laws.

In the State of New York, we had a license to research and grow hemp in response to the numerous public announcements by former New York Governor Andrew Cuomo that New York State intends to become a leading grower and producer of hemp and hemp-derived products. In Canada, we previously conducted sponsored research on the hemp plant with Anandia Laboratories, Inc. ("Anandia") in Vancouver, British Columbia, in full compliance with Canadian regulations. Anandia was later sold to Aurora Cannabis Inc. ("Aurora") and we continue to maintain a relationship with them to license unique technology to other cannabis companies. Currently, we are in the process of obtaining a license in the State of Maryland to grow hemp.

In Europe and the United States, we are currently working with KeyGene NV ("KeyGene"), a global leader in plant research involving high-value genetic traits and increased crop yields. In our exclusive, worldwide collaboration with KeyGene, we are 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. In 2021, we further enhanced our partnership with KeyGene to extend our relationship for an additional three years and to solidify a governance structure whereby we agree on specific research activities to develop intellectual property jointly with KeyGene in the future.

In late 2019, we made a minority investment in Panacea Life Sciences ("Panacea" or "PLS"), a vertically integrated producer of CBD consumer products. Since that time our strategy in hemp/cannabis has evolved with our focus now shifting towards developing intellectual property for specific traits of the cannabis plant. We believe that our

scientific capability will enable us to execute on this strategy and could result in long term royalty streams for us. To address this, we realigned our relationship with PLS in 2021 as described below.

In 2021, we entered into several research contracts with plant breeders and organizations committed to researching the potential effects which cannabis products have on human cell biology. We have evolved our strategy to align with companies which provide for excellent synergies to our research efforts. We continue to review potential candidate companies in the hemp/cannabis field for strategic collaborations, affiliations, joint ventures, investments, and/or acquisitions.

Investment in Panacea Life Sciences

On December 3, 2019, we closed on an investment in Panacea for $13.2 million for a 15.8% ownership interest. Panacea is 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 investment consisted of a $7 million convertible note receivable, 3,733,334 shares of Series B preferred stock, and a warrant to purchase additional shares of Series B preferred stock.

On July 1, 2021, we restructured our investment in Panacea, in line with the ongoing development of our strategic partnership network. Under terms of the agreements, 22nd Century's $7 million note in Panacea was exchanged for ownership of Needle Rock Farms, a Colorado hemp/cannabis growing operation consisting of land, water rights and equipment appraised at $2.2 million. We also received a new $4.3 million note and $500,000 in Panacea's Series B Preferred Stock (which was subsequently converted to Exactus common stock under the Securities Exchange Agreement; this balance is reflected in final shares as stated below). The new note is backed by a mortgage on the Panacea Life Sciences operations building located in Golden, CO, appraised at $10.7 million. Panacea retained certain farm assets under its own nameplate of PANA Organic Botanicals at Needle Rock. Also under the agreement, $7.0 million in Panacea Life Sciences Series B Preferred Stock held by 22nd Century was converted into 91 million shares of Exactus, Inc. (OTCQB: EXDI). We believe this agreement to restructure our investment with Panacea will provide us with an agricultural asset that will allow us to conduct further commercial research and development on various lines of hemp/cannabis genetics in our intellectual property portfolio.

On October 25, 2021, Exactus announced the completion of a 1 for 28 reverse stock split as well as an entity name change to Panacea Life Sciences Holdings, Inc (OTCQB: PLSH). Panacea Life Sciences Holdings, Inc. was assigned a temporary stock symbol of "EXDID" which formally changed to "PLSH" after twenty business days. As a result of the reverse stock split, our 91,016,026 shares were adjusted to 3,250,573 shares.

Hops

On August 30, 2021, we announced our intention to commence research and development in hops, a plant which possesses similar biological characteristics to hemp/cannabis. Tobacco, hemp/cannabis and hop plants are all considered alkaloid plants and possess certain traits which can be modulated with the genetic engineering techniques we are applying to both tobacco and hemp/cannabis.

In early 2022, we expanded our research agreement with KeyGene to identify specific traits which, if appropriately engineered, could benefit consumers of hop products in both the beer and nutraceuticals segment on the industry. Additionally, we have focused business development resources in place to further identify such opportunities for the future.

Research & Development (R&D) & Intellectual Property (IP)

Tobacco R&D

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 our funded research. In all such 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.

On June 22, 2018, we entered into an amendment to our existing license agreement with NCSU under which we exclusively licensed several bright and burley tobacco plant lines with Very Low Nicotine Content that are not genetically modified (non-GMO) plants. The amendment provides for the Company to pay NCSU a total exclusive license fee of $1.2 million—refer to Note 8 to our consolidated financial statements for additional information. We 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, we entered into a license agreement with the University of Kentucky ("UK") to license on a non-exclusive basis a next-generation very low nicotine content burley tobacco plant lines that are not genetically modified (non-GMO) plants. The UK license agreement provides for the Company to pay UK a total license fee of $1.2 million—refer to Note 8 to our consolidated financial statements for additional information. We 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.

On December 1, 2021, we relocated our own laboratory from Buffalo, New York to Rockville, Maryland, where we are conducting our own proprietary research and development activities in tobacco. The new laboratory space has over four thousand square feet, is near our strategic research partner, KeyGene, and will help support our continued growth and R&D partnerships.

After several field trial evaluations throughout the United States, we produced new non-GMO burley and bright tobacco varieties with 95% reduced nicotine. These new varieties include technology previously licensed from NCSU, which is protected with a patent portfolio.

Our research also showed a successful introduction of the non-GMO VLNC technology on several oriental lines and we expect to have 95% reduced nicotine oriental tobacco in the future.

We are currently developing new versions of our VLNC cigarettes utilizing these non-GMO tobacco lines for future commercialization in the U.S. and globally.

Tobacco IP

Our intellectual property enables us to alter the level of nicotine and other nicotinic alkaloids in tobacco 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. Our patent families related to nicotine biosynthesis are expected to expire between 2026 and 2041, 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 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.

We also have exclusive plant variety protection rights in the United States and many other countries. Plant variety protection certificates are issued in the United States by the U.S. Department of Agriculture ("PVP"). 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 addition to our patents, patent applications, and PVP certificates, we own various registered trademarks in the United States and around the world.

Hemp/Cannabis R&D and IP

Our intellectual property and know-how enables us to alter the levels of cannabinoids in 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 developed various types of cannabis plants with agronomically desirable traits for commercial uses and/or unique cannabinoid/terpenoid levels. We believe that we have many types of superior and unique cannabis plant varieties in development, including (i) plants with low to no amounts of THC and other desirable agronomic traits for the legal hemp industry and (ii) plants with high levels of cannabinoids (including THC, CBD and many minor cannabinoids) for use in legal cannabinoid markets.

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 cannabis plant that are required for the production of cannabinoids in the cannabis plant or any microorganism, including yeast or bacteria. Three of these patents are essential for all the cannabinoids' core biosynthesis and one is specific for CBC and derivatives. The Anandia Sublicense continues through the life of the last-to-expire patent, which is expected to be in 2035.

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 million 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 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 varieties of hemp. In 2018 and 2019, we continued to use our proprietary hemp plants for plantings with UVA in Virginia. 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. This project with UVA completed in December 2019 and all seeds and plants were transferred to KeyGene for further research and development.

Through our partnership with KeyGene, we have 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. Towards this end, we have identified several lines with superior cannabinoids and terpenoids profiles using standard genomics and molecular breeding technologies. Also, we have developed metabolomics methods, male-female flower induction, and rapid cycle breeding.

On February 10, 2021, we announced that we have developed and launched a new, cutting-edge technology platform that will enable us and our strategic partners to quickly identify and incorporate commercially valuable traits of hemp/cannabis plants to create new, stable hemp/cannabis lines. The platform incorporates a suite of proprietary molecular tools and a large library of genomic markers and gene-trait correlations. The platform was developed in collaboration with researchers at KeyGene, a global leader in plant research involving high-value genetic traits and increased crop yields. Using this new breeding technology, we have already characterized millions of high-value single nucleotide polymorphisms (SNPs). SNPs are molecular markers or guideposts within a plant's genome that indicate important variations in Deoxyribonucleic acid (DNA) sequences. Targeting these newly identified SNPs, we were able to locate and isolate specific sections of genetic code from genome assemblies present in our state-of-the-art hemp/cannabis bioinformatics database.

Our bioinformatics database continues to grow and already contains hundreds of hemp/cannabis genomes and thousands of expression datapoints across a wide array of hemp/cannabis varieties and phenotypes. The ability to identify specific genetic variations allows researchers to isolate high-value traits, like increased CBD or tetrahydrocannabinol (THC) production, and then introduce those traits in new plant lines using modern plant breeding techniques, including trait tracking using molecular marker profiles and proprietary accelerated breeding.

On December 14, 2021, we announced a three-way non-exclusive agreement to license the Anandia biosynthesis intellectual property jointly owned with Aurora to Cronos Group Inc., intended to assist in the advancement of research and development on the biosynthesis of cannabinoids.

On February 23, 2022, we made a breakthrough in our hemp/cannabis plant research. We successfully transformed the hemp/cannabis plant genome using a proprietary plant transformation and regeneration technology, resulting in clear protein expression by the introduced genes. We are one of the first companies to show proof of the successful modification of the hemp/cannabis plant genome via transformation techniques directly leading to functional protein expression in hemp/cannabis. This new transformation methodology is a critical enabling technology that dramatically enhances our ability to directly and quickly modify specific target genes in hemp/cannabis. This unique know-how adds another essential tool to our modern plant science capabilities that also includes an extensive library of hemp and cannabis germplasm, a genome database, marker-assisted, rapid-cycle molecular breeding, and mutagenesis, all supported by KeyGene's bioinformatics and genome sequencing capabilities utilizing machine learning and artificial intelligence. Together, these tools are being used to create new, proprietary hemp/cannabis plants tailored to differentiate the content of specific major and minor cannabinoids, terpenoids or eliminate unwanted metabolites to develop new commercial lines tailored to the preferences and needs of end-users, often at a fraction of the time and cost of traditional breeding methods.

Tobacco Master Settlement Agreement

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 our wholly-owned subsidiary.

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 $3.2 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. On August 29, 2014, the Company became a subsequent participating manufacture under the MSA. Since 2015, we have manufactured and sold our *SPECTRUM*® variable nicotine research cigarettes, as well as third-party filtered cigar brands and MSA-compliant cigarette brands, at our factory in North Carolina.

The 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 and our MRTP-designation VLN® brand cigarettes featuring 95% less nicotine than the top 100 leading brands sold in the United States. In January 2022, our cigarette manufacturing facility completed production of the first cartons of VLN® King and VLN® Menthol King cigarettes destined for retail sale.

Sources of Raw Materials

We obtain our reduced nicotine 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 other tobacco through third parties. In anticipation of the FDA's authorization of our MRTP application for our VLN® cigarettes, we increased the amount of tobacco leaf we obtain directly from growers under contract during 2021. In 2022, we plan to again increase our growing quantities of VLNC tobacco to supply the launch and expansion of VLN® cigarette sales.

Government Regulation

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.

Tobacco

The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") provides the FDA with broad authority to regulate the design, manufacture, packaging, advertising, promotion, sale and distribution of tobacco products; the authority to require disclosures of related information; and the authority to enforce the Tobacco Control Act and related regulations. 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. The FDA has authority to restrict marketing and advertising, impose regulations on packaging, mandate warnings and disclosure of flavors or other ingredients, prohibit the sale of tobacco products with certain flavors or other characteristics, limit or prohibit the sale of tobacco products by certain retail establishments and the sale of tobacco products in certain packaging sizes, and seek to hold retailers and distributors responsible for the adverse health effects associated with both smoking and exposure to environmental tobacco 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.

The Tobacco Control Act, its implementing regulations and its 2016 deeming regulations establish broad FDA regulatory authority over all tobacco products and, among other provisions:

- impose restrictions on the advertising, promotion, sale and distribution of tobacco products;
- establish pre-market review pathways for new and modified tobacco products;
- prohibit any express or implied claims that a tobacco product is or may be less harmful than other tobacco products without FDA authorization;
- authorize the FDA to impose tobacco product standards that are appropriate for the protection of the public health; and
- equip the FDA with a variety of investigatory and enforcement tools, including the authority to inspect product manufacturing and other facilities.

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. The FDA has several investigatory and enforcement tools available to it, including document requests and other required information submissions, facility inspections, examinations and investigations, injunction proceedings, monetary penalties, product withdrawal and recall orders, and product seizures.

We expect significant regulatory developments to 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.

Hemp/Cannabis

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 USDA. In addition, the FDA is regulating products derived from hemp, including 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.

As of February 1, 2022, (i) federal law and the laws of 47 states in the United States and the District of Columbia have legalized hemp, (ii) 37 states in the United States, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands have enacted 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) 18 states in the United States, the District of Columbia, Guam, and the Northern Mariana Islands have legalized cannabis/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 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, Oregon, and Canada with third-parties and in Colorado and New York with Company personnel, while 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.

Environmental Regulations

We are subject to a variety of federal, state and local environmental laws and regulations. We have developed specific programs across our business units for ensuring high standards of environmental compliance, including, standard operating practices and procedures at our manufacturing facility as well at our research and development centers. We believe that our manufacturing facility complies with all federal, state, and local environmental regulations, including the Clean Air Act, the Clean Water Act, and the Resource Conservation and Recovery Act.

In addition, any new products introduced by us are subject to a comprehensive environmental assessment by an independent third-party expert, including an assessment of how such products may create environmental risks. For our PMTA product, the FDA prepared a programmatic environmental assessment (PEA), based on our submitted data in accordance with the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40). The PEA concluded that the marketing orders would have no significant impact and that environmental impact statements would not be required.

Excise Taxes

Tobacco products are subject to substantial excise taxes in the U.S. and other countries. Significant increases in tobacco-related taxes or fees have been proposed or enacted and are likely to continue to be proposed or enacted at the federal, state and local levels within the U.S. and other countries. The frequency and magnitude of excise tax increases can be influenced by various factors, including the composition of executive and legislative bodies. Federal, state and local cigarette excise taxes have increased substantially over the past two decades. Tax increases have an adverse impact on sales of tobacco products.

Competition

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 Niconovum 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 aware that several domestic cigarette companies and other research groups are working to research and grow very low nicotine tobacco and have filed patent applications.

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., ITG Brands, 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.

In the hemp/cannabis and hop industries, there are numerous companies conducting research and development on the hemp/cannabis and hop plants in order to develop new and differentiated products. 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.

Human Capital Resources

As of December 31, 2021, we had 76 employees and we consider our employee relations to be good. Our human capital resource objectives are designed to attract, and retain, highly motivated and well qualified employees. We believe that we offer a competitive compensation package and have also worked diligently to provide a flexible and safe work environment—especially during the unforeseen COVID-19 global pandemic. The health and safety of our employees and clientele is of the upmost importance to us. We have taken significant steps to protect our workforce during COVID-19 including but not limited to, working remotely, increased cleaning and sanitization of facilities, and social distancing protocols consistent with guidelines issued by federal, state, and local governments.

Corporate Information

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.

Our corporate headquarters is located at 500 Seneca Street, Suite 507, Buffalo, New York 14204. Our telephone number is (716) 270-1523. Our internet address is www.xxiicentury.com. All of our filings with the Securities and Exchange Commission, including our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K 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 and positive cash flows from operations.

As a result of our extensive research and development activities and regulatory expenses seeking FDA approvals, we have experienced net losses of approximately $32.6 million, $19.7 million and $26.6 million during the years ended December 31, 2021, 2020, and 2019, respectively, and negative cash flow from operations of approximately $22.8 million during the year ended December 31, 2021.

While our current balance of cash and cash equivalents and short-term investment securities is adequate to sustain our current planned operations, generating positive cash flows in the future will depend on our ability to successfully operate our manufacturing facility, our ability to generate market acceptance for our VLN® cigarettes and our ability to create, sell and market other proprietary tobacco and hemp products, and/or generate royalty revenue from the licensing of our intellectual property. There is no guarantee that we will be able to achieve or sustain positive cash flows and profitability in the future. Our inability to successfully achieve positive cash flows and profitability will decrease our long-term viability and prospects.

Our competitors generally have, and any future competitors may have, greater financial resources and name recognition 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.

In the tobacco industry, we are competing with large tobacco companies and large pharmaceutical companies that have greater resources that us. The tobacco 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, research and development, marketing, sales, manufacturing, scaling capacity, distribution, lobbying and other resources and name recognition substantially greater than ours. In addition, we expect new competitors will enter the markets for similar tobacco products in the future and the nature and extent of this market entrance cannot be quantified at this time. In the cannabis industry, many large companies are entering into the cannabis space, along with smaller regional companies and competition from the black market.

Potential customers may choose to do business with more established competitors because of their perception that our competitors are more stable, can scale operations more quickly, have greater manufacturing capacity, have robust marketing and sale programs and lend greater credibility to governmental regulators and others. In addition, large companies have the ability to provide entry-level pricing for premium products in order make us less competitive. If we are unable to compete successfully against larger companies with more financial resources and name recognition, our business and prospects would be materially adversely affected.

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

If our competitors develop very low nicotine tobacco without infringing on our intellectual property or other products that are less expensive, safer or otherwise more appealing than our VLNC cigarettes or any of our other potential products, or that reach the market before ours, we may not achieve commercial success. Currently, there are numerous companies developing Modified Risk Tobacco products, working to develop low nicotine tobacco and other tobacco alternative products in an effort to provide products that are potentially safer for human consumption or to otherwise assist consumers to cease or begin to switch from smoking. If one of such competitors develops a cigarette that is safe for human consumption, a safer alternative for nicotine that is widely accepted, superior low nicotine tobacco or otherwise develops a superior quitting method, it could render our VLNC tobacco and cigarettes obsolete, which would have a material adverse impact on our business and operations and our ability to achieve profitability. In the cannabis industry, there are numerous companies conducting research and development on the cannabis plant in order to develop new and differentiated products. 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:

- develop and market similar or new products that are less expensive, safer, or otherwise more appealing than our products;
- develop similar or new technologies and products that render our products obsolete;
- 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;
- commercialize competing products before we or our partners can launch our products;
- initiate or withstand substantial price competition more successfully than we can; and/or
- take advantage of acquisition or other opportunities more readily than we can.

Our research and development process may not develop marketable products, which would result in loss of our investment into such process.

We do not know whether our research and development process will result in marketable products. Even if we develop marketable products, we may not be able to obtain the necessary approvals or marketing authorizations for these potential products or our anticipated time of bringing these potential products to the market may be substantially delayed. The development of new products is costly, time-consuming, and has no guarantee of success. Any such delays or the inability to effectively develop new products in a cost-effective manner, or at all, would have a material adverse effect on our business and a loss of our financial resources.

We may 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 or result in losses..

We may 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 or may not yield the benefits that we expect.

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.

The coronavirus pandemic (COVID-19) or another pandemic may cause a variety of business disruptions and future business risks.

The COVID-19 pandemic continues to adversely impact the U.S. economy and supply chains. The COVID-19 pandemic has disrupted our business operations in the past and there is a risk that state and federal authorities' responses to the COVID-19 pandemic or another pandemic may disrupt our business in the future. The COVID-19 pandemic poses a risk to our business which includes delays by third party providers of goods or services to our business, inability to operate in-person at our offices, interruptions to our sales, research and development, and administrative activities, and disruptions to our manufacturing operations, including the ability to staff our manufacturing operations at full capacity or at all. Similarly, state or federal authorities may also be affected in their capacity or capability to operate as normal and may impact the timeline of product authorizations which may disrupt our business plans. Our corporate office, laboratory in Rockville and production facility remain open and are operating under strict safety protocols. We continue to encourage remote work arrangements by our employees where job duties permit. At times during 2020 and 2021, we were unable to have our full staff (or any staff) in our laboratory in Buffalo (and subsequently in Rockville) and some of our external research and development partners operated (or are still operating) on a modified or limited schedule, which slowed our research activities. To date, these interruptions have had a minimal impact on our research operations. Our executive leadership team and staff are monitoring this evolving situation and its impacts on our business. We will continue to monitor the local, state and federal guidance regarding our business practices.

The future extent of the impact of the COVID-19 pandemic or another pandemic, including our ability to execute our business strategies as planned, will depend on future developments, including the duration and severity of the pandemic, which are highly uncertain and cannot be predicted.

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. However, 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. Any cybersecurity incident could cause substantial harm to our business and result in regulatory action, fines, and/or substantial costs.

We have limited 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 December 31, 2021, we grew from nine (9) employees to seventy-six (76) employees. Any future 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 and such failure would have a material adverse impact on our operations.

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), pandemics (including the COVID-19 pandemic), 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 COVID-19 or another pandemic could disrupt our supply chain for tobacco, as well as negatively impact employee productivity, including affecting the availability of employees reporting for work. Any business interruption caused by such unforeseen events could have a material adverse impact on our business and operations.

Risks Related to the Tobacco Industry

We may be unsuccessful at commercializing our VLNC tobacco as a Modified Exposure Cigarette.

While we have recently received authorization for our MRTP application by the FDA, there are no guarantees regarding the commercial viability of our VLNC tobacco cigarettes. To date, there has never been a comparable product sold in the marketplace and we have not yet generated any significant sales. These products may not achieve consumer acceptance and may have low or unfavorable sales. Further, 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. There can be no assurance that the FDA will implement such new regulations or, if implemented, when

such regulations would take effect or whether such regulations would increase or create demand for our VLNC cigarettes.

The commercial success of our VLNC tobacco cigarettes will depend on a number of factors, including, but not limited to our ability to:

- achieve, maintain and grow market acceptance of, and demand for, such products;
- our ability to market the product with the phrase "*Helps You Smoke Less*";
- maintain, manage or scale the necessary sales, marketing, manufacturing and other capabilities and infrastructure that are required to successfully commercialize such products;
- grow or otherwise maintain an adequate supply of VLNC tobacco;
- maintain and extend intellectual property protection for such products;
- comply with applicable legal and regulatory requirements, including FDA and MSA regulations on advertising;
- competitively price our products;
- compete with other similar products or new technologies (if any); and
- effectively sell our products into established markets where there is substantial market dominance by large tobacco enterprises.

If we are unsuccessful in commercializing our VLNC tobacco cigarettes, or such commercialization takes longer or costs more than we currently expect, our financial results, business and future prospects would be materially adversely effected.

We have no experience marketing and selling Modified Exposure Cigarettes and our working capital and inventory estimates based on demand expectations may be incorrect, which could harm our operating results and financial condition.

While members of management and our board of directors are experienced in the selling of conventional cigarette products, we have no experience in selling Modified Exposure Cigarettes or any hemp/cannabis plant-derived products on a commercial basis. As we work towards commercializing one or more of our potential products for sale, including our VLN cigarettes, we intend to base our working capital and inventory decisions on management's estimates of future demand. If demand for such potential new products does not increase as quickly as we have estimated, our inventory costs and working capital expenses could rise, and our business and operating results could suffer. Alternatively, if we experience sales in excess of our estimates, our working capital and inventory needs may be higher than those currently anticipated. Since our VLNC tobacco is not widely available and must be grown specifically for our potential products, any shortage in such tobacco could prevent us from increasing sales to meet demand and any surplus could result in inventory obsolescence and become a total loss.

Our inability to incorrectly estimate demand for future products could negatively harm our operating results and financial condition.

The manufacturing of tobacco products subjects us to significant governmental regulation and the failure to comply with such regulations could have a material adverse effect on our business and subject us to substantial fines or other regulatory actions.

Currently, most of the revenues of our manufacturing business are from the production of tobacco cigarettes and filtered cigars, including flavored cigars, made for third-party brand owners of such products and we anticipate generating future revenue from the sales of our VLNC cigarettes and other Modified Risk Tobacco products. Companies

that manufacture and/or sell tobacco products face significant governmental regulation, 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, requiring compliance with certain environmental standards, 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.

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.

We and our customers for whom we manufacture tobacco products also 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.

We expect significant regulatory developments to 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. Our operating results could be significantly affected by any significant increase in the cost of complying with new regulatory requirements.

Compliance with current and future regulations regarding tobacco could have a material impact on our business and operations and could result in fines, government actions to restrict or prevent sales of products, as well as result in substantial costs and expenses.

We may become subject to litigation related to cigarette smoking and/or 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 Exposure Cigarettes or other tobacco products we sell or manufacture in the future. 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.

Our production facility is integral to our business and adverse changes or developments affecting our facility may have an adverse impact on our business.

Our NASCO facility is integral to our business. Adverse changes or developments affecting this facility, including, but not limited to, disease or infestation of our raw materials, a fire, an explosion, a power failure, a natural disaster, an epidemic, pandemic or other public health crisis, or a material failure of our security infrastructure, could reduce or require us to entirely suspend operations.

A significant failure of our site security measures and other facility requirements, including failure to comply with applicable regulatory requirements, could have an impact on our ability to continue operating under our facility licenses and our prospects of renewing our licenses, and could also result in a suspension or revocation of these licenses.

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 a small number of large customers, and we do not have agreements with such customers 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.

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 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 and any such claim could cause us to incur substantial losses or damage our reputation.

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 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 Exposure 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.

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

We depend on a small number of independent tobacco farmers to grow our specialty proprietary tobaccos with specific nicotine contents for our 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. This risk is greater for us, as there would be no alternative supply of VLNC tobacco in the event that

one of our growers experienced a material adverse event with respect to a particular VLNC tobacco crop or the quantity or quality was not as we anticipated, and we would not be able to supply leaf for our VLN® cigarettes.

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.

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

In addition to the recent receipt of approval to market and sell our VLNC tobacco cigarettes as a Modified Exposure 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 in the future. Failure to obtain necessary regulatory approvals could impair our ability to generate revenue from international sources.

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.

We may be unsuccessful in anticipating changes in adult consumer preferences, responding to changes in consumer purchase behavior or managing through difficult competitive and economic conditions, which could have an adverse effect on business.

In the tobacco industry, we are subject to intense competition and changes in adult consumer preferences. To be successful, we must:

- anticipate and respond to new and evolving adult consumer preferences;
- develop, manufacture, market and distribute new and innovative products that appeal to adult consumers (including, where appropriate, through arrangements with, or investments in, third parties);
- improve productivity; and
- protect or enhance margins through cost savings and price increases.

The willingness of adult consumers to purchase premium consumer tobacco products, such as our VLNC cigarettes, depends in part on economic conditions. In periods of economic uncertainty, adult consumers may purchase more discount brands and/or, in the case of tobacco products, consider lower-priced tobacco products, which could have a material adverse effect on the business and profitability.

We may be unsuccessful in developing and commercializing adjacent products or processes, including innovative tobacco products that may reduce the health risks associated with certain other tobacco products and that appeal to adult tobacco consumers.

Some innovative tobacco products may reduce the health risks associated with certain other tobacco products, while continuing to offer adult tobacco consumers products that meet their taste expectations and evolving preferences. Examples include tobacco-containing and nicotine-containing products that reduce or eliminate exposure to cigarette

smoke and/or constituents identified by public health authorities as harmful, such as electronically heated tobacco products, oral nicotine pouches, and e-vapor products. We may not succeed in our efforts to develop and commercialize any adjacent products.

Further, we cannot predict whether regulators, including the FDA, will permit the marketing or sale of any particular innovative products (including products with claims of reduced risk to adult consumers), the speed with which they may make such determinations or whether regulators will impose an unduly burdensome regulatory framework on such products. In addition, the FDA could, for a variety of reasons, determine that innovative products currently on the market, or those that have previously received authorization, including with a claim of reduced exposure, are not appropriate for the public health and the FDA could require such products be taken off the market. We also cannot predict whether any products will appeal to adult tobacco consumers or whether adult tobacco consumers' purchasing decisions would be affected by reduced-risk claims on such products if permitted. Adverse developments on any of these matters could negatively impact the commercial viability of such products.

If we do not succeed in their efforts to develop and commercialize innovative tobacco products or to obtain regulatory approval for the marketing or sale of products, including with claims of reduced risk, but one or more of our competitors does succeed, we may be at a competitive disadvantage, which could have an adverse effect on our ability to commercialize our products.

An extended disruption at a facility or in service by a supplier, distributor or distribution chain service provider could have a material adverse effect on our business.

We face risks inherent in reliance on one manufacturing facility and a small number of key suppliers, distributors and distribution chain service providers. A pandemic (including COVID-19), natural or man-made disaster or other disruption that affects the manufacturing operations, the operations of any key supplier, distributor or distribution chain service provider or any other disruption in the supply or distribution of goods or services (including a key supplier's inability to comply with government regulations or unwillingness to supply goods or services to a tobacco company) could adversely impact our operations.

Some state governors also have issued executive orders requiring that certain businesses temporarily suspend operations for varying periods of time while the COVID-19 pandemic persists. Our operations could be suspended temporarily once or multiple times, or closed permanently, depending on various factors, including how long the COVID-19 pandemic persists and the extent to which state, local and federal governments, as well as foreign countries, impose restrictions on the operation of facilities or otherwise place limits on the supply and distribution chains. An extended disruption in operations or in the supply or distribution of goods or services by one or more key suppliers, distributors or distribution chain service providers could have a material adverse effect on our business.

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 authorization of our MRTP application on December 23, 2021, 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.

Risk Factors Related to the Cannabis Industry

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.

Numerous states and countries have enacted 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 a smaller subset have legalized cannabis/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 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, Maryland, Oregon, Colorado, New York 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.

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.

A key aspect of the revised strategy for cannabis is to reach an agreement with third parties to research characteristics of the cannabis plant and commercialize patented products through the value chain.

Any inability to produce hemp/cannabis products due to regulatory restrictions or otherwise would have a material adverse impact on our business and operations.

The cannabis industry and market are relatively new and evolving, which could impact our ability to succeed in this industry and market.

We are operating our business in a relatively new industry and market that is expanding globally. To be competitive, we will need to innovate new products, build brand awareness and make significant investments in our business strategy and production capacity. These investments include introducing new products into the markets in which we operate, adopting quality assurance protocols and procedures, building our international presence and undertaking research and development. These activities may not promote our products as effectively as intended, or at all, and we expect that our competitors will undertake similar investments to compete with us for market share. Competitive conditions, consumer preferences, regulatory conditions, patient requirements, prescribing practices, and spending patterns in this industry and market are relatively unknown and may have unique characteristics that differ from other existing industries and markets and that cause our efforts to further our business to be unsuccessful or to have undesired consequences. As a result, we may not be successful in our efforts to develop new cannabis products and produce and distribute these products in time to be effectively commercialized, or these activities may require significantly more resources than we currently anticipate in order to be successful.

Research regarding the health effects of cannabis is in relatively early stages and subject to further study which could impact demand for cannabis products.

Research and clinical trials on the potential benefits and the short-term and long-term effects of cannabis use on human health remains in relatively early stages and there is limited standardization. As such, there are inherent risks associated with using cannabis and cannabis derivative products. Moreover, future research and clinical trials may draw opposing conclusions to statements contained in articles, reports and studies we relied on or could reach different or negative conclusions regarding the benefits, viability, safety, efficacy, dosing or other facts and perceptions related to cannabis, which could adversely affect social acceptance of cannabis and the demand for any products.

United States regulations relating to hemp-derived CBD products are unclear and rapidly evolving, and changes may not develop in the timeframe or manner most favorable to our business objectives.

Any participation in the market for hemp-derived CBD products in the United States and elsewhere may require us to employ novel approaches to existing regulatory pathways. Although the passage of the 2018 Farm Bill legalized the cultivation of hemp in the United States to produce products containing CBD and other non-THC cannabinoids, it remains unclear how the FDA will regulate these products, and whether and when the FDA will propose or implement new or additional regulations. While, to date, there are no laws or regulations enforced by the FDA which specifically address the manufacturing, packaging, labeling, distribution, or sale of hemp or hemp-derived CBD products and the FDA has issued no formal regulations addressing such matters, the FDA has issued various guidance documents and other statements reflecting its non-binding opinion on the regulation of such products.

The FDA has stated in guidance and other public statements that it is prohibited to sell a food, beverage or dietary supplement to which THC or CBD has been added. While the FDA does not have a formal policy of enforcement discretion with respect to any products with added CBD, the agency has stated that its primary focus for enforcement centers on products that put the health and safety of consumers at risk, such as those claiming to prevent, diagnose, mitigate, treat, or cure diseases in the absence of requisite approvals. The FDA could also issue new regulations that prohibit or limit the sale of hemp-derived CBD products. Such regulatory actions and associated compliance costs may hinder our ability to successfully compete in the market for any products.

In addition, any products may be subject to regulation at the state or local levels. State and local authorities have issued their own restrictions on the cultivation or sale of hemp or hemp-derived CBD. This includes laws that ban the cultivation or possession of hemp or any other plant of the cannabis genus and derivatives thereof, such as CBD. State regulators may take enforcement action against food and dietary supplement products that contain CBD, or enact new laws or regulations that prohibit or limit the sale of such products.

The regulation of hemp and CBD in the United States has been constantly evolving, with changes in federal and state laws and regulation occurring on a frequent basis. Violations of applicable FDA and other laws could result in warning letters, significant fines, penalties, administrative sanctions, injunctions, convictions or settlements arising from civil proceedings. Unforeseen regulatory obstacles or compliance costs may hinder our ability to successfully compete in the market for such products.

Risks Related to Intellectual Property

Certain of our proprietary rights have expired or 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.

Our issued patents may be subject to challenge and potential invalidation by third parties and our competitors may develop processes to achieve similar results without infringing on our patents. 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 develop alternative methods of regulating nicotine in tobacco or obtain patent rights to similar products or technology without infringing on our intellectual property rights, 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. This could result 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 independent researchers or 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 license agreements and 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 and may in some instances retain rights to the intellectual property that allows them to compete with us. 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 and trade secrets. 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.

If any of our license agreements or other intellectual property agreements are not effective at preventing others from competing with us and/or using our intellectual property, our business could be adversely affected.

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 listed on the NASDAQ Capital market (“NASDAQ”). However, even if our common stock continues to be listed on the NASDAQ, 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 NASDAQ. If we are ever no longer listed on the NASDAQ 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 NASDAQ 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;
- third-party articles regarding us or our securities;
- pending or future shareholder litigation;
- 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 any of 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.

As of December 31, 2021, we had five leased properties and one hemp farm that we owned in the following locations:

	City	State
Corporate Headquarters	Buffalo	NY
Research and Development Laboratory	Rockville	MD
Manufacturing Facility and Warehouse	Mocksville	NC
Tobacco Storage Warehouse	Wilson	NC
Office Space	Paoli	PA
Hemp Farm	Crawford	CO

In April 2021, the Company relocated our corporate headquarters to downtown Buffalo, NY. The new leased office space is in a state-of-the-art facility joined by other multinational technology and professional services companies. In June 2021, the Company acquired the ownership of Needle Rock Farms, our 224 acre hemp farm in Crawford, CO. In December 2021, the Company relocated our R&D laboratory from Buffalo, NY to Rockville, MD. The new laboratory space has over four thousand square feet and is expected to support the Company's continued growth and R&D partnerships. In addition, the Company leases a small office space in Paoli, PA. Refer to Note 4 to our consolidated financial statements for additional information.

We believe that all facilities are adequate for our current needs.

Item 3. Legal Proceedings.

See Note 12 - 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 12 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 12 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 Nasdaq Capital Market under the symbol "XXII." As of February 22, 2022, there were 84 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 May 20, 2021, the stockholders of 22nd Century Group, Inc. (the "Company") approved the 22nd Century Group, Inc. 2021 Omnibus Incentive Plan (the "Plan"). The Plan allows for the granting of equity awards to eligible individuals over the life of the Plan, including the issuance of up to 5,000,000 shares of the Company's common stock and any remaining shares under the Company's 2014 Omnibus Incentive Plan pursuant to awards under the Plan. The Plan 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 the Plan and the number of shares of common stock to underlie each such award under the Plan. As of December 31, 2021, we had available 7,526,630 shares remaining for future awards under the Plan.

The following table summarizes the number of shares of common stock to be issued upon exercise of outstanding options and vesting of restricted stock units under the Plan and our prior 2010 and 2014 Equity Incentive Plans, the weighted-average exercise price of such stock options, and the number of securities available to be issued under the Plan as of December 31, 2021:

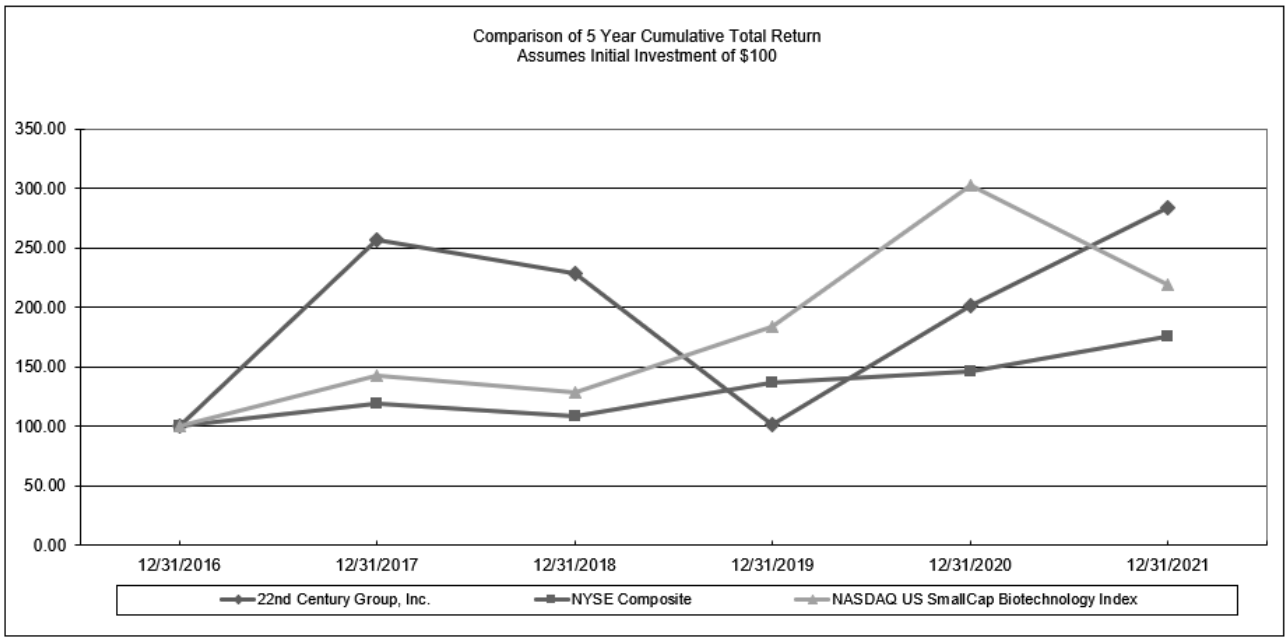
	Number of securities to be issued upon exercise of outstanding options, and restricted stock units, (a)	Weighted average exercise price of outstanding options (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	8,335,971 (1)	$ 1.65	7,526,630
Equity compensation plans not approved by security holders	—	N/A	—
Total	8,335,971	—	7,526,630 (2)

(1) Number of outstanding options are 5,171,105 and number of unvested restricted stock units are 3,164,866.

(2) Consists of shares available for award under the Plan.

Stock Performance Graph

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, 2016 through December 31, 2021. The comparison of total return assumes that a fixed investment of $100 was invested on December 31, 2016 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.



The information in this Item 5 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.

Item 6. [Reserved]

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 2021 and 2020 items and year-to-year comparisons of 2021 to 2020. Discussions of 2019 items and year-to-year comparisons of 2020 and 2019 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, 2020. 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 "Cautionary Note Regarding Forward-Looking Statements and Risk Factor Summary." 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.

($ in thousands, except per share data or unless otherwise specified)

Executive Overview of Full Year 2021 Results

Key Business and Financial Highlights

- On December 23, 2021, the FDA granted MRTP authorization for our reduced nicotine cigarettes, VLN® King and VLN® Menthol King. In addition to authorizing the Company to market VLN® cigarettes with the claim, "95% less nicotine", to clarify the purpose of the brand, the FDA also authorized the claim, "*Helps You Smoke Less*." Pending state regulatory approval, we plan to launch VLN® King and VLN® Menthol King in our first U.S. market on or before March 23, 2022.
- Since reporting third quarter 2021 earnings, we have signed our first IP licensing agreement in hemp/cannabis, as well as recognized our first revenue from the sale of biomass grown at our Needle Rock farms location.
- We believe that we have secured the key partnerships needed to maximize each component in the upstream segment of the hemp/cannabis value chain and expect to continue to expand this network of resources to support our business growth. We believe these partnerships will enable us to accelerate the new development of valuable, commercial hemp/cannabis lines and intellectual property to market.
- Revenue increased 8.9% year-over-year to $7,960 for the fourth quarter of 2021 and improved by 10.1% to $30,948 for the full year versus 2020.
- Gross profit for the fourth quarter of 2021 was $387 compared to $588 in the prior year fourth quarter and increased to $2,069 for the full year compared to $1,438 in 2020.
- Net loss in the fourth quarter of 2021 was $13,965 and included a $4,954 non-cash unrealized loss related to the fair value of investments, compared to the fourth quarter of 2020 net loss of $6,405. Net loss for the full year of 2021 was $32,609 and included a $6,994 non-cash unrealized loss related to the fair value of investments, an increase of $12,898 compared to a net loss of $19,711 for the full year of 2020.

Corporate Business Highlights

- During February and March of 2021, our warrant holders exercised all 11,293,211 outstanding warrants for cash in exchange for common stock. In connection with these exercises, we received net proceeds of $11,782.
- On April 1, 2021, we moved our corporate headquarters to the up-and-coming Larkinville District in downtown Buffalo, New York. Our new Buffalo office space is in a state-of-the-art, restored manufacturing facility located at 500 Seneca Street, joining other multinational technology and professional services companies. Our new headquarters accommodates all of our staff from our previous office location in nearby Williamsville and has significant room for expansion.
- On June 7, 2021, we completed a registered direct common stock offering generating net proceeds of $38,206.

- On August 16, 2021, we transferred from the NYSE American market and commenced trading on the Nasdaq Capital Market.

- On August 18, 2021, we appointed Anthony Johnson as a new member of our Board of Directors. Mr. Johnson is co-founder, President, and CEO of Kodikaz Therapeutic Solutions, a next-generation, non-viral gene therapy company, and a founding partner of Buffalo Biosciences, a life science strategic business management firm that supports the evaluation and commercialization of bioscience technologies from concept to market.

- On November 15, 2021, we appointed Richard F. Fitzgerald as our Chief Financial Officer. Fitzgerald's other roles include serving as Chief Financial Officer and Secretary of CleanTech Acquisition Corp, (Nasdaq: CLAQU), a SPAC focused on the CleanTech sector. Previously, he was a consulting CFO for Atrin Pharmaceuticals, Co-Founder and CFO of SIRPant Immunotherapeutics and CFO of Immunome (Nasdaq: IMNM). He holds a B.S., Business Administration, Accounting from Bucknell University. John Franzino, the Company's previous Chief Financial Officer, transitioned to Chief Administrative Officer, where he is responsible for further developing the Company's business processes and leading the Company's financial planning and analysis, operational finance, human resources, and information technology functions.

- On January 17, 2022, we appointed James A. Mish, our Chief Executive Officer, as a new member of our Board of Directors, enhancing the Board's depth of experience in the commercialization of science-driven consumer products.

Tobacco Franchise Highlights and Notable Accomplishments

- We believe that our proprietary, reduced nicotine content cigarettes, VLN®, have massive global market opportunity. In 2018, the global tobacco market was worth $817 billion and of that, $714 billion, or approximately 90% of the global tobacco market is comprised of combustible cigarettes. There are more than 1 billion global and 34 million U.S. adult smokers. More than two-thirds of adult smokers want to quit, yet less than ten percent of them are able to quit successfully. We believe that smokers are actively seeking alternatives to addictive combustible cigarettes. Based on our consumer perception studies, 60% of adult smokers indicate a likelihood to use VLN®.

- Our VLN® cigarettes contain 95% less nicotine than conventional cigarettes and feature a familiar combustible product format that replicates the conventional cigarette experience, including the sensory and experiential elements of taste, scent, smell, and "hand-to-mouth" behavior. VLN® contains 0.5 milligrams of nicotine per gram of tobacco, an amount cited by the FDA, based on clinical studies, to be "minimally or non-addictive". The lack of reward from nicotine creates a dissociation between the act of smoking and the introduction of nicotine to the bloodstream, which helps adult smokers to smoke less and reduce the harm caused by smoking.

- Since 2011, our reduced nicotine content cigarettes have been used in more than 50 independent scientific clinical studies by universities and institutions. The studies, using our reduced nicotine content tobacco cigarettes, show that smokers who use our products: (i) reduce their nicotine exposure and dependence, (ii) smoke fewer cigarettes per day, (iii) increase their number of smoke-free days, and (iv) double their quit attempts – all with minimal or no evidence of nicotine withdrawal or compensatory smoking.

- In December 2019, the FDA granted a PMTA authorization for our reduced nicotine content cigarettes, giving us the ability to sell the product.

- On December 23, 2021, the FDA authorized the marketing of the Company's VLN® King and VLN® Menthol King reduced nicotine content cigarettes as modified risk tobacco products with a modified exposure classification (MRTPs). In doing so, the FDA stated that VLN® - which smokes, tastes, and smells like a conventional cigarette but contains 95% less nicotine than conventional, highly addictive cigarettes – "help reduce exposure to, and consumption of, nicotine for smokers who use them." In its marketing order granting the MRTPs, the FDA authorized an additional fourth claim: "*Helps You Smoke Less*" that we must use on the packaging of all VLN® products where other approved claims are also used.

- Following FDA authorization, we commenced activities to launch VLN® within 90 days, including discussions with potential partners in the independent, regional, and national retail trade. We anticipate a phased rollout of VLN® in select geographies and plan to position VLN® in the premium pricing segment of the cigarette market.

- On January 11, 2021, we announced that we expanded our growing program and increased planting in the 2021 crop year for VLN® reduced nicotine content tobacco, leading to a record harvest. This new planting for VLN® tobacco was in addition to our existing VLN® inventory, which we plan to use for initial sales of VLN®.
- We believe that recent political changes will likely be favorable to our business prospects from a policy priority and regulatory standpoint. Under the new administration and new leadership at the FDA and Center for Tobacco Products (CTP), we believe that the FDA will refocus on implementing a menthol ban on combustible high nicotine cigarettes and its ground-breaking Comprehensive Plan for Tobacco and Nicotine Regulation, in particular the agency's plan to cap the amount of nicotine in combustible cigarettes to a "minimally or non-addictive" level. We believe that the MRTP authorization and the launch of VLN® serves as a starting point for the FDA's proposed policies.
- Our research cigarettes, SPECTRUM®, continue to fuel numerous independent, scientific studies to validate the enormous public health benefit identified by the FDA and others of implementing a national standard requiring all cigarettes to contain "minimally or non-addictive" levels of nicotine.
- We believe that our next generation, non-GMO, plant research is the key to commercializing our reduced nicotine content tobacco and technology in international markets where non-GMO products are preferred, or GMO products are banned. In partnership with North Carolina State University, we completed successful research field trials. During the first quarter of 2021, we published a new U.S. patent, entitled "A Genetic Approach for Achieving Ultra Low Nicotine Content in Tobacco" (PCT/US2021/012742). The new technology provides us with methods and a new approach to introduce very low nicotine traits into virtually any variety of tobacco, including bright, burley, and oriental tobacco varieties. We have successfully applied our non-GMO technology to bright and burley varieties of tobacco and have developed a VLN® 2.0 prototype cigarette. We have also run our first field trial of non-GMO reduced nicotine varieties in the southern hemisphere.
- In the spring of 2022, we plan to plant our first commercial crops of non-GMO flue cured and burley reduced nicotine tobacco varieties. The reduced tobacco leaves harvested from these crops will support future VLNC cigarette products.

Hemp/Cannabis Franchise Highlights and Notable Accomplishments

- We continue to place an emphasis on our hemp/cannabis strategy to target the upstream segments of the cannabinoid value chain in the areas of plant biotechnology research, gene modification and engineering, modern plant breeding and development, and extraction. We believe that we can differentiate ourselves in the hemp/cannabis industry by building upon our core strength and expertise in plant science and the ingredient value chain and through our strategic, operational partnerships.
- We have launched a new, cutting-edge technology platform that we expect to enable us and our strategic partners to quickly identify and incorporate commercially valuable traits of hemp/cannabis plants to create new, stable hemp/cannabis lines. The platform, developed in collaboration with researchers at KeyGene, incorporates a suite of proprietary molecular tools and a large library of genomic markers and gene-trait correlations. We have already characterized millions of high-value single nucleotide polymorphisms (SNPs). By targeting these newly identified SNPs, we have been able to locate and isolate specific sections of genetic code from genome assemblies present in our state-of-the-art hemp/cannabis bioinformatics database. This breakthrough enables us to quickly and easily identify the genes responsible for specific traits in a plant, which we expect to be a powerful tool for us and the hemp/cannabis industry. We have already begun discussions to license this platform to strategic partners to help them improve their plant breeding techniques and optimize their hemp/cannabis lines.

- We continue to secure commercially, valuable patents and intellectual property through our internal research capabilities and external research partnerships. Citing one of the leading achievements in 2021, we are the first Company to show the introduction of genetic material via transformation techniques directly leading to functional protein expression in hemp/cannabis. This new transformation methodology enhances our ability to directly modify specific target genes in hemp/cannabis with potential commercial value, as compared to the broad-based approaches we currently deploy such as molecular breeding and mutagenesis. These modifications can be tailored to differentiate the content of specific major and minor cannabinoids, terpenoids or eliminate unwanted metabolites. With the addition of this highly targeted plant transformation capability to 22nd Century's existing molecular breeding and gene editing capabilities we are now able to increase our bandwidth for the production of highly tailored new plant strains at accelerated rates, lower cost and lower risk to our customers.
- We have secured an exclusive agreement with CannaMetrix, LLC for the use of their proprietary, human cell-based testing CannaMetrix EC50Array™ technology that we believe will enable us to accelerate the commercialization of new, disruptive hemp/cannabis plant lines and intellectual property. CannaMetrix's proprietary CannaMetrix EC50Array™ technology serves as a high-throughput roadmap for developing new hemp/cannabis plant lines with tailor-made cannabinoid and terpenoid profiles for use in the life science, consumer product, and pharmaceutical markets. The human cell-based assay has the ability to measure and validate the potency and efficacy of cannabinoids and/or terpenoids through defined biomarkers and receptor activity and can rapidly identify optimum plant profiles by measuring the potency and effect on the human cell system.
- In May 2021, we announced an extended and expanded plant research partnership agreement with our partner KeyGene, a global leader in plant research involving high-value genetic traits and increased crop yields. The new partnership agreement extends the length of the exclusive worldwide collaboration 22nd Century has with KeyGene to develop new, disruptive hemp/cannabis plants and intellectual property for the life science, medicinal, and pharmaceutical end-use markets. It also expands the partnership to include research and development activity for non-combustible, alternative tobacco plant applications, such as protein production, and 22nd Century's third plant franchise, specialty hops.
- We believe that we can accelerate the development of commercially, valuable hemp/cannabis lines and related intellectual property through selective partnerships and have the key partnerships needed to maximize each component in the upstream segment of the cannabinoid value chain.
- On December 14, 2021, we announced a three-way non-exclusive agreement to license biosynthesis intellectual property with Aurora Cannabis Inc. (NASDAQ: ACB) to Cronos Group Inc. (NASDAQ: CRON), intended to assist in the advancement of research and development on the biosynthesis of cannabinoids.

Specialty Franchise Highlights and Notable Accomplishments

- In August 2021, we announced entry into the global specialty hops market, our third and newest plant franchise. We will leverage our existing know-how with the tobacco and hemp/cannabis plants along with the proprietary tools and technologies possessed by our upstream partnerships with CannaMetrix and KeyGene to bring hop breeding into the 21st century. Our relationships with the world's leading alkaloid plant producer-breeders, including Extractas Bioscience, Sawatch Agriculture, and Folium Botanical, will facilitate year-round growing capabilities at locations in both the southern and northern hemispheres.

2022 Priorities and Areas of Focus

1. We remain focused on launching commercial sales of our VLN® products following our MRTP authorization by the FDA. We have also initiated international sales launch in select markets.
2. We continue to support and advance the FDA's plan to require that all cigarettes sold in the U.S. be made "minimally or non-addictive" by limiting their nicotine content to just 0.5 milligrams of nicotine per gram of tobacco and the proposed ban on menthol high nicotine combustible cigarettes.
3. We continue to target the upstream segment of the cannabinoid value chain; creating proprietary, commercially valuable new plant lines and related intellectual property with stabilized genetics to harness and optimize

hemp/cannabis plant potential. We intend to continue to work to monetize our existing hemp/cannabis IP and will continue to bring disruptive technology forward with new plant lines.

4. We will develop our third, plant-based franchise in specialty hops leveraging our plant science expertise to develop and secure valuable intellectual property and sign strategic partnerships to support the development of this franchise.
5. We will maintain diligent financial execution, efficient operating structure, and balance sheet strength to support our growth initiatives.

Results of Operations

Year Ended December 31, 2021 compared to Year Ended December 31, 2020.

Amounts in thousands, except for share and per-share data

Revenue - Sale of products, net

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Sale of products, net	$ 30,948	$ 28,111	$ 25,833
Dollar Change from Prior Year	$ 2,837	$ 2,278	

The increase in revenue for the year ended December 31, 2021, compared to the year ended December 31, 2020, was primarily the result of an increase in sales of filtered cigars of $4,629, primarily driven by increased volume, fulfillment of our SPECTRUM® research cigarettes of $680, which did not occur in the prior period, and revenue pertaining to our hemp/cannabis business of $44 which did not occur in the prior period. This was partially offset by decreased sales of contract manufactured cigarettes of $2,484 during 2021, which was primarily due to a lower volume of orders received.

Costs of goods sold – Products / Gross profit

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Cost of goods sold	$ 28,879	$ 26,673	$ 25,818
Percent of Product Sales	93.3 %	94.9 %	99.9 %
Dollar Change from Prior Year	$ 2,206	$ 855	

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Gross profit	$ 2,069	$ 1,438	$ 15
Percent of Product Sales	6.7 %	5.1 %	0.1 %
Dollar Change from Prior Year	$ 631	$ 1,423	

For the year ended December 31, 2021, the increase in gross profit as compared to 2020 was primarily driven by improved contract manufactured sales mix due to new customer contracts, cigarette price increases and sales of our higher margin SPECTRUM® research cigarettes.

Research and development expense

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Research and Development	$ 3,256	$ 4,090	$ 6,381
Percent of Product Sales	10.5 %	14.6 %	24.7 %
Dollar Change from Prior Year	$ (834)	$ (2,291)	

R&D expense during the year ended December 31, 2021, decreased $834 as compared to the prior year, primarily driven by lower costs for R&D personnel, consulting and professional services, and licenses and contracts, as well as a 2020 tobacco leaf inventory impairment of $360 that did not recur in 2021. Personnel expense decreased by $222 year over year, due to more focused R&D headcount to accomplish our strategies. Consulting and professional services decreased by $65 and license and contract costs decreased $100 compared to the prior year primarily due to fewer milestone payments for certain research agreements which were not required in 2021. We continue to prioritize our R&D activities to achieve our strategic objectives.

Sales, general and administrative expense

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Sales, general and administrative	$ 25,881	$ 14,971	$ 12,954
Percent of Product Sales	83.6 %	53.3 %	50.1 %
Dollar Change from Prior Year	$ 10,910	$ 2,017	

The increase in sales, general and administrative ("SG&A") expense during the year ended December 31, 2021, as compared to the prior year, was driven by increased investor relations and corporate communications expense of $3,198, strategic consulting expense of $2,598, higher non-cash equity compensation expense of $2,294, increased insurance expense of $1,188, and higher personnel expense of $996 due mainly to the hiring of the executives during 2020 and 2021. In addition, during 2021 director fees increased by $322, legal fees rose by $156 and travel and entertainment expense increased $113.

We have invested in this incremental SG&A spending to continue to ramp up our efforts to allow us to move toward market readiness in both tobacco and hemp/cannabis. We will continue to invest in SG&A spending as growth and opportunities present themselves.

Impairment of intangible assets

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Impairment of intangible assets	$ 78	$ 176	$ 1,142
Percent of Product Sales	0.3 %	0.6 %	4.4 %
Dollar Change from Prior Year	$ (98)	$ (966)	

During the year ended December 31, 2021, management conducted a review of intellectual property assets and determined that an adjustment was necessary for the carrying value of certain trademark costs. As such, we recorded a charge of approximately $78 in 2021. This compares to an impairment charge of $176 reflected in 2020 for certain patents and trademarks. Refer to Note 5 to our consolidated financial statements for additional information.

Depreciation expense

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Depreciation	$ 633	$ 688	$ 589
Percent of Product Sales	2.0 %	2.4 %	2.3 %
Dollar Change from Prior Year	$ (55)	$ 99	

The decrease in depreciation expense during 2021 was primarily due to impairments taken for the former Williamsville corporate office during the fourth quarter of 2020.

Amortization expense

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Amortization	$ 615	$ 658	$ 836
Percent of Product Sales	2.0 %	2.3 %	3.2 %
Dollar Change from Prior Year	$ (43)	$ (178)	

Amortization expense relates to amortization taken on capitalized patent costs and license fees. The decrease in 2021 was primarily due to amortization expense on a lower base of amortizable intangible assets.

Unrealized (loss) gain on investments

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Unrealized gain (loss) on investments	$ (6,994)	$ (434)	$ (2,419)
Percent of Product Sales	(22.6)%	(1.5)%	(9.4)%
Dollar Change from Prior Year	$ (6,560)	$ 1,985	

Unrealized loss on investments includes fair value adjustments for our investment in Aurora Cannabis, Inc. (“Aurora”) stock warrants and our investment in Panacea Holdings common stock. Both investments are considered equity securities and are adjusted to fair value at each reporting period as discussed within Note 7 to our consolidated financial statements included herein.

The warrants to purchase 81,164 shares of Aurora common stock were valued at $5 as of December 31, 2021, using the Black-Scholes pricing model, which resulted in an unrealized loss of $234 for the year ended December 31, 2021.

Our shares of Panacea Holdings common stock were valued based on the closing share price as of December 31, 2021. As of December 31, 2021, the shares were valued at $2,340 resulting in the recognition of an unrealized loss of $6,761 for the year. Our investment in Panacea Holdings is a small microcap stock which can be subject to large market volatility resulting in fluctuations to our net loss and loss per share—due to unrealized gains or losses that are recognized within the Consolidated Statements of Operations. Our investment is described further within Note 6 to our financial statements included herein.

Impairment of Panacea Investment

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Impairment of Panacea Investment	$ —	$ (1,741)	$ —
Percent of Product Sales	— %	(6.2)%	— %
Dollar Change from Prior Year	$ 1,741	$ (1,741)	

During 2020, we incurred impairment charges on our investment in Panacea. Refer to Note 6 to our consolidated financial statements for additional information regarding our investment in Panacea and the conversion related thereto.

Gain on Panacea investment conversion

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Gain on Panacea investment conversion	$ 2,548	$ —	$ —
Percent of Product Sales	8.2 %	— %	— %
Dollar Change from Prior Year	$ 2,548	$ —	

On June 30, 2021, we entered into a Promissory Note Exchange Agreement with Panacea and a Securities Exchange Agreement with Panacea, Exactus, Inc. (“Exactus”) (OTCQB:EXDI), renamed to Panacea Life Sciences Holdings, Inc. (OTCQB:PLSH) as of October 25, 2021 (“Panacea Holdings”), and certain other Panacea shareholders. Pursuant to the Securities Exchange Agreement, Exactus fully acquired Panacea. These transactions resulted in the (i) conversion of all of our existing Series B Preferred Stock in Panacea into 91,016,026 shares of common stock in Exactus valued at $9,102 as of June 30, 2021 and (ii) the conversion of our existing debt in Panacea by converting the outstanding $7,000 principal balance convertible note receivable and all accrued but unpaid interest thereon for fee simple ownership of Needle Rock Farms (224 acres in Delta County, Colorado) and equipment valued at $2,248, $500 in Panacea’s Series B Preferred Stock (which was subsequently converted to Exactus common stock under the Securities Exchange Agreement; this balance is reflected in final shares as stated above), and a new $4,300 promissory note (the “Promissory note receivable”) with a maturity date of June 30, 2026 and a 0% interest rate. The Promissory note receivable is with a related party of Panacea and is fully secured by a first priority lien on Panacea’s headquarters located in Golden, Colorado.

The conversion was recorded as a non-monetary transaction, based on the fair value of the assets received, and resulted in a gain of $2,548 which is included within the Consolidated Statements of Operations. Our shares of Panacea Holdings common stock were initially valued based on a closing share price of $0.10 per share as published on June 30, 2021. Our investment is described further within Note 6 to our financial statements included herein.

Interest income, net

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Interest Income, net	$ 321	$ 1,751	$ 1,066
Percent of Product Sales	1.0 %	6.2 %	4.1 %
Dollar Change from Prior Year	$ (1,430)	$ 685	

Interest income, net (interest income less investment fees) is comprised of cash interest income and non-cash interest accretion. Cash interest income is primarily derived from interest earned on our short-term investment securities and non-cash interest income is primarily related to accretion of short-term investment securities purchased at a discount or premium and accretion of certain other assets recorded at a discount.

Cash interest income for the year ended December 31, 2021 decreased $925 as compared to the prior year, primarily due to lower bond interest yields on our short-term investment securities. Non-cash interest accretion for the year ended December 31, 2021, decreased $506, as compared to the prior year, primarily due to our Panacea investment conversion which is further described within Note 6 to our financial statements included herein.

Interest expense

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Interest Expense	$ (58)	$ (72)	$ (56)
Percent of Product Sales	(0.2)%	(0.3)%	(0.2)%
Dollar Change from Prior Year	$ 14	$ (16)	

Interest expense decreased for the year ended December 31, 2021, as compared to the year ended December 31, 2020, primarily due to the reduction of our severance liability and lower note payable balances for our licenses.

Net loss

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Net Loss	$ (32,609)	$ (19,711)	$ (26,558)
Percent of Product Sales	(105.4)%	(70.1)%	(102.8)%
Dollar Change from Prior Year	$ (12,898)	$ 6,847	

The increase in net loss for the year ended December 31, 2021, as compared to the prior year, was primarily the result of higher operating expenses of $9,860, an increase in unrealized loss on investments of $6,560, primarily relating to our Aurora stock warrants and Panacea Holdings common stock investments, and lower interest income in the amount of $1,430. This was partially offset by a $631 increase in gross profit, a gain on our Panacea investment conversion of $2,548, and a 2020 impairment charge of $1,741 for our investment in Panacea which did not recur in 2021.

Other comprehensive income (loss)

	Year Ended		
	December 31 2021	December 31 2020	December 31 2019
Other Comprehensive Income (Loss)	$ (236)	$ 67	$ (14)
Percent of Product Sales	(0.8)%	0.2 %	(0.1)%
Dollar Change from Prior Year	$ (303)	$ 81	

We maintain an account for short-term investment securities that are classified as available-for-sale securities and consist of money market funds and corporate bonds 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 loss on short-term investment securities in the amount of $236 resulting in other comprehensive loss for the year ended December 31, 2021, as compared to an unrealized gain of $67 for the prior year.

Liquidity and Capital Resources

	Year-to-Date		
	December 31 2021	December 31 2020	December 31 2019
Net cash provided by (used in) operating activities	$ (22,839)	$ (15,621)	$ (14,588)
Net cash provided by (used in) investing activities	(27,729)	16,469	4,552
Net cash provided by (used in) financing activities	50,875	(304)	9,916
Net increase (decrease) in cash and cash equivalents	307	544	(120)
Cash and cash equivalents - beginning of period	1,029	485	605
Cash and cash equivalents - end of period	$ 1,336	$ 1,029	$ 485
Short-term investment securities	$ 47,400	$ 21,313	$ 38,477

Working Capital

As of December 31, 2021, we had working capital of approximately $45,958 compared to working capital of approximately $20,998 as of December 31, 2020, an increase of $24,960. This increase in working capital was primarily due to a $26,394 increase in cash, cash equivalents and short-term investment securities resulting from (i) net proceeds of $11,782 from the cash exercises of all outstanding warrants during the first quarter of 2021; and (ii) net proceeds of $38,206 from a capital raise in June 2021 described below, offset primarily by cash and cash equivalents consumed in the operating activities of the Company.

On June 7, 2021, we entered into a placement agent agreement (the "Placement Agent Agreement") with Cowen and Company, LLC (the "Placement Agent") relating to a registered direct offering (the "Offering") to a select investor (the "Investor"). Pursuant to the Placement Agent Agreement, we agreed to pay the Placement Agent a cash fee of 3.0% of the gross proceeds from the Offering. In addition, on June 7, 2021, we and the Investor entered into a securities purchase agreement relating to the issuance and sale of shares of common stock. The Investor purchased $40,000 of shares, consisting of an aggregate of 10,000,000 shares of common stock at $4.00 per share, resulting in net proceeds of $38,206. The common stock was offered and sold pursuant to our Form S-3 shelf registration statement.

Net cash used in operating activities

Cash used in operations increased $7,218 from $15,621 in 2020 to $22,839 in 2021. The primary driver for this increase was higher SG&A spending, most notably in the areas of investor relations and corporate communication, strategic consulting, insurance and the addition of senior management personnel.

Net cash provided by (used in) investing activities

Cash used in investing activities amounted to $27,729 in 2021 as compared to cash provided by investing activities of $16,469 in 2020. This overall change of $44,198 in cash used in investing activities was primarily related to activity in our short-term investments, which was mainly due to increased funds for investment from the warrant exercises and capital raise described above. We used $1,071 in 2021 to invest in the acquisition of intangible assets and property, plant and equipment, as compared to $522 in 2020. The increase in cash used for the acquisition of machinery and equipment and the acquisition of patents, trademarks and licenses was primarily due to new office furnishings and additional intellectual property costs.

Net cash provided by (used in) financing activities

During the year ended December 31, 2021, cash provided by financing activities increased by $51,179 resulting from (i) the net proceeds of $11,782 resulting from cash exercises of all outstanding warrants during the first quarter of 2021; (ii) net proceeds of $38,206 resulting from a capital raise in June 2021; (iii) net proceeds pertaining to notes payable issuances and payments of $49; and (iv) net proceeds from stock option exercises of $1,307. These increases were partially offset by cash paid for taxes related to settlement of restricted stock units of $469.

Cash demands on operations

Our principal sources of liquidity are our cash and cash equivalents, short-term investment securities, and cash generated from our contract manufacturing business. As of December 31, 2021, we had approximately $48,736 of cash and cash equivalents and short-term investments which is an increase of $26,394 from December 31, 2020. This increase was primarily due to the cash exercise of our outstanding warrants in the first quarter of 2021 and a capital raise in the second quarter of 2021. We believe our short-term investment securities, along with sustained contract manufacturing sales and anticipated growth in our VLN® product line, provide sufficient resources for estimated contractual commitments, described further in Note 12 to our consolidated financial statements included herein, and normal cash requirements for operations beyond the next twelve months. In addition to the commitments described in Note 12 to our consolidated financial statements included herein, we have secured contracts with select tobacco farmers to assist with the growing of our VLNC tobacco. These contracts will increase the quantity of our current leaf inventory which will help support expected demand of VLN®, particularly now that MRTP authorization was granted by the FDA in December 2021. The cost of such growing efforts is dependent on the final agricultural yields and leaf quality, but we expect the cost to be approximately $4.6 million for deliveries received and to be received in 2022 and early 2023. We also believe that we have appropriate liquidity to successfully manufacture and distribute our VLN® cigarette within 90 days of MRTP authorization by the FDA which was received in December 2021, as well as appropriate liquidity for continued R&D investment in all our plant franchises.

We also have an effective S-3 shelf registration statement on file with the U.S. Securities and Exchange Commission (SEC), which provides us flexibility and optionality to raise additional capital as needed. However, there can be no assurance that capital will be available to us on acceptable terms or at all.

Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") which requires management to make estimates, judgements, and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. For a discussion of our significant accounting policies, refer to Note 1 to our consolidated financial statements. We believe that our most critical accounting estimates relate to investment valuation and impairment of long-lived intangible assets.

Conversion of Panacea Investment –As described further within Note 6 to our consolidated financial statements included herein, in June 2021 we exchanged certain assets pertaining to our investment in Panacea. The determination of the carrying value of the assets received required us to use certain estimates. For instance, we received farmland and equipment for which we relied in part by an independent valuation firm to assess the current market value of these assets. In addition, we received a secured, non-interest bearing $4,000 note. Based on the stated term of the note, we used current market interest rates for a comparable security to determine an implied interest rate and adjust the value of the note recorded in our consolidated financial statements.

Impairment of Long-Lived Assets – Our intangible asset portfolio consists of both definite-lived and indefinite-lived intangible assets which include patents, trademarks, licenses, and our inclusion within the tobacco MSA. Our intangible assets subject to amortization are reviewed for strategic importance and commercialization opportunity prior to expiration. If it is determined that the asset no longer supports the Company's strategic objectives and/or will not be commercially viable prior to expiration, the asset is impaired. To determine if an asset's carrying value is appropriate, we are required to estimate the expected commercialization of our tobacco and cannabis intellectual property—either through future product sales or potential license opportunities. This estimate process includes expected future cash flow projections, industry market assessments, and assumptions around positive regulatory developments from government agencies—including ongoing developments following the recent approval of our MRTP application.

For our indefinite-lived intangible assets—MSA, cigarette brand predicate and trademarks—we consider current and future sales projections, strategic objectives, future market and economic conditions, competition, and federal and state regulations to determine if it is more likely than not that that the asset is impaired. If it is more likely than not that the asset is impaired, we will compare the asset carrying value to fair value and record the difference as an impairment.

Management has discussed these critical accounting policies and estimates with the Audit Committee of the Company's Board of Directors. While our estimates and assumptions are based on our knowledge of current events and future actions, actual results may ultimately differ from these estimates and assumptions.

Off-Balance Sheet Arrangement

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various market risks in the ordinary course of our business, which consist primarily of interest rate risk associated with our cash and cash equivalents and short-term investments and foreign exchange rate risk. Additionally, the value of our stock in Panacea Holdings is based on the trading price of their common stock, and our stock warrants in Aurora is primarily based on the underlying price of Aurora's common stock and fluctuations in those values could impact the fair value of our holdings.

Interest Rate Risk

We do not believe we are exposed to material direct interest rate risk associated with changes in interest rates other than with respect to our cash equivalents and short-term investments securities. We invest excess cash in cash equivalents and short-term investment securities primarily consisting of money market funds, corporate bonds, U.S. government agency bonds, U.S. treasury securities, commercial paper, and certificates of deposit that earn interest based on fluctuating interest rates. We believe changes in these interest rates will not have a material impact on our financial statements. Additionally, we have no interest rate sensitive debt, and as such, are not exposed to interest rate changes relating to debt instruments.

Foreign Exchange Risk

The majority of our revenues and expenses are transacted in U.S. dollars. A small portion of our vendors are paid in foreign currencies. Our Canadian subsidiary conducts its business in Canadian dollars, and we have limited exposure to foreign currency translation. The exercise price on the Aurora stock warrants is stated in Canadian dollars. Accordingly, we have some foreign currency risk with respect to such exercise price. We do not believe that fluctuations in foreign currency rates associated with these non-U.S. dollars transaction will have a material impact on our financial statements.

Equity Risk

The stock warrants we received from Aurora are considered equity securities and are carried at fair value using the Black-Scholes pricing model. These stock warrants are exposed to market volatilities, changes in the underlying stock price of Aurora, and interest rates.

The shares of common stock we have in Panacea Holdings are considered equity securities and are carried at fair value using the observable trading price of Panacea Holdings. Our investment in this stock is exposed to market volatilities.

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) and are incorporated by reference into this Item 8.

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 chief 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 chief executive officer 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 chief executive officer 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 chief executive officer 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, 2021.

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, 2021 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection

Not applicable.

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 2022 Annual Meeting of Stockholders.

Set forth below is information regarding our directors, executive officers, and key personnel as of March 1, 2022:

Name	Age	Position	
James A. Mish	57	Chief Executive Officer and Director	
Michael Zercher	51	President and Chief Operating Officer	
Richard F. Fitzgerald	58	Chief Financial Officer	
John Franzino	65	Chief Administrative Officer	
Dr. Michael Koganov	71	Director	(1)
Richard M. Sanders	68	Director	(2)
Nora B. Sullivan	63	Director	(3)
Clifford B. Fleet	51	Director	(4)
Roger D. O'Brien	73	Director	(5)
Anthony Johnson	46	Director	(6)

(1) Since 2019, Dr. Koganov has served as President and Co-Founder of Intellebio LLC, a consulting and testing firm focused on the development of novel technologies, advanced test methods, and breakthrough products in the life science field.

(2) 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. Mr. Sanders is also an active Angel and private placement investor.

(3) 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.

(4) Since January 2020, Mr. Fleet has served as President and CEO of the Colonial Williamsburg Foundation. Prior to that, Mr. Fleet previously served as the President and Chief Executive Officer of the Company from August 3, 2019 until December 13, 2019 and served as a strategic advisor consultant to the Company from December 2018 to August 3, 2019. Prior to that, Mr. Fleet served as President and CEO of Philip Morris USA.

(5) 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. Mr. O'Brien has also served as an officer of several publicly held companies, including Sun Microsystems and Ultralife Batteries, Inc.

(6) Mr. Johnson is co-founder, President, and CEO of Kodikaz Therapeutic Solutions, a next-generation, non-viral gene therapy company, and a founding partner of Buffalo Biosciences, a life science strategic business management firm that supports the evaluation and commercialization of bioscience technologies from concept to market.

Code of Ethics

We adopted a Code of Ethics that applies to all our employees. A copy of our Code of Ethics is available on our website at http://www.xxiicentury.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., 500

Seneca Street, Suite 507, Buffalo, New York 14204. 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 2022 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 2022 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 2022 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 2022 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements

(b) Financial Statement Schedules

(c) Exhibits

Item 16. Form 10-K Summary.

None.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinions on the Financial Statements and Internal Control Over Financial Reporting
We have audited the accompanying consolidated balance sheets of 22nd Century Group, Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, 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, 2021, and the related notes and schedules to the consolidated financial statements (collectively, the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, 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 financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

Basis for Opinions
The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Annual Report on Internal Controls Over Financial Reporitng". Our responsibility is to express an opinion on the Company's financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements 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. Our audit of internal control over financial reporting 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Intangible Assets – impairment analysis

Critical Audit Matter Description

As discussed in Note 1 to the consolidated financial statements, 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 patents from third parties (2) license fees paid for third-party intellectual property (3) costs to become a signatory under the tobacco Master Settlement Agreement and (4) license fees paid to acquire a predicate cigarette brand. 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. On at least an annual basis, the Company assesses whether events or changes in circumstances indicate that the carrying amount may not be recoverable. If any such indicators are present, the Company will test for recoverability. Intangible assets subject to amortization are reviewed for strategic importance and commercialization opportunity prior to expiration. If it is determined that the asset no longer supports the Company's strategic objectives and/or will not be commercially viable prior to expiration, the asset is impaired. In addition, the Company will assess the expected future undiscounted cash flows for its intellectual property based on consideration of future market and economic conditions, competition, federal and state regulations, and licensing opportunities. If the carrying value of such assets are not recoverable, the carrying value will be reduced to fair value. Indefinite-lived intangible asset carrying values are reviewed at least annually or more frequently if events or changes in circumstances indicate that it is more likely than not that an impairment exists. The Company first performs a qualitative assessment and considers its current strategic objectives, future market and economic conditions, competition, and federal and state regulations to determine if an impairment is more likely than not.

Because the Company has not fully commercialized its core intellectual property and the markets for those products are not yet developed, the Company assesses recoverability by reviewing the strategic importance and commercialization opportunities and making assumptions related to future market and economic conditions, competition, federal and state regulations, and licensing opportunities. Due to the magnitude of intangible assets and subjectivity of these assumptions, we identified the impairment analysis of intangible assets as a critical audit matter, which required a high degree of auditor judgment.

Addressing the matter involved performing subjective procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. The primary procedures we performed include: obtaining an understanding of the process and assumptions used by management to perform the impairment test; testing the completeness and accuracy of the gross and net capitalized costs by asset group used in the analysis; evaluating the reasonableness and consistency of the methodology and assumptions applied by management, and obtaining an understanding and testing the operating effectiveness of management's controls related to the impairment test.

Panacea Life Sciences – restructuring agreement

Critical Audit Matter Description

As discussed in Note 6 to the consolidated financial statements, a conversion of the Panacea Life Sciences, Inc. (Panacea) investment occurred on June 30, 2021. As part of this transaction, Exactus, Inc. (Exactus) fully acquired Panacea and (i)

the Series B Preferred Stock of Panacea owned by the Company was converted into shares of Exactus, and (ii) the convertible note receivable and all accrued interest from Panacea was converted into 1) Panacea owned farm related land and equipment 2) additional shares of Panacea's Series B Preferred Stock, which was subsequently converted to Exactus common stock and 3) a new non-interest bearing promissory note due June 30, 2026 (the Promissory Note). All other rights and obligations of the Company were terminated, including the warrant rights and obligation for further investment. This transaction was accounted for as a non-monetary exchange, resulting in all assets received being recorded at fair value and a gain reflected in the Consolidated Statements of Operations and Comprehensive Loss. The Promissory Note was recorded net of a discount representing the present value of the payments and is included in Other assets on the balance sheet. The Company intends to hold the Promissory note to maturity and the associated discount will be amortized into interest income over the term if the note. The farmland and equipment is included Property, plant and equipment on the balance sheet. The Company concluded that the common shares in Exactus are considered equity securities with a readily determinable fair value, which are included in Investments on the balance sheet. Changes in fair value each period are reflected as gains or losses included in net loss in the Statement of Operations and Comprehensive loss.

Due to the magnitude of the assets involved, the complexity of the terms of the agreements, the multiple accounting conclusions required, and the need to determine the fair value of the assets acquired, we identified this transaction as a critical audit matter.

Addressing the matter involved performing subjective procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. The primary procedures we performed include: inquiring of management and examining the terms of various agreements to gain an understanding of the transaction; evaluating accounting conclusions reached; evaluating assumptions and methodologies used to estimate the fair value of assets acquired; agreeing pre and post transaction balances to underlying support ensuring such information was complete and accurate in all material respect; and obtaining and understanding and testing the operating effectiveness of management's controls related to the transaction.

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

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

Buffalo, New York
March 1, 2022

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
($ in thousands, except per-share data)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,336	$ 1,029
Short-term investment securities	47,400	21,313
Accounts receivable, net	585	2,159
Inventory, net	2,881	2,034
Prepaid expenses and other assets	2,183	1,806
Total current assets	54,385	28,341
Property, plant and equipment, net	5,841	2,483
Operating leases right-of-use assets, net	1,723	247
Intangible assets, net	7,919	8,211
Investments	2,345	6,536
Other assets	3,741	5,876
Total assets	$ 75,954	$ 51,694
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Notes payable	$ 596	$ 539
Operating lease obligations	308	247
Accounts payable	2,173	1,116
Accrued expenses	1,489	931
Accrued payroll	2,255	2,208
Accrued excise taxes and fees	1,270	1,691
Accrued severance	217	339
Deferred income	119	272
Total current liabilities	8,427	7,343
Long-term liabilities:		
Operating lease obligations	1,432	—
Severance obligations	21	241
Total liabilities	9,880	7,584
Commitments and contingencies (Note 12)		
Shareholders' equity		
Preferred stock, $.00001 par value, 10,000,000 shares authorized		
Common stock, $.00001 par value, 300,000,000 shares authorized		
Capital stock issued and outstanding:		
162,872,875 common shares (139,061,690 at December 31, 2020)		
Common stock, par value	2	1
Capital in excess of par value	244,247	189,439
Accumulated other comprehensive (loss) income	(162)	74
Accumulated deficit	(178,013)	(145,404)
Total shareholders' equity	66,074	44,110
Total liabilities and shareholders' equity	$ 75,954	$ 51,694

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
($ in thousands, except per-share data)

	Year Ended December 31,		
	2021	**2020**	**2019**
Revenue:			
Sale of products, net	$ 30,948	$ 28,111	$ 25,833
Cost of goods sold (exclusive of depreciation shown separately below):			
Products	28,879	26,673	25,818
Gross profit (loss)	2,069	1,438	15
Operating expenses:			
Research and development	3,256	4,090	6,381
Research and development - MRTP	18	38	1,679
Sales, general and administrative	25,881	14,971	12,954
Impairment of intangible assets	78	176	1,142
Depreciation	633	688	589
Amortization	615	658	836
Total operating expenses	30,481	20,621	23,581
Operating loss	(28,412)	(19,183)	(23,566)
Other income (expense):			
Unrealized gain (loss) on investments	(6,994)	(434)	(2,419)
Impairment of Panacea investment	—	(1,741)	—
Gain on Panacea investment conversion	2,548	—	—
Realized gain (loss) on short-term investment securities	—	5	221
Litigation settlement	—	—	(1,891)
Gain on the sale of property, plant and equipment	—	1	87
Interest income, net	321	1,751	1,066
Interest expense	(58)	(72)	(56)
Total other income (expense)	(4,183)	(490)	(2,992)
Loss before income taxes	(32,595)	(19,673)	(26,558)
Income taxes	14	38	—
Net loss	$ (32,609)	$ (19,711)	$ (26,558)
Other comprehensive income (loss):			
Unrealized gain (loss) on short-term investment securities	(236)	72	207
Reclassification of (gain) loss to net loss	—	(5)	(221)
Other comprehensive income (loss)	(236)	67	(14)
Comprehensive loss	$ (32,845)	$ (19,644)	$ (26,572)
Net loss per common share - basic and diluted	$ (0.21)	$ (0.14)	$ (0.21)
Weighted average common shares outstanding - basic and diluted (in thousands)	156,208	138,813	125,883

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
($ in thousands)

	Years Ended December 31, 2021, 2020, and 2019					
	Common Shares Outstanding	Par Value of Common Shares	Capital in Excess of Par Value	Other Comprehensive Income (Loss)	Accumulated Deficit	Shareholders' Equity
Balance at December 31, 2018	**124,642,593**	**$ 1**	**$ 170,391**	**$ 21**	**$ (99,135)**	**$ 71,278**
Stock issued in connection with warrant exercises	11,293,211	—	10,616	—	—	10,616
Stock issued in connection with option exercises	39,988	—	—	—	—	—
Stock issued in connection with RSU vesting	100,000	—	—	—	—	—
Equity-based compensation	—	—	3,540	—	—	3,540
Stock issued in connection with litigation expense	990,000	—	1,891	—	—	1,891
Stock issued in connection with Panacea investment	1,297,017	—	1,297	—	—	1,297
Unrealized gain (loss) on short-term investment securities	—	—	—	207	—	207
Reclassification of losses (gains) to net loss	—	—	—	(221)	—	(221)
Net loss	—	—	—	—	(26,558)	(26,558)
Balance at December 31, 2019	**138,362,809**	**1**	**187,735**	**7**	**(125,693)**	**62,050**
Stock issued in connection with option exercises	146,081	—	50	—	—	50
Stock issued in connection with RSU vesting	552,800	—	—	—	—	—
Equity-based compensation	—	—	1,654	—	—	1,654
Unrealized gain (loss) on short-term investment securities	—	—	—	72	—	72
Reclassification of losses (gains) to net loss	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(19,711)	(19,711)
Balance at December 31, 2020	**139,061,690**	**1**	**189,439**	**74**	**(145,404)**	**44,110**
Stock issued in connection with warrant exercises	11,293,211	1	11,781	—	—	11,782
Stock issued in connection with option exercises	983,613	—	1,307	—	—	1,307
Stock issued in connection with RSU vesting, net of shares withheld for taxes	1,534,361	—	(469)	—	—	(469)
Stock issued in connection with capital raise	10,000,000	—	38,206	—	—	38,206
Equity-based compensation	—	—	3,983	—	—	3,983
Unrealized gain (loss) on short-term investment securities	—	—	—	(236)	—	(236)
Net loss	—	—	—	—	(32,609)	(32,609)
Balance at December 31, 2021	**162,872,875**	**2**	**244,247**	**(162)**	**(178,013)**	**66,074**

See accompanying notes to consolidated financial statements.

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
($ in thousands)

	Year Ended December 31,		
	2021	2020	2019
Cash flows from operating activities:			
Net loss	$ (32,609)	$ (19,711)	$ (26,558)
Adjustments to reconcile net loss to cash used in operating activities:			
Impairment of intangible assets	78	176	1,142
Impairment of Panacea investment	—	1,741	—
Amortization and depreciation	999	1,094	1,186
Amortization of license fees	249	251	239
Amortization of ROU Asset	288	182	212
Unrealized (gain) loss on investment	6,994	434	2,419
Realized (gain) loss on short-term investment securities	—	(5)	(221)
Litigation settlement	—	—	1,891
Gain on the sale of machinery and equipment	—	(1)	(87)
Gain on Panacea investment conversion	(2,548)	—	—
Accretion of non-cash interest expense (income)	143	(326)	26
Equity-based employee compensation expense	3,983	1,654	3,540
Inventory write-off	317	521	985
(Increase) decrease in assets:			
Accounts receivable	1,574	(1,292)	4
Inventory	(1,164)	(289)	(207)
Prepaid expenses and other assets	(547)	(787)	280
Increase (decrease) in liabilities:			
Operating lease obligations	(272)	(552)	(212)
Accounts payable	11	(936)	(732)
Accrued expenses	533	499	243
Accrued payroll	47	1,121	498
Accrued excise taxes and fees	(421)	563	51
Accrued severance	(341)	(225)	792
Deferred income	(153)	267	(78)
Net cash provided by (used in) operating activities	(22,839)	(15,621)	(14,588)
Cash flows from investing activities:			
Acquisition of patents, trademarks, and licenses	(326)	(468)	(565)
Acquisition of property, plant and equipment	(745)	(54)	(527)
Proceeds from the sale of machinery and equipment	—	6	166
Investment in Panacea	—	—	(12,000)
Sales and maturities of short-term investment securities	63,749	39,728	19,320
Purchase of short-term investment securities	(90,407)	(22,743)	(1,842)
Net cash provided by (used in) investing activities	(27,729)	16,469	4,552
Cash flows from financing activities:			
Payment on note payable	(2,604)	(2,549)	(700)
Proceeds from note payable issuance	2,653	2,195	—
Net proceeds from option exercise	1,307	50	—
Net proceeds from warrant exercise	11,782	—	10,616
Net proceeds from issuance of common stock	38,206	—	—
Taxes paid related to net share settlement of RSUs	(469)	—	—
Proceeds from SBA loan	—	1,183	—
Repayment of SBA loan	—	(1,183)	—
Net cash provided by (used in) financing activities	50,875	(304)	9,916
Net increase (decrease) in cash and cash equivalents	307	544	(120)
Cash and cash equivalents - beginning of period	1,029	485	605
Cash and cash equivalents - end of period	$ 1,336	$ 1,029	$ 485
Supplemental disclosures of cash flow information:			
Net cash paid for:			
Cash paid during the period for interest	$ 37	$ 29	$ 3
Non-cash transactions:			
Patent and trademark additions included in accounts payable	$ 51	$ 55	$ 155
Property, plant and equipment additions included in accounts payable	$ 998	$ 2	$ —
Right-of-use assets and corresponding operating lease obligations	$ 1,816	$ 198	$ 814
Patent and trademark additions included in accrued expenses	$ 25	$ 28	$ —
Stock issued in connection with investment	$ —	$ —	$ 1,297
Panacea investment conversion	$ 12,485	$ —	$ —

See accompanying notes to consolidated financial statements.

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

Principles of Consolidation – The accompanying consolidated financial statements include the accounts of (i) 22nd Century Group, Inc. ("22nd Century Group"); (ii) its four wholly-owned subsidiaries, 22nd Century Limited, LLC ("22nd Century Ltd"), NASCO Products, LLC ("NASCO"), Botanical Genetics, LLC ("Botanical Genetics"), and 22nd Century Canada, Inc. ("22nd Century Group Canada"); (iii) two wholly-owned subsidiaries of 22nd Century Ltd, Goodrich Tobacco Company, LLC ("Goodrich Tobacco") and Heracles Pharmaceuticals, LLC ("Heracles Pharma"); and (iv) one wholly-owned subsidiary of Botanical Genetics, 22nd Century Holdings, LLC ("22nd Century Holdings"). This group of subsidiaries is referred to as collectively with 22nd Century Group as the "Company". All intercompany accounts and transactions have been eliminated.

Nature of Business – 22nd Century Group is a leading agricultural biotechnology and intellectual property company focused on tobacco harm reduction, reduced nicotine tobacco and improving health and wellness through plant science. 22nd Century Ltd performs research and development related to the level of nicotine and other nicotinic alkaloids in tobacco plants and Botanical Genetics performs research and development related to hemp/cannabis plants. Goodrich Tobacco and Heracles Pharma are business units for the Company's potential modified exposure tobacco products. 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. 22nd Century Holdings and 22nd Century Group Canada are two newly formed subsidiaries where 22nd Century Holdings own and operate the newly acquired Needle Rock Farm assets and 22nd Century Group Canada will allow for future international business opportunities in Canada.

COVID-19 Pandemic – The COVID-19 pandemic has adversely impacted the U.S. economy and supply chains and created volatility in U.S. financial markets. The COVID-19 pandemic has had a minimal impact on the Company's operations in 2020 and 2021, but there is a risk that state and federal authorities' responses to the COVID-19 pandemic or another pandemic may disrupt our business in the future.

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.

Foreign currency translation– The functional currency of our foreign subsidiaries is generally the respective local currency. The translation from the applicable foreign currencies to U.S. dollars is performed for balance sheet accounts using period-end rates of exchange and for revenue and expense accounts using an average rate of exchange during the period. The resulting translation adjustments are recognized as a component of AOCI. Gains or losses resulting from foreign currency denominated transactions are included in selling, general, and administrative expenses.

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. There are no restrictions on the Company's cash and cash equivalents.

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 extends credit to customers in the normal course of business. Trade accounts receivable are recorded at their invoiced amounts, net of allowance for doubtful accounts. 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, 2021 and December 31, 2020.

Inventory – Inventories are valued at the lower of historical cost or net realizable value. Cost is determined using (i) an average cost method for tobacco leaf inventory and raw materials inventory, and (ii) a standard cost method, approximating average costs, 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.

Property, plant and equipment – Plant and equipment are recorded at their acquisition cost and depreciated on a straight-line basis over their estimated useful lives. Leasehold improvements are depreciated on a straight-line basis over the term of the lease or the estimate useful life of the asset, whichever is shorter. Depreciation commences when the asset is placed in service.

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 rights to use.

The Company's capitalized intellectual property costs are amortized using the straight-line method over the remaining statutory life of the patent assets in each of the Company's patent families, which have estimated expiration dates ranging from 2026 to 2042. 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 have expected expiration dates from 2028 through 2036. The Company believes that costs associated with becoming a signatory to the MSA, costs related to the acquisition of a predicate cigarette brand and trademarks have indefinite lives. As such, no amortization is taken. At each reporting period, the Company evaluates whether events and circumstances continue to support the indefinite-lived classification.

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. On at least an annual basis, the Company assesses whether events or changes in circumstances indicate that the carrying amount may not be recoverable. If any such indicators are present, the Company will test for recoverability in accordance with ASC 360-*Property, plant, and equipment* or ASC 350- *Intangibles, Goodwill, and Other*.

Intangible assets subject to amortization are reviewed for strategic importance and commercialization opportunity prior to expiration. If it is determined that the asset no longer supports the Company's strategic objectives and/or will not be commercially viable prior to expiration, the asset is impaired. In addition, the Company will assess the expected future undiscounted cash flows for its intellectual property based on consideration of future market and economic conditions, competition, federal and state regulations, and licensing opportunities. If the carrying value of such assets are not recoverable, the carrying value will be reduced to fair value and record the difference as an impairment.

Indefinite-lived intangible asset carrying values are reviewed at least annually or more frequently if events or changes in circumstances indicate that it is more likely than not that an impairment exists. The Company first performs a qualitative assessment and considers its current strategic objectives, future market and economic conditions, competition, and federal and state regulations to determine if an impairment is more likely than not. If it is determined that an impairment is more likely than not, a quantitative assessment is performed to compare the asset carrying value to fair value.

Right-of-use ("ROU") assets and Lease Obligations – The Company reviews any lease arrangements in accordance with 2016-02, Subtopic ASC 842, Leases. Any lease having a lease term greater than twelve months will be recognized on the Consolidated Balance Sheets as an ROU asset with an associated lease obligation—all other leases are considered short-term in nature and will be expensed on a month-to-month basis. The ROU assets and lease obligations are recognized as of the commencement date at the net present value of the fixed minimum lease payments for the lease term. The lease term is determined based on the contractual conditions, including whether renewal options are reasonably certain to be exercised. The discount rate used is the interest rate implicit in the lease, if available, or the Company's incremental borrowing rate which is determined using a base line rate plus an applicable spread.

Refer to Note 4 for additional information regarding our ROU assets and liabilities.

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, 2021 and December 31, 2020. Additionally, 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, 2018 through December 31, 2020 are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2021.

Stock Based Compensation – The Company's Omnibus Incentive Plan allows for various types of equity-based incentive awards. Stock based compensation expense is based on awards that are expected to vest over the requisite service periods and are based on the fair value of the award measured on the grant date. Vesting requirements vary for directors, officers, and employees. In general, time-based awards fully vest after one year for directors and vest in equal annual installments over a three-year period for officers and employees. Performance-based awards vest upon achievement of certain milestones. Forfeitures are accounted for when they occur.

Revenue Recognition – The Company recognizes revenue when it satisfies a performance obligation by transferring control of the product to a customer. For additional discussion on revenue recognition, refer to Note 16.

Derivatives –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, if applicable, 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. During 2020 and 2021, the Company did not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks.

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. Refer to Note 13 for additional information.

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 promissory note receivable, accounts payable, accrued expenses, and notes payable. The carrying values of these financial instruments approximate fair value. The Company carries cash equivalents, short-term investment securities, investments, and other assets at fair value which is described further in Note 7.

Investments –The Company's equity securities are recorded at fair value with changes in fair value included within 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 certain 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.

Loss Contingencies – 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. Our current legal matters are discussed further in Note 12.

Recent Accounting Pronouncement(s) –

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—excluding small reporting companies (SRCs), based on a determination date as of November 15, 2019, which have an effective date beginning after December 15, 2022 and interim periods within those fiscal years. The Company is evaluating the expected impacts of the ASU.

We consider the applicability and impact of all ASUs. If the ASU is not listed above, it was determined that the ASU was either not applicable or would have an immaterial impact on our financial statements and related disclosures.

NOTE 2. – INVENTORY

Inventories at December 31, 2021 and December 31, 2020 consisted of the following:

	December 31, 2021	December 31, 2020
Inventory - tobacco leaf	$ 1,352	$ 821
Inventory - hemp/cannabis	10	—
Inventory - finished goods		
Cigarettes and filtered cigars	256	171
Inventory - raw materials		
Cigarette and filtered cigar components	1,363	1,142
Less: inventory reserve	(100)	(100)
	$ 2,881	$ 2,034

During the year ended December 31, 2021, the Company wrote off inventory totaling $317 which is included within costs of goods sold on the Company's Consolidated Statement of Operations and Comprehensive Loss. During the year ended December 31, 2020, the Company wrote off inventory totaling $521 on the Company's Consolidated Statement of Operations and Comprehensive Loss ($361 included within research and development expenses and $161 included within cost of goods sold.)

NOTE 3. – PROPERTY, PLANT AND EQUIPMENT, NET

Property, plant and equipment, net at December 31, 2021 and December 31, 2020 consisted of the following:

	Useful Life	December 31, 2021	December 31, 2020
Land		$ 1,665	$ —
Building and leasehold improvements	7 to 40 years	309	123
Manufacturing equipment	3 to 10 years	5,541	4,893
Office furniture, fixtures and equipment	3 to 5 years	139	20
Laboratory equipment	5 years	198	117
Construction in progress		1,289	—
Less: accumulated depreciation		(3,300)	(2,670)
Property, plant and equipment, net		$ 5,841	$ 2,483

Depreciation expense was $633, $688, and $589 for the years ended December 31, 2021, 2020 and 2019, respectively.

NOTE 4. – RIGHT-OF-USE ASSETS, LEASE OBLIGATIONS, AND OTHER LEASES

The Company leases a manufacturing facility and warehouse in North Carolina, a corporate headquarters in Buffalo, New York, and a laboratory space in Rockville, Maryland.

During the fourth quarter of 2020, the Company made the decision to not renew its corporate headquarters lease in Williamsville, NY which had an initial term expiring on January 1, 2021. Upon adoption of ASC 842-Leases, the Company assumed all three optional one-year renewal options which created a lease term expiration inclusive of all initial renewal options within the lease agreement—which assumed a lease term expiration in 2023. With the non-renewal decision, the Company's lease operated on a month-to-month basis beginning on January 1, 2021. As such, the ROU asset and lease obligation was removed from the Consolidated Balance Sheets as of December 31, 2020.

On January 15, 2021, the Company signed a lease agreement to relocate its corporate headquarters to the Larkinville District in downtown Buffalo, New York. The Company moved into the new office location in April 2021 and signed an amended lease agreement which revised the original lease commencement date to April 1, 2021. The lease has a monthly base rent of $6, which escalates 2.5% annually after the first year, and an initial term of 36 months—with two twenty-four-month optional renewal options at the Company's discretion.

On July 28, 2021, the Company signed a lease agreement for a new research and development ("R&D") laboratory in Rockville, MD. The new laboratory space has over four thousand square feet and will support the Company's continued growth and R&D partnerships. The lease has an initial monthly base rent of $12 (escalating 2.5% annually after the first year), a term of 51 months, and commenced on December 1, 2021. The lease also calls for abatement of 100% of the base rent for the first five months following the lease commencement date.

On October 18, 2021, the Company signed a lease extension for its manufacturing facility and warehouse in North Carolina. The lease commenced upon expiration of the previous lease term, which was November 1, 2021. The lease has a monthly base rent of $17 and an initial term of twenty-four months—with one twenty-four month renewal option at the Company's discretion.

The following table summarized the Company's discount rate and remaining lease terms as of December 31, 2021:

Weighted average remaining lease term in years	4.6
Weighted average discount rate	3.4 %

Future minimum lease payments as of December 31, 2021 are as follows:

2022	373
2023	429
2024	448
2025	418
2026	111
Thereafter	108
Total lease payments	1,887
Less: imputed interest	(147)
Total	$ 1,740

The Company also leases warehouse space in North Carolina and a small office space in Paoli, PA which do not fall under ASC 842 and are not included within our Consolidated Balance Sheets.

Operating lease costs for the years ended December 31, 2021, 2020 and 2019, were $301, $335 and $250 respectively.

NOTE 5. – INTANGIBLE ASSETS

Our intangible assets at December 31, 2021 and December 31, 2020 consisted of the following:

	December 31, 2021	December 31, 2020
Intangible assets, net		
Patent and trademark costs	$ 5,991	$ 5,667
Less: accumulated amortization	(3,303)	(2,936)
Patent and trademark costs, net	2,688	2,731
License fees	3,876	3,876
Less: accumulated amortization	(1,197)	(948)
License fees, net	2,679	2,928
MSA signatory costs	2,202	2,202
License fee for predicate cigarette brand	350	350
	$ 7,919	$ 8,211

Amortization expense relating to the above intangible assets for the years ended December 31, 2021, 2020 and 2019 amounted to $615, $658, and $836, respectively.

During the year ended December 31, 2021, the Company incurred a charge of $78 related to a write-down of our trademarks. During the years ended December 31, 2020 and 2019, the Company incurred an impairment related to patent intellectual property that either would be expired prior to expected commercialization or did not align to the Company's strategic objectives. Impairment expense for the year ended December 31, 2020 and 2019, amounted to $176 (cost of approximately $448 less accumulated amortization of approximately $302) and $1,142 (cost of $2,092 less accumulated amortization of approximately $950), respectively.

The impairment charges are included as a separate line item in operating expenses on the Company's Consolidated Statements of Operations and Comprehensive Loss.

The estimated annual average amortization expense for the next five years is approximately $387 for patent costs and $249 for license fees.

NOTE 6. – INVESTMENTS & OTHER ASSETS

Investment in Panacea Life Sciences, Inc.

Initial Investment:

On December 3, 2019, the Company entered into a securities purchase agreement with Panacea Life Sciences, Inc. ("Panacea") for consideration valued at $13,297 ($12,000 cash and $1,297 of the Company's shares of common stock valued at $1 per share) in exchange for a 15.8% ownership interest. The Company's investment consisted of three instruments: shares of Series B preferred stock ("preferred stock"); a convertible note receivable with a $7,000 face value; and a warrant ("stock warrant") to purchase additional shares of Series B preferred stock, to obtain 51% ownership of Panacea, at an exercise price of $2.344 per share. The convertible note receivable had a term of five years, interest of 10% per annum, and could be converted to shares of Series B preferred stock at the Company's discretion. The embedded conversion option was not considered a derivative instrument for accounting purposes. The preferred stock carried an annual 10% cumulative dividend, compounded annually, and had an implicit put option after the fifth anniversary date so long that the stock warrants had not been exercised. The put option was not considered a derivative instrument for accounting purposes. The stock warrant was exercisable at any time after the fifth anniversary date and would be accelerated if Panacea achieved certain sales targets for two consecutive years. The Series B preferred stock

also included first priority equity preferences in the event of a liquidation, sale, or transfer of Panacea assets. These rights entitled the Company to the original Series B issuance price of $7,000 plus any unpaid accrued dividends.

To allocate the cost of the stock warrant, the Company calculated a fair value based on the following assumptions: volatility of 70%, discount of 25% for lack of marketability, and a risk-free rate of 2%. The value of the stock warrant was allocated to the preferred stock and the convertible note receivable, equally, at a discount to the acquisition price. The discount on the preferred stock was determined to be for lack of control and the discount on the convertible note receivable was determined to be for issuing the note at a below market interest rate for similar instruments.

The convertible note receivable and the preferred stock investment were considered available for sale debt securities with a private company that was not traded in active markets. Since observable price quotations were not available at acquisition, fair value was estimated based on cost less an appropriate discount upon acquisition. The discount of each instrument is accreted into interest income over the respective term as shown within the Company's Consolidated Statements of Operations and Comprehensive Loss. See Note 7 for additional information on these fair value measurements. The stock warrant was recorded at its cost basis in accordance with the practicability exception under ASU 2016-01.

Impairment of Panacea Investment:

As a result of increased competition and other macroeconomic factors, the Company recognized an impairment of $1,062 on the Panacea stock warrant during the second quarter of 2020. The impairment is recorded within the Consolidated Statements of Operations and Comprehensive Loss as "Impairment of Panacea Investment." During the fourth quarter of 2020, the Company entered into a non-binding agreement with Panacea to potentially restructure the investment and business relationship—including the transfer of an agricultural facility and other assets. As of December 31, 2020, the Company adjusted certain assets to represent the fair value outlined in the non-binding agreement.

The Company's non-binding agreement with Panacea to restructure the investment and business relationship generally provided for (i) the transfer of $7,170 in operational assets, including an agricultural facility and various extraction and distillation equipment, from Panacea to the Company in exchange for the cancellation of the $7,000 convertible note receivable plus accrued interest; (ii) an amendment of transaction documents to remove any future investment rights and obligations of the Company in Panacea, (iii) cancellation of the stock warrant to purchase additional Series B preferred stock; and (iv) various other amendments to Panacea's charter to amend various investors rights therein.

As a result of the expected outcome of this non-binding agreement, the Company determined that the carrying value of the stock warrant and the convertible note receivable plus accrued interest exceeded the fair value outlined in the non-binding agreement. As such, the Company recorded an impairment of $679, which reduced the stock warrant carrying value, so that the carrying value of the stock warrant, and convertible note receivable plus accrued interest amounted to a value of $7,170 as of December 31, 2020. The impairment is recorded within the Consolidated Statements of Operations and Comprehensive Loss as "Impairment of Panacea Investment."

In accordance with ASC 326- *Financial Instruments-Credit Losses*, the Company reviewed the fair value of its preferred stock investment and considered the following: (i) increased competition in the cannabinoid industry; (ii) the Company's preferred stock priority equity preferences; and (iii) other macroeconomic factors. Based on the assessment performed, it was determined that no credit loss existed for the preferred stock available-for-sale debt security.

Conversion of Panacea Investment:

On June 30, 2021, the Company entered into a Promissory Note Exchange Agreement with Panacea and a Securities Exchange Agreement with Panacea, Exactus, Inc. ("Exactus") (OTCQB:EXDI) and certain other Panacea shareholders. Pursuant to the Securities Exchange Agreement, Exactus fully acquired Panacea. These transactions effected the (i) conversion of all of the Company's Series B Preferred Stock in Panacea into 91,016,026 shares of common stock in Exactus valued at $9,102 as of June 30, 2021 and (ii) the conversion of the Company's existing debt in Panacea by converting the outstanding $7,000 principal balance convertible note receivable and all accrued but unpaid

interest thereon for fee simple ownership of Needle Rock Farms (224 acres in Delta County, Colorado) and equipment valued at $2,248, $500 in Panacea's Series B Preferred Stock (which was subsequently converted to Exactus common stock under the Securities Exchange Agreement; this balance is reflected in final shares as stated above), and a new $4,300 promissory note (the "Promissory note receivable") with a maturity date of June 30, 2026 and a 0% interest rate. The Promissory note receivable is with a related party of Panacea and is fully secured by a first priority lien on Panacea's headquarters located in Golden, Colorado. All other rights and obligations of the Company in Panacea and Panacea's affiliate, Quintel-MC Incorporated, were terminated by this transaction—including all warrant rights and obligations for future investment. The conversion was recorded as a non-monetary transaction, based on the fair value of the assets received, and resulted in a gain of $2,548 which is included within the Consolidated Statements of Operations and Comprehensive Loss as "Gain on Panacea investment conversion."

The Promissory note receivable was valued at $3,684 ($4,300 face value less $616 discount) and is included within the Consolidated Balance Sheets as "Other Assets." The Company intends to hold the Promissory note receivable to maturity and the associated discount will be amortized into interest income over the term of the note. The ownership of Needle Rock Farms and related equipment is included within "Property, plant, and equipment, net" on the Consolidated Balance Sheets. The common shares of Exactus, Inc. are considered equity securities in accordance with ASC 321 and are recorded at fair value—changes in fair value will be included within the statement of operations. See Note 7 for additional information on the fair value measurements.

On October 25, 2021, Exactus announced the completion of a 1 for 28 reverse stock split as well as an entity name change to Panacea Life Sciences Holdings, Inc (OTCQB: PLSH). Panacea Life Sciences Holdings, Inc. was assigned a temporary stock symbol of "EXDID" which formally changed to "PLSH" after twenty business days. As a result of the reverse stock split, our 91,016,026 shares were adjusted to 3,250,573 shares.

As of December 31, 2021, the total carrying value of the Company's investment in Panacea is outlined below, net of 2020 impairment expense:

	December 31, 2021	December 31, 2020
Panacea preferred stock	$ —	$ 5,173
Panacea stock warrant	—	1,124
Accrued interest on convertible note receivable *(included within prepaid expenses and other assets)*	—	170
Convertible note receivable	—	5,876
Promissory note receivable	3,741	—
Panacea Holdings common stock	2,340	—
Total	$ 6,082	$ 12,343

Investment in Aurora Cannabis, Inc.

In 2018, in connection with the sale of its investment in a Canadian plant biotechnology company, the Company acquired stock warrants to purchase 973,971 common stock of Aurora Cannabis, Inc. ("Aurora"), a Canadian company (NYSE: ACB and TSX: ACB). The stock warrants have a five-year contractual term ending August 8, 2023 and had an exercise price of $9.37 Canadian Dollars (CAD) per share. During the second quarter of 2020, Aurora announced a 12-to-1 reverse stock split which adjusted our total warrant to purchase 81,164 shares of Aurora common stock (from 973,971) at an exercise price of $112.44 CAD per share (from $9.37 CAD per share). The warrants are considered equity securities in accordance with 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 to unrealized gain/loss as shown within the Company's Consolidated Statements of Operations and Comprehensive Loss. See Note 7 for additional information on the fair value measurements.

The carrying value of the Company's investments at December 31, 2021 and December 31, 2020 consisted of the following:

	December 31, 2021	December 31, 2020
Aurora stock warrants	$ 5	$ 239
Panacea preferred stock	—	5,173
Panacea stock warrant	—	1,124
Panacea Holdings common stock	2,340	—
Total Investments	$ 2,345	$ 6,536
Convertible note receivable	$ —	$ 5,876
Promissory note receivable	$ 3,741	$ —

NOTE 7. – 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, 2021 and December 31, 2020, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	Fair Value December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets				
Short-term investment securities:				
Money market funds	$ 8,919	$ —	$ —	$ 8,919
Corporate bonds	—	38,481	—	38,481
Total short-term investment securities	$ 8,919	$ 38,481	$ —	$ 47,400
Investment - Aurora stock warrants	$ —	$ —	$ 5	$ 5
Investment - Panacea Holdings common shares	$ 2,340	$ —	$ —	$ 2,340

	Fair Value December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets				
Short-term investment securities:				
Money market funds	$ 8,636	$ —	$ —	$ 8,636
Corporate bonds	—	12,677	—	12,677
Total short-term investment securities	$ 8,636	$ 12,677	$ —	$ 21,313
Investment - Aurora stock warrants	$ —	$ —	$ 239	$ 239
Investment - Panacea preferred stock	$ —	$ —	$ 5,173	$ 5,173
Convertible note receivable	$ —	$ —	$ 5,876	$ 5,876

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.

Corporate bonds are valued using pricing models maximizing the use of observable inputs for similar securities.

The investment in the Aurora stock warrants is measured at fair value using the Black-Scholes pricing model and is classified within Level 3 of the valuation hierarchy. The unobservable input is an estimated volatility factor of 92% and 137% as of December 31, 2021 and December 31, 2020, respectively. Therefore, changes in market volatility will impact the fair value measurement of our Aurora investment.

A 20% increase or decrease in the volatility factor used as of December 31, 2021 would have the impact of increasing or decreasing the fair value measurement of the stock warrants by an average of approximately $6. A 20% increase or decrease in the volatility factor used at December 31, 2020 would have the impact of increasing or decreasing the fair value measurement of the stock warrants by an average of approximately $115.

The investment in Panacea Holdings common shares is considered an equity security with a readily determinable fair value. The fair value is determined using the quotable market price as of the last trading day of the fiscal quarter.

The Panacea convertible note receivable and the preferred stock investment are considered available-for-sale debt securities with a private company 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 upon acquisition. See Note 6 for further information regarding the Company's investment in Panacea.

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, 2021.

Fair Value at December 31, 2019	$ 11,127
Unrealized loss as a result of change in fair value	(434)
Accretion of interest on Panacea investment	595
Fair Value at December 31, 2020	$ 11,288
Unrealized loss on Aurora stock warrants	(233)
Accretion of interest on Panacea preferred stock	142
Panacea investment conversion	(11,192)
Fair Value at December 31, 2021	$ 5

The following tables set forth a summary of the Company's available-for-sale debt securities from amortized cost basis to fair value as of December 31, 2021 and December 31, 2020:

	Available for Sale Debt Securities December 31, 2021			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 38,643	$ 1	$ (163)	$ 38,481

	Available for Sale Debt Securities December 31, 2020			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 12,603	$ 74	$ —	$ 12,677
Convertible note receivable	5,876	—	—	5,876
Investment - Panacea preferred stock	5,173	—	—	5,173
	$ 23,652	$ 74	$ —	$ 23,726

The following table sets forth a summary of the Company's available-for-sale debt securities from amortized cost basis and fair value by contractual maturity as of December 31, 2021 and December 31, 2020:

	Available for Sale Debt Securities			
	December 31, 2021		December 31, 2020	
	Amortized Cost Basis	Fair Value	Amortized Cost Basis	Fair Value
Due in one year or less	$ 8,286	$ 8,280	$ 11,692	$ 11,753
Due after one year through five years	30,357	30,201	11,960	11,973
	$ 38,643	$ 38,481	$ 23,652	$ 23,726

NOTE 8. – NOTES PAYABLE

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 was obligated to pay NCSU milestone payments totaling $1,200, which originally amounted to a present value of $1,175. As of June 30, 2020, the Company paid the final milestone payment of $300. The cost of the of acquired license amounted to $1,175 and is included in Intangible assets, net on the Company's Consolidated Balance Sheets, and is 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, of which $300 was payable upon execution, and $300 will be payable annually over 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. As of November 30, 2021, the Company paid the final milestone payment of $300. The cost of the of acquired licenses amounted to $1,151 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.

CARES Act Paycheck Protection Program Loan

On May 1, 2020, the Company received a U.S. Small Business Administration Loan ("SBA Loan") from Bank of America, N.A. related to the COVID-19 crisis in the amount of $1,200. On May 12, 2020, the Company repaid the SBA loan in full.

D&O Insurance

During the second quarter of 2021, the Company renewed its Director and Officer ("D&O") insurance for a one-year policy premium totaling $3,315. The Company paid $662 as a premium down payment and financed the remaining $2,653 of policy premiums over nine months at a 3.49% annual percentage rate.

During the second quarter of 2020, the Company renewed its D&O insurance for a one-year policy premium totaling $2,744. The Company paid $549 as a premium down payment and financed the remaining $2,195 of policy premiums over nine months at a 3.19% annual percentage rate.

The financed amount is recorded within current notes payable on the Company's Consolidated Balance Sheets.

The table below outlines our notes payable balances as of December 31, 2021 and December 31, 2020:

	December 31, 2021	December 31, 2020
License Fees	$ —	$ 293
D&O Insurance	596	246
Total current notes payable	$ 596	$ 539

Accretion of non-cash interest expense amounted to $7, $20, and $36 for the years ended December 31, 2021, 2020 and 2019, respectively.

NOTE 9. – SEVERANCE LIABILITY

During the second quarter of 2020, the Company recorded an accrual for severance benefits for $306 in accordance with FASB ASC 712 - "Compensation – Nonretirement Postemployment Benefits." Consistent with certain contractual obligations related to a resignation, the Company will provide these severance benefits over a twelve-month period.

During 2019, the Company recorded an accrual for severance benefits for $881 in accordance with FASB ASC 712 - "Compensation – Nonretirement Postemployment Benefits." Consistent with certain contractual obligations, $771 of the related accrual will be paid via a monthly consulting fee for a period of forty-two months.

The current and long-term accrued severance balance remaining as of December 31, 2021 was $217 and $21, respectively. The current and long-term accrued severance balance remaining as of December 31, 2020 was $339 and $241, respectively.

NOTE 10. – CAPITAL RAISE AND WARRANTS FOR COMMON STOCK

On June 7, 2021, the Company entered into a placement agent agreement (the "Placement Agent Agreement") with Cowen and Company, LLC (the "Placement Agent") relating to the Company's registered direct offering (the "Offering") to a select investor (the "Investor"). In addition, on June 7, 2021, the Company and the Investor entered into a securities purchase agreement relating to the issuance and sale of shares of common stock pursuant to which the Investor purchased 10,000,000 shares of common stock at $4.00 per share. The net proceeds to the Company from the Offering, after deducting Placement Agent fees and offering expenses, was $38,206.

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 $7,400. 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 $10,600 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 (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 in to a Warrant Amendment Agreement with the holders of the 2019 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.

During the first quarter of 2021, the Company’s warrant holders exercised all 11,293,211 outstanding warrants for cash in exchange for common stock. In connection with these exercises, the Company received net proceeds of $11,782. No warrants remain outstanding as of December 31, 2021. The following table summarizes the Company’s warrant activity since December 31, 2018:

	Number of Warrants
Warrants outstanding at December 31, 2018	11,293,211
Exercised	(11,293,211)
Issued	11,293,211
Warrants outstanding at December 31, 2019	11,293,211
Exercised	—
Issued	—
Warrants outstanding at December 31, 2020	11,293,211
Exercised	(11,293,211)
Issued	—
Warrants outstanding at December 31, 2021	—

NOTE 11. – 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, 2021, 2020 and 2019 amounted to $171, $150 and $157, respectively.

NOTE 12. – COMMITMENTS AND CONTINGENCIES

License agreements and sponsored research – The Company has entered into various license, sponsored research, collaboration, and other agreements (the "Agreements") with various counter parties in connection with the Company's plant biotechnology business relating to tobacco and hemp/cannabis. The schedule below summarizes the Company's commitments, both financial and other, associated with each Agreement. Costs incurred under the Agreements are generally recorded as research and development expenses on the Company's Consolidated Statements of Operations and Comprehensive Loss.

				Future Commitments						
Commitment	**Counter Party**	**Product Relationship**	**Commitment Type**	**2022**	**2023**	**2024**	**2025**	**2026 & After**	**Total**	
Research Agreement	KeyGene	Hemp / Cannabis	Contract fee	$ 1,150	$ 1,200	$ 1,227	$ 1,264	$ 1,630	$ 6,471	(1)
License Agreement	NCSU	Tobacco	Annual royalty fee	225	—	—	—	—	225	(2), (3)
License Agreement	NCSU	Tobacco	Minimum annual royalty	50	50	50	50	550	750	(2)
License Agreement	NCSU	Tobacco	Minimum annual royalty	50	50	50	50	450	650	(2)
Sublicense Agreement	Anandia Laboratories, Inc.	Hemp / Cannabis	Annual license fee	10	10	10	10	100	140	(3)
Growing Agreements	Various	Various	Contract fee	38	—	—	—	—	38	(4)
Consulting Agreements	Various	Various	Contract fee	1,370	808	—	—	—	2,178	(5)
				$ 2,893	$ 2,118	$ 1,337	$ 1,374	$ 2,730	$ 10,452	

(1) Exclusive agreement with the Company with respect to the *Cannabis Sativa L.* plant (the "Field"). The initial term of the agreement was five years with an option for an additional two years. On April 30, 2021, the Company and KeyGene entered into a First Amended and Restated Framework Collaborative Research Agreement which extended the agreement term, from first-quarter 2024 to first-quarter 2027, and preserves the Company's option for an additional 2-year extension, now through first quarter of 2029.

The Company will exclusively own all results and all intellectual property relating to the results of the collaboration with KeyGene (the "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.

(2) The Company is also responsible for reimbursing NCSU for actual third-party patent costs incurred, including capitalized patent costs and patent maintenance costs. These costs vary from year to year and the Company has certain rights to direct the activities that result in these costs.

(3) The Company is also responsible for the payment of certain costs, including, capitalized patent costs and patent maintenance costs, a running royalty on future net sales of products made from the sublicensed intellectual property, and a sharing of future sublicensing consideration received from sublicensing to third parties in all countries except for Canada. Anandia retains all patent rights, and is responsible for all patent maintenance, in Canada.

(4) Various R&D growing agreements for hemp / cannabis and tobacco.

(5) General corporate consulting agreements.

Litigation -

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 $1,891, 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

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*.

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*.

On May 28, 2019, the 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.

Plaintiffs in the *Bull* case filed an Amended Complaint on November 19, 2019 that 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. On July 31, 2020, the Court heard oral arguments on the motion to dismiss. On January 14, 2021, the Court granted motion, dismissing all claims with prejudice. The Plaintiffs filed a notice of appeal on February 12, 2021 to the Second Circuit Court of Appeals. The Second Circuit has granted an expedited briefing schedule and

Plaintiff's/Appellant's was filed on April 12, 2021 and the Company's was filed on May 17, 2021. The Second Circuit heard oral arguments on September 2, 2021 and the matter remains pending with the Second Circuit.

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.

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 generally alleging the same allegations as in the Klein case. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. On August 15, 2019, the Court consolidated the *Mathew* and *Klein* actions pursuant to a stipulation by the parties (Western District of New York, Case No. 1-19-cv-0513). 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 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 a 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.

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 generally the same allegations as the Brocutto case. 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.

On March 25, 2020, the Court ordered the *Brocutto* and *Wayne* cases consolidated and stayed pursuant to a joint stipulation from the parties. 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.

NOTE 13. – LOSS PER COMMON SHARE

The following table sets forth the computation of basic and diluted loss per common share for the years ended December 31, 2021, 2020 and 2019, respectively. Outstanding warrants, options, and restricted stock units were excluded from the calculation of diluted EPS as the effect was antidilutive.

	Year Ended December 31,		
	2021	2020	2019
	(in thousands, except for per-share data)		
Net loss	$ (32,609)	$ (19,711)	$ (26,558)
Weighted average common shares outstanding - basic and diluted	156,208	138,813	125,883
Net loss per common share - basic and diluted	$ (0.21)	$ (0.14)	$ (0.21)
Anti-dilutive shares are as follows as of December 31:			
Warrants	—	11,293	11,293
Options	5,171	6,581	7,837
Restricted stock units	3,165	2,938	951
	8,336	20,812	20,081

NOTE 14. – EQUITY BASED COMPENSATION

On May 20, 2021, the stockholders of 22nd Century Group, Inc. (the “Company”) approved the 22nd Century Group, Inc. 2021 Omnibus Incentive Plan (the “2021 Plan”). The 2021 Plan allows for the granting of equity awards to eligible individuals over the life of the 2021 Plan, including the issuance of up to 5,000,000 shares of the Company’s common stock, in addition to any remaining shares under the Company’s 2014 Omnibus Incentive Plan pursuant to awards under the 2021 Plan. The 2021 Plan 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 the 2021 Plan and the number of shares of common stock to underlie each such award under the 2021 Plan. As of December 31, 2021, the Company had available 7,526,630 shares remaining for future awards under the 2021 Plan.

Restricted Stock Units ("RSUs"). We typically grant RSUs to employees and non-employee directors. The following table summarizes the changes in unvested RSUs from December 31, 2018 through December 31, 2021.

	Unvested RSUs	
	Number of Shares	Weighted Average Grant-date Fair Value
	in thousands	$ per share
Unvested at December 31, 2018	—	$ —
Granted	1,301	$ 2.21
Vested	(100)	$ 2.02
Forfeited	(250)	$ 2.02
Unvested at December 31, 2019	951	$ 2.15
Granted	2,885	$ 0.71
Vested	(325)	$ 1.07
Forfeited	(573)	$ 1.90
Unvested at December 31, 2020	2,938	$ 0.85
Granted	2,200	$ 3.25
Vested	(1,660)	$ 0.85
Forfeited	(313)	$ 1.04
Unvested at December 31, 2021	3,165	$ 2.50

The fair value of RSUs that vested during the years ended December 31, 2021 and 2020 was approximately $5,262 and $601, respectively, based on the stock price at the time of vesting.

Stock Options. Our outstanding stock options were valued using the Black-Scholes option-pricing model on the date of the award. A summary of all stock option activity since December 31, 2018 is as follows:

	Number of Options in thousands	Weighted Average Exercise Price $ per share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2018	8,672	$ 1.54		
Granted	600	$ 2.07		
Exercised	(75)	$ 0.93		
Forfeited	(1,360)	$ 2.09		
Outstanding at December 31, 2019	7,837	$ 1.49		
Exercised	(399)	$ 1.04		
Forfeited	(169)	$ 1.83		
Expired	(688)	$ 1.51		
Outstanding at December 31, 2020	6,581	$ 1.50		
Granted	235	$ 3.10		
Exercised	(984)	$ 1.37		
Forfeited	(600)	$ 1.00		
Expired	(61)	$ 2.64		
Outstanding at December 31, 2021	5,171	$ 1.65	3.6 years	$ 7,431
Exercisable at December 31, 2021	4,836	$ 1.56	3.4 years	$ 7,375

The intrinsic value of a stock option is the amount by which the current market value or the market value upon exercise of the underlying stock exceeds the exercise price of the option.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. No option awards were granted in 2020. The following assumptions were used for the years ended December 31, 2021 and 2019:

	2021	2019
Risk-free interest rate (1)	0.54 %	1.54 %
Expected dividend yield (2)	— %	— %
Expected volatility (3)	87.92 %	70 %
Expected term of stock options (4)	4.09 years	5.15 years

(1) The risk-free interest rate is based on the period matching the expected term of the stock options based on the U.S. Treasury yield curve in effect on the grant date.
(2) The expected dividend yield is assumed as zero. The Company has never paid cash dividends nor does it anticipate paying dividends in the foreseeable future.
(3) The expected volatility is based on historical volatility of the Company's stock.
(4) The expected term represents the period of time that options granted are expected to be outstanding based on vesting date and contractual term.

Compensation Expense. The Company recognized the following compensation costs, net of actual forfeitures, related to RSUs and stock options:

	Year Ended December 31,		
	2021	2020	2019
Sales, general, and administrative	$ 3,821	$ 1,526	$ 3,166
Research and Development	162	128	374
Total RSUs and stock option compensation	$ 3,983	$ 1,654	$ 3,540

As of December 31, 2021, unrecognized compensation expense amounted to $4,685 which is expected to be recognized over a weighted average period of approximately 0.8 years. In addition, there is approximately $517 of unrecognized compensation expense that requires the achievement of certain milestones which are not yet probable.

NOTE 15. – INCOME TAXES

The following is a summary of the components giving rise to the income tax provision (benefit) for the years ended December 31, 2021, 2020 and 2019:

	2021	2020	2019
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Total current	$ —	$ —	$ —
Deferred:			
Federal	(7,566)	(3,932)	(5,607)
State	(1)	(200)	55
Total deferred	(7,567)	(4,132)	(5,552)
Change in valuation allowance	7,581	4,170	5,552
Total income taxes	$ 14	$ 38	$ —

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:

	2021	2020	2019
Statutory federal rate	(21.0)%	(21.0)%	(21.0)%
Other items	0.5	(0.3)	(0.1)
Litigation Settlement	—	—	1.5
Derivative liability	—	—	—
Stock based compensation	(2.7)	0.7	1.8
Research and development credit carryforward	(0.1)	0.2	(3.3)
State tax provision, net of federal benefit	—	(0.8)	0.2
Equity investment	—	—	—
Federal tax rate change	—	—	—
Valuation allowance	23.3	21.4	20.9
Effective tax rate (benefit) provision	— %	0.2 %	— %

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

	2021	2020	2019
Deferred tax assets:			
Net operating loss carry-forward	$ 24,859	$ 18,498	$ 14,996
Inventory	104	115	52
Stock-based compensation	1,326	1,099	1,049
Start-up expenditures	177	199	221
Research and development credit carryforward	1,192	1,171	1,209
Accrued bonus	411	423	200
Severance liability	50	122	134
Unrealized loss on investments	1,366	371	40
Operating lease obligations	365	52	127
Capital loss on investment	107	—	—
Other	18	18	22
	$ 29,975	$ 22,068	$ 18,050
Deferred tax liabilities:			
Machinery and equipment	(254)	(237)	(239)
Patents and trademarks	(373)	(358)	(351)
Gain on investment	—	(13)	(104)
Accrued expense	—	(24)	(51)
Operating lease right-of-use assets	(362)	(52)	(126)
Other intangible assets	(259)	(224)	(189)
	(1,248)	(908)	(1,060)
Valuation allowance	(28,779)	(21,198)	(16,990)
Net deferred taxes	$ (52)	$ (38)	$ —

The Company has net operating loss ("NOL") carryforwards of approximately $70,658 as of December 31, 2021, that do not expire. The Company had accumulated an NOL carryforward of approximately $46,920 through December 31, 2017 and this NOL carryforward begins to expire in 2031. As of December 31, 2021, the Company has a research and development credit carryforward of approximately $1,192 that begins to expire in 2031. The Company has a capital loss carryover of approximately $510 as of December 31, 2021, which expires in 2026. Utilization of these NOL 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, 2021.

NOTE 16. – REVENUE RECOGNITION

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. Revenue from the sale of the Company's products, which includes excise taxes and shipping and handling charges billed to customers, is recognized net of cash discounts, sales returns and allowances. There was no allowance for discounts or returns and allowances at December 31, 2021 and

December 31, 2020. Excise taxes recorded in Cost of Goods Sold on the Consolidated Statement of Operations and Comprehensive Loss for 2021, 2020, and 2019 were $10,135, $9,859, and $9,187, respectively.

Contract Assets and Liabilities

Unbilled receivables (contract assets) represent revenues recognized for performance obligations that have been satisfied but have not been billed. These receivables are included as Accounts receivable, net on the Consolidated Balance Sheets. 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. Deferred revenue (contract liabilities) relates to down payments received from customers in advance of satisfying a performance obligation. This deferred revenue is included as Deferred income on the Consolidated Balance Sheets.

Total contract assets and contract liabilities are as follows:

	December 31, 2021	December 31, 2020
Unbilled receivables	$ 178	$ 349
Deferred revenue	(119)	(272)
Net contract assets	$ 59	$ 77

Disaggregation of Revenue

The Company's net sales revenue is derived from customers located primarily in the United States of America and is disaggregated by the timing of revenue recognition—net sales transferred over time and net sales transferred at a point in time. Revenue is primarily related to contract manufacturing.

	Year Ended December 31,		
	2021	2020	2019
Net sales-over time	$ 21,061	$ 16,326	$ 16,466
Net sales-point in time	9,887	11,785	9,367
Total Revenue	$ 30,948	$ 28,111	$ 25,833

The Company had certain customers whose revenue individually represented 10% or more of the Company's total revenue. For the year ended December 31, 2021, three customers accounted for approximately 84% of total revenue. For the year ended December 31, 2020, two customers accounted for approximately 91% of total revenue. For the year ended December 31, 2019, three customers accounted for approximately 93% of total revenue.

NOTE 17. – SUBSEQUENT EVENT

Investment in Change Agronomy

On December 10, 2021, we entered into a subscription agreement to invest £500 (pounds sterling, in thousands), in exchange for 592,888 ordinary shares of Change Agronomy Ltd. ("CAL"), a private company existing under the laws of England, at a price per share of £0.84333. CAL is a vertically integrated sustainable industrial hemp business that combines world-class genetics with leading agronomic techniques and infrastructure to provide full-service industrial hemp products to multiple global end markets. CAL presently has operations in Manitoba, Canada, and Italy. This equity investment was part of an Offer for Subscription by CAL for a minimum total of £3,000 at the same price per ordinary share. Approximately U.S. $682 in funds were wired to CAL on January 26, 2022, and our investment of £500 equates to approximately 1.8% of CAL's total equity.

Item 15(b). Financial Statement Schedules

22nd CENTURY GROUP, INC. AND SUBSIDIARIES
SCHEDULE II-VALUATION AND QUALIFYING ACCOUNTS
($ in thousands)

Column A	Column B	Column C		Column D	Column E
	Balance at beginning of period	Charged to costs and expenses	Charged to other accounts	Deductions	Balance at end of period
Valuation allowance on net deferred tax assets:					
Year Ended December 31, 2021	$ 21,198	$ 7,581	$ —	$ —	$ 28,779
Year Ended December 31, 2020	$ 16,990	$ 4,208	$ —	$ —	$ 21,198
Year Ended December 31, 2019	$ 11,438	$ 5,552	$ —	$ —	$ 16,990
Allowance for slow moving or obsolete inventory:					
Year Ended December 31, 2021	$ 100	$ 317	$ —	$ (317)	$ 100
Year Ended December 31, 2020	$ 100	$ 521	$ —	$ (521)	$ 100
Year Ended December 31, 2019	$ 100	$ 985	$ —	$ (985)	$ 100

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	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).
3.1.1	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).
3.2	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).
3.2.1	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).
4.1*	Description of Securities Registered Pursuant to Section 12
10.1†	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).
10.2†	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)
10.3††	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).
10.3.1	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).
10.4	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).
10.5†	Form of Restricted Stock Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).
10.6†	Form of Stock Option Award Agreement (incorporated by reference to Form 10-Q filed on May 10, 2013).
10.7†	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).
10.8†	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).
10.9†	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 22, 2019).

10.10†	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).
10.11†	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).
10.12†††	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).
10.13†	Employment Agreement between the Company and James Mish (incorporated by reference to exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Commission on June 3, 2020).
10.14†	Employment Agreement between the Company and John Franzino (incorporated by reference to exhibit 10.2 of the Company's Current Report on Form 8-K filed with the Commission on June 3, 2020).
10.15†	22nd Century Group, Inc. 2021 Omnibus Incentive Plan (incorporated by reference from Appendix A to the Company's definitive proxy statement filed April 5, 2021)
10.16†	Form of Option Award Agreement under 22nd Century Group, Inc. 2021 Omnibus Incentive Plan (incorporated by reference to exhibit 10.2 of the Company's Current Report on Form 8-K filed with the Commission on May 21, 2021).
10.17†	Form of Executive RSU Award Agreement under 22nd Century Group, Inc. 2021 Omnibus Incentive Plan (incorporated by reference to exhibit 10.3 of the Company's Current Report on Form 8-K filed with the Commission on May 21, 2021).
10.18†	Form of Director RSU Award Agreement under 22nd Century Group, Inc. 2021 Omnibus Incentive Plan (incorporated by reference to exhibit 10.4 of the Company's Current Report on Form 8-K filed with the Commission on May 21, 2021).
10.19†††	First Amended and Restated Framework Collaborative Research Agreement between 22nd Century Group, Inc. and Keygene N.V. dated April 16, 2021 (incorporated by reference to exhibit 10.1 of the Company's Form 10-Q filed with the Commission on August 5, 2021).
10.20	Promissory Note Exchange Agreement between 22nd Century Group, Inc. and Panacea dated June 30, 2021 (incorporated by reference to exhibit 10.2 of the Company's Form 10-Q filed with the Commission on August 5, 2021).
10.21	Securities Exchange Agreement between 22nd Century Group, Inc. and PLS, Exactus, Inc. dated June 30, 2021 (incorporated by reference to exhibit 10.3 of the Company's Form 10-Q filed with the Commission on August 5, 2021).
10.22†	Employment Agreement between the Company and Richard Fitzgerald (incorporated by reference to exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Commission on November 19, 2021).
23.1*	Consent of Freed Maxick CPAs, P.C.
31.1*	Section 302 Certification.

31.2*	Section 302 Certification.
32.1*	Written Statement of Principal Executive Officer and Chief Financial Officer pursuant to 18.U.S.C §1350.
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*
Exhibit 104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 1, 2022 By: /s/ James A. Mish
James A. Mish
Chief Executive Officer and Director
(Principal Executive Officer)

Date:March 1, 2022 By: /s/ Richard F. Fitzgerald
Richard F. Fitzgerald
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 1, 2022 By:/s/ Nora B. Sullivan
Nora B. Sullivan
Director

Date:March 1, 2022 By:/s/ Richard M. Sanders
Richard M. Sanders
Director

Date:March 1, 2022 By:/s/ Clifford B. Fleet
Clifford B. Fleet
Director

Date:March 1, 2022 By:/s/ Roger D. O'Brien
Roger D. O'Brien
Director

Date:March 1, 2022 By:/s/ Dr. Michael Koganov
Dr. Michael Koganov
Director

Date:March 1, 2022 By:/s/ Anthony Johnson
Anthony Johnson
Director

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Leadership Team

James A. Mish
Chief Executive Officer

Richard Fitzgerald
Chief Financial Officer

Michael J. Zercher
President & Chief Operating Officer

Calvin Treat
Chief Scientific Officer

John Franzino
Chief Administrative Officer

John Ellegate
Vice President, Trade Marketing

John Pritchard
Vice President,
Regulatory Science

Steve Przybyla
General Counsel and Corporate Secretary

Nathan Schmitt
Vice President,
Operations

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

Board of Directors

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

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

Anthony Johnson
Director
Co-founder, President, & CEO,
Kodikaz Therapeutic Solutions

Dr. Michael Koganov
Director
President & Co-Founder,
Intellebio LLC

James A. Mish
Director
Chief Executive Officer,
22nd Century Group

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

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