**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, 2022**

**or**

**☐ Transition 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 pursuant to 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 pursuant to 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 ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, the last day of the registrant's most recently completed second fiscal quarter, was approximately $420 million based upon the closing price reported for such date on the Nasdaq Capital Market. On March 1, 2023, the registrant had 215,704,036 shares of common stock issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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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 be unsuccessful in our ability to integrate the operations of GVB Biopharma into ours and achieve the expected synergies with the acquired business.

- 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 "VLN" 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 biotechnology company focused on utilizing advanced alkaloid plant technologies to improve health and wellness with reduced nicotine tobacco, hemp/cannabis and hops. We use modern plant breeding technologies, including genetic engineering, gene-editing, and molecular breeding to deliver solutions for the consumer goods and pharmaceutical 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 products is dedicated to reduce the harms of smoking by commercializing our proprietary, very low nicotine content "VLNC" tobacco plants and cigarette products. We received the first and only Food and Drug Administration ("FDA") Modified Risk Tobacco Product ("MRTP") authorization of a combustible cigarette in December 2021. Beginning in April 2022, we launched our proprietary VLN® reduced nicotine cigarettes, first through a pilot program conducted in select Circle K stores in and around Chicago, Illinois. Following our successful pilot program, we initiated an ongoing state-by-state, region-by-region rollout strategy.

Our mission in hemp/cannabis is to develop and monetize proprietary varieties of hemp with valuable cannabinoid and terpene profiles and other superior agronomic traits. We are a global scale provider of cannabinoid ingredients and Active Pharmaceutical Ingredients ("API"), as well as a contract development and manufacturing organization (CDMO) provider of hemp-derived consumer products.

In hops, our mission is to leverage our experience with tobacco and hemp/cannabis, a close hop plant relative, to accelerate the development of proprietary specialty hop varieties with valuable traits, for 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. We continue to prioritize research and development activities to achieve our strategic and investment priorities.

#### Our Recent Acquisitions

In May 2022, we completed the acquisition of GVB Biopharma ("GVB"), a privately held contract development and manufacturing organization (CDMO). GVB is believed to be one of the largest providers of hemp-derived active ingredients for the pharmaceutical and consumer goods industries worldwide based on total tonnage. GVB has industry-leading market positions and expertise in many facets of the hemp/cannabis industry, which include: research and genetics, proprietary cryogenic hemp extraction; refining, conversion, and product formulation technology; leading supplier of API's; low-cost, scalable manufacturing capabilities; regulatory and compliance expertise; industry trusted high-quality products; and current international capabilities

We believe that GVB's strengths complement our existing upstream and downstream value chains, which includes expertise in cannabinoid receptor science with CannaMetrix, plant research, molecular breeding, and proprietary genetics through our KeyGene partnership, and breeding expertise with Extractas Bioscience (formerly Tasmanian Alkaloids PTY). The combination with us results in a vertically integrated, novel cannabinoid value chain by controlling the product cycle from plant genetics to finished ingredients and CDMO formulated products that meet exacting standards required by global consumer and products and pharmaceutical companies.

The acquisition of GVB has expanded our global footprint adding U.S. and international assets and capabilities. GVB operates three primary manufacturing facilities that have significant capacity to support growth. These three facilities are located in Grass Valley, Oregon (refinement facility), Las Vegas, Nevada (Private Label/Contract Manufacturing), and Prineville, Oregon (crude extraction). GVB's new Prineville, Oregon facility is one of the largest hemp extraction plants in the world, with expected CBD crude output capacity exceeding 15,000 kg/month at full capacity. The new facility is expected to be fully operational in the first half of 2023, allowing GVB greater vertical integration and improved gross margins as it ramps volume. We are actively pursuing additional business development through both our and GVB's existing relationships to further accelerate its growth.

In January 2023, we completed the acquisition of RX Pharmatech Ltd ("RXP"), a privately held leading United Kingdom distributor of cannabinoids with 1,276 novel food applications with the U.K. Food Standards Agency ("FSA"). RXP's products include CBD isolate and numerous variations of finished products like gummies, oils, drops, candies, tinctures, sprays, capsules and others. The U.K. is not accepting new novel food applications for cannabinoid products at this time and denied tens of thousands of product applications earlier in 2022 during the FSA's first round of screening. Accordingly, we believe this market dynamic could allow us to open new opportunities to land highly accretive contracts with multinationals for quality CBD and hemp-derived consumer products dependent on the novel food licenses.

**Tobacco Segment Overview**

We are dedicated to reducing the harms of smoking by commercializing our proprietary VLNC tobacco plants and cigarette products, which contain 95% less nicotine than conventional tobacco and cigarettes. The FDA publicly announced on July 28, 2017, that tobacco use remains the leading cause of preventable disease and death in the United States. The website 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 health 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. That said, CDC statistics state that while more than two-thirds of adult smokers want to quit successfully, less than ten percent of them are able to quit successfully.

Utilizing GMO and non-GMO methods, we have successfully modified and developed unique proprietary bright, burley, and oriental VLNC tobaccos that grow with at least 95% less nicotine than tobacco used in conventional cigarettes. In 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 CDC. Since 2011, we31.6 have provided more than 32.8 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 (measured in cigarettes per day), nicotine exposure and nicotine dependence with little to no evidence of compensatory smoking and without serious adverse events. A list of ongoing as well as 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. We do not incorporate third party studies or the information on our website into this Annual Report on Form 10-K.

Our reduced nicotine content cigarettes have been used in more than 50 independent scientific clinical studies by universities and institutions. These studies 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. Our research cigarettes, SPECTRUM®, continue to be used in numerous independent, scientific studies to validate the enormous public health benefit identified by the FDA and others of implementing a national product standard requiring all cigarettes to contain "minimally or nonaddictive" levels of nicotine. Our SPECTRUM® variable nicotine research cigarettes are the precursor to our VLN® cigarette products.

We believe that our proprietary reduced nicotine content cigarettes, sold under the brand name VLN®, have a large global market opportunity. According to a 2021 report by the Foundation for a Smoke Free World, global nicotine retail sales totaled approximately $853 billion and of that, 84.1% was comprised of combustible cigarettes. According to the CDC and the World Health Organization ("WHO"), there are more than 1 billion global and 30 million U.S. adult smokers. CDC statistics state that while more than two-thirds of adult smokers want to quit, less than ten percent of them are able to quit successfully. Despite the proliferation of vape and other nicotine delivery systems, we believe that smokers are still seeking alternatives to addictive combustible cigarettes. In our consumer perception studies, 60% of adult smokers indicated a likelihood to use VLN®.

Our VLN® cigarettes contain 95% less nicotine content than conventional cigarettes in a familiar combustible product format that replicates the conventional cigarette smoking experience, including the sensory and experiential elements of taste, scent, smell, and "hand-to-mouth" behavior. The tobacco in VLN® cigarettes contain a target of just 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." It is believed that the reduced nicotine content of VLN® creates a dissociation between the act of smoking and the rapid introduction of nicotine to the bloodstream, which helps adult smokers to smoke less.

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 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 ].

In December 2022, the New Zealand government parliamentary body passed the Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Bill requiring all combustible tobacco cigarettes sold in New Zealand to contain no more than 0.8 mg of nicotine per gram of tobacco. After becoming law by Royal Asset later that month, the requirement will take effect within 27 months.

We believe that recent political changes will likely be favorable to our business prospects from a policy priority and regulatory standpoint. Under the new leadership at the FDA and Center for Tobacco Products ("CTP"), we believe that the FDA will refocus on implementing 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 powerful catalyst for the FDA's proposed policies.

On January 27, 2022, the FDA posted an update on its FDA Voices site stating that it "remains on track" with its plans to prohibit menthol in combustible tobacco products. We continue to support upcoming FDA action and believe VLN® Menthol King reduced nicotine cigarettes could be exempted from the menthol ban to help current menthol smokers transition away from highly addictive nicotine cigarettes. The FDA published a proposed tobacco product standard to ban menthol as a characterizing flavor in cigarettes in April 2022. The proposed FDA rule includes a process for firms to request an exemption from the standard for specific products of certain types on a case-by-case basis, indicating "reduced nicotine" as an example of such an exemption. On August 1, 2022, we submitted public comments in support of a tobacco product standard for menthol in cigarettes.

Subsequently, in January 2023 the FDA's proposed ban on menthol as a flavoring in combustible cigarettes advance to final rule status, with expectations of a final decision in August 2023.

In June 2022, the FDA announced that the Biden-Harris Administration published plans for future regulatory action that includes the FDA's plans to develop a proposed product standard that would establish a maximum nicotine level to reduce the addictiveness of cigarettes and certain other combusted tobacco products. On June 21, 2022, a proposed rule for a tobacco product standard for nicotine level of certain tobacco products was published in the Spring 2022 Unified Agenda of Regulatory and Deregulatory Actions.

In late October 2022, in coordination with the FDA, the National Institute on Drug Abuse (NIDA), and others, we received an order for 2.8 million variable nicotine cigarettes. Our research cigarettes will continue to fuel numerous independent, scientific studies to validate the enormous public health benefits identified by the FDA and others of implementing a national standard requiring all cigarettes to contain minimally or non-addictive levels of nicotine.

We continue to advance on our reduced nicotine technology as 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 where GMO products are banned. Our patented, non-GMO technology can introduce very low nicotine traits into virtually any variety of tobacco, including bright, burley, and oriental. We have successfully applied our non-GMO technology to bright and burley varieties of tobacco and have initiated commercial growing activities for our non-GMO bright and burley reduced nicotine varieties. We anticipate commercial production of our American blend cigarettes featuring a mix of bright and burly VLN® tobacco varieties to begin in 2023.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 further 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, for our reduced nicotine 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 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 contains 95% less nicotine. Marketing product claims requires the FDA to authorize an MRTP application.

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,*" an evidence-based headline claim to our requested claims.

In previous years, we contracted with farmers to grow considerable quantities of VLNC tobacco in anticipation of FDA authorization of our 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. In April 2022, we launched 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*

In April 2022, we initiated VLN® sales in more than 150 Circle K stores in the Chicago metro area through a pilot launch. After the pilot concluded and, given the positive results, we made the decision to further deepen our reach in the state of Illinois and launch VLN® in Colorado to more than 3,000 potential locations across the state with our network of retailers and distribution partners, including Eagle Rock Distributing Company and Creager Mercantile.

The pilot enabled us to refine our VLN® rollout strategy and helped us develop our VLN® Sales Launch Blueprint, an efficient, reproducible sales plan that focuses our resources to achieve the greatest returns. In November 2022, we announced that we intend to expand our VLN® launch to Arizona, New Mexico, and Utah, and announced plans to expand into up to 18 U.S. states over the following 12 months. In January 2023 we announced distribution partnerships with Core-Mark International and Eby-Brown Company, two of the largest convenience store distributors in the U.S., providing access to retailers in virtually every key U.S. market.

By concentrating and going deeper into select geographies and markets with high cigarette volume and large adult smoker populations, we believe we can capture greater market share effectively. We also plan to target states where there is a tax exemption for MRTP products. As of March 1, 2023, we have secured regulatory authorizations to sell VLN® in 48 states and the District of Columbia.

To meet anticipated demand for our VLN® products in the U.S. and elsewhere, we contracted with third parties to plant our largest ever VLN® tobacco crop in 2022, which includes our second-generation reduced nicotine tobacco plants. We are seeing 30% higher yields, enhanced quality leaf, improved disease resistance, a reduction in nutrient inputs, and increased stability across various environments and geographies. We have also expanded our existing manufacturing operations to increase capacity by 25%, including installation of a new production line and initiation of a second shift.

*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.

*Tobacco 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, we became a subsequent participating manufacturer 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 began production of VLN® King and VLN® Menthol King cigarettes.

*Tobacco Sources of Raw Materials*

We obtain our reduced nicotine tobacco leaf from third party-growers, primarily 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 any other party. We purchase conventional tobacco destined for contract manufacturing operations 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 and 2022. In 2023, we will again grow substantial quantities of VLNC tobacco to supply the expansion of VLN® cigarette sales.

**Hemp/Cannabis Segment Overview**

Following the May 2022 acquisition of GVB, our hemp/cannabis business is a global scale provider of hemp-derived cannabinoid ingredients and API, as well as a CDMO to the consumer goods industry. We are also a solutions provider to companies that utilize cannabinoids in their consumer products, companies looking to optimize their plant genetics and companies seeking large-scale production of high-quality finished products. Our vertically integrated, novel cannabinoid value chain covers elements from receptor science and plant genetics to finished ingredients and CDMO formulated products that meet the exacting standards required by global consumer product and pharmaceutical companies.

Our innovative product development cycle can potentially produce new, disruptive, and highly differentiated product solutions, including plant lines or ingredients (flower, extracts, distillates, isolates, etc.) derived from hemp/cannabis plants. Most existing hemp/cannabis plant lines do not exhibit the stable genetics, predictable yield, and specific composition of cannabinoids required to fully unlock the value of the hemp/cannabis industry. We believe our plant genetics and innovative upstream cannabinoid value chain provide for rapid development and optimization of plant products and scale-up as the industry evolves toward mass production.

We believe we are set to be one of the largest providers of hemp-derived active ingredients for the pharmaceutical and consumer goods industries worldwide based on total tonnage. We have industry leading market positions and expertise in all facets of the hemp/cannabis industry, which include: research and genetics, proprietary cryogenic hemp extraction; refining, conversion, and product formulation technology; leading supplier of Active Pharmaceutical Ingredients (API); low-cost, scalable manufacturing capabilities; regulatory and compliance expertise; industry trusted high-quality products; current international capabilities

We believe that GVB's strengths complement our existing upstream and downstream value chains, which includes expertise in cannabinoid receptor science with CannaMetrix, plant research, molecular breeding, and proprietary genetics through our KeyGene partnership, and breeding expertise with Extractas Bioscience (formerly Tasmanian Alkaloids PTY). The combination of the Companies has resulted in a vertically integrated novel cannabinoid value chain by (1) controlling the product cycle from plant genetics to finished ingredients, (2) allows for CDMO formulated products that meet exacting standards required by global consumer products and pharmaceutical companies, and (3) has expanded our global footprint adding U.S. and international assets and capabilities.

At the time of the acquisition, GVB operated three primary manufacturing facilities with significant capacity to support growth with limited capital expenditure. These three facilities are located in Grass Valley, Oregon (refinement facility), Las Vegas, Nevada (Private Label/Contract Manufacturing), and Prineville, Oregon (crude extraction). Our new Prineville, Oregon facility is one of the largest hemp extraction plants in the world, with expected CBD crude output capacity exceeding 15,000 kg/month at full capacity. The new facility is expected to be fully operational in the first half of 2023, allowing us greater vertical integration and improved gross margins as it ramps volume. We are actively pursuing additional business development through both our and GVB's existing relationships to further accelerate its growth.

During the third quarter 2022, we passed the NSF International Audit with a grade A, and no deficiencies were found and, as a result, we obtained a renewal of our cGMP registration for Dietary Supplements Registration for our manufacturing facilities. NSF is one of the largest third-party compliance and standards organizations globally. It provides testing, auditing, and certification services, assuring suppliers that an independent organization has reviewed a product or system to comply with specific standards for safety, quality, sustainability or performance. Our cGMP registration encompasses dietary supplements, dietary ingredients, and functional food facility certification. With this audit and certification secured, we plan to pursue pharma-grade manufacturing.

In November 2022, a fire occurred at our Grass Valley manufacturing facility in Oregon, where we manufactured bulk ingredients, primarily CBD isolate and distillate. The site was safely evacuated and there were no serious reported injuries; however, there was extensive damage to the manufacturing site. We promptly shifted sourcing to alternate suppliers in order to continue fulfilling customer orders. Operations for bulk ingredient customers will have minor disruptions continuing in the first half of 2023. We are presently establishing interim distillate and isolate production capabilities, which we believe will replace the approximate capacity lost at our Grass Valley facilities. Longer term, we are evaluating options to build a comprehensive production and manufacturing campus with appropriate scale and expansion capabilities to meet both present and future demand requirements for our manufactured bulk ingredients.

In January 2023, we submitted a Drug Master File (DMF) to the FDA to produce and supply cannabinoid-based APIs for the medical and pharmaceutical industries requiring the highest quality cannabinoids in the U.S. We also expect to pursue The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q7 international pharma-grade audit standard certification so we can supply naturally derived hemp/cannabis APIs to companies globally.

In November 2022, we opened a central distribution facility in the Netherlands to support the growing demand for hemp/cannabis products in Europe, the Middle East, and Africa (EMEA). The facility is intended to speed up transaction flow and optimize cross border tax and customs treatment.

In January 2023, we completed the acquisition of RXP, a privately held distributor of cannabinoids with 1,276 novel food applications with the U.K.'s FSA. RXP has exclusively utilized GVB's technical data and worked closely with the FSA on developing their highly effective application and compliance programs that secured 1,276 novel food applications. RXP's products include CBD isolate and numerous variations of finished products like gummies, oils, drops, candies, tinctures, sprays, capsules and others.

*Hemp/Cannabis Regulatory Background*

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 March 1, 2023, (i) federal law and the laws of 50 states in the United States and the District of Columbia have legalized hemp to at least some degree, (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) 31 states in the United States, the District of Columbia, Guam, and the Northern Mariana Islands have decriminalized 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 working with legal hemp in full compliance with U.S. federal and state laws. Hemp and marijuana are from the same *cannabis* genus. One major difference is 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 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, and outside the U.S., we operate in full compliance with the laws of each country in which we operate.

In 2022, we expanded our research facilities in Rockville, Maryland with new state of art laboratory with more than 4,500 square feet and obtained a license in the State of Maryland to do research on and grow hemp.

*Hemp/Cannabis Partnerships*

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 collaboration with KeyGene, we are focused on traditional and molecular breeding along with genetic engineering using gene editing and mutagenesis to develop 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 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.

**Hops Business Overview**

On August 30, 2021, we announced our intention to commence research and development in hops, a plant that possesses similar biological characteristics to hemp/cannabis. We are leveraging our experience with tobacco and hemp/cannabis to accelerate the development of proprietary specialty hop varieties with valuable competitive advantages to increase yields and distinctive aroma, flavor, nutraceutical and medicinal properties, and disease/pest resistance. We believe that our innovative upstream alkaloid plant value chain is critical to unlocking new disruptive hop plant varieties and IP at large-scale. We are leveraging research findings from the closely related hemp/cannabis plant and our strategic partnerships to support the development of our new technologies based on molecular breeding, flowering time, and double haploid breeding to accelerate the stabilization or creation of hop varieties. Industry reliance on high-risk traditional breeding techniques makes hops ripe for disruption with our new accelerated molecular breeding technologies and gene editing tools.

Hops is a large global addressable market with well-established hops providers and consumer brands. We are actively engaged in discussions with multiple hops growers and consumer product partners to develop specific desired traits in leading hop strains that are already well-accepted by the brewing industry. In early 2022, we expanded our exclusive 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. We believe hops presents a faster route to commercialization than tobacco and hemp/cannabis due to lower regulatory barriers.

**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 provided for us 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 us from sales of products that contain any portions of the plant materials that have been received by us 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 provided for us 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 from sales of products that contain any portions of the plant materials that have been received 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.

In 2022, our R&D collaboration with NCSU delivered the proof of concept and field data for a new gene combination (non-GMO) to reduce nicotine below 95%. This unique gene combination enables the production of a better-quality leaf and an increase in yield. In January 2022, a utility patent to protect the new combination was filed. Our exclusive NCSU collaboration also yielded proof of concept and field data for Oriental lines with a 90-95% nicotine reduction. These results will give us the option in the future to produce VLN cigarettes that comprise burley, oriental, and bright tobacco thus improving overall quality. In addition, this year we extended our VLN production field trial to include new burley and flue-cured VLN (non-GMO).

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 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"), which further restricts third-parties from using such plants.

We also have exclusive plant variety protection rights in the United States and many other countries. PVP certificates are issued in the United States by the U.S. Department of Agriculture. 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 and gene-edited (new breeding techniques) varieties of other 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 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.

In the second quarter of 2022, a significant milestone in our research was the development of gene-editing transformation technology to create non-GMO plants in hemp/cannabis. We led the research with our partner KeyGene for this breakthrough in hemp/cannabis using a proprietary plant transformation and regeneration technology. This development allows us to use macronuclease constructs to gene edit the cannabis biosynthesis pathway. Another 2022 milestone from the KeyGene cannabis collaboration was the successful development of the directed mutagenesis program targeting 30 genes involved in cannabinoid biosynthesis, disease resistance, yield, and terpene regulations. This program will deliver a number of mutational changes (non-GMO) to relevant commercial traits.

In April 2022, we signed a development agreement and license of our hemp/cannabis lines to Extractas Bioscience (Australia). This agreement gives us the capability to enter the Asian/ Pacific region and test our lines for commercialization in the southern hemisphere. In addition, we extended for 2 years our development and exclusive IP license with CannaMetrix company. This collaboration is developing technology based on a cell-based assay for quantifying the potency (ED50) and efficacy of one or more cannabinoids and terpenoids, alone or in combination, using a cellular transduction mechanism.

**Government Regulation**

The development, testing, manufacturing, and marketing of our products and 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.

In April, 2022, the FDA announced proposed product standards to prohibit menthol as a characterizing flavor in cigarettes (Notice of Proposed Rule Making, NPRM) and prohibit all characterizing flavors (other than tobacco) in cigars. We provided a robust response to the public consultation on the rule in August 2022. We supported the proposed ban of menthol in highly addictive cigarettes and maintain that this rule should not extend to the companies previously authorized PMTA and MRTP products. In January 2023, the Semi-Annual Agenda for Fall 2022 was released in the US. Here, the Department of Health and Human Services (HHS), informed that it currently intends to issue a Final Rule on Menthol in Cigarettes. This product standard would prohibit menthol as a characterizing flavor in cigarettes, and is currently indicated to be issued in August, 2023. Similarly, in 2022, the State of California banned tobacco retailers from selling most flavored and menthol tobacco products, including VLN® Menthol King. The state of Massachusetts has similar laws prohibiting the sale of flavored tobacco sales, including menthol cigarettes. There has been increasing activity on the state and local levels with respect to scrutiny of menthol and flavored tobacco products.

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 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 reduced 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 in the hemp/cannabis industry are primarily smaller or niche companies focused in a specific product or service as opposed to our vertically integrated business model. 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, 2022, we had 198 employees, of which 99 are attributable to the acquisition of GVB. Substantially all employees are located in the United States 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.

**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.

We are a Nevada corporation and 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 and our web site address is included as an inactive textual reference only.

## 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.***

We have experienced net losses of approximately $59.8 million and $32.6 million during the years ended December 31, 2022 and 2021, respectively, and negative cash flow from operations of approximately $51.7 million during the year ended December 31, 2022.

While our current balance of cash and cash equivalents, short-term investment securities, working capital, and proceeds from senior secured credit facility are adequate to sustain our current planned operations, generating positive cash flows in the future will depend on our ability to successfully generate revenue from our contract manufacturing operations and sales of our VLN® cigarettes and hemp based cannabinoid products as well as our ability to cost-effectively develop, create, acquire, sell and/or 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 and many companies are selling hemp and cannabis-derived 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;
- be more effective in marketing and creating brand awareness of their products that we are;
- develop tobacco or hemp plants with superior traits to ours;
- 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 cost-effectively or at all, 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 be unable to successfully integrate GVB's operations into ours and, even if successfully integrated, we may be unable achieve the expected benefits of such acquisition.***

The integration of an acquired company requires, among other things, coordination of administrative functions, research and development operations, accounting and finance functions, and the expansion of information and management systems. Integration, especially a large integration such as the integration of GVB, may prove to be difficult due to the necessity of coordinating geographically separate organizations and integrating key personnel with disparate business backgrounds and accustomed to different corporate cultures. Any difficulties or problems encountered in the integration of GVB's business or operations could have a material adverse effect on our business.

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

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

We may continue to acquire or invest in complementary solutions, services, technologies, or businesses in the future, such as our acquisition of GVB. 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. In addition, we may only be able to conduct limited due diligence on an acquired company's operations. Following an acquisition, we may be subject to liabilities arising from an acquired company's past or present operations and these liabilities may be greater than the warranty and indemnity limitations that we negotiate. Any liability that is greater than these warranty and indemnity limitations could have a negative impact on our financial condition.

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 previously disrupted our business operations 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 caused delays by third party providers of goods or services to our business, the 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. 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.

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, 2022, we grew from nine (9) employees to one hundred ninety-eight (198) employees. The continued future growth in our business will place a significant strain on our managerial, administrative, operational, financial, information technology and other resources. We intend to continue to 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), widespread power outage or internet failure or hack, 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 in our efforts to commercialize our VLNC tobacco as a Modified Exposure Cigarette.***

While we have received authorization for our MRTP application by the FDA and have been rolling out our VLN® in select markets across the United States and abroad, 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 only rolled out the cigarettes on a limited basis. These products may not achieve consumer acceptance at levels that make the product commercially viable for profitable sales. In addition, the process of rolling out such product and creating consumer awareness could take longer and cost more than we expect. 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;
- successfully create consumer awareness of such products;
- 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);
- obtain cost-effective distribution outlets; 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 limited 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 limited experience in selling Modified Exposure Cigarettes. As we work towards commercializing one or more of our potential products for sale, including our VLN cigarettes, we 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.***

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

Our NASCO production facility is integral to our tobacco 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 serious injury or fatality, 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 distribute and sell our products outside of the U.S., which subjects us to other regulatory risks.***

In addition to the approval to market and sell our VLNC tobacco cigarettes as a Modified Exposure Cigarette in the U.S., we continue 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 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. In addition, the authorization to market our VLN® cigarettes as MRTP products was granted for a period of five years, which is the maximum duration for a marketing granted order for such products under the Family Smoking Prevention & Tobacco Control Act (PUBLIC LAW 111–31—JUNE 22, 2009). Consequently, the Company will need to reapply to FDA to under a new MRTP application to extend its marketing granted authorization beyond December 23, 2026. The MRTP authorization process is a complex, substantial and lengthy regulatory undertaking. The FDA may or may not grant continued authorization, based on FDA's assessment of whether the product application(s) satisfy the statutory requirements for such an order.. Any adverse action by the FDA to remove our products from the U.S. market or the

failure to have our authorization to market our VLN® cigarettes renewed would have a material adverse impact on our business.

***A ban on menthol or flavored tobacco products could have a material adverse impact on our business.***

On April 27, 2022, the FDA proposed new rules to prohibit menthol as a characterizing flavor in cigarettes and prohibit all characterizing flavors (other than tobacco) in cigars. There has been increasing activity on the state and local levels with respect to scrutiny of menthol and flavored tobacco products, including a recent law passed by the State of California prohibiting tobacco retailers from selling most flavored and menthol tobacco products, including VLN® Menthol King. If these proposed rules are finalized and implemented, if new rules are proposed or if additional states or governments pass laws similar to the State of California, we could be negatively impacted through decreased sales, a requirement to remove non-compliant tobacco products from the marketplace, associated interruptions in manufacturing or business disruptions. In addition, although we expect that our VLN® Menthol King reduced nicotine cigarettes will be exempted from FDA's menthol ban on cigarettes, there is no guarantee that they will be exempted by the FDA or any other state or local government. Accordingly, the implementation of these proposed or new laws or rules may have a material adverse impact on our results of operations.

**Risk Factors Related to the Hemp/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.

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.

***We have limited supply sources for industrial hemp, and price increases or supply shortages of key raw materials could materially and adversely affect our business, financial condition and results of operations.***

Our hemp-based cannabinoid products are composed of certain key raw materials. If the prices of such raw materials increase significantly, it could result in a significant increase in our product development costs. If raw material prices increase in the future, we may not be able to pass on such price increases to our customers. A significant increase in the price of industrial hemp or other raw materials that cannot be passed on to customers could have a material adverse effect on our business, financial condition and results of operations.

Our success will depend upon the availability of industrial hemp and other raw materials that permit us to meet our labeling claims and quality control standards. The supply of our industrial hemp is subject to the same risks normally associated with agricultural production, such as climactic conditions, insect infestations and availability of manual labor or equipment for harvesting. Any significant delay in or disruption of the supply of raw materials could substantially increase the cost of such materials, could require product reformulations, the qualification of new suppliers and repackaging and could result in a substantial reduction or termination by us of our sales of certain products, any of which could have a material adverse effect upon us. Accordingly, there can be no assurance that the disruption of our supply sources will not have a material adverse effect on us.

***Loss of key contracts with our customer and/or suppliers, renegotiation of such agreements on less favorable terms or other actions these third parties may take could harm our business.***

Most of our agreements with customers and suppliers of our industrial hemp and hemp-derived products are short term. The loss of these agreements, or the renegotiation of these agreements on less favorable economic or other terms, could limit our ability to procure raw material to manufacture and sell our products. This could negatively affect our ability to meet consumer demand for our products. Upon expiration or termination of these agreements, our competitors may be able to secure industrial hemp from our existing customers or suppliers which will put the company at a competitive disadvantage in the market.

***Our hemp production and processing facilities are integral to our hemp business and adverse changes or developments affecting our facilities may have an adverse impact on our business.***

Our hemp processing facilities are integral to our business and the licenses issued by applicable regulatory authorities is specific to each of these facilities. Adverse changes or developments affecting these facilities, including, but not limited to, disease or infestation of our crops, a fire (such as the fire in our Grass Valley, Oregon manufacturing facility), an explosion, a power failure, a serious injury or fatality, 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 at the affected facilities. While we believe that we maintain sufficient levels of insurance to potentially offset against the losses experienced in such an event, such insurance may not be sufficient to offset all of the costs and losses associated with such event (such as costs associated with finding temporary space and opportunity costs in the form of lost revenue or higher expenses) and in some events the insurance may not cover us at all. With respect to our fire in Grass Valley, while we expect to collect insurance to offset against some of our losses, such insurance will likely not be sufficient to offset against the opportunity costs associated with losing one of our manufacturing facilities.

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.

***Some jurisdictions may never develop markets for cannabis.***

Many jurisdictions place restrictions on or prohibit commercial activities involving cannabis. Such restrictions or prohibitions may make it impossible or impractical for us to enter or expand our operations in such jurisdictions unless there is a change in law or regulation.

***There is limited availability of clinical studies related to hemp-based products.***

Although hemp plants have a long history of human consumption, there is little long-term experience with human consumption of certain of these innovative product ingredients or combinations thereof in concentrated form. Although we perform research and/or tests the formulation and production of our products, there is limited clinical data regarding the safety and benefits of ingesting industrial hemp-based products. Any instance of illness or negative side effects of ingesting industrial hemp-based products would have a material adverse effect on our business and operations.

***Costs associated with compliance with various laws and regulations could negatively impact our financial results.***

The manufacture, labeling and distribution of hemp-based cannabinoid products is regulated by various federal, state and local agencies. These governmental authorities may commence regulatory or legal proceedings, which could restrict our ability to market such products in the future. The FDA regulates our products to ensure that the products are not adulterated or misbranded. We may also be subject to regulation by other federal, state and local agencies with respect to our hemp-based products. Our advertising activities are subject to regulation by the FTC under the Federal Trade Commission Act. In recent years, the FTC and state attorneys general have initiated numerous investigations of dietary and nutritional supplement companies and products. Any actions or investigations initiated against us by governmental authorities or private litigants could have a material adverse effect on our business, financial condition and results of operations. Any actions or investigations initiated against us by governmental authorities or private litigants could have a material adverse effect on our business, financial condition and results of operations.

The shifting regulatory environment necessitates building and maintaining of robust systems to achieve and maintain compliance in multiple jurisdictions and increases the possibility that we may violate one or more of the legal requirements applicable to our business and products. If our operations are found to be in violation of any applicable laws or regulations, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, injunctions, or product withdrawals, recalls or seizures, any of which could adversely affect our ability to operate our business, our financial condition and results of operations.

***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.

***International expansion of our business exposes us to additional regulatory risks and compliance costs.***

As we expand to engage in the international sale of our hemp-derived products, we will become subject to the laws and regulations of the foreign jurisdictions in which we operate, or in which we import or export products or materials, including, but not limited to, customs regulations in the importing and exporting countries. The varying laws and rapidly changing regulations may impact our operations and ability to ensure compliance. In addition, we may avail itself of proposed legislative changes in certain jurisdictions to expand our product portfolio, which expansion may include unknown business and regulatory compliance risks. Failure to comply with the evolving regulatory framework in any jurisdiction could have a material adverse effect on our business, financial condition and results of 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.

***We may be subject to product liability claims.***

As a manufacturer and distributor of products designed to be ingested by humans, we face an inherent risk of exposure to product liability claims, regulatory action and litigation if our products are alleged to have caused significant loss or injury. In addition, the manufacture and sale of hemp-derived products involve the risk of injury to consumers due to tampering by unauthorized third parties or product contamination. Previously unknown adverse reactions resulting from human consumption of hemp-derived products alone or in combination with other medications or substances could occur. We may in the future be subject to product liability claims that include, among others, our products caused injury or illness, incorrect labeling, inadequate instructions for use or inadequate warnings concerning possible side effects or interactions with other substances. A product liability claim or regulatory action against us could result in increased costs, could adversely affect our reputation with our consumers generally, and could have a material adverse effect on our business, financial condition and results of operations.

There can be no assurances that we will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive and may not be available in the future on acceptable terms, or at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of products.

***The presence of trace amounts of THC in our products may cause adverse consequences to users of such products that will expose us to the risk of litigation, liability and other consequences.***

Some of our products that contain hemp-derived CBD, or other hemp-derived cannabinoids, may contain trace amounts of THC. THC is a controlled substance in many jurisdictions, including under the federal laws of the U.S. Whether or not ingestion of THC (at low levels or otherwise) is permitted in a particular jurisdiction, there may be adverse consequences to consumers of our products who test positive for any amounts of THC because of the presence of trace amounts of THC in our hemp products. In addition, certain metabolic processes in the body may negatively affect the results of drug tests. Positive tests for THC may expose us to litigation from our consumers, adversely affect our reputation, our ability to obtain or retain customers and individuals' participation in certain athletic or other activities. A claim or regulatory action against us based on such positive test results could materially and adversely affect our business, financial condition, operating results, liquidity, cash flow and operational performance.

***Our cannabis operations are subject to risks inherent in an agricultural business.***

Our business involves the growing of cannabis, an agricultural product, in certain jurisdictions where that activity is permitted. As such, the business is subject to the risks inherent in the agricultural business, such as insects, plant diseases and similar agricultural risks that may create crop failures and supply interruptions for our customers and there can be no assurance that such risks will not have a similarly material adverse effect on the production of our products.

Hemp is typically harvested in or around the month of October and can be vulnerable to various pathogens including bacteria, fungi, viruses and other miscellaneous pathogens. Such instances often lead to reduced crop quality, stunted growth and/or death of the plant. Moreover, hemp is "phytoremediative" (meaning that it may extract toxins or other undesirable chemicals or compounds from the ground in which it is planted). Various regulatory agencies have established maximum limits for pathogens, toxins, chemicals and other compounds that may be present in agricultural materials. If hemp used in our products is found to have levels of pathogens, toxins, chemicals or other undesirable compounds that exceed limits permitted by applicable law, it may have to be destroyed. Should the hemp used in our products be lost due to pathogens, toxins, chemicals or other undesirable compounds, or if we or our suppliers are otherwise unable to obtain hemp for use in our products on an ongoing basis, it may have a material and adverse effect on our business, financial condition, operating results, liquidity, cash flow and operational performance.

***Competition from the illicit cannabis market could impact our ability to succeed.***

We face competition from illegal market operators that are unlicensed and unregulated including illegal dispensaries and illicit market suppliers selling cannabis and cannabis-based products. As these illegal market participants do not comply with the regulations governing the cannabis industry, their operations may have significantly lower costs. The perpetuation of the illegal market for cannabis may have a material adverse effect on our business, results of operations, as well as the perception of cannabis use.

**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:

- 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.**

Our principal executive office and headquarters is located in Buffalo, New York, a leased facility. As of December 31, 2022, we operated eight facilities primarily in the United States. Of these locations, the tobacco segment had one manufacturing facility, hemp/cannabis segment had three manufacturing or inventory storage facilities, one office space, and one owned farm. Additionally, we have one leased research and development laboratory. We believe the facilities we operate and their equipment are effectively utilized, well maintained, generally are in good condition, and will be able to accommodate our capacity needs to meet current and growing levels of demand. We continuously review our anticipated requirements for facilities and, on the basis of that review, may from time to time acquire additional facilities, expand or dispose of existing facilities.

**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, 2023, there were 183 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, 2022, we had available 4,461,984 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, 2022:

| | 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 | 8,945,064 (1) | $1.67 | 4,461,984 |
| Equity compensation plans not approved by security holders | — | N/A | — |
| Total | 8,945,064 | — | 4,461,984 (2) |

(1) Consists of outstanding options of 4,912,105 and unvested restricted stock units of 4,032,959.

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

**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. 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**

- Executive overview
- Recent business acquisitions
- Tobacco business highlights
- Hemp/cannabis business highlights
- Corporate business highlights
- Financial overview

**Our Financial Results**

- Fiscal 2022 compared with fiscal 2021
- Liquidity and capital resources
- Impact of recently issued accounting standards

**Critical Accounting Estimates**

- Inventories
- Valuation of long-lived assets
- Business combinations

**Executive Overview**

- 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."
- Commenced pilot market sales in Chicago during the first quarter of 2022 of VLN® King and VLN® Menthol King 95% reduced nicotine content cigarettes, the first and only FDA authorized MRTP designated combustible cigarettes.
- Based on strong pilot outcomes, announced plans for the expansion of VLN® into additional Illinois locations and the Colorado market as of September 2022. The Company also announced that it will launch VLN® in three additional states – Arizona, New Mexico, and Utah – covering the Four Corners region.
- Contracted the largest VLN® tobacco planting in 2022 to support expansion in both the U.S. and international markets.
- Announced an industry-first breakthrough in hemp/cannabis plant transformation with our partner KeyGene, expanding the Company's capabilities in modifying the principal genes controlling cannabinoid biosynthesis in the plant.

***Recent Business Acquisitions and Other Events***

- On May 13, 2022, we completed the acquisition of GVB Biopharma ("GVB"), a privately held contract development and manufacturing organization (CDMO). We believe GVB is one of the largest providers of hemp-derived active ingredients for the pharmaceutical and consumer goods industries worldwide based on total tonnage. GVB has industry leading market positions and expertise in all facets of the hemp/cannabis industry, including: research and genetics, proprietary cryogenic hemp extraction; refining, conversion, and product formulation technology; lead supplier of Active Pharmaceutical Ingredients (API); low-cost, scalable manufacturing capabilities; regulatory and compliance expertise; industry trusted high-quality products; and international capabilities

- On November 20, 2022, a fire occurred at the GVB Biopharma distillate and isolate manufacturing facility located in Grass Valley, OR. There were no reported life-threatening injuries, but the fire damaged the refinement facility requiring all hemp refining operations on site to be curtailed. Additional equipment and inventory stored in adjacent buildings was not damaged and was relocated to nearby facilities as part of the Company's business continuity plans. The Company subsequently commenced the insurance claims process and believes that losses resulting from the fire will be covered by its property and business interruption policies. Subsequent to the fire, the Company implemented backup sourcing and production plans to continue fulfilling customer orders and to resume production of distillate and isolate ingredients.

- On January 19, 2023, we acquired RX Pharmatech Ltd ("RXP"), a privately held leading United Kingdom distributor of cannabinoids with 1,276 novel food applications with the U.K. Food Standards Agency ("FSA"). RXP's products include CBD isolate and numerous variations of finished products like gummies, oils, drops, candies, tinctures, sprays, capsules and others. The U.K. is not accepting new novel food applications for cannabinoid products at this time and denied tens of thousands of product applications earlier in 2022 during the FSA's first round of screening. Accordingly, we believe this market dynamic could allow us to open new opportunities to land highly accretive contracts with multinationals for quality CBD and hemp-derived consumer products dependent on the novel food licenses.

Refer to Note 2 "Business Acquisitions" and Note 21 "Subsequent Events" of the Notes to Consolidated Financial Statements contained in Item 8 of this report for additional information about the acquisition of GVB and RXP.

***Tobacco Business Highlights***

- Leveraged the exceptional Chicago pilot results to expand VLN® sales in Illinois and launch in Colorado, where the state employs a favorable MRTP excise tax program. Announced additional launch plans in Arizona, New Mexico and Utah.
- Commenced an aggressive multi-state VLN® rollout strategy, targeting up 18 states by year-end 2023, aimed at penetrating geographies and markets with large adult smoker populations, including those with favorable MRTP state excise tax savings, which can be used toward consumer incentives, distribution support, and additional programming to raise awareness of VLN® products.
- Initiated agreements with national-scale C-store distribution partners, including Core-Mark/Eby-Brown and others pending, to facilitate state-wide or multi-state launches of VLN® at hundreds of stores within our target markets in an accelerated timeline.
- Announced expansion into Texas, California and Florida, expected in conjunction with the largest multi-state U.S. C-store chain leveraging these new national scale distribution capabilities.
- Secured additional retail point of sale placements with regional C-stores, such as Texas based CEFCO, and new regional distribution agreements with Hub, Inc., serving regional Midwestern and tribal accounts, and Chambers & Owen, Inc., serving the upper Midwest.
- Gained authorization to test VLN® sales at four United States military bases located in California, Arizona and North Carolina, beginning in the second quarter.
- Poised to benefit from federal, state and international regulatory appetite for banning menthol and mandating reduced nicotine content. The Company has the only FDA-authorized combustible cigarette able to meet the stringent reduced nicotine content product standard under the FDA's Comprehensive Plan requiring that all cigarettes be made "minimally or non-addictive."
    - Proposed FDA menthol cigarette ban, in final rules status, could leave VLN® Menthol King as the only combustible menthol cigarette on the market, providing a critical off-ramp to help current menthol smokers to smoke less, a final decision expected in August 2023.
    - In December 2022, New Zealand became the first country to pass a nationwide mandate permitting only reduced nicotine content cigarettes to be sold starting in early 2025.
- Planted the largest ever VLN® tobacco crop in 2022, including the second-generation VLN® 2.0 reduced nicotine tobacco plants, which have demonstrated approximately 30% higher yields, enhanced quality leaf, improved disease resistance, reduction in nutrient requirements and increased stability across various environments and geographies.
    - Announced a dedicated seed cultivation program designed to generate enough tobacco to support the entire New Zealand cigarette marketplace with reduced nicotine content tobacco, more than 2 billion sticks annually.
- Completed expansion of existing manufacturing operations and increased capacity by 25%, including installation of a new production line and initiation of a second shift.

***Hemp/Cannabis Business Highlights***

- Fundamentally shifted hemp/cannabis business, moving from primarily research and development efforts to a fully commercialized company with the acquisition of GVB Biopharma, a global scale provider of hemp-derived cannabinoid ingredients and API to the pharmaceutical and consumer goods industries with world-class CDMO capabilities.
- Positioned for global leadership as the largest provider of cannabinoid extracts and isolates in North America, focused on cannabidiol (CBD) and cannabigerol (CBG) extracted and refined at industrial scale into distillates.
- Completed vertical integration of novel cannabinoid value chain from receptor science to finished goods and now CDMO+D capabilities for complete category management to retail points of sale.
- Advancing multiple verticalized license agreements with major consumer CBD and alternative cannabinoid brands to manufacture and distribute key cannabinoid product offerings to retailers throughout the U.S. as a new turnkey solution for consumer facing cannabis product brands.
- Continued expanding CBD crude production capabilities with new Prineville, Oregon facility, one of the largest hemp extraction plants in the world, with expected capacity exceeding 15,000 kg/month at full operation, further improving gross margin on all GVB cannabinoid products.
- Responded to a fire at the Company's Grass Valley manufacturing facility, immediately shifting to alternate supply sources to fulfill all customer deliveries planned in the fourth quarter. New facilities are being established, replacing the prior capacity, as the Company plans for construction of a new, larger and more efficient distillate and isolate manufacturing campus.
- Submitted DMF to the FDA to produce and supply APIs for the medical and pharmaceutical industries while also pursuing The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q7 international pharma-grade audit standard certification in order to supply naturally derived hemp/cannabis APIs.
- Announced a global sales, marketing and distribution agreement with Cannabinoid API Solutions (CAS) and Transo-Pharm for APIs to accelerate opportunities to supply to the largest and most innovative pharmaceutical and consumer goods manufacturers.
- Acquired RX Pharmatech Ltd. in an accretive transaction securing a portfolio of 1,276 CBD product and ingredient based Novel Food Applications with the U.K. Food Standards Agency, accelerating CBD product growth in the U.K. and EU food and nutraceuticals markets.
- Announced the Company's central distribution facility in the Netherlands, opened in November 2022, will support growing demand for hemp/cannabis products in Europe, the Middle East, and Africa (EMEA).

***Corporate Business Highlights***

- Dr. Calvin Treat joined the Company as our Chief Scientific Officer on May 23, 2022, further enhancing our deep expertise in plant-based biotechnology across all three of our plant franchises. Dr. Treat has led global plant biotechnology programs at Bayer and Monsanto, including corn, soybean, and cotton crop improvement technologies.
- R. Hugh Kinsman was appointed Chief Financial Officer on June 16, 2022, expanding his role at GVB Biopharma to include corporate financial leadership functions.
- The Company announced that the position of President and Chief Operating Officer was eliminated effective September 30, 2022. James A. Mish, assumed the responsibilities of Corporate President, and operations have been integrated into the tobacco and hemp/cannabis business teams.
- Lucie S. Salhany was appointed to the Company's Board of Directors in September 2022, extending her experience in positioning unique products for successful launch, corporate strategy, and entrepreneurial ventures to help raise 22nd Century's profile in tobacco harm reduction and the hemp/cannabis industry.
- The Company announced that John Miller was appointed as an executive officer and President of Tobacco effective November 11, 2022. John J. Miller initially joined our tobacco business in May 2022, to help achieve the full potential of our tobacco franchise. Mr. Miller was the President and CEO of Swisher International, Inc., the largest manufacturer and exporter of cigars and smokeless tobacco products in America.

***Financial Overview – Fourth Quarter and Full Year 2022 Results***

- Net revenues for the fourth quarter of 2022 were $19,206, an increase of 141.3% from $7,960 in 2021.
    - Revenue from tobacco-related products was $9,951, an increase of 25.7% from 2021, primarily driven by volume increases in contract manufacturing and initial VLN® sales as part of the early rollout in Illinois and Colorado.
        - Fourth quarter 2022 cartons sold of 1,354 compared to 1,144 in the comparable prior year period.
    - Revenue from hemp/cannabis-related products was $9,255, compared to $43 in the prior year fourth quarter, reflecting the acquisition of GVB.
- Net revenues for the full year 2022 were $62,111, an increase of 100.7% from $30,948 in 2021.
- Gross profit for the fourth quarter of 2022 was a loss of $646 compared to profit of $231 in the prior year period.
    - Gross profit from tobacco-related products was $(44), a decrease of $400 compared to the prior year period, reflecting lower margin sales mix in contract manufacturing products.
    - Gross profit from hemp/cannabis-related products was a loss of $(601) compared to $(125) in the prior year. Margin declines in the fourth quarter were primarily due to impact of the Grass Valley fire. On a proforma basis, as if the GVB acquisition had occurred effective January 1, 2021, gross profit would have been $1,594 in the fourth quarter 2021.
- Gross profit for the full year 2022 was $1,174, a decrease of 21.0% from 2021.
- Total operating expenses for the fourth quarter 2022 increased to $22,512 compared to $9,262 in the prior year quarter driven by:
    - Sales, general and administrative expenses increased to $14,097 driven primarily by the acquisition of GVB, higher strategic consulting and marketing, legal, and personnel costs to expand the launch of VLN®
    - Research and development expenses increased to $2,093, driven by personnel expenses and costs associated with the Company's hemp/cannabis and hops research programs.
    - Other operating expenses, net was $6,322 reflecting the unusual and infrequent charges recorded in connection with the Grass Valley fire in November 2022.
- Operating loss for the fourth quarter 2022 was $23,158, compared to a loss of $9,031 in the prior year period. Operating loss for the full year 2022 was $57,106, compared to a loss of $28,412 in the prior year.
- Net loss in the fourth quarter of 2022 was $26,283, representing a net loss per share of $0.12 compared with net loss in the fourth quarter of 2021 of $13,964, representing a net loss per share of $.09. Net loss for the full year 2022 was $59,801, representing a net loss per share of $0.31 compared with net loss for the full year 2021 of $32,609, representing a net loss per share of $.21.
- As of December 31, 2022, we had $21,213 in cash, cash equivalents and short-term investments securities.
    - During the first quarter of 2023, the Company received $5,000 of casualty loss insurance recoveries from the Grass Valley fire with business interruption insurance claims proceeds expected thereafter.
    - On March 3, 2023, the Company announced a $21,052 senior credit facility to fund increased working capital needs related to the significant consumer demand for its VLN® product and GVB business lines.
        - The new three-year credit facility was issued at 5% original issuance discount (OID), will bear cash interest at a rate of 7% per annum, and commence principal amortization in the

second year at a rate of 2% of the original balance per month. The Company has the option to redeem the facility early starting in the second year.

- The Company's strengthened balance sheet supports growing working capital needs driven by increased VLN® product shipments to multiple national-scale distribution partners as well as strong customer demand for hemp/cannabis bulk ingredients.
- 22nd Century's operating cash requirements are anticipated to decrease through fiscal 2023, reflecting higher sales volume of higher margin contract manufacturing operations (CMO) cigarettes and VLN® products, as well as continued organic growth of GVB's operations.

**Our Financial Results**

The following table presents selected financial information derived from our Consolidated Financial Statements, contained in Item 8 of this report, for the periods presented (dollars in thousands, except per share amounts):

| | Year Ended | | Change | |
|---|---|---|---|---|
| | December 31 2022 | December 31 2021 | $ | % |
| Tobacco revenues, net | $ 40,501 | $ 30,905 | $ 9,596 | 31.0 |
| Hemp/cannabis revenues, net | 21,610 | 43 | 21,567 | NM |
| Total revenues, net | 62,111 | 30,948 | 31,163 | 100.7 |
| Cost of goods sold | 60,937 | 29,462 | 31,475 | 106.8 |
| Gross profit | 1,174 | 1,486 | (312) | (21.0) |
| *Gross profit as a % of revenues, net* | 1.9 % | 4.8 % | | |
| Operating expenses: | | | | |
| Sales, general and administrative ("SG&A") | 44,517 | 25,908 | 18,609 | 71.8 |
| *SG&A as a % of revenues, net* | 71.7 % | 83.7 % | | |
| Research and development ("R&D") | 6,561 | 3,912 | 2,649 | 67.7 |
| *R&D as a % of revenues, net* | 10.6 % | 12.6 % | | |
| Other operating expenses, net ("OOE") | 7,202 | 78 | 7,124 | 9,170.4 |
| Total operating expenses | 58,280 | 29,898 | 28,382 | 94.9 |
| Operating loss | (57,106) | (28,412) | (28,694) | 101.0 |
| *Operating loss as a % of revenues, net* | (91.9)% | (91.8)% | | |
| Other income (expense): | | | | |
| Unrealized loss on investment | (5) | (6,994) | 6,989 | (99.9) |
| Realized (loss) gain on Panacea investment | (2,789) | 2,548 | (5,337) | (209.5) |
| Realized loss on short-term investment securities | (366) | - | (366) | NM |
| Other income, net | 71 | - | 71 | NM |
| Interest income, net | 313 | 321 | (8) | (2.5) |
| Interest expense | (353) | (58) | (295) | 503.9 |
| Total other expense | (3,129) | (4,183) | 1,054 | (25.2) |
| Loss before income taxes | (60,235) | (32,595) | (27,640) | 84.8 |
| (Benefit) provision for income taxes | (434) | 14 | (448) | (3,196.5) |
| Net loss | $ (59,801) | $ (32,609) | (27,192) | 83.4 |
| *Net loss as a % of revenues, net* | (96.3)% | (105.4)% | | |
| Net loss per common share (basic and diluted) | $ (0.31) | $ (0.21) | (0.10) | 47.6 |

NM - calculated change not meaningful

Refer to Note 17, "Segment and Geographic Information," of the Notes to Consolidated Financial Statements contained in Item 8 of this report for additional information regarding operating results for our two operating and reportable segments: (1) Tobacco, (2) Hemp/cannabis.

***Fiscal 2022 Compared with Fiscal 2021***

***Revenue - Sale of products, net***

| | Year Ended | | Change | |
|---|---|---|---|---|
| | December 31 2022 | December 31 2021 | $ | % |
| Tobacco | $ 40,501 | $ 30,905 | $ 9,596 | 31.0 |
| Hemp/cannabis | 21,610 | 43 | 21,567 | NM |
| Total revenues, net | $ 62,111 | $ 30,948 | 31,163 | 100.7 |

The increase in revenue for the year ended December 31, 2022, compared to the year ended December 31, 2021, was primarily the result of an increase in tobacco revenue of $9,596 or 31.0% from 2021 primarily driven by volume increases in the number of cartons sold. Full year 2022 cartons sold were of 5,782 compared to 4,331 in the comparable prior year period.

Hemp/cannabis revenue was $21,610 in the current year compared to negligible revenues in 2021, primarily as a result of the GVB acquisition.

***Gross profit***

| | Year Ended | | Change |
|---|---|---|---|
| | December 31 2022 | December 31 2021 | $ |
| Gross profit | $ 1,174 | $ 1,486 | (312) |
| Percent of Revenues, net | 1.9 % | 4.8 % | |

The decrease in gross profit and gross profit as a percent of revenues, net for the year ended December 31, 2022, compared to the year ended December 31, 2021, was primarily driven by an increase of $218 from favorable tobacco volume offset by losses from hemp/cannabis of $530. Hemp/cannabis gross profit was unfavorable mainly due to non-recurring charges of $1,259, primarily attributable to amortization of inventory step-up resulting from the acquisition of GVB. Additionally, hemp/cannabis gross profits in the fourth quarter were negatively impacted from the Grass Valley fire. We anticipate subsequent recoveries in 2023 of gross profit negatively impacted by the fire through our business interruption insurance claims.

***Sales, general and administrative expense***

| | Change 2022 vs 2021 | |
|---|---|---|
| | $ | % |
| Compensation and benefits (a) | $ 2,922 | 24.9 |
| Legal (b) | 497 | 48.7 |
| Strategic consulting (c) | 4,994 | 63.9 |
| Sales and marketing (d) | 1,305 | 412.9 |
| Other (e) | 1,099 | 22.0 |
| GVB (f) | 7,793 | 100.0 |
| Net increase in SG&A expenses | $ 18,609 | 71.8 |

(a) Increases in compensation and benefits primarily due to $821 increased headcount mainly due to the increase in selling and marketing personnel driven by the ongoing expansion and accelerated launch of VLN®, $1,486 increase in equity comp ($1,237 related to accelerated vesting of an employee's outstanding equity awards as part of the termination severance agreement), and an increase of $615 in severance.

(b) Increased legal expenses due to regulatory compliance for VLN® launch, and enforcement of our patent portfolios.

(c) Increase of strategic consulting due to additional business development, recruitment, and investor relations expenses.

(d) Increases due to the ongoing expansion and accelerated launch of VLN®.

(e) Other expenses increased due to $529 of travel and entertainment, $239 of technology expenses, $215 in public accounting fees, and other $335 offset by a decrease in insurance expenses of $219.

(f) Increased SG&A as a result of the acquisition of GVB on May 13, 2022, including corporate personnel costs and general overhead.

***Research and development expense***

| | Change 2022 vs 2021 | |
|---|---|---|
| | $ | % |
| Compensation and benefits (a) | $ 438 | 72.3 |
| Contract costs (b) | 1,250 | 56.9 |
| Consulting and professional services (c) | 526 | 630.7 |
| Other (d) | 325 | 31.7 |
| GVB (e) | 110 | 100.0 |
| Net increase in R&D expenses | $ 2,649 | 67.7 |

(a) Increased compensation and benefits related to the additional executive and R&D personnel in the current year.

(b) Increased expenses due to our contracts related to field trials, hemp/cannabis programs, new hops R&D and royalty fees.

(c) Increased consulting to evaluate strategic opportunities related to our tobacco patent portfolio.

(d) Other increases include facilities expenses from our new Maryland lab, amortization expenses of new patents, increased patent maintenance costs and testing costs.

(e) Increased R&D as a result of the acquisition of GVB on May 13, 2022.

***Other operating expenses, net***

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Grass Valley fire: | | |
| Fixed asset write-offs | $ 5,550 | $ - |
| Inventory charges | 3,998 | - |
| Compensation & benefits | 195 | - |
| Professional services | 36 | - |
| Lease obligations | 20 | - |
| Insurance recoveries | (5,000) | - |
| Total Grass Valley fire (a) | 4,799 | - |
| Acquisition costs (b) | 1,046 | - |
| Impairment of intangible assets (c) | 1,488 | 78 |
| Impairment of inventory (c) | 237 | - |
| (Gain) loss on sale or disposal of property, plant and equipment (d) | (368) | - |
| Total other operating expenses, net | $ 7,202 | $ 78 |

(a) In November 2022, there was a fire at our Grass Valley manufacturing facility in Oregon, which manufactures bulk ingredients, primarily CBD isolate and distillate. The total charges of $9,799 were offset by $5,000 of insurance proceeds.

(b) Acquisition costs attributable to the acquisition of GVB on May 13, 2022.

(c) Other general charges include impairment of intangible assets that no longer meet the Company's strategic objectives and inventory impairment as a result of unavoidable casualty from a weather event.

(d) Reflects gain on sale resulting from sale of older tobacco manufacturing equipment.

Refer to Note 19, "Other operating expenses, net," of the Notes to Consolidated Financial Statements contained in Item 8 of this report for additional information regarding these charges.

***Other income (expense)***

| | Year Ended | | Change | |
|---|---|---|---|---|
| | December 31 2022 | December 31 2021 | $ | % |
| **Other income (expense):** | | | | |
| Unrealized loss on investment (a) | $ (5) | $ (6,994) | $ 6,989 | (99.9) |
| Realized (loss) gain on Panacea investment (b) | (2,789) | 2,548 | (5,337) | (209.5) |
| Realized loss on short-term investment securities | (366) | - | (366) | NM |
| Other income, net | 71 | - | 71 | NM |
| Interest income, net | 313 | 321 | (8) | (2.5) |
| Interest expense (c) | (353) | (58) | (295) | 503.9 |
| Total other expense | $ (3,129) | $ (4,183) | $ 1,054 | (25.2) |

NM - calculated change not meaningful

(a) Unrealized loss on investment includes fair value adjustments for our investment in Panacea Life Sciences Holdings, Inc. ("PLSH") during the year ended December 31, 2021 and Aurora Cannabis Inc ("Aurora") stock warrants during the years ended December 31, 2022 and 2021, respectively.

(b) Realized (loss) gain on PLSH investment reflects the change in fair value and write-off of our investment in PLSH common stock during the year ended December 31, 2022 of $2,340 and extinguishment of note receivable of $500 less adjusted discount of $51.

(c) Interest expense increased in 2022, as compared to the prior year period, primarily due to the interest recognized from the GVB bridge notes resulting from the GVB acquisition.

***Liquidity and Capital Resources***

| | December 31 2022 | December 31, 2021 |
|---|---|---|
| Cash and cash equivalents | $ 3,020 | $ 1,336 |
| Short-term investment securities | $ 18,193 | $ 47,400 |
| Working capital | $ 31,587 | $ 45,958 |

Cash, cash equivalents and short-term investment securities decreased by $27,523 primarily as a result of cash used in operating activities, offset by net proceeds from issuance of common stock in July 2022 described below.

***Working Capital***

As of December 31, 2022, we had working capital of approximately $31,587 compared to working capital of approximately $45,958 as of December 31, 2021, a decrease of $14,371. This decrease in working capital was primarily due to increases from normal fluctuations of current assets such as inventory (i.e. tobacco leaf grow) and an increase of $10,156 attributable to GVB, offset by a decrease of $27,523 in cash, cash equivalents and short-term investment securities.

***Summary of Cash Flow***

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Cash provided by (used in): | | |
| Operating activities | $ (51,714) | $ (22,839) |
| Investing activities | 22,578 | (27,729) |
| Financing activities | 30,820 | 50,875 |
| Net change in cash and cash equivalents | $ 1,684 | $ 307 |

***Net cash used in operating activities***

Cash used in operations increased $28,875 from $22,839 in 2021 to $51,714 in 2022. The primary driver for this increase was higher net loss of $27,192, driven by increased spending in SG&A and R&D both from the acquisition of GVB and acceleration of the launch of VLN®, an increase of $9,154 related to net adjustments to reconcile net loss to cash, and an increase in cash used for working capital components related to operations in the amount of $10,837 for the year ended December 31, 2022, as compared to the year ended December 31, 2021.

***Net cash provided by (used in) investing activities***

Cash provided by investing activities amounted to $22,578 in 2022 as compared to cash used in investing activities of $27,729 in 2021. The decrease in cash used in investing activities of $50,307 was primarily the result of a net increase in the net cash provided by our short-term investments in the amount of $55,235 offset by an increase in the cash used for acquisition of property, plant and equipment, the acquisition of patents, trademarks and licenses, acquisition of GVB and investment in Change Agronomy Ltd. in the amount of $3,358 for the year ended December 31, 2022 compared to the year ended December 31, 2021.

***Net cash provided by financing activities***

During the year ended December 31, 2022, cash provided by financing activities decreased by $20,055 resulting from (i) the net proceeds of $11,782 resulting from cash exercises of all outstanding warrants in 2021 that did not occur in 2022; (ii) the change in net proceeds of issuance of common stock of $5,722; (iii) the change in net proceeds pertaining to notes payable issuances and payments of $1,709; (iv) change in net proceeds from stock option exercises of $1,133. These decreases were partially offset by the change in cash paid for taxes related to settlement of restricted stock units of $320.

***Cash demands on operations***

Our principal sources of liquidity are our cash and cash equivalents, short-term investment securities, cash generated from our tobacco contract manufacturing business and hemp/cannabis business and proceeds from debt and equity financing activities. As of December 31, 2022, we had approximately $21,213 of cash and cash equivalents and short-term investments, and $5,000 insurance recovery receivable related to the Grass Valley fire, which we anticipate collecting in the first half of 2023. We have additional business interruption coverage with policy limits of up to $15,000, which we continue pursuing in connection with such incident.

As described below, on July 25, 2022, we completed a $35,000 above-market registered direct offering with institutional investors generating net proceeds of $32,484, and on March 3, 2023 we entered into a $21,052 senior secured credit facility generating net proceeds to us of approximately $20,000. Proceeds from these financing activities are intended to be used to continue with the launch of our VLN® products and to meet increased GVB customer demands and volume.

Our cash, cash equivalents, short-term investment securities, insurance recovery proceeds, and credit facility financing, as well as the sustained tobacco contract manufacturing and hemp/cannabis sales, will 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 well beyond the next twelve months. We are selectively deploying capital to accelerate the launch of VLN®, expand tobacco manufacturing operations, invest in GVB's production capacity and increase inventory levels to meet growing demand for both hemp/cannabis and tobacco products and for research and development. Our cash requirements in future periods are anticipated to decrease, reflecting higher sales volume for VLN® products through fiscal 2023 and continued organic growth of hemp/cannabis operations, providing adequate liquidity from the current balance sheet to complete our planned strategic initiatives.

***New Senior Secured Credit Facility***

On March 3, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with each of the purchasers party thereto (each, including its successors and assigns, a "Purchaser" and collectively, the "Purchasers") and JGB Collateral, LLC, a Delaware limited liability company, as collateral agent for the Purchasers (the "Agent"). Pursuant to the Purchase Agreement, the Company agreed to sell to the Purchasers (i) 5% Original Issue Discount Senior Secured Debentures (the "Debentures") with an aggregate principal amount of $21,052,632 and (ii) warrants to purchase up to 5,000,000 shares of the Company's common stock, par value $0.00001 per share (the "Common Stock"), for an exercise price of $1.275 per share, a 50% premium to the VWAP on the closing date (the "JGB Warrants"), subject to adjustments as set forth in the JGB Warrants, for a total purchase price of $20,000,000.

The Debentures bear interest at a rate of 7% per annum, payable monthly in arrears as of the last trading day of each month and on the maturity date. The Debentures mature on March 3, 2026. At the Company's election, subject to certain conditions, interest can be paid in cash, shares of the Company's common stock, or a combination thereof. The Debentures are subject to an exit payment equal to 5% of the original principal amount, or $1,052,632, payable on the maturity date or the date the Debentures are paid in full (the "Exit Payment"). Any time after, March 3, 2024, the Company may irrevocably elect to redeem all of the then outstanding principal amount of the Debentures for cash in an amount equal to the entire outstanding principal balance, including accrued and unpaid interest, the Exit Payment and a prepayment premium in an amount equal to 3% of the outstanding principal balance as of the prepayment date (collectively, the "Prepayment Amount"). Upon the entry into a definitive agreement that would effect a change in control (as defined in the Debentures) of the Company, the Agent may require the Company to prepay the outstanding principal balance in an amount equal to the Prepayment Amount. Commencing on March 3, 2024, at its option, the holder of a Debenture may require the Company to redeem 2% of the original principal amount of the Debentures per calendar month which amount may at the Company's election, subject to certain exceptions, be paid in cash, shares of the Company's common stock, or a combination thereof.

The JGB Warrants are exercisable for five years from September 3, 2023, at an exercise price of $1.275 per share, a 50% premium to the VWAP on the closing date, subject, with certain exceptions, to adjustments in the event of stock splits, dividends, subsequent dilutive offerings and certain fundamental transactions, as more fully described in the JGB Warrant.

*GVB Bridge Loan*

On March 3, 2023, the Company executed a Subordinated Promissory Note (the "Subordinated Note") with a principal amount of $2,864,767 in favor of Omnia Ventures, LP ("Omnia"). The Subordinated Note refinanced the 12% Secured Promissory Note with a principal amount of $1,000,000 dated as of October 29, 2021 payable to Omnia (the "October Note") and the 12% Secured Promissory Note with a principal amount of $1,500,000 dated as of January 14, 2022 payable to Omnia (the "January Note", and together with the October Note, the "Original Notes"), which were assumed by the Company in connection with the acquisition of GVB Biopharma.

Under the terms of the Subordinated Note, the Company is obligated to make interest payments in-kind (the "PIK Interest"). The PIK Interest accrues at a rate of 26.5% per annum, payable monthly. The Company is not permitted to prepay all or any portion of the outstanding balance on the Subordinated Note prior to maturity. The maturity date of the Subordinated Note is May 1, 2024.

***July 2022 Equity Raise***

On July 25, 2022, we completed a capital raise through a registered direct offering and issued 17,073 shares of common stock for net cash proceeds of $32,484. This excludes the proceeds, if any, from the exercise of the 17,073 warrants sold in the private placement that occurred concurrently with this offering.

***Impact of Recently Issued Accounting Standards***

In the normal course of business, we evaluate all new accounting pronouncements issued by the Financial Accounting Standards Board ("FASB"), SEC, or other authoritative accounting bodies to determine the potential impact they may have on our Consolidated Financial Statements. Refer to Note 1 "Summary of Significant Accounting Policies" of the Notes to Consolidated Financial Statements contained in Item 8 of this report for additional information about these recently issued accounting standards and their potential impact on our financial condition or results of operations.

**Critical Accounting Estimates**

Management's discussion and analysis of financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with GAAP. We make estimates and assumptions in the preparation of our consolidated financial statements that affect the reported amounts of assets and liabilities, revenue and expenses and related disclosures of contingent assets and liabilities. We base our estimates and judgments upon historical experience and other factors that are believed to be reasonable under the circumstances. Changes in estimates or assumptions could result in a material adjustment to the consolidated financial statements.

We have identified several critical accounting estimates. An accounting estimate is considered critical if both: (a) the nature of the estimates or assumptions is material due to the levels of subjectivity and judgment involved, and (b) the impact of changes in the estimates and assumptions have had or are reasonably likely to have a material effect on the consolidated financial statements. This listing is not a comprehensive list of all of our accounting policies. For further information regarding the application of these and other accounting policies, see Note 1 "Summary of Significant Accounting Policies" of the Notes to Consolidated Financial Statements contained in Item 8 of this report.

***Inventories***

Inventories are measured on a first-in, first-out basis at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The valuation of inventory requires us to estimate obsolete or excess inventory, as well as inventory that is not of saleable quality.

Historically, our adjustments or write-off charges recorded against inventory have been adequate to cover our losses. However, variations in methods or assumptions or volatility in spot pricing for hemp/cannabis could have a material impact on our results. Additionally, if our demand forecasts for specific products is greater than actual demand and we fail to reduce manufacturing output accordingly, we could be required to record additional inventory write-down or expense a greater amount of overhead costs, which would negatively impact our gross profit and net income.

***Valuation of Long-Lived Assets***

We make assumptions in establishing the carrying value, fair value and, if applicable, the estimated lives of our intangible and other long-lived assets. Goodwill and intangible assets determined to have an indefinite useful life are not amortized. Instead, these assets are evaluated for impairment on an annual basis on December 1, the measurement date, and whenever events or business conditions change that could indicate that the asset is impaired. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (asset group) may not be recoverable.

*Evaluation of goodwill for impairment*

We test each reporting unit's goodwill for impairment on the measurement date and between annual tests if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of a reporting unit below its carrying value. In conducting this annual impairment testing, we may first perform a qualitative assessment of whether it is more-likely-than-not that a reporting unit's fair value is less than its carrying value. A qualitative assessment requires that the Company consider events or circumstances including, but not limited to, macro-economic conditions, market and industry conditions, cost factors, competitive environment, changes in strategy, changes in customers, changes in the Company's stock price, results of the last impairment test, and the operational stability and the overall financial performance of the reporting units. If not, no further goodwill impairment testing is required. If it is more-likely-than-not that a reporting unit's fair value is less than its carrying value, or if we elect not to perform a qualitative assessment of a reporting unit, a quantitative analysis is performed, in which the fair value of the reporting unit is compared to its carrying value. To determine the fair values, the Company uses a weighted combination of the market approach based on comparable publicly traded companies and the income approach based on estimated discounted future cash flows. The

cash flow assumptions consider historical and forecasted revenue, operating costs and other relevant factors. If the carrying value of a reporting unit exceeds its fair value, an impairment loss is recognized equal to the excess, limited to the amount of goodwill allocated to that reporting unit.

We completed our annual goodwill impairment test as of December 1, 2022, and determined, after performing a quantitative assessment of the Hemp/cannabis reporting unit, the fair value of the Hemp/cannabis reporting unit exceeded its carrying amount. Resulting from the quantitative analysis, the fair value exceeded the carrying value of the Hemp/cannabis reporting unit by approximately 25%. We do not believe that any of our reporting units are at risk for impairment. However, changes to the factors considered above could affect the estimated fair value of one or more of our reporting units and could result in a goodwill impairment charge in a future period. We may be unaware of one or more significant factors that, if we had been aware of, would cause our conclusion to change, which could result in a goodwill impairment charge in a future period.

*Evaluation of indefinite-lived intangible assets for impairment*

Our indefinite-lived intangible assets include the certain trademarks and tradename and licenses. Similar to goodwill, we perform an annual impairment review of our indefinite-lived intangible assets on the last day of our fiscal year, unless events occur that trigger the need for an interim impairment review. We have the option to first assess qualitative factors in determining whether it is more-likely-than-not that an indefinite-lived intangible asset is impaired. If we elect not to use this option, or we determine that it is more-likely-than-not that the asset is impaired, we perform a quantitative assessment that requires us to estimate the fair value of each indefinite-lived intangible asset and compare that amount to its carrying value. Fair value is estimated using the relief-from-royalty method. Significant assumptions inherent in this methodology include estimates of royalty rates and discount rates. The discount rate applied is based on the risk inherent in the respective intangible assets and royalty rates are based on the rates at which comparable tradenames are being licensed in the marketplace. Impairment, if any, is based on the excess of the carrying value over the fair value of these assets.

For our indefinite-lived intangible assets—MSA, cigarette brand predicate and trademarks—we performed a qualitative evaluation and considered factors such as current and future sales projections, strategic objectives, future market and economic conditions, competition, and federal and state regulations. We determined it is more likely than not that that the assets are not impaired.

For our indefinite-lived intangible asset relate to the GVB tradename, we performed a quantitative assessment to test the asset for impairment as of December 1, 2022. The fair value was determined by utilizing the relief from royalty method with valuation assumptions consisting of royalty rate of 1.0% and discount rate of 24.5%. The estimated fair value was concluded to be below carrying value and as a result an impairment charge of $1,453 was recorded.

We do not believe that our indefinite-lived intangible assets are at risk for further impairment. However, a significant increase in the discount rate, decrease in the terminal growth rate, increase in tax rates, decrease in the royalty rate or substantial reductions in our revenue assumptions could have a negative impact on the estimated fair value of our tradename and require us to recognize additional impairment in a future period.

*Evaluation of long-lived assets for impairment*

When impairment indicators exist, we determine if the carrying value of the long-lived asset(s) or definite-lived intangible asset(s) including, but not limited to, PP&E and right-of-use lease assets, exceeds the related undiscounted future cash flows. In cases where the carrying value exceeds the undiscounted future cash flows, the carrying value is written down to fair value. Fair value is generally determined using a discounted cash flow analysis. When it is determined that the useful life of an asset (asset group) is shorter than the originally estimated life, and there are sufficient cash flows to support the carrying value of the asset (asset group), we accelerate the rate of depreciation/amortization in order to fully depreciate/amortize the asset over its shorter useful life.

Estimation of the cash flows and useful lives of long-lived assets and definite-lived intangible assets requires significant management judgment. Events could occur that would materially affect our estimates and assumptions. Unforeseen changes, such as the loss of one or more significant customers, technology obsolescence, or significant manufacturing disruption, among other factors, could substantially alter the assumptions regarding the ability to realize the return of our investment in long-lived assets, definite-lived intangible assets or their estimated useful lives.

***Business Combinations***

The Company accounts for business combinations in accordance with ASC Topic 805, *Business Combinations*. The fair value of the consideration paid is assigned to the underlying net assets of the acquired business based on the respective fair values of identifiable assets acquired and liabilities assumed on the date of acquisition. Any excess purchase price over the fair value of net assets acquired is recorded to goodwill. Determining the fair value of these items requires management's judgment and often also requires the use of independent valuation specialists. Fair value determinations and useful life estimates are based on, among other factors, estimates of expected future cash flows from revenues of the intangible assets acquired, estimates of appropriate discount rates used to present value expected future cash flows, estimated useful lives of the intangible assets acquired and other factors. The judgments made in the determination of the estimated fair values assigned to the assets acquired and the liabilities assumed, as well as the estimated useful life of certain assets and liabilities, can materially impact the financial statements in periods after acquisition, such as through depreciation and amortization expense. For more information see Note 2 "Business Combinations" of the Notes to Consolidated Financial Statements.

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**

Not required for smaller reporting companies.

**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, 2022.

On May 13, 2022, we completed a purchase of substantially all of the assets of GVB's business dedicated to hemp-based cannabinoid extraction, refinement, contract manufacturing and product development (the "Transaction"). As the Transaction occurred in the middle of 2022, the scope of our evaluation of the effectiveness of internal control over financial reporting does not include GVB. This exclusion is in accordance with the SEC's general guidance that an assessment of a recently acquired business may be omitted from our scope for a period not to exceed one year from the date of the acquisition.

The financial results of GVB are included in our consolidated financial statements from the date of acquisition. The financial results of GVB constituted 19% of total assets, 35% of revenues, net and 25% of net loss of the consolidated financial statement amounts as of and for the year ended December 31, 2022. The Company is in the process of evaluating the existing controls and procedures of the acquired business and integrating the acquired business into its system of internal control over financial reporting. As a result, management was unable, without incurring unreasonable effort or expense, to conduct an assessment of internal control over financial reporting for the acquired business.

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.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to a permanent exemption for smaller reporting companies.

**Changes in Internal Controls over Financial Reporting**

During the fourth quarter of 2022, we continued the process of evaluating the existing controls and procedures of GVB and integrating into its system of internal control over financial reporting.

Other than with respect to the integration of GVB, there was no change in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect our 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.

***Officers and Directors***

Set forth below is information regarding our directors, executive officers, and key personnel as of March 1, 2023:

| Name | Age | Position |
|---|---|---|
| James A. Mish | 59 | Chief Executive Officer and Director |
| John Franzino | 66 | Chief Administrative Officer |
| John J. Miller | 58 | President, Tobacco Division |
| R. Hugh Kinsman | 56 | Chief Financial Officer |
| Peter Ferola | 54 | Chief Legal Officer |
| Dr. Michael Koganov | 72 | Director |
| Richard M. Sanders | 69 | Director |
| Nora B. Sullivan | 65 | Director |
| Clifford B. Fleet | 52 | Director |
| Roger D. O'Brien | 74 | Director |
| Anthony Johnson | 47 | Director |
| Lucille S. Salhany | 76 | Director |

Directors:

*James A. Mish, Chief Executive Officer.* Mr. Mish has served as our Chief Executive Officer since June 22, 2020 and as a director since January 2022. He has an outstanding track record of delivering profitable growth at both privately-held and publicly-traded science-driven companies with a focus on pharmaceutical and consumer products commercialization. Prior to joining 22nd Century, he served as President and Chief Executive Officer of Purisys, a synthetic cannabinoid API, ingredients and solutions provider to pharmaceutical and consumer products companies, from 2019 to 2020 and Noramco, a global leader in the production of controlled substances for the pharmaceutical industry, from 2016 to 2019. There, Mr. Mish led the private equity carve out of Noramco from Johnson & Johnson/Janssen Pharmaceuticals and spearheaded the subsequent creation and spinoff of Purisys from Noramco. Mr. Mish began his career at Pfizer in research and development before holding positions of increasing responsibility at several companies including as President of Ashland Specialty Ingredients - Consumer Specialties, a major division of Ashland Corporation, a premier, global specialty materials company serving customers in a wide range of consumer and industrial markets from 2008 to 2016. Mr. Mish has a M.B.A. from The Wharton School of the University of Pennsylvania and a Bachelor of Science in Physics and Chemistry from Pennsylvania State University. Mr. Mish's strong leadership skills and pharmaceutical and consumer products experience led to our conclusion that he should serve as a director.

*Clifford B. Fleet.* Mr. Fleet has served as a director since his appointment on August 3, 2019 by the Board to fill a vacancy in the Class I director position resulting from the resignation of Henry Sicignano, III as of July 26, 2019. Mr. Fleet also served as the President and Chief Executive Officer of the Company from August 3, 2019 until December 13, 2019, at which time he resigned, effective on December 31, 2019. Mr. Fleet also served as a strategic advisor consultant to the Company from December 2018 to August 3, 2019. Mr. Fleet currently serves as the President and CEO of the Colonial Williamsburg Foundation, the world's largest living history museum and a national leader in American education. Prior to the Colonial Williamsburg Foundation, Mr. Fleet served as the President and CEO of 22nd Century Group. From 1995 to 2017 Mr. Fleet worked at Altria Group (NYSE: MO), serving in a variety of senior-level management positions in

Finance, Operations, Marketing, and Business Strategy and Development. From 2013 to 2017, Mr. Fleet served as the President and CEO of Philip Morris USA, Altria's largest subsidiary, when he ran Philip Morris USA, the nation's largest tobacco company, and John Middleton, a leading machine-made cigar manufacturer. During his tenure he led both organizations to business success in highly regulated environments. In addition, Mr. Fleet is an adjunct professor at the College of William & Mary teaching in the business school. Mr. Fleet holds a Bachelor of Arts, Master of Arts, Master of Business Administration and Juris Doctor from the College of William & Mary. Mr. Fleet's extensive experience in the tobacco industry led to our conclusion that he should serve as a director.

*Anthony Johnson*. Mr. Johnson has served as a director since August 2021 and is co-founder, President, and CEO of Kodikaz Therapeutic Solutions, a world-class next-generation non-viral gene therapy company since 2019. He is also a founding partner of Buffalo Biosciences in 2006, a life science strategic business management firm that supports the evaluation and commercialization of bioscience technologies from concept to market. Previously he was president and CEO of Empire Genomics, where he transformed a concept formed at a university lab into a preeminent oncology molecular testing enterprise, from 2006 - 2019. He also served as the business leader of the stem cell and regenerative medicine franchise for Thermo Fisher (Invitrogen Corporation). Mr. Johnson is an Aspen Institute Health Innovation Fellow and a member of the Aspen Global Leadership Network. He currently serves on the boards of several organizations including the WNED/PBS broadcasting service of Western New York. He has leveraged his business experience and board positions to mentor numerous technology startups and entrepreneurs, spur state and local job creation, and introduce STEM curriculum into early childhood education. Mr. Johnson is also a founding board member of the Communities of Giving Legacy Initiative, which works to create positive change in the lives of low-income youth of color via access to people, places, and experiences that help them achieve their life goals. Additionally, he serves as Michigan Street African-American Heritage Corridor Commissioner and was an Opportunities Council member for University of Buffalo. Formerly, he was a 15-year volunteer with the Big Brother Big Sister Foundation. Mr. Johnson holds an MBA from Manchester Business School, Manchester, UK, with an emphasis in international strategy, and a BA in biology from Fisk University, Nashville, TN. Mr. Johnson's experience commercializing bioscience technologies and life sciences experience led to our conclusion that he should serve as a director.

*Michael Koganov.* Dr. Koganov has served as a director since September 11, 2020. Dr. Koganov is recognized as a leading expert in the development of natural products using plant biotechnology and has achieved considerable accomplishments in physico-chemistry, biochemistry, bioelectrochemistry, and biotechnology. He is credited with developing Electro-Membrane technology for the comprehensive processing of plants to produce protein concentrates and secondary metabolites. Dr. Koganov co-founded Intellebio LLC, which developed the proprietary and sustainable Zeta Fraction™ technology that selectively isolates efficacious components from living plants and marine sources to produce a wide range of biofunctional ingredients. After the award-winning technology was acquired by AkzoNobel and then Ashland Global Holdings Inc., Dr. Koganov directed the research, product development, and commercialization of patented multifunctional bioactive Zeta Fractions that are used as key, signature ingredients in numerous products of global companies in the OTC and personal care spaces; and various synergistic compositions of Zeta Fractions obtained from living plants from twelve major plant families. He is the 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. Dr. Koganov received his Master of Science degree in Biochemistry from the State University, Dnipropetrovsk, USSR; his Ph.D. in Bioelectrochemistry from Institute of Chemical Technology, Dnipropetrovsk, USSR; and Full Doctor of Sciences (Sc.D.) degree in biotechnology from the Higher Attestation Commission of the USSR's Council of Ministers. He has written more than 70 publications, secured over 100 granted patents, and is the author of two books. Dr. Koganov's expertise in the area of plant biotechnology and experience developing novel technologies led to our conclusion that he should serve as a director.

*Roger D. O'Brien.* Mr. O'Brien has served as a director since his appointment on January 10, 2020 by the Board to fill a vacancy in the Class II director position resulting from the death of Dr. Joseph A. Dunn on November 30, 2019. Mr. O'Brien has served since 2000 as 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, marketing and strategy development. From 1998 to 1999, Mr. O'Brien served as the Chief Operating Officer of Ultralife Batteries, Inc. (NASDAQ: ULBI) and from 1991 to 1996, he was the Chief Executive Officer and a major shareholder of Holotek Ltd., a high-technology company with a proprietary position in the design, development, manufacture and sales of laser imaging systems worldwide. Previously, Mr. O'Brien

served as a senior executive for Exxon Venture Capital, Tenneco Automotive and as an early officer of Sun Microsystems (NASDAQ: SUN) prior to the company's acquisition by Oracle Corporation. Mr. O'Brien is currently a member of the Board of Directors of Innovative Technology Solutions and Bristol-ID Technologies, Inc. In addition, Mr. O'Brien is an adjunct professor at the Rochester Institute of Technology, where he is a graduate instructor in Rochester, New York and in Croatia. Mr. O'Brien holds a Bachelor of Science degree in Nuclear Engineering from New York University and an MBA degree from The Wharton School of the University of Pennsylvania. Mr. O'Brien's experience with strategic advisory consulting and his prior public company experience led to our conclusion that he should serve as a director.

*Lucille Salhany*. Ms. Salhany became a director in September 2022 pursuant to the terms of the Reorganization and Acquisition Agreement with GVB Biopharma. Ms. Salhany has served as President and Chief Executive Officer of JHMedia, a consulting company she founded, since 1997. She was also one of the founding partners of Echo Bridge Entertainment and CEO & President of LifeFX Networks, Inc. After serving as Chairperson of the Twentieth Television division of Fox, Ms. Salhany was appointed as the Chairmanship of Fox Broadcasting. After chairing Fox, Ms. Salhany accepted the post of Chief Executive Officer and President of United Paramount Network (UPN), launching and growing UPN to become the fifth major broadcast network. She also previously served on the Board of Directors for Echo Bridge Entertainment, Compaq / Hewlett-Packard, Fox, Inc., Avid Technologies, and American Media, Inc. Ms. Salhany was also a trustee of Emerson College and Lasell College, where she received Honorary Doctorates. Ms. Salhany's well-established track record of success in business and strong background in and knowledge of the media industry led to our conclusion that she should serve as a director.

*Richard M. Sanders*. Mr. Sanders has served as a director since December 9, 2013. 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. From January 2002 until June 2009, Mr. Sanders served as President and CEO of Santa Fe Natural Tobacco Company ("SFNTC"), a division of Reynolds American, Inc., which manufactures and markets the Natural American Spirit cigarette brand. During his 7-year tenure as head of SFNTC, Mr. Sanders tripled Natural American Spirit's market share and SFNTC's operating earnings and directed the successful expansion of Natural American Spirit into international markets in Western Europe and Asia. Prior to directing SFNTC's robust growth, Mr. Sanders worked for R.J. Reynolds Tobacco Company where he began his career as a marketing assistant in 1977. From 1987 to 2002, he served in a wide spectrum of executive positions including, among others, Senior Vice President of Marketing and Vice President of Sales. A native of Minneapolis, Mr. Sanders earned a Bachelor's Degree in political science from Hamline University in St. Paul and an M.B.A. Degree in Marketing from Washington University in St. Louis, Missouri. Mr. Sanders' deep experience in the tobacco industry and expertise in management and marketing led to our conclusion that he should serve as a director.

*Nora B. Sullivan.* Ms. Sullivan has served as a director since May 18, 2015. Ms. Sullivan is also currently President of Sullivan Capital Partners, LLC, a financial services company providing investment banking and mergers and acquisitions services to companies seeking acquisitive growth, strategic partnerships and joint venture relationships. Her experience includes the development and advancement of strategic initiatives and the implementation of best practice governance policies. Prior to founding Sullivan Capital Partners in 2004, Ms. Sullivan worked for Citigroup Private Bank from 2000 to 2004, providing capital markets and wealth management services to high net worth individuals and institutional clients. From 1995 to 1999, Ms. Sullivan was Executive Vice President of Rand Capital Corporation (NASDAQ: RAND), a publicly traded closed-end investment management company providing capital and managerial expertise to small and mid-size businesses. Ms. Sullivan is also a member of the Boards of Directors of Evans Bancorp, Inc. (NYSE American: EVBN), Robinson Home Products, and Rosina Food Products. She is also a member of the Investment Committee of the Patrick P Lee Foundation, Chairman of the Technology Transfer Committee of the Roswell Park Comprehensive Cancer Center, and a member of the Board of Directors of the Cortland College Foundation. Ms. Sullivan holds an M.B.A. Degree in Finance and International Business from Columbia University Graduate School of Business and a Juris Doctor degree from the University of Buffalo School of Law. Ms. Sullivan's expertise in finance and corporate governance, experience with mergers and acquisitions and status as an audit committee financial expert led to our conclusion that she should serve as a director.

Executive Officers:

For information with respect to Mr. Mish, please refer to the Directors section above.

*R. Hugh Kinsman*, *Chief Financial Officer*. Mr. Kinsman has served as our Chief Financial Officer since June 2022. Prior to that time, he was serving as Chief Financial Officer of GVB Biopharma and served in this role since March, 2020 Since 2017, Mr. Kinsman has served as a Director at TerraNova Capital Partners, a boutique investment banking firm, where he has served as CFO of several portfolio companies including iQ International, a leading manufacturer and distributor of highly efficient lead acid batteries for the global automotive and storage markets from 2017 to 2020. Previously, Mr. Kinsman served as a member of the Structured Finance group at GE Capital (NYSE: GE). Mr. Kinsman was also a senior accountant at Asher & Company, CPAs (now BDO). Mr. Kinsman received his B.S. in Finance from Pennsylvania State University and his Master's in Business Administration from Cornell University.

*John J. Miller*, *President of Tobacco*. Mr. Miller has served as our President of Tobacco since November 2022. Prior to that time, he was the President and CEO of Swisher International, Inc., a manufacturer and exporter of cigars and smokeless tobacco products in America. Mr. Miller joined Swisher in November of 2012 as Senior Vice President of Sales & Marketing, was promoted to President in 2017 and named CEO in March 2021 until his retirement in September 2021. Mr. Miller's experience also includes more than 20 years in various management positions at US Smokeless Tobacco Co. Mr. Miller holds a Bachelor of Science Degree in Finance from UNLV and earned an MBA from Pepperdine University, The George L. Graziadio School of Business Management.

*John Franzino, Chief Administrative Officer*. Mr. Franzino served as our Chief Financial Officer from June 3, 2020 until November 2021 when he transitioned to Chief Administrative Officer. He has a successful track record of strategic financial leadership in high-growth, highly regulated, consumer-facing industries as well as not-for-profit higher education organizations. Most recently, Mr. Franzino served as Chief Financial Officer of the West Point Association of Graduates, which supports the U.S. Military Academy at West Point. Prior to his experience in higher education, Mr. Franzino served as Chief Financial Officer of Santa Fe Natural Tobacco Company, a subsidiary of Reynolds American, Inc., and as Chief Financial Officer of Labatt USA, a subsidiary of Anheuser-Busch. In both roles, he was responsible for the financial planning and control function as well as information systems and technology. Mr. Franzino is a certified public accountant and holds a Master of Business Administration from Fairleigh Dickinson University and a Bachelor of Arts degree from the University of Maine at Farmington.

*Peter Ferola, Chief Legal Officer*. Mr. Ferola was promoted to the position of Chief Legal Officer in February 2023. Mr. Ferola has served as our General Counsel and Secretary since November 2022. Mr. Ferola has over 30 years of progressive leadership experience in business management, legal affairs and corporate governance. Most recently, he served as Project Counsel in Greenberg Traurig LLP's corporate securities group. From 2011 to 2020 he served as Senior Vice President and General Counsel at BioTelemetry, Inc. (NASDAQ: BEAT). From 2009 to 2011, Mr. Ferola served as Vice President, General Counsel and Secretary of Nipro Diagnostics, Inc. (formerly Home Diagnostics, Inc., NASDAQ: HDIX). Prior to joining Home Diagnostics, Mr. Ferola worked as a corporate and securities attorney with Greenberg Traurig, LLP and with Dilworth Paxson, LLP in Washington, D.C., focusing on mergers, acquisitions, public securities offerings and corporate governance matters. From 1989 to 2002, Mr. Ferola worked in executive management roles for an American Stock Exchange listed company, most recently serving as Vice President—Administration and Corporate Secretary, overseeing the company's administrative functions, legal matters and investor relations. Mr. Ferola earned a Bachelor of Science and Juris Doctor degree from Nova Southeastern University and a Master of Laws in Securities and Financial Regulation from Georgetown University Law Center. Mr. Ferola has authored numerous articles on corporate and securities laws, with a particular focus on audit committees and regulations implemented in the wake of the Sarbanes-Oxley Act. Mr. Ferola also serves as a FINRA arbitrator and a panelist on the NASDAQ Listing Qualifications Panel.

***Corporate Governance***

The Company's Board of Directors is classified into three classes of directors, with one class of directors being elected at each annual meeting of stockholders of the Company to serve for a term of three years or until the earlier of: (i) expiration of the term of their class of directors; or (ii) until their successors are elected and take office. The Bylaws of the Company provide that the Board will determine the number of directors to serve on the Board. The number of authorized directors of the Company as of March 1, 2023 is eight, with eight persons currently serving as directors (three Class II directors, two Class I directors and two Class III directors). There are no family relationships among our directors.

Our Board held 8 meetings during 2022. All directors attended at least 75% of all meetings of the Board and Board committees on which they served during 2022. We do not have a formal policy requiring directors to attend annual meetings of stockholders. However, all of our directors attended our 2022 annual meeting and we anticipate that all of continuing directors will attend the 2023 annual meeting.

Our Board of Directors currently has three standing committees: (i) an Audit Committee, (ii) a Compensation Committee, and (iii) a Corporate Governance and Nominating Committee. Each of these Board committees are described below. Members of these committees are elected annually by the Board. The charters of each committee are each available on the investor relations section of our website at www.xxiicentury.com. In addition, we have a Scientific Advisory Board which is chaired by Michael Koganov.

*Audit Committee*

| MEMBERS | KEY RESPONSIBILITIES |
|---|---|
| **Nora B. Sullivan*, Chair**<br>**Anthony Johnson**<br>**Richard M. Sanders**<br>**Dr. Michael Koganov**<br><br>The Board has determined that each member of the audit committee is independent as defined under the applicable listing standards of the Nasdaq Stock Market and Rule 10A-3 under the Securities Exchange Act of 1934, as amended.<br><br>**The Committee met 4 times in 2022** | ▪ Assists the Board in monitoring the integrity of financial statements and our compliance with legal and regulatory requirements;<br>▪ Reviews the independence and performance of our internal and external auditors;<br>▪ Has the ultimate authority and responsibility to select, evaluate, terminate and replace our independent registered public accounting firm;<br>▪ Has oversight of the Company's policies with respect to risk assessment and risk management; and<br>▪ Approves the Audit Committee Report. The report further details the Audit Committee's responsibilities.<br><br>*Audit Committee Financial Expert: Our Board has determined that Ms. Sullivan qualifies as an "audit committee financial expert" as defined by the rules of the Securities and Exchange Commission. Furthermore, all members of the Audit Committee meet the financial literacy requirements of the Nasdaq Stock Market and no members of the Audit Committee serves on the Audit Committee of more than three public companies. |

*Compensation Committee*

| MEMBERS | KEY RESPONSIBILITIES |
|---|---|
| **Richard M. Sanders, Chair**<br>**Nora B. Sullivan**<br>**Dr. Michael Koganov**<br>**Lucille Salhany**<br><br>The Board has determined that each member of the Compensation Committee is independent within the meaning of the Company's independence standards and applicable listing standards of the Nasdaq Stock Market.<br><br>**The Committee met 7 times in 2022** | ▪ Establishes and regularly reviews our compensation and benefits philosophy and program in a manner consistent with corporate financial goals and objectives;<br>▪ Approves compensation arrangements for senior management, including annual incentive and long-term compensation;<br>▪ Administers grants under our equity incentive plans;<br>▪ Evaluates our CEO's performance; and<br>▪ Reviews leadership development and succession planning. |

*Corporate Governance and Nominating Committee*

| MEMBERS | KEY RESPONSIBILITIES |
|---|---|
| **Anthony Johnson, Chair**<br>**Nora B. Sullivan**<br>**Lucille Salhany**<br><br>The Board has determined that each member of the Corporate Governance and Nominating Committee is independent within the meaning of the Company's independence standards and applicable listing standards of the Nasdaq Stock Market.<br><br>**The Committee met 6 times in 2022** | ▪ Assists our Board in establishing criteria and qualifications for potential Board members;<br>▪ Identifies high quality individuals who have the core competencies, characteristics and experience to become members of our Board;<br>▪ Establishes corporate governance practices in compliance with applicable regulatory requirements and consistent with the highest standards, and recommends to the Board the corporate governance guidelines applicable to us;<br>▪ Leads the Board in its annual review of the Board's performance;<br>▪ Recommends nominees for each committee of the Board; and<br>▪ Oversees the Company's Environmental Social and Governance ("ESG") policies and practices. |

*Scientific Advisory Board*

| MEMBERS | KEY RESPONSIBILITIES |
|---|---|
| **Dr. Michael Koganov, Chair**<br>**James A. Mish**<br>**Anthony Johnson**<br><br>The Scientific Advisory Board met 1 time in 2022 | Provides advice and recommendations to the Board regarding:<br>▪ Company scientific research, technology and innovation strategies;<br>▪ opportunities including potential partnerships and M&A; and<br>▪ emerging science and technology issues and trends. |

*Director Nominee Selection Process*

Our Corporate Governance and Nominating Committee evaluates the specific personal and professional attributes of each director candidate versus those of existing Board members to ensure diversity of competencies, experience, personal history and background, thought, skills and expertise across the full Board. In the evaluation of director candidates, our Corporate Governance and Nominating Committee gives consideration to diversity in terms of gender, ethnic background, age and other similar attributes that could contribute to Board perspective and effectiveness. The Corporate Governance and Nominating Committee also assesses diversity through its annual assessment of Board structure and composition and annual Board and committee performance self-assessment process. We believe that fostering Board diversity best serves the needs of the Company and the interests of its stockholders, and it is one of the many factors considered when identifying individuals for Board membership. We believe that diversity with respect to gender, ethnicity, tenure, experience and expertise is important to provide both fresh perspectives and deep experience and knowledge of the Company.

When vacancies develop, the Corporate Governance and Nominating Committee solicits input regarding potential new candidates from a variety of sources, including existing directors and senior management. From time to time, we have used an executive search firm in search of candidates that have diversity in experience, skills and perspective. Through these and other means, the Board has continued to refresh the Board by adding directors who bring a sufficient range of different perspectives, generate appropriate challenge and discussion, and fulfill its oversight responsibilities to foster significant value creation for our stockholders. The Committee evaluates potential candidates based on their background, experiences and qualifications and also arranges personal interviews of qualified candidates by one or more committee members, other Board members and senior management.

*Stockholder Recommendations for Potential Director Nominees*

Nominations of persons for election to the Board at the annual meeting may also be made by any stockholder entitled to vote for the election of directors at the meeting who complies with the notice procedures set forth in our bylaws. Such nominations by any stockholder shall be made pursuant to timely notice in writing to the Secretary. To be timely, a stockholder's notice shall be delivered to the Secretary at our principal executive offices not later than the close of business on the ninetieth (90th) day nor earlier than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than thirty (30) days before or more than seventy (70) days after such anniversary date, notice by the stockholder must be so delivered not earlier than the close of business on the one hundred twentieth (120th) day prior to such annual meeting and not later than the close of business on the later of the ninetieth (90th) day prior to such annual meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made.

*Delinquent Section 16(a) Reports*

Section 16(a) of the Exchange Act, requires our executive officers, directors, and "beneficial owners" of more than 10% of our common stock to file stock ownership reports and reports of changes in ownership with the SEC. Based on a review of those reports and written representations from the reporting persons, we believe that during 2022, all transactions were reported on a timely basis except for a late Form 3 by R. Hugh Kinsman reporting his initial ownership and a late Form 4 (filed on Form 5) by James A. Mish reporting the withholding of shares to satisfy tax liability upon the vesting of restricted stock.

**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.**

***Executive Compensation***

**Compensation Discussion and Analysis**

This compensation discussion and analysis describes the material elements of compensation awarded to, earned by, or paid to each of our named executive officers, whom we refer to as our "NEOs," during 2022 and describes our policies and decisions made with respect to the information contained in the following tables, related footnotes and narrative for 2022. The NEOs are identified below under "Our Named Executive Officers." In this compensation discussion and analysis, we also describe various actions regarding NEO compensation taken before or after 2022 when we believe it enhances the understanding of our executive compensation program.

*Our Named Executive Officers*

**James A. Mish**
Chief Executive Officer

**R. Hugh Kinsman**
Chief Financial Officer

**John J. Miller**
President of Tobacco Division

**John Franzino**
Chief Administrative Officer

**2022 Financial Highlights**

2022 was a strong year for us, as we shifted our business to commercial activity, positioned ourselves to meet and out-perform our long-term strategic financial metrics, and accomplished acquisitions intended to strengthen our position in key markets. In April, we commenced a successful Chicago-area pilot program for our VLN® reduced nicotine content tobacco cigarettes with our partner, Circle K, after which we leveraged the pilot results into additional consumer market testing, allowing us to expand distribution to both Illinois and Colorado. In addition to this, our success in those markets has led to the announcement of plans for our launch in Arizona, New Mexico and Utah. We acquired GVB Biopharma in May 2022, which we believe to be the North American leader in cannabinoid supply by volume, commencing revenue

operations in our hemp/cannabis business unit and adding a comprehensive CDMO capability. This acquisition expanded our vertically integrated supply chain capabilities from receptor science to finished white label goods.

We remain confident in the prospect of a robust financial performance in 2023, and intend to achieve such goals, in part, by accelerating the VLN® launch with key national distribution agreements, such that we anticipate selling VLN® in up to eighteen (18) states, representing in excess of 50% of the addressable combustible tobacco cigarette market in the U.S. prior to year-end 2023. We also anticipate scaling GVB revenue and gross margin to achieve cash-positive operating results in 2023, as well as the ability to expand capital to fuel growth through our new $21.1M lending facility.

**Our Executive Compensation Philosophy and Design**

Our executive compensation programs are driven by a pay-for-performance philosophy that is directly linked to our business strategies and company-wide goals. Prior to the FDA's authorization of the marketing of our VLN® King and VLN® Menthol King reduced nicotine content cigarettes as modified risk tobacco products (MRTPs) in December 2021 and our May 2022 acquisition of GVB Biopharma, our business had historically been focused on developing products through research and development and securing regulatory approval to market and sell such products. While we had limited revenues through the sale of SPECTRUM® research cigarettes and contract manufacturing of cigarettes and filtered cigars, we believe the primary driver of stockholder value was derived from the success of our rollout of our new our VLN® King and VLN® Menthol King reduced nicotine content cigarettes as well as the development of disruptive, plant-based solutions for the life science, consumer product, and pharmaceutical markets that we license to third parties and/or manufacture and sell. Accordingly, our compensation program has historically focused less on objective financial metrics typically applicable to other companies. As our Company transitions from a research and development based platform to a revenue generating business model, the Compensation Committee, after thoughtful deliberations, intends to update the compensation program for 2023 for further alignment with long-term interests of stockholders. Specifically, metrics to assess performance of the named executive officers will be based on more objective quantitative metrics including but not limited to revenue and other financial metrics.

**Our Pay for Performance Philosophy**

Our Compensation Committee seeks to attract and retain executive officers who have the experience, temperament, talents and convictions to drive our future success. Our compensation programs are designed to:

- motivate our executives by providing compensation that is directly linked to both our short- and long-term performance;

- tightly align their incentives and economic interests with our stockholders to build long-term stockholder value by delivering a substantial portion of our executive officer's compensation through equity awards; and

- ensure that our executive compensation program is designed and administered in a manner that appropriately manages risk to safeguard the interests of our stockholders', as well as our employees'.

We have designed our executive compensation program with specific features to help achieve these goals and to promote related objectives that are important to our long-term success.

**Roles and Responsibilities**

Our Compensation Committee has primary responsibility for, among other things, determining our compensation philosophy, evaluating the performance of our executive officers, setting the compensation and other benefits of our executive officers, overseeing the Company's response to the outcome of the advisory votes of stockholders on executive compensation (as discussed below), assessing the relative enterprise risk of our compensation program and administering our incentive compensation plans.

Our Board, our Compensation Committee and our CEO each play a role in setting the compensation of our NEOs. Our Board appoints the members of our Compensation Committee and delegates to the Compensation Committee the direct responsibility for overseeing the design and administration of our executive compensation program. Our Board and our Compensation Committee value the opinions of our stockholders and are committed to ongoing engagement with our stockholders on executive compensation practices. As discussed below, the Compensation Committee specifically considers the results from the annual stockholder advisory vote on executive compensation in making compensation decisions.

In February 2022, our Compensation Committee engaged the governance consulting firm of Morrow Sodali to assist with Say-on-Pay and the election of new directors.

In August 2022, our Compensation Committee engaged the compensation consulting firm of Pay Governance to assist the Committee in developing a peer group to benchmark executive compensation against other biotechnology, pharmaceutical and life science companies with similar revenues and market capitalizations. Pay Governance then reviewed our current executive compensation program and made recommendations with respect to future compensation decisions.

To assure independence, the Compensation Committee pre-approves all other work unrelated to executive compensation proposed to be provided by any compensation consultant it engages and considers all factors relevant to their independence from management, including but not limited to the following factors:

- The provision of other services that the consultant provides to us;
- The amount of fees received from us as a percentage of the consultant's total revenue;
- The consultant's policies and procedures designed to prevent conflicts of interest;
- Business or personal relationships of the consultant with our Compensation Committee members;
- The amount of our stock owned by the consultant; and
- Business or personal relationships of the consultant with our executive officers.

**Our Say-on-Pay Vote; Stockholder Outreach**

The Board and Compensation Committee are committed to soliciting feedback to inform the Board's decisions and guide our compensation program. Our stockholder outreach in 2021, 2022 and into 2023 provided the Board with valuable insights into our stockholders' perspectives on our executive compensation. We are committed to sound compensation practices and will continue to enhance our compensation program as a result of stockholder input.

We have followed a consistent approach to the design of our executive compensation program for many years. The history of our Say-on-Pay results before 2020 generally demonstrated stockholder support for our program over several years. At our 2022 Annual Meeting of Stockholders, approximately 10.5% of our outstanding shares voted against our 2022 executive compensation resolution. As noted below, we conducted a Board-driven stockholder outreach and engaged with our top holders to better understand their concerns.

Following the 2022 Annual Meeting of Stockholders, the Compensation Committee commenced a stockholder outreach program. This outreach focused on better understanding the perspectives of our stockholders with regard to our executive compensation program structures and best practices in aligning executive compensation to the interests of our stockholders.

The executive compensation outreach initiative is in addition to our regular ongoing stockholder engagement. As part of our ongoing outreach efforts to inform our corporate policies, the Company proactively reached out to filing institutional stockholders to discuss the Company's executive compensation philosophy, goals and plans and to obtain an understanding of our stockholders' concerns in advance of this filing. Approximately 19.4% of the Company's outstanding shares of common stock were owned by filing institutional stockholders.

*By The Numbers: Stockholder Engagement*

| | |
|---|---|
| We contacted **15** of our top institutional stockholders, representing approximately **10%** of our total shares outstanding and approximately **53%** of our shares held by institutional stockholders, with invitations to meet with our management and directors. These institutional stockholders represent the majority of our institutional investors at this time. | Our Independent Board Chair and Chair of our Compensation Committee participated in **all** of the stockholder engagement meetings. |

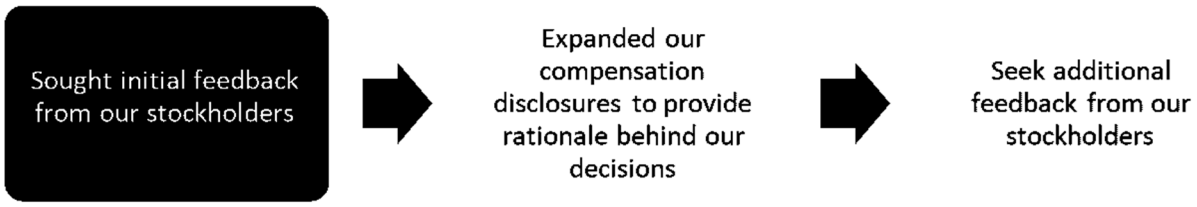
*Feedback from Stockholder Engagement*

We heard a range of perspectives on our executive compensation program from stockholders during our outreach, all of which were considered by our Compensation Committee and the Board.

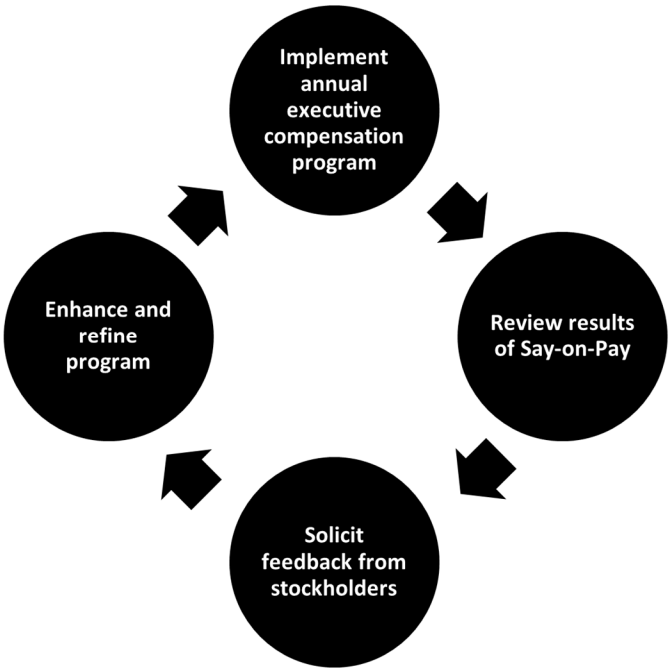
Our stockholders expressed a continuing desire to understand the specifics behind our executive compensation plan design including, rationale, key performance indicators, and qualitative metrics that align to both the short, mid and long-term strategy of the Company.

| What We Heard | | How We Are Responding |
|---|---|---|
| Desire to see expanded disclosure of our compensation philosophy, design and rationale. | → | We have greatly expanded our Compensation Discussion and Analysis to provide more specific details into our compensation programs and philosophy and the rationale behind our compensation decisions. |

Our work to solicit stockholder feedback into our executive compensation program continues into the future.



Following each annual meeting of stockholders, our Compensation Committee will review the Say-on-Pay results and engage with our stockholders to solicit feedback on our compensation program. Our Compensation Committee will use the stockholder feedback to inform and guide its compensation decisions for the following year. Our annual compensation cycle is generally as follows:




**Elements of Executive Compensation**

Our compensation program consists of the following three primary elements:

(1) *Base Salary.* We provide a base salary for each NEO based on their job description and scope of responsibilities of that position. We target the base salary for each NEO at the 50$^{th}$ percentile range of our peer group (discussed below) for each position. Our philosophy is to have a significant portion of each NEO's total cash compensation "at-risk."

(2) *Annual Cash Bonus Opportunity*. The annual cash bonus is our primary short-term performance incentive. Our NEO target bonus awards range from 75% to 150% of their base pay, representing the "at risk" portion of the NEO's total cash compensation. The Compensation Committee aims to set performance goals for cash bonuses that align pay with performance. During 2022 and in prior years, our Compensation Committee prioritized the accomplishment of critical strategic and operational milestones. With the Company entering into its revenue phase with the roll-out of its VLN cigarettes and acquisition of GVB Biopharma, the Compensation Committee expects to focus performance measures in 2023 and in the future on more objective quantitative metrics including but not limited to revenue and other financial metrics.

(3) *Long-Term Incentive Awards*. Long-term incentive awards are our primary retention tool and serve to provide for the continuity of key executives with incentives that align our executives' interests with those of our stockholders'. For 2021 and 2022, these long-term incentive awards were generally comprised of restricted stock units with multi-year vesting, subject to continued service with us. Beginning in 2023, we expect to enhance our Long-Term Incentive Program by introducing performance-based equity awards to the award mix.

***Peer Group***

We endeavor to set total compensation, which consists of base salary, annual cash bonuses and the expected value of long-term incentives, for target performance levels in range of the expected median of peer companies, depending on various factors including the experience level of the individual executive and competitive market conditions. We use our peer group median compensation values to help determine the optimal compensation mix and as a general guide to determine salary recommendations, target annual cash bonus opportunity, and target annual long-term incentive value for each executive position. Compensation for top executives can be highly variable due to heavy weighting toward incentive compensation rather than fixed components.

With the assistance of Pay Governance, during late 2022, our Compensation Committee established a peer group consisting primarily of similarly situated biotechnology, pharmaceutical and life science companies with revenues and a market capitalization similar to ours. The peer group established consists of the following companies:

| | | | | |
|---|---|---|---|---|
| Achieve Life Sciences | AquaBounty Technologies | Avid Bioservices | Benson Hill | Charlotte's Web Holdings |
| ChromaDex Corporation | Cronos Group | GreenLight Biosciences | Hawkins | Jushi Holdings |
| Laird Superfood | Landec Corporation | Pear Therapeutics | PRECIGEN | Societal CDMO |
| The Valens Company | TILT Holdings | Village Farms International | Zynerba Pharmaceuticals | |

***Base Salary***

We pay our NEOs a base salary to compensate them for services rendered and to provide them with a steady source of income for living expenses throughout the year. We have historically determined the base salary of each NEO based on the job description and scope of responsibilities of that position and assign each position a target annual salary equal to the base salary in the 50$^{th}$ percentile range of the Survey Group. After a base salary is set initially, we have historically provided a base salary increase of 0% - 5% annually depending on the performance of the NEO during the prior year and taking into account any other factors, such as recent salary increases, bonuses or other compensation. Every two to three years, we generally reviewed each NEO's salary against a peer group of similarly situated companies and made salary increases to the extent necessary to maintain a base salary in the 50$^{th}$ percentile range of such group. In 2023 and into the future, we expect to target annual salary equal to the base salary in the 50th percentile range of the peer group described above.

For 2022, we took the following actions with respect to the base salaries of our NEOs:

- James Mish's base salary increased from $450,000 to $472,500, a 4% increase.
- John Franzino's base salary increased from $315,000 to $330,750, a 5% increase.
- John Miller joined the Company in 2022 with a base salary of $425,000.
- R. Hugh Kinsman joined the Company in 2022 with a base salary of $290,000.

In February 2023, our Compensation Committee reviewed the 2022 base salaries our NEOs in connection with the establishment of the new peer group. Other than Mr. Kinsman, no other NEO received a base salary increase because our NEOs base salaries were generally within the 50th percentile range of the peer group described above for their respective positions. Hugh Kinsman's salary was increased based on his individual performance and in order to bring his salary closer to the 50$^{th}$ percentile range for CFO's in the established peer group. The base salaries of each of our NEOs for 2023 is as follows:

| Name | 2023 Base Salary | Percentage Increase Over 2022 Base Salary |
|---|---|---|
| James A. Mish | $486,675 | 3% |
| John Franzino | $330,750 | 0% |
| John Miller | $425,000 | 0% |
| R. Hugh Kinsman | $370,000 | 28% |

***2022 Annual Cash Bonus Opportunity***

In general, our NEO target bonus awards range from 75% - 150% of an NEOs base salary depending on their position. The Compensation Committee aims to set performance goals for cash bonuses that align pay with performance. A number of factors are considered when calibrating goals, including the Company's business strategies and company-wide goals. Prior to entering into its revenue phase, our Compensation Committee believed that the primary driver of stockholder value was derived from the development of disruptive, plant-based solutions for the life science, consumer product, and pharmaceutical markets that we license to third parties and/or manufacture and sell. Accordingly, our compensation program has historically focused less on objective metrics typically applicable to other companies. In 2023, with the Company entering into its revenue phase with the roll-out of its VLN® cigarettes and acquisition of GVB Biopharma, the Compensation Committee intends to introduce quantitative performance measures such as revenue and other financial metrics for a direct link to executive pay.

For 2022, we did not weight individual goals or achievements in setting our potential cash bonus awards because our Compensation Committee desired to maintain flexibility in awarding cash bonuses to our NEOs for their performance during the year and to provide flexibility to our NEOs to advance our strategic position or goals as a company in one or more areas opportunistically. In addition, our cash bonus awards included an element of discretion as relegated to the Compensation Committee in order to compensate NEOs that performed extraordinarily well and incentivize and motivate our NEOs.

For 2022, our Compensation Committee challenged our NEOs with a number of strategic goals and objectives for 2022, including but not limited to:

- Launch of VLN® reduced nicotine content cigarettes internationally;
- Launch of VLN® reduced nicotine content cigarettes nationally following the successful pilot launch;
- Increase gross profit for cigar and cigarette contract manufacturing operations by $1,000,000;
- Advance VLN® through securing strategic partnerships;
- Increase regulatory and legislative advocacy for VLN®, as well as within the hemp and cannabis business units;
- Develop intellectual property for next generation VLN® blends;
- Develop merger & acquisition strategy and business plan for hemp cannabis division;
- Develop innovative intellectual property for hemp cannabis, tobacco and hops products;
- Increase cash position though capital markets activities;
- Enhance operational finance process/reports;
- Improve human resources and IT functions and processes; and
- Establish compensation benchmarking.

At the end of the year, the Compensation Committee reviews each NEO's individual performance objectives and goals against their performance during the year, which performance is rated by both the individual NEO through a self-assessment as well as a review of performance by the CEO (for NEOs other than himself) and the Compensation Committee. The target cash bonus amounts (and percentage of base salary) and the actual cash bonuses earned by our NEOs for 2022 are as follows:

| Name | Target Cash Bonus (and percentage of Base Salary) | Actual Cash Bonus Earned | Bonus Earned as a % of Target |
|---|---|---|---|
| James A. Mish | $708,750 (150%) | $481,950 | 68% |
| John Franzino | $248,062 (75%) | $238,140 | 96% |
| R. Hugh Kinsman | $217,500 (75%) | $90,575 | 50% |
| John Miller | $318,750 (75%) | $160,000 | 50% |

***2022 Long-Term Incentive Program Awards***

Our Compensation Committee strongly believes that using equity awards with multi-year vesting periods reinforces the alignment of the interests of executives with those of stockholders and assists us to retain our executives. We maintain our omnibus incentive plan for the purpose of granting various types of equity awards, including restricted stock units, to provide incentives for management to increase stockholder value. In addition, the multi-year nature of the vesting periods encourages executives to stay with the Company, which is important to us in light of the competitive labor market for talented executives.

Our Compensation Committee has authority to determine eligible participants, the types of awards and the terms and conditions of awards. As part of their total compensation package, each NEO is assigned an annual dollar value target for these long-term incentive plan awards that is adjusted up or down depending on the individual's and the Company's actual performance during the prior year. For 2021 and 2022, NEOs were generally awarded restricted stock units with a three-year vesting period, subject to continued service with us. The number of restricted stock units for each award is determined by converting the dollar value into a number of shares based on our average closing stock price during the six months preceding the award date. The Compensation Committee expects to continue this practice in 2023.

During 2022, Mr. Miller received an award of 750,000 performance shares, with one-third of such shares vesting annually in 2023, 2024 and 2025 provided that our tobacco business plan revenue objectives and other performance requirements are satisfied. The performance shares were issued to incentivize Mr. Miller to successfully roll-out our VLN® pilot program. For 2022, our Compensation Committee determined that Mr. Miller earned 150,000 of the initial one-third tranche of such shares in light of his performance in consulting and then ultimately leading our VLN® roll-out strategy and business plan. In addition, during 2022, Mr. Mish received a special equity award of 950,000 restricted stock units vesting annually over a two-year period plus his normal three-year vesting award. The special equity award was issued to Mr. Mish as a catch-up issuance from 2020 and 2021.

The long-term incentive plan awards are used to motivate and retain employees as well as promote employee stock ownership. We do not issue the shares until the vesting conditions have been satisfied. We currently do not use stock options as part of our compensation package. Since we grant fewer shares with these types of awards than we would have granted in the form of options, stock grants help us manage dilution that we would otherwise experience in granting options.

As we continue to grow, our Compensation Committee is committed to exploring ways to further and more directly tie future long-term incentive plan award vesting to performance and the achievement of future company and individual goals.

For 2022, we awarded our NEOs the following RSUs:

| Name | RSU Grant Value | Number of Shares |
|---|---|---|
| James A. Mish[(1)] | $3,025,989 | 1,381,730 |
| John Franzino | $264,736 | 120,884 |
| John Miller[(2)] | $982,500 | 750,000[(2)] |
| R. Hugh Kinsman[(3)] | N/A | N/A |

(1) Comprises a one-time RSU grant of 950,000 vesting 50% over two (2) years and an annual grant of 431,730 vesting over three (3) years.
(2) Represents performance shares, as discussed above.
(3) Due to the timing of his appointment, Mr. Kinsman was not awarded a long-term equity incentive award during 2022.

## SUMMARY COMPENSATION TABLE FOR 2022

The following table summarizes the compensation of our NEOs for 2022. The amounts reported for stock awards may not represent the amounts that the NEOs will actually realize from the awards. Whether, and to what extent, a named executive officer realizes value will depend on our performance, stock price and continued employment.

| Name and Principal Position | Year | Salary | Bonus | Option Awards (1) | Stock Awards (2) | All Other Compensation (3) | Total |
|---|---|---|---|---|---|---|---|
| James A. Mish | 2022 | $ 470,976 | $ 481,950 | $ — | $ 3,025,989 | $ 32,179 | $ 4,011,094 |
| Chief Executive Officer | 2021 | $ 452,763 | $ 608,000 | $ — | $ 1,440,000 | $ 33,721 | $ 2,534,484 |
| | 2020 | $ 241,093 | $ 675,000 | $ — | $ 118,230 | $ 8,760 | $ 1,043,083 |
| R. Hugh Kinsman (4) | 2022 | $ 160,033 | $ 90,575 | $ — | $ — | $ 4,646 | $ 255,254 |
| Chief Financial Officer | | | | | | | |
| John J. Miller (5) | 2022 | $ 277,836 | $ 160000 | $ — | $ 982,500 | $ 19,625 | $ 1,439,961 |
| President of Tobacco | | | | | | | |
| John Franzino | 2022 | $ 294,606 | $ 238,140 | $ — | $ 264,736 | $ 30,323 | $ 824,805 |
| Chief Administrative Officer | 2021 | $ 308,849 | $ 200,813 | $ — | $ 576,000 | $ 26,179 | $ 1,111,841 |
| | 2020 | $ 158,213 | $ 125,000 | $ — | $ 142,005 | $ 10,030 | $ 435,248 |
| Michael J. Zercher | 2022 | $ 291,923 | $ — | $ — | $ 416,525 | $ 726,962 | $ 1,479,909 |
| Former President and Chief Operating Officer | 2021 | $ 368,060 | $ 638,100 | $ 192,950 | $ 1,440,000 | $ 33,721 | $ 2,672,831 |
| | 2020 | $ 366,431 | $ 366,100 | $ — | $ 447,831 | $ 31,970 | $ 1,212,332 |
| Richard Fitzgerald | 2022 | $ 159,892 | $ — | $ — | $ 273,141 | $ 4,473 | $ 437,505 |
| Former Chief Financial Officer | 2021 | $ 43,860 | $ 75,000 | $ — | $ — | $ 807 | $ 119,667 |

(1) Represents the grant date fair value computed in accordance with FASB ASC 718. The assumptions used for the option awards are set forth in Note 15 “Equity Based Compensation” of the Notes to the Consolidated Financial Statements contained in Item 8 of this report.
(2) The fair value of each restricted stock unit is based on the stock price of the Company’s common stock on the grant date of the award.
(3) All Other Compensation consists of the following:

| Name | Year | Fringe Benefits * | Severance | Employer Contributions to Company 401(k) Plan | All Other Compensation Total |
|---|---|---|---|---|---|
| James A. Mish | 2022 | $ 23,029 | $ — | $ 9,150 | $ 32,179 |
| R. Hugh Kinsman | 2022 | $ 3,977 | $ — | $ 669 | $ 4,646 |
| John J. Miller | 2022 | $ 19,625 | $ — | $ — | $ 19,625 |
| John Franzino | 2022 | $ 21,173 | $ — | $ 9,150 | $ 30,323 |
| Michael J. Zercher | 2022 | $ 21,150 | $ 691,662 | $ 9,150 | $ 726,962 |
| Richard Fitzgerald | 2022 | $ 4,473 | $ — | $ — | $ 4,473 |

* Includes Company paid premiums for health insurance, dental insurance, group-term life insurance, and long-term disability insurance.

(4) Mr. Kinsman joined the Company in May 2022.
(5) Mr. Miller joined the Company in May 2022.

### CEO Pay Ratio

We have estimated the ratio between our 2022 Chief Executive Officer’s total compensation and the median annual total compensation of all employees (except the Chief Executive Officer). In searching for the median employee we considered taxable compensation totals in 2022. We identified the “Median Employee” based on the taxable compensation of all active full-time and part-time employees employed by us on December 31, 2022 (annualizing salaries for hires made mid-year), then we calculated the Median Employee’s compensation under the Summary Compensation Table rules. Our Chief Executive Officer had annual total compensation in 2022 of $4,011,094 and our Median Employee had annual total compensation of $55,150. Therefore, we estimate that our Chief Executive Officer’s annual total compensation in 2022 is 73 times that of the median of the annual total compensation of all of our employees.

*Grants of Plan-Based Awards*

**GRANTS OF PLAN BASED AWARDS DURING 2022**

As described above in the Compensation Discussion and Analysis, we granted restricted stock units to our NEOs in 2022. The following table sets forth information regarding all such awards:

| Name | Grant Date | Date of Board Action | Restricted Stock Unit Awards: Number of Shares of Stock (#) | Stock Option Awards: Number of Shares (#) | Exercise Price of Option Awards ($) | Grant Date Fair Value Restricted Stock Units, Stock Awards and Option Awards ($) (2) |
|---|---|---|---|---|---|---|
| James A. Mish | 3/21/2021 | 3/19/2022 | 431,730 (1) | — | — | $ 945,489 |
| | 3/21/2022 | 3/21/2022 | 950,000 (2) | — | — | $ 2,080,500 |
| R. Hugh Kinsman | — | — | — | — | — | $ — |
| John J. Miller | 10/31/2022 | 10/31/2022 | 750,000 (3) | — | — | $ 982,500 |
| John Franzino | 3/21/2022 | 3/21/2022 | 120,884 (1) | — | — | $ 264,736 |
| Richard Fitzgerald | 3/21/2022 | 3/21/2022 | 124,722 (1) | — | — | $ 273,141 |
| Michael J. Zercher | 3/21/2022 | 3/21/2022 | 210,742 (1) | — | — | $ 461,525 |

(1) Represents RSUs which vest in equal increments over three years on March 21, 2023, 2024 and 2025, subject to continued service.
(2) Represents RSUs which vest in equal increments over two years on March 21, 2023 and 2024, subject to continued service.
(3) Represent an award of 750,000 performance shares, with one-third of such shares vesting on each of May 1, 2023, 2024 and 2025 provided that our tobacco business plan revenue objectives and other performance requirements are satisfied at such times

## Outstanding Equity Awards

The following table sets forth information about outstanding equity awards held on December 31, 2022 by our NEOs.

| Name | Number of Securities Underlying Unexercised Options Exercisable (#) | Number of Securities Underlying Unexercised Options Unexercisable (#) | Option Exercise Price | Option Expiration Date | Equity Incentive Plan Awards: Number of Unearned Shares, Restricted Stock Units or Other Rights That Have Not Vested (#) | Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Restricted Stock Units or Other Rights That Have Not Vested ($) (5) |
|---|---|---|---|---|---|---|
| James A. Mish | — | — | — | — | 431,730 (1) | $ 397,623 |
| | — | — | — | — | 950,000 (2) | $ 874,950 |
| | — | — | — | — | 300,000 (3) | $ 276,300 |
| R. Hugh Kinsman | — | — | — | — | — | $ — |
| John J. Miller | — | — | — | — | 750,000 (4) | $ 690,750 |
| John Franzino | — | — | — | — | 120,884 (1) | $ 111,334 |
| | — | — | — | — | 120,000 (3) | $ 110,520 |
| Richard Fitzgerald | — | — | — | — | — | $ — |
| Michael J. Zercher | 650,000 | — | $ 1.07 | 9/30/2024 | — | $ — |
| | 68,000 | — | $ 1.39 | 9/30/2024 | — | $ — |
| | 77,875 | — | $ 2.76 | 9/30/2024 | — | $ — |
| | 85,000 | — | $ 3.2 | 9/30/2024 | — | $ — |

(1) Represents RSUs which vest in equal increments over three years on March 21, 2023, 2024 and 2025.
(2) Represents RSUs which vest in equal increments over two years on March 21, 2023 and 2024.
(3) Represents RSUs which vest in equal increments over two years on March 19, 2023 and 2024.
(4) Represents performance shares, with one-third of such shares vesting on each of May 1, 2023, 2024 and 2025 provided that our tobacco business plan revenue objectives and other performance requirements are satisfied at such times.
(5) The amounts in this column are based on the closing stock price of the Company's common stock on December 31, 2022. These amounts do not reflect the actual amounts that may be realized.

## Option Exercises and Stock Vested in 2022

| Name | Option Awards | | Stock Awards | |
|---|---|---|---|---|
| | Number of Shares Acquired on Exercise (#) | Value Realized on Exercise ($) | Number of Shares Acquired on Vesting (#) | Value Realized on Vesting ($) (1) |
| James A. Mish | — | $ — | 150,000 | $ 352,500 |
| R. Hugh Kinsman | — | $ — | — | $ — |
| John J. Miller | — | $ — | — | $ — |
| John Franzino | — | $ — | 135,000 | $ 281,750 |
| Richard Fitzgerald | — | $ — | — | $ — |
| Michael J. Zercher | — | $ — | 906,802 | $ 1,342,044 |

(1) The value realized on vesting is based on the closing stock price of the Company's common stock on the date of vesting or date of exercise. The amount does not reflect the actual amount that may be realized.

## Pay for Performance

| Year | Summary Compensation Table Total for PEO (1) | Compensation Actually Paid to PEO (2) | Average Summary Compensation Table Total for Non-PEO-NEOs (3) | Average Compensation Actually Paid to Non-PEO-NEOs (2) | Value of Initial Fixed $100 Investment Based on Total Shareholder Return | Net Income (Loss) |
|---|---|---|---|---|---|---|
| 2022 | $ 4,011,094 | $ 1,495,978 | $ 888,087 | $ 411,232 | $ 84 | $ (59,801) |
| 2021 | $ 2,534,464 | $ 2,829,984 | $ 1,301,446 | $ 895,493 | $ 281 | $ (32,609) |

(1) Consists of compensation payable to our CEO, James A. Mish.
(2) Total summary compensation amount is adjusted as (i) less total equity compensation, (ii) plus the fair value of unvested shares as of December 31, 2022 of current year equity awards, (iii) plus or minus the change in fair value of unvested shares as of December 31, 2022 of prior year equity awards, (iv) plus or minus the change in fair value of vested shares during 2022 of prior year equity awards as of the vesting date, (v) plus the fair value of equity awards granted and vested in the current year, as of the vesting date.
(3) For 2022, consists of compensation payable to John Franzino, Michael J. Zercher, R. Hugh Kinsman, John J. Miller and Richard Fitzgerald. For 2021, consists of compensation payable to Richard Fitzgerald, John Franzino and Michael J. Zercher.

## Employment Agreements with Named Executive Officers

We have entered into employment agreements with each of our NEOs as follows:

*James A. Mish.* Pursuant to the employment agreement entered into between James A. Mish and the Company on May 22, 2020, Mr. Mish will earn an initial base salary of $450,000 (which has been increased to $491,400) and shall be eligible for future cash bonuses and awards of performance units as a percentage of base salary based on the achievement of performance targets to be established by the Company. As a one-time inducement, the Company agreed to an award of 150,000 RSUs, vesting on the one-year anniversary of the date of grant, subject to continued service.

If Mr. Mish's employment is terminated by the Company without Cause or by such executive for Good Reason (as such terms are defined in the employment agreement), then he will be entitled to a severance benefit in the form of (i) a continuation of his then-base salary for a period ending on the earlier of 12 months or the remaining term of the employment agreement (plus continuing health care coverage during such period) and (ii) the payment of a pro-rated bonus award.

*R. Hugh Kinsman.* Pursuant to the employment agreement entered into between R. High Kinsman and the Company on June 15, 2022, Mr. Kinsman will earn an initial base salary of $290,000 (which has been increased to $301,600) and he shall be eligible for future cash bonuses and awards of performance units as a percentage of base salary based on the achievement of performance targets to be established by the Company. If Mr. Kinsman's employment is terminated by the Company without Cause (as defined in the employment agreement), then he will be entitled to a severance benefit in the

form of a continuation of his then-base salary for a period of 12 months (plus continuing health care coverage during such period).

*John Franzino.* Pursuant to the employment agreement entered into between John Franzino and the Company dated April 8, 2020, Mr. Franzino earned an initial base salary of $250,000 (which has been increased to $343,980) and shall be eligible for future cash bonuses and equity awards. As a one-time inducement, the Company agreed to an award of 100,000 RSUs, with 50,000 RSUs vesting on the one-year anniversary of the date of grant and 50,000 RSUs vesting on the two-year anniversary of the grant date, subject to continued service.

If Mr. Franzino's employment is terminated by the Company without Cause or by such executive for Good Reason (as such terms are defined in the employment agreement), then he will be entitled to a severance benefit in the form of (i) a continuation of his then-base salary for a period of 12 months and (ii) the payment of any earned but unpaid bonus award.

The employment agreement of Mr. Franzino also provides that in the event of a change in control (as defined in his employment agreement) of our Company, then during the three (3)-year period following such change in control if certain triggering events occur, such as if he is terminated other than for Cause (as defined in his employment agreement), death or disability, or if his responsibilities are diminished after the change in control as compared to his responsibilities prior to the change in control, or if his base salary or benefits are reduced, or he is required to relocate more than twenty-five (25) miles from his then current place of employment, then in any such events he will have the option, exercisable within ninety (90) days of the occurrence of such an event, to resign his employment with us, in which case he will be entitled to receive: (a) his base salary for twelve (12) months thereafter; and (b) the immediate vesting of all options and/or restricted stock grants previously granted or to be granted to him.

*John Miller*. We entered into an employment agreement with Mr. Miller for an initial term until May 2025 pursuant to which he earns an annual base salary of approximately $425,000 and previously received an award of 750,000 performance shares, with one-third of such shares vesting on each of May 1, 2023, 2024 and 2025 provided that the Company's tobacco business plan revenue objectives and other performance requirements are satisfied at such times. The performance shares shall automatically vest upon the occurrence of change in control of the Company or similar event or in the event Mr. Miller terminates his employment for "Good Cause"; which means either an involuntary reduction in pay, change in reporting structure or a requirement to relocate.

**Compensation on Termination of Employment**

The following table illustrates the additional compensation that we estimate would be payable to each of our NEOs on termination of employment under each of the circumstances described above, assuming the termination occurred on December 31, 2022. The amounts shown are estimates and do not necessarily reflect the actual amounts that these individuals would receive on termination of employment.

**Estimated Additional Compensation Triggered by Termination of Employment If Termination on the Last Business Day of 2022**

| Name | Salary Multiple | Salary | Fringe Benefits (1) | Early Vesting of Restricted Stock Units (2) | Early Vesting of Stock Options | Total |
|---|---|---|---|---|---|---|
| **Termination by the Company Without Cause or by the Executive for Good Reason** | | | | | | |
| James A. Mish | 1x | $ 486,675 | $ 21,488 | $ 1,548,873 | $ — | $ 2,057,037 |
| R. Hugh Kinsman | 1x | $ 370,000 | $ 21,367 | $ — | $ — | $ 391,367 |
| John J. Miller | 1x | $ 425,000 | $ 21,488 | $ 690,750 | $ — | $ 1,137,238 |
| John Franzino | 1x | $ 330,750 | $ — | $ 221,854 | $ — | $ 552,604 |
| **Death or Disability** | | | | | | |
| James A. Mish | n/a | $ — | $ — | $ 1,548,873 | $ — | $ 1,548,873 |
| R. Hugh Kinsman | n/a | $ — | $ — | $ — | $ — | $ — |
| John J. Miller | n/a | $ — | $ — | $ 690,750 | $ — | $ 690,750 |
| John Franzino | n/a | $ — | $ — | $ 221,854 | $ — | $ 221,854 |
| **Change of Control with Triggering Event** | | | | | | |
| James A. Mish | 1x | $ 486,675 | $ 21,488 | $ 1,548,873 | $ — | $ 2,057,037 |
| R. Hugh Kinsman | 1x | $ 370,000 | $ 21,367 | $ — | $ — | $ 391,367 |
| John J. Miller | 1x | $ 425,000 | $ 21,488 | $ 690,750 | $ — | $ 1,137,238 |
| John Franzino | 1x | $ 330,750 | $ — | $ 221,854 | $ — | $ 552,604 |

(1) Health and dental insurance payments and group-term life insurance and long-term disability insurance payments have been estimated based on current rates for a period of 12 months.
(2) The dollar amount is calculated based on the closing price of our common stock on December 31, 2022.

### *Compensation Committee Report*

For the year ended December 31, 2022, the Compensation Committee reviewed and discussed the CD&A with our management. Based on this review and discussion, the Compensation Committee recommended to our Board of directors that the CD&A be included in this Annual Report on Form 10-K.

Richard M. Sanders, Chair
Anthony Johnson
Roger O'Brien
Nora B. Sullivan

### *Compensation Committee Interlocks and Insider Participation*

During the last fiscal year, no member of the Compensation Committee had a relationship with us that required disclosure under Item 404 of Regulation S-K. During the past fiscal year, none of our executive officers served as a member of the Board of Directors or Compensation Committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who served as members of our Board of Directors or our Compensation Committee. None of the members of our Compensation Committee is an officer or employee of our Company, nor have they ever been an officer or employee of our Company.

***Director Compensation***

Non-employee directors are compensated for their service on our Board as shown below. Directors who are employees of the Company receive no additional compensation for serving as directors. The Compensation Committee periodically reviews the compensation of our non-employee directors and considers market practices. In February 2021, the Compensation Committee retained Korn Ferry ("KF") to conduct an independent assessment of our director compensation versus the competitive market and the "fit" of our compensation program to our pay philosophy. To establish the competitive market for directors, KF identified a comparator group of 17 publicly traded companies in the United States and Canada within the biotechnology and pharmaceuticals industries with median revenues of $95 million and median market capitalizations of $1.2 billion. Based on the KF review, the Compensation Committee recommended, and the Board approved, the following director compensation for 2022:

| | |
|---|---|
| Annual cash retainer: | $ 75,000 |
| Additional annual cash retainer for: | |
| Chair of the Board | $ 50,000 |
| Chair of a Board Committee | $ 20,000 |
| Member of a Board Committee | $ 10,000 |
| Annual RSU award value: | $ 135,000 |

During 2022, the Compensation Committee retained Pay Governance LLC ("Pay Governance") to conduct an independent assessment of our director compensation versus a peer group that was developed (see "Compensation Discussion and Analysis – Peer Group" for a discussion of our peer group). Based on the Pay Governance review, the Compensation Committee approved maintaining the 2022 level of non-employee director compensation for 2023.

As with many small cap companies, our stock price has been volatile historically. For example, between January 1, 2019 and December 31, 2022, our stock price ranged from a low of $0.55 per share to a high of $6.07 per share. In order to eliminate some of the volatility from our stock price when making equity awards, in 2020 our Compensation Committee decided to implement a policy to determine the number of RSUs to issue for annual awards by dividing the annual RSU award value approved by the Compensation Committee ($135,000) with the average closing stock price over the six months prior to the date of the award. As a result of this policy, the grant date fair value of our RSU awards reported in our Director Compensation table below will vary (up or down) from the annual RSU award value approved by the Compensation Committee depending on the closing market price on the date of the award and the average market price over the prior six months. Our Compensation Committee expects to adhere to this policy for director RSU awards made during 2023 and will evaluate the policy annually.

**NON-EMPLOYEE DIRECTOR COMPENSATION FOR 2022**

| Name | Fees earned or paid in cash | Option Awards | Restricted Stock Unit Awards[1] | All Other Compensation | Total |
|---|---|---|---|---|---|
| Clifford B. Fleet | $ 105,000 | $ — | $ 113,460 | $ — | $ 218,460 |
| Anthony Johnson | $ 105,000 | $ — | $ 113,460 | $ — | $ 218,460 |
| Michael Koganov | $ 105,000 | $ — | $ 113,460 | $ — | $ 218,460 |
| Roger D. O'Brien | $ 127,500 | $ — | $ 113,460 | $ — | $ 240,960 |
| Richard M. Sanders | $ 135,000 | $ — | $ 113,460 | $ — | $ 248,460 |
| Lucille S. Salhany[2] | $ 30,014 | $ — | $ 28,440 | $ — | $ 58,454 |
| Nora B. Sullivan | $ 195,000 | $ — | $ 113,460 | $ — | $ 308,460 |

(1) The fair value of each restricted stock unit is based on the stock price of the Company's common stock on the grant date of the award.
(2) Ms. Salhany was appointed as a director on September 7, 2022 and received pro rata compensation for service during 2022.

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

The following table sets forth information regarding the beneficial ownership of our common stock as of March 1, 2023, by (i) each of our current directors and executive officers, and (ii) all our current directors and executive officers as a group. To our knowledge, no person owns more than 5% of our common stock, Derivative securities exercisable or convertible into shares of our common stock within sixty (60) days of March 1, 2023 are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding securities but are not deemed outstanding for computing the percentage of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*). The address of named beneficial owners that are officers and/or directors of the Company is: c/o 22nd Century Group, Inc., 500 Seneca Street, Suite 507, Buffalo, New York 14204. The following table is based upon information supplied by officers and directors, and with respect to 5% or greater stockholders who are not officers or directors, information filed with the SEC.

| Name of Beneficial Owner | Number of Shares Beneficially Owned | Percentage Beneficially Owned (1) |
|---|---|---|
| ***Officers and Directors:*** | | |
| James A. Mish (2) | 305,070 | * |
| R. Hugh Kinsman | 52,327 | * |
| John Franzino (3) | 139,690 | * |
| John Miller (4) | 75,000 | * |
| Nora B. Sullivan (5) (7) | 950,431 | * |
| Richard M. Sanders (6) (7) | 596,068 | * |
| Clifford B. Fleet (7) | 256,195 | * |
| Roger D. O'Brien (7) | 308,595 | * |
| Michael Koganov (7) | 179,372 | * |
| Anthony Johnson (7) | 91,808 | * |
| Lucille Salhany(8) | 27,612 | * |
| All directors, director nominees and executive officers as a group (11 persons) (2) - (8) | 2,982,168 | 1.40% |

(1) Based on 215,704,036 shares of common stock issued and outstanding as of March 1, 2023.
(2) 1,681,730 restricted stock units are not included in the number of beneficially owned shares because they do not vest within 60 days of March 1, 2023.
(3) 265,884 restricted stock units are not included in the number of beneficially owned shares because they do not vest within 60 days of March 1, 2023.
(4) Excludes 750,000 performance shares, with one-third of such shares vesting on each of May 1, 2023, 2024 and 2025 provided that the Company's tobacco business plan revenue objectives and other performance requirements are satisfied at such times.
(5) Consists of (a) 748,707 shares of common stock held directly and (b) 201,724 shares of common stock issuable upon exercise of stock options.
(6) Consists of (a) 444,344 shares of common stock held directly and (b) 151,724 shares of common stock issuable upon exercise of stock options.
(7) Includes 51,808 restricted stock units vesting on March 21, 2023, subject to continued service.
(8) Consists of restricted stock units vesting on March 21, 2023, subject to continued service.

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

### *Related Party Transactions*

Our policy is to enter into transactions with related persons on terms that, on the whole, are no less favorable to us than those available from unaffiliated third parties. Our Board of Directors has adopted written policies and procedures regarding related person transactions. For purposes of these policies and procedures:

- A "related person" means any of our directors, executive officers, nominees for director, holder of 5% or more of our common stock or any of their immediate family members; and
- A "related person transaction" generally is a transaction (including any indebtedness or a guarantee of indebtedness) in which we were or are to be a participant and the amount involved exceeds $120,000 and in which a related person had or will have a direct or indirect material interest.

Each of our executive officers, directors or nominees for director is required to disclose to our Audit Committee certain information relating to related person transactions for review, approval or ratification by our Audit Committee. In making a determination about approval or ratification of a related person transaction, our Audit Committee will consider the information provided regarding the related person transaction and whether consummation of the transaction is believed by the Audit Committee to be in our best interests. Our Audit Committee may take into account the effect of a director's related person transaction on the director's status as in independent member of our Board of Directors and eligibility to serve on committees of our Board under SEC rules and the listing standards of the Nasdaq Stock Market. Any related person transaction must be disclosed to our full Board of Directors. There were no related party transactions in 2022 and 2021.

***Independent Directors***

Our Board of Directors has determined that Anthony Johnson, Dr. Michael Koganov, Roger D. O'Brien, Lucille S. Salhany, Richard M. Sanders and Nora B. Sullivan are "independent" as defined by applicable Nasdaq Stock Market listing standards. The Board annually reviews all business and other relationships of directors and determines whether directors meet these categorical independence tests. In addition, each member of our Audit Committee, Compensation Committee, and Corporate Governance and Nominating Committee is "independent" as defined by applicable Nasdaq Stock Market listing standards and applicable SEC rules for service on such committee.

## Item 14. Principal Accounting Fees and Services.

The following table shows the fees billed to us for the audits and other services provided by Freed Maxick CPAs, P.C. ("Freed"), our independent registered certified public accounting firm, for the fiscal years ended December 31, 2022 and 2021, respectively.

| | 2022 | 2021 |
|---|---|---|
| Audit fees | $ 430,100 | $ 312,275 |
| Audit-related fees | — | — |
| Tax fees | — | — |
| All other fees | — | — |
| | $ 430,100 | $ 312,275 |

Audit Fees consist of the aggregate fees billed for professional services rendered for the audit of our consolidated annual financial statements and the quarterly reviews of financial statements and for any other services that are normally provided by our independent registered public accountants in connection with our statutory and regulatory filings or engagements.

*Audit Committee Policies and Procedures For Pre-Approval of Independent Auditor Services*

The Audit Committee, in accordance with its charter, must pre-approve all non-audit services provided by our independent registered public accountants. The Audit Committee generally pre-approves specified series in the defined categories of audit services, audit related services and tax services up to specified amounts. Pre-approval may also be given as part of our Audit Committee's approval of the scope of the engagement of the independent registered public accountants or on an individual, explicit case-by-case basis before the independent auditor is engaged to provide each service.

The Audit Committee has considered whether the provision of the services not related to the audit of the financial statements acknowledged in the table above was compatible with maintaining the independence of Freed and is of the opinion that the provision of these services was compatible with maintaining Freed's independence.

## PART IV

**Item 15. Exhibits and Financial Statement Schedules.**

(a) (1) Financial Statements



(a) (2) Financial Statement Schedules

Financial statement schedules have been omitted because they are not required.

(b) Exhibits

Exhibits required by Item 601 of Regulation S-K are listed in the Exhibit Index below following the Financial Statements, which are incorporated herein by this reference.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

**Opinion on the Financial Statements**
We have audited the accompanying consolidated balance sheets of 22nd Century Group, Inc. and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

**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.

**Business acquisition**
*Critical Audit Matter Description*

As discussed in Note 2 of the consolidated financial statements, during the year ended December 31, 2022, the Company completed a business acquisition of GVB Biopharma (GVB) for an aggregate purchase price of approximately $53 million. As discussed in Note 1 of the consolidated financial statements, the Company applies the acquisition method of accounting for business combinations. Under this method, identifiable assets acquired, liabilities assumed, and consideration transferred are measured at their acquisition-date fair value. Any purchase price in excess of the net assets is recorded as goodwill. As discussed in Note 2 to the consolidated financial statements, various assumptions that require management's judgement were used to determine the fair value of the assets acquired.

The judgments made in the determination of the estimated fair values assigned to the assets acquired and the liabilities assumed, as well as the estimated useful life of certain assets and liabilities, can materially impact the financial statements in the current period, as well as periods after acquisition. Due to the subjectivity involved we identified the fair value estimate of assets acquired as a critical audit matter, which required a higher degree of auditor judgement as well as the use of professionals with specialized skill and knowledge.

*How the Critical Audit Matter Was Addressed in the Audit*

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 implemented controls as it relates to the determination of the fair value of assets acquired; identifying key inputs and assumptions used by management to estimate the fair values of the assets purchased; and testing the completeness and accuracy of source information used, mathematical accuracy of management's calculations, and reviewing assumptions for reasonableness.

**Impairment tests for indefinite-lived intangible assets and goodwill**
*Critical Audit Matter Description*

As discussed in Note 1 of the consolidated financial statements, indefinite-lived intangible assets and goodwill are tested for impairment at least annually or more frequently if events or changes in circumstances indicate that it is more likely than not that an impairment exists. As discussed in Notes 6 and 19, the GVB fire, as well as shifts in strategy and changes in expected cash flows resulted in changes in circumstances captured in the annual impairment tests of the tradename and goodwill. As discussed in Notes 1 and 8 to the consolidated financial statements, various assumptions that require management's judgement were used to determine the fair value of the tradename and goodwill.

The judgments made in the determination of the estimated fair values assigned to the asset and reporting unit can materially impact the financial statements. Due to the subjectivity involved we identified the fair value estimate of the assets and reporting unit tested for impairment as a critical audit matter, which required a higher degree of auditor judgement as well as the use of professionals with specialized skill and knowledge.

*How the Critical Audit Matter Was Addressed in the Audit*
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 implemented controls as it relates to management's impairment analysis; identifying key inputs and assumptions used by management to estimate the fair values; and testing the completeness and accuracy of source information used, mathematical accuracy of management's calculations, and reviewing assumptions for reasonableness.

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

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

Buffalo, New York
March 9, 2023

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

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 3,020 | $ 1,336 |
| Short-term investment securities | 18,193 | 47,400 |
| Accounts receivable, net | 5,641 | 585 |
| Inventories | 10,008 | 2,881 |
| Insurance recoveries | 5,000 | — |
| Prepaid expenses and other current assets | 2,743 | 2,183 |
| **Total current assets** | 44,605 | 54,385 |
| Property, plant and equipment, net | 13,093 | 5,841 |
| Operating lease right-of-use assets, net | 2,675 | 1,723 |
| Goodwill | 33,160 | — |
| Intangible assets, net | 16,853 | 7,919 |
| Investments | 682 | 2,345 |
| Other assets | 3,583 | 3,741 |
| **Total assets** | $ 114,651 | $ 75,954 |
| | | |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Notes and loans payable - current | $ 908 | $ 596 |
| Operating lease obligations | 681 | 308 |
| Accounts payable | 4,168 | 2,173 |
| Accrued expenses | 1,428 | 1,489 |
| Accrued payroll | 3,199 | 2,255 |
| Accrued excise taxes and fees | 1,423 | 1,270 |
| Deferred income | 831 | 119 |
| Other current liabilities | 380 | 217 |
| **Total current liabilities** | 13,018 | 8,427 |
| **Long-term liabilities:** | | |
| Notes and loans payable | 3,001 | — |
| Operating lease obligations | 2,141 | 1,432 |
| Other long-term liabilities | 516 | 21 |
| **Total liabilities** | 18,676 | 9,880 |
| **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: | | |
| 215,238,198 common shares (162,872,875 at December 31, 2021) | | |
| Common stock, par value | 2 | 2 |
| Capital in excess of par value | 333,898 | 244,247 |
| Accumulated other comprehensive loss | (111) | (162) |
| Accumulated deficit | (237,814) | (178,013) |
| **Total shareholders' equity** | 95,975 | 66,074 |
| **Total liabilities and shareholders' equity** | $ 114,651 | $ 75,954 |

See accompanying notes to consolidated financial statements.

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

| | Year Ended December 31, | |
|---|---|---|
| | **2022** | **2021** |
| Revenues, net | $ 62,111 | $ 30,948 |
| Cost of goods sold | 60,937 | 29,462 |
| Gross profit | 1,174 | 1,486 |
| Operating expenses: | | |
| Sales, general and administrative | 44,517 | 25,908 |
| Research and development | 6,561 | 3,912 |
| Other operating expense, net | 7,202 | 78 |
| Total operating expenses | 58,280 | 29,898 |
| Operating loss | (57,106) | (28,412) |
| Other income (expense): | | |
| Unrealized loss on investments | (5) | (6,994) |
| Realized (loss) gain on Panacea investment | (2,789) | 2,548 |
| Realized loss on short-term investment securities | (366) | — |
| Other income, net | 71 | — |
| Interest income, net | 313 | 321 |
| Interest expense | (353) | (58) |
| Total other expense | (3,129) | (4,183) |
| Loss before income taxes | (60,235) | (32,595) |
| (Benefit) provision for income taxes | (434) | 14 |
| Net loss | $ (59,801) | $ (32,609) |
| | | |
| Net loss per common share - basic and diluted | $ (0.31) | $ (0.21) |
| Weighted average common shares outstanding - basic and diluted (in thousands) | $ 192,837 | $ 156,208 |
| | | |
| Net loss | $ (59,801) | $ (32,609) |
| Other comprehensive loss: | | |
| Unrealized loss on short-term investment securities | (316) | (236) |
| Foreign currency translation | 1 | — |
| Reclassification of realized losses to net loss | 366 | — |
| Other comprehensive income (loss) | 51 | (236) |
| Comprehensive loss | $ (59,750) | $ (32,845) |

See accompanying notes to consolidated financial statements.

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

| | Years Ended December 31, 2022 and 2021 | | | | | |
|---|---|---|---|---|---|---|
| | Common Shares Outstanding | Par Value of Common Shares | Capital in Excess of Par Value | Other Comprehensive Income (Loss) | Accumulated Deficit | Shareholders' Equity |
| **Balance at January 1, 2021** | **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 |
| Other comprehensive loss | — | — | — | (236) | — | (236) |
| Net loss | — | — | — | — | (32,609) | (32,609) |
| **Balance at December 31, 2021** | **162,872,875** | **$ 2** | **$ 244,247** | **$ (162)** | **$ (178,013)** | **$ 66,074** |
| Stock issued in connection with option exercises | 150,000 | — | 174 | — | — | 174 |
| Stock issued in connection with RSU vesting, net of shares withheld for taxes | 2,242,148 | — | (149) | — | — | (149) |
| Stock issued in connection with acquisition | 32,900,000 | — | 51,653 | — | — | 51,653 |
| Stock issued in connection with capital raise, net of issuance costs of 2,516 | 17,073,175 | — | 32,484 | — | — | 32,484 |
| Equity-based compensation | — | — | 5,489 | — | — | 5,489 |
| Other comprehensive income | — | — | — | 51 | — | 51 |
| Net loss | — | — | — | — | (59,801) | (59,801) |
| **Balance at December 31, 2022** | **215,238,198** | **$ 2** | **$ 333,898** | **$ (111)** | **$ (237,814)** | **$ 95,975** |

See accompanying notes to consolidated financial statements.

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

| | Year Ended December 31, | |
|---|---|---|
| | **2022** | **2021** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (59,801) | $ (32,609) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Impairment of intangible assets | 1,488 | 78 |
| Amortization and depreciation | 2,858 | 1,248 |
| Amortization of right-of-use asset | 733 | 288 |
| Amortization of inventory step-up | 978 | — |
| Unrealized loss on investment | 5 | 6,994 |
| GVB fire write-offs | 4,549 | — |
| Realized loss on short-term investment securities | 366 | — |
| Change in allowance for doubtful accounts | 770 | — |
| Gain on the sale of machinery and equipment | (368) | — |
| Realized loss (gain) on Panacea investment | 2,789 | (2,548) |
| Accretion of non-cash interest expense (income), net | 197 | 143 |
| Equity-based employee compensation expense | 5,489 | 3,983 |
| Deferred income taxes | (434) | — |
| Inventory write-off | 237 | 317 |
| Changes in operating assets and liabilities, net of acquisition: | | |
| Accounts receivable | (2,881) | 1,574 |
| Inventory | (8,789) | (1,164) |
| Prepaid expenses and other assets | (920) | (547) |
| Accounts payable | 416 | 11 |
| Accrued expenses | (582) | 533 |
| Accrued payroll | 748 | 47 |
| Accrued excise taxes and fees | 153 | (421) |
| Other liabilities | 285 | (766) |
| **Net cash used in operating activities** | (51,714) | (22,839) |
| **Cash flows from investing activities:** | | |
| Acquisition of patents, trademarks, and licenses | (772) | (326) |
| Acquisition of property, plant and equipment | (3,657) | (745) |
| Proceeds from the sale of machinery and equipment | 409 | — |
| Acquisition, net of cash acquired and debt assumed | (1,297) | — |
| Investment in Change Agronomy Ltd. | (682) | — |
| Sales and maturities of short-term investment securities | 101,990 | 63,749 |
| Purchase of short-term investment securities | (73,413) | (90,407) |
| **Net cash provided by (used in) investing activities** | 22,578 | (27,729) |
| **Cash flows from financing activities:** | | |
| Payment on note payable | (3,822) | (2,604) |
| Proceeds from note payable issuance | 2,162 | 2,653 |
| Other financing activities | (29) | — |
| Net proceeds from option exercise | 174 | 1,307 |
| Net proceeds from warrant exercise | — | 11,782 |
| Proceeds from issuance of common stock | 35,000 | 40,000 |
| Payment of common stock issuance costs | (2,516) | (1,794) |
| Taxes paid related to net share settlement of RSUs | (149) | (469) |
| **Net cash provided by financing activities** | 30,820 | 50,875 |
| **Net increase in cash and cash equivalents** | 1,684 | 307 |
| **Cash and cash equivalents - beginning of period** | 1,336 | 1,029 |
| **Cash and cash equivalents - end of period** | $ 3,020 | $ 1,336 |
| | | |
| **Supplemental disclosures of cash flow information:** | | |
| Net cash paid for: | | |
| Cash paid during the period for interest | $ 34 | $ 37 |
| Cash paid during the period for income taxes | $ 14 | $ — |
| Non-cash transactions: | | |
| Capital expenditures incurred but not yet paid | $ 94 | $ 1,074 |
| Right-of-use assets and corresponding operating lease obligations | $ — | $ 1,816 |
| Panacea investment conversion | $ — | $ 12,485 |
| Stock issued in connection with acquisition | $ 51,653 | $ — |

See accompanying notes to consolidated financial statements.

## NOTE 1. – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

22nd Century Group, Inc. (together with its consolidated subsidiaries, "22nd Century Group" or the "Company") is a publicly traded Nevada corporation on the NASDAQ Capital Market under the symbol "XXII." 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.

***Basis of Presentation and Principles of Consolidation*** – The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of 22nd Century Group and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

As described in Note 2, on May 13, 2022, the Company acquired substantially all of the assets of GVB Biopharma's ("GVB") business dedicated to hemp-based cannabinoid extraction, refinement, contract manufacturing and product development, which allows the Company to leverage its expertise in receptor and plant science to develop its hemp/cannabis franchise.

As a result of the acquisition of GVB and ongoing evaluation of the Company's strategy across our plant science and intellectual property platform, the Company reevaluated its operating and reporting segments, which was finalized during the fourth quarter of 2022. The Company now organizes its business into two reportable segments: (1) Tobacco and (2) Hemp/cannabis. This segment structure reflects the financial information and reports used by the Company's management, specifically its Chief Operating Decision Maker ("CODM"), to make decisions regarding the Company's business, including resource allocations and performance assessments. This segment structure reflects the Company's current operating focus in compliance with Accounting Standards Codification ("ASC") 280, *Segment Reporting*. As a result of the new segment reporting structure, the Company has reclassified prior year amounts to conform them to the current year presentation. The revised segment structure and the related presentation changes did not impact consolidated net loss, earnings (loss) per share, total current assets, total assets or total stockholders' equity. Refer to Note 17 "Segment and Geographic Information," for additional information on the Company's reportable segments.

***Use of Estimates*** – The preparation of financial statements in conformity with GAAP 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.

***Reclassifications*** – As a result of the acquisition of GVB (see Note 2), the Company has revised the presentation and classification of depreciation and amortization in the Consolidated Statement of Operations and Comprehensive Loss to conform with the acquiree, as follows:

| | Year Ended December 31, 2021 | | |
|---|---|---|---|
| | As originally reported | Reclass | Revised |
| Revenues, net | $ 30,948 | $ — | $ 30,948 |
| Cost of goods sold | 28,879 | 583 | 29,462 |
| Gross profit | 2,069 | (583) | 1,486 |
| Operating expenses: | | | |
| Sales, general and administrative | 25,881 | 27 | 25,908 |
| Research and development | 3,274 | 638 | 3,912 |
| Impairment of intangible assets | 78 | (78) | — |
| Other operating expenses, net | — | 78 | 78 |
| Depreciation | 633 | (633) | — |
| Amortization | 615 | (615) | — |
| Total operating expenses | 30,481 | (583) | 29,898 |
| Operating loss | $ (28,412) | $ — | $ (28,412) |

***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 Accumulated other comprehensive loss. Gains or losses resulting from foreign currency denominated transactions are included in Other income (expense) in the Consolidated Statement of Operations and Comprehensive Loss.

***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 that may extend beyond 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. Some of the Company's short-term investment securities are fixed-income debt instruments, and accordingly, 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, net*** – 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 recorded an allowance for doubtful accounts of $372 and $0 for years ended December 31, 2022 and December 31, 2021.

***Inventories*** – Inventories are valued at the lower of historical cost or net realizable value. Cost is determined using an average cost method for tobacco leaf inventory and raw materials inventory. Standard cost is primarily used for finished goods inventory. Cost of hemp biomass consists of initial third-party acquisition costs plus analytical testing costs. Costs of extracted and hemp oil inventory are comprised of initial acquisition cost of the biomass and all direct and indirect processing costs including labor related costs, consumables, materials, packaging supplies, utilities, facility costs, analytical testing costs, and production related depreciation. 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. The following table shows estimated useful lives of property, plant and equipment:

| Classification | Estimated Useful Lives |
|---|---|
| Buildings | 25 to 40 years |
| Laboratory equipment | 5 years |
| Land improvements | 15 years |
| Leasehold improvements | shorter of 20 years or lease term |
| Manufacturing equipment | 5 to 15 years |
| Office furniture, fixtures and equipment | 3 to 10 years |
| Vehicles | 5 years |

***Acquisitions -*** The Company accounts for acquisitions under the acquisition method of accounting for business combinations. Results of operations of acquired companies are included in the Company's results of operations as of the respective acquisition dates. The purchase price of each acquisition is allocated to the net assets acquired based on estimates of their fair values at the date of the acquisition. Any purchase price in excess of these net assets is recorded as goodwill. The allocation of purchase price in certain cases may be subject to revision based on the final determination of fair values during the measurement period, which may be up to one year from the acquisition date.

All direct acquisition-related costs are expensed as incurred and are recognized in Other operating expenses, net on the Company's Consolidated Statements of Operations and Comprehensive Loss.

***Goodwill -*** Goodwill represents the excess of cost over the fair value of identifiable net assets of a business acquired and is assigned to one or more reporting units. The Company's reporting units are the same as its reportable segments, Tobacco and Hemp/cannabis. The Company tests its reporting unit's goodwill for impairment at least annually as of the measurement date and between annual tests if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of a reporting unit below its carrying amount.

In conducting its goodwill test, the Company either performs a qualitative assessment or a quantitative assessment. A qualitative assessment requires that the Company consider events or circumstances including, but not limited to, macro-economic conditions, market and industry conditions, cost factors, competitive environment, changes in strategy, changes in customers, changes in the Company's stock price, results of the last impairment test, and the operational stability and the overall financial performance of the reporting units. If, after assessing the totality of events or circumstances, the Company determines that it is more likely than not that the fair values of its reporting units are greater than the carrying amounts, then the quantitative goodwill impairment test is not performed. The Company may elect to bypass the qualitative analysis and perform a quantitative analysis.

If the qualitative assessment indicates that the quantitative analysis should be performed or if management elects to bypass a qualitative analysis to perform a quantitative analysis, the Company then evaluates goodwill for impairment by comparing the fair value of each of its reporting units to its carrying value, including the associated goodwill. To determine the fair values, the Company uses a weighted combination of the market approach based on comparable publicly traded companies and the income approach based on estimated discounted future cash flows. The cash flow assumptions consider historical and forecasted revenue, operating costs and other relevant factors.

The Company completed its annual goodwill impairment test as of December 1, 2022 and determined, after performing a quantitative assessment of its Hemp/cannabis reporting unit, the fair value of the Hemp/cannabis reporting unit exceeded its carrying amount.

***Intangible Assets*** – Intangible assets recorded at fair value as a component of purchase accounting consist of purchased customer relationships and tradename. Definite lived intangible assets related to customer relationship is amortized on an accelerated basis, which approximates the projected cash flows used to determine the fair value of the definite-lived intangible asset at the time of acquisition. The tradename asset is considered indefinite-lived and is not amortized.

Other definite lived 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 2043. 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.

The Company completed its annual impairment test as of December 1, 2022 of indefinite lived intangible assets and determined, after performing a quantitative assessment using the relief from royalty method, the fair value was below its carrying amount and accordingly recorded an impairment charge.

Refer to Note 6 “Goodwill and Other Intangible Assets, Net” for further details of the Company’s goodwill and other intangible assets and Note 8 “Fair Value Measurements” for further details of the inputs and assumptions utilized in managements quantitative assessment of indefinite lived intangible assets.

***Leases*** – The Company determines if an arrangement is, or contains, a lease at inception and classifies it as operating or finance. The Company has operating and finance leases for office and manufacturing facilities, machinery and vehicles. Finance lease assets and corresponding liabilities are not material to the consolidated financial statements.

Any operating lease having a lease term greater than twelve months will be recognized on the Consolidated Balance Sheets as a right-of-use (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 5 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, 2022 and December 31, 2021. 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, 2019 through December 31, 2021 are currently open to audit under the statutes of limitations. There are no pending audits as of December 31, 2022.

***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 18.

***Fair Value of Financial Instruments –*** 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 Company estimates that the carrying amounts reported on the Consolidated Balance Sheets for cash and cash equivalents, accounts receivable, contract assets, promissory note receivable, accounts payable and accrued expenses, and notes and loans payable approximate their fair value due to the short-term nature of these items. Note 8 contains additional information on assets and liabilities recorded at fair value in the Consolidated Financial Statements.

***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.

***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.

***Gain and 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.

The Company maintains general liability insurance policies for its facilities. Under the terms of our insurance policies, in the case of loss to a property, the Company follows the guidance in ASC 610-30, *Other Income —Gains and Losses on Involuntary Conversions,* for the conversion of nonmonetary assets (the properties) to monetary assets (insurance recoveries). Under ASC 610-30, once the recovery is deemed probable the Company recognizes an asset for the insurance recovery receivable in the Consolidated Balance Sheets, with corresponding income that is offsetting to the casualty losses recorded in the Consolidated Statements of Operations and Comprehensive Loss. If the insurance recovery is less than the amount of the casualty charges recognized, the Company will recognize a loss whereas if the insurance recovery is greater than the amount of casualty loss recognized, the Company will only recognize a recovery up to the amount of the casualty loss and will account for the excess as a gain contingency in accordance with ASC 450-30, *Gain Contingencies.* Business interruption insurance is treated as a gain contingency. Gain contingencies are recognized when earned and realized, which typically will occur at the time of final settlement or when cash is received.

Refer to further discussion of all commitments and contingencies in Note 12.

***Severance charges -*** From time to time, the Company evaluates its resources and optimizes its business plan to align to changing needs of executing on its strategy. These actions may result in voluntary or involuntary employee termination benefits. Voluntary termination benefits are accrued when an employee accepts the related offer. Involuntary termination benefits are accrued upon the commitment to a termination plan and the benefit arrangement is communicated to affected employees, or when liabilities are determined to be probable and estimable, depending on the existence of a substantive plan for severance or termination. The following table summarizes the change in accrued liabilities, presented within Other current liabilities and Other long-term liabilities Consolidated Balance Sheets:

| | |
|---|---|
| Balance at January 1, 2022 | $ 238 |
| Accruals | 692 |
| Cash payments | (296) |
| Balance at December 31, 2022 | $ 634 |

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Current | $ 349 | $ 217 |
| Noncurrent | 285 | 21 |
| Total severance liability | $ 634 | $ 238 |

In addition, during the year ended December 31, 2022, the Company recorded $1,237 of accelerated equity compensation expense in connection with the vesting of an employee's outstanding equity awards as part of the termination severance agreement. Amounts are recorded as Selling, general and administrative in the Consolidated Statements of Operations and Comprehensive Loss.

***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 provisions of the ASU have an effective date for the Company beginning after December 15, 2022 and interim periods within those fiscal years.

The standard was effective for the Company on January 1, 2023 and will be adopted using a modified retrospective transition method through a cumulative-effect adjustment to retained earnings. The Company does not expect the new credit loss standard to have a material impact to the Consolidated Financial Statements.

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. – BUSINESS ACQUISITIONS**

On May 13, 2022, the Company entered into and closed the transactions contemplated by the Reorganization and Acquisition Agreement (the "Reorganization Agreement") with GVB. Under the terms of the Reorganization Agreement, the Company acquired substantially all of the assets of GVB's business dedicated to hemp-based cannabinoid extraction, refinement, contract manufacturing and product development (the "Transaction"). The acquisition of GVB allows the Company to leverage its expertise in receptor and plant science to develop its hemp/cannabis franchise and add significant scale. GVB is included in the Company's Hemp/cannabis reportable segment.

The aggregate consideration for the Transaction consisted of (i) the assumption of approximately $4,637 of debt, (ii) the assumption and direct payment of certain third-party transaction costs incurred by GVB in connection with the Transaction totaling approximately $1,753 and (iii) the issuance to GVB of 32,900,000 unregistered shares of common stock of the Company (the "Shares") with a fair value of $51,653. The fair value of the Company's common stock issued as part of the consideration was determined based upon the opening stock price of the Company's shares as of the acquisition date. The Shares are subject to a lock-up and restrictions on transfer for at least six months following closing and thereafter, one-third of the Shares will be released from the lock-up after six months, one-third will be released from the lock-up after nine months and the remainder will be released after one year.

The Transaction was structured as a tax-free re-organization pursuant to Internal Revenue Code Section 368(a)(1)(c). Accordingly, the tax basis of net assets acquired retain their carry over tax basis and holding period in purchase accounting.

The Company recorded provisional estimated fair values for the assets purchased, liabilities assumed and purchase consideration as of the date of the acquisition during the second quarter of 2022, resulting in goodwill of $44,200. The determination of estimated fair value required management to make significant estimates and assumptions based on information that was available at the time the Consolidated Financial Statements were prepared.

During the measurement period, the preliminary fair values of the assets acquired and liabilities assumed as of May 13, 2022 were adjusted to reflect the ongoing acquisition valuation analysis procedures of property and equipment, intangible assets, deferred taxes, and working capital adjustments. These adjustments resulted in a combined reduction to goodwill of $11,040. The impact of depreciation and amortization to Operating loss recorded in the third quarter of 2022 as a result of completing valuation procedures for property and equipment and intangible assets, that would have been recorded in the prior period since the date of acquisition was $70.

The amounts reported are considered provisional as the Company is finalizing the valuations that are required to allocate the purchase price through the measurement period, which remains open as of December 31, 2022, as the final stub period income tax returns have not yet been completed. As a result, the allocation of the provisional purchase price may change in the future, which could be material.

The following table presents management's purchase price allocation:

| | | |
|---|---|---|
| Cash | $ | 456 |
| Accounts receivable | | 2,944 |
| Inventory | | 3,551 |
| Other assets | | 519 |
| Property, plant & equipment | | 11,388 |
| Operating leases right-of-use assets, net | | 1,231 |
| Goodwill | | 33,161 |
| Tradename | | 4,600 |
| Customer relationships | | 5,800 |
| Accounts payable and accrued expenses | | (2,777) |
| Other current liabilities | | (944) |
| Lease liabilities | | (1,259) |
| Auto loans | | (387) |
| Deferred tax liability | | (627) |
| Bridge loan | | (4,250) |
| Fair value of net assets acquired | $ | 53,406 |

The fair values of the assets acquired were determined using one of three valuation approaches: market, income or cost. The selection of a particular method for a given asset depended on the reliability of available data and the nature of the asset, among other considerations.

The market approach estimates the value for a subject asset based on available market pricing for comparable assets. The income approach estimates the value for a subject asset based on the present value of cash flows projected to be generated by the asset. The projected cash flows were discounted at a required rate of return that reflects the relative risk of the asset and the time value of money. The projected cash flows for each asset considered multiple factors from the perspective of a marketplace participant including revenue projections from existing customers, attrition trends, tradename life-cycle assumptions, marginal tax rates and expected profit margins giving consideration to historical and expected margins. The cost approach estimates the value for a subject asset based on the cost to replace the asset and reflects the estimated reproduction or replacement cost for the asset, less an allowance for loss in value due to depreciation or obsolescence, with specific consideration given to economic obsolescence if indicated. These fair value measurement approaches are based on significant unobservable inputs, including management estimates and assumptions.

***Current Assets and Liabilities***

The fair value of current assets and liabilities, excluding inventory, was assumed to approximate their carrying value as of the acquisition date due to the short-term nature of these assets and liabilities.

The fair value of in-process and finished goods inventory acquired was estimated by applying a version of the income approach called the comparable sales method. This approach estimates the fair value of the assets by calculating the potential revenue generated from selling the inventory and subtracting from it the costs related to the completion and sale of that inventory and a reasonable profit allowance for these remaining efforts. Based upon this methodology, the Company recorded the inventory acquired at fair value resulting in an increase in inventory of $978, which was fully amortized in the three month period ended June 30, 2022 in the Consolidated Statement of Operations and Comprehensive Loss.

***Property, Plant and Equipment***

The fair value of PP&E acquired was estimated by applying the cost approach for personal property and leasehold improvements. The cost approach was applied by developing a replacement cost and adjusting for economic depreciation and obsolescence.

***Leases***

The Company recognized operating lease liabilities and operating lease right-of-use assets for office and manufacturing facilities in (i) Las Vegas, Nevada (ii) Grass Valley, Oregon (iii) Prineville, Oregon, and (iv) Tygh Valley, Oregon, accordance with ASC 842, *Leases*.

The following table summarizes the Company's discount rate and remaining lease terms as of the acquisition date:

| | |
|---|---|
| Weighted average remaining lease term in years | 3.8 |
| Weighted average discount rate | 8.3 % |

The Company concluded there were no off-market lease intangibles on the date of acquisition based on an evaluation of market rents per square foot, geographic location and nature of use of the underlying asset, among other considerations.

***Intangible assets***

The purchase price was allocated to intangible assets as follows:

| Definite-lived Intangible Assets | Fair Value Assigned | Weighted Average Amortization Period (Years) | Weighted Average Discount Rate |
|---|---|---|---|
| Customer relationships | $ 5,800 | 10 | 23.50% |
| Tradename | $ 4,600 | Indefinite | 23.50% |

***Customer Relationships***

Customer relationships represent the estimated fair value of contractual and non-contractual customer relationships GVB had as of the acquisition date. These relationships were valued separately from goodwill at the amount that an independent third party would be willing to pay for these relationships. The fair value of customer relationships was determined using the multi-period excess-earnings method, a form of the income approach. The estimated useful life of the existing customer base was based upon the historical customer annual attrition rate of 20%, as well as management's understanding of the industry and product life cycles.

***Tradename***

Tradename represents the estimated fair value of GVB's corporate and product names. The acquired tradename was valued separately from goodwill at the amount that an independent third party would be willing to pay for use of these names. The fair value of the tradename was determined by utilizing the relief from royalty method, a form of the income approach, with a royalty rate of 1.0%. The GVB tradename was assumed to have an indefinite useful life based upon long-term management expectations and future operating plans.

***Deferred Taxes***

The Company determined the deferred tax position to be recorded at the time of the GVB acquisition in accordance with ASC Topic 740, *Income Taxes*, resulting in recognition of deferred tax liabilities for future reversing of taxable temporary differences primarily for intangible assets and property, plant and equipment. This resulted in a preliminary net deferred tax liability of $627, which includes the carryover basis of historical recognized deferred tax assets, liabilities and valuation allowance.

The net deferred tax liabilities recorded as a result of the acquisition of GVB was determined by the Company to also provide future taxable temporary differences that allow for the Company to utilize certain previously fully reserved deferred tax assets. Accordingly, the Company recognized a reduction to its valuation allowance resulting in a net tax benefit of approximately $434 for the year ended December 31, 2022.

***Goodwill***

The excess of the purchase price over the fair value of net tangible and intangible assets acquired and liabilities assumed was allocated to goodwill. A variety of factors contributed to the goodwill recognized, including the value of GVB's assembled work force, the incremental value resulting from GVB's capabilities in hemp/cannabis, operational synergies across the plant science platform, and the expected revenue growth over time that is attributable to increased market share from future products and customers. Goodwill recorded in the transaction will be non-deductible.

***Actual and Pro Forma (unaudited) disclosures***

The results of operations and assets from the GVB acquisition have been included in the Company's consolidated financial statements since the acquisition date. For the year ended December 31, 2022, net revenues related to GVB were $21,610, and net loss was $14,771.

The following unaudited pro forma information presents the consolidated results of operations of the Company and assumes the acquisition occurred on January 1, 2021:

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| | (in thousands, except for per-share data) | | | |
| Revenues, net | $ 19,482 | $ 16,724 | $ 73,112 | $ 60,374 |
| Net loss | $ (25,629) | $ (11,259) | $ (59,710) | $ (31,848) |
| Net loss per common share - basic and diluted | $ (0.12) | $ (0.06) | $ (0.29) | $ (0.17) |
| Weighted average common shares outstanding - basic and diluted | 215,293 | 195,668 | 204,825 | 189,108 |

The unaudited pro forma results are presented for illustrative purposes only and do not reflect the realization of potential cost savings, and any related integration costs. Certain costs savings may result from the acquisition; however, there can be no assurance that these cost savings will be achieved. These unaudited pro forma results do not purport to be indicative of the results that would have been obtained, or to be a projection of results that may be obtained in the future. These unaudited pro forma results include certain adjustments, primarily due to amortization expense due to the fair value adjustment of inventory, acquisition related costs and the impact of income taxes on the pro forma adjustments.

***Acquisition costs***

During the year ended December 31, 2022, direct costs incurred as a result of the acquisition of GVB of $1,046 were expensed as incurred and included in Other operating expenses, net in the Consolidated Statements of Operations and Comprehensive Loss.

**NOTE 3. – INVENTORIES**

Inventories at December 31, 2022 and 2021 consisted of the following:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Raw materials | $ 8,743 | $ 2,634 |
| Work in process | 441 | — |
| Finished goods | 824 | 247 |
| | $ 10,008 | $ 2,881 |

During the year ended December 31, 2022, the Company wrote off inventory totaling $4,236 ($3,999 related to the GVB fire as discussed in Note 19) which is included within Other operating expenses, net on the Company's Consolidated Statement of Operations and Comprehensive Loss and $281 which is included with Cost of goods sold on the Company's Consolidated Statement of Operations and Comprehensive Loss.

During the year ended December 31, 2021, the Company wrote off inventory totaling $317 which is included within Cost of goods sold on the Company's Consolidated Statement of Operations and Comprehensive Loss.

## NOTE 4. – PROPERTY, PLANT AND EQUIPMENT, NET

Property, plant and equipment, net at December 31, 2022 and 2021 consisted of the following:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Land | $ 1,665 | $ 1,665 |
| Land improvements | 167 | — |
| Buildings | 331 | 130 |
| Laboratory equipment | 744 | 198 |
| Leasehold improvements | 358 | 179 |
| Manufacturing equipment | 10,469 | 5,541 |
| Office furniture, fixtures and equipment | 557 | 139 |
| Vehicles | 950 | — |
| Construction in progress | 3,774 | 1,289 |
| | 19,015 | 9,141 |
| Less: accumulated depreciation | (5,922) | (3,300) |
| Property, plant and equipment, net | $ 13,093 | $ 5,841 |

As of December 31, 2022, the Construction in progress balance primarily relates to the ongoing development of the Prineville, Oregon crude extraction facility, anticipated to be placed in service in the first quarter of 2023. As of December 31, 2021, Construction in progress primarily related to tobacco machinery and equipment, which was placed in service during 2022.

Depreciation expense was $2,178 and $633 for the year ended December 31, 2022 and 2021, respectively. Due to the GVB fire in 2022 (see Note 19), total property, plant and equipment write offs amounted to $5,499 which is included within Other operating expenses, net on the Company's Consolidated Statement of Operations and Comprehensive Loss.

## NOTE 5. – RIGHT-OF-USE ASSETS, LEASE OBLIGATIONS, AND OTHER LEASES

The Company leases office space, laboratory space and manufacturing facilities in (i) Mocksville, North Carolina, (ii) Buffalo, New York, (iii) Rockville, Maryland, (iv) Las Vegas, Nevada, (v) Prineville, Oregon, and (vi) multiple locations in Madras, Oregon.

The following table summarized the Company's discount rate and remaining lease terms as of December 31, 2022:

| | |
|---|---|
| Weighted average remaining lease term in years | 6.8 |
| Weighted average discount rate | 6.1 % |

Future minimum lease payments as of December 31, 2022 are as follows:

| | |
|---|---|
| 2023 | $ 835 |
| 2024 | 706 |
| 2025 | 676 |
| 2026 | 219 |
| 2027 | 195 |
| Thereafter | 1,142 |
| Total lease payments | 3,773 |
| Less: imputed interest | (951) |
| Present value of lease liabilities | 2,823 |
| Less: current portion of lease liabilities | (681) |
| Total long-term lease liabilities | $ 2,141 |

Operating lease costs for the year ended December 31, 2022 and 2021, were $891 and $301, respectively.

Supplemental cash flow information for leases for fiscal years 2022 and 2021 are comprised of the following:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Cash paid for operating leases | $ 849 | $ 239 |
| Assets acquired under operating leases | $ 729 | $ 1,816 |

During the fiscal year ended December 31, 2022, the Company extended the lease terms for one of its manufacturing facilities. As a result of these lease modifications, the Company re-measured the lease liability and adjusted the ROU asset on the modification dates.

## NOTE 6. – GOODWILL AND OTHER INTANGIBLE ASSETS, NET

*Goodwill*

The change in the carrying amount of goodwill during fiscal year 2022 was as follows:

| | |
|---|---|
| Balance at January 1, 2022 | $ — |
| GVB acquisition (see Note 2) | 44,200 |
| Measurement period adjustments | (11,040) |
| Balance at December 31, 2022 | $ 33,160 |

*Intangible Assets*

Our intangible assets at December 31, 2022 and 2021 consisted of the following:

| December 31, 2022 | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount |
|---|---|---|---|
| ***Definite-lived:*** | | | |
| Patent | $ 6,513 | $ (3,711) | $ 2,802 |
| License Fees | 3,876 | (1,446) | 2,430 |
| Customer relationships | 5,800 | (20) | 5,780 |
| Total amortizing intangible assets | $ 16,189 | $ (5,177) | $ 11,012 |
| ***Indefinite-lived:*** | | | |
| Tradename and trademarks | | | $ 3,289 |
| MSA signatory costs | | | 2,202 |
| License fee for predicate cigarette brand | | | 350 |
| Total indefinite-lived intangible assets | | | $ 5,841 |
| Total intangible assets, net | | | $ 16,853 |

| December 31, 2021 | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount |
|---|---|---|---|
| ***Definite-lived:*** | | | |
| Patent | $ 5,902 | $ (3,303) | $ 2,599 |
| License Fees | 3,876 | (1,197) | 2,679 |
| Total amortizing intangible assets | $ 9,778 | $ (4,500) | $ 5,278 |
| ***Indefinite-lived:*** | | | |
| Tradename and trademarks | | | $ 89 |
| MSA signatory costs | | | 2,202 |
| License fee for predicate cigarette brand | | | 350 |
| Total indefinite-lived intangible assets | | | $ 2,641 |
| Total intangible assets, net | | | $ 7,919 |

See Note 2 “Business Acquisitions” for additional details regarding goodwill and intangible assets acquired during 2022 as a result of the acquisition of GVB, including measurement period adjustments.

Aggregate intangible asset amortization expense comprises of the following:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Cost of goods sold | $ 10 | $ 10 |
| Sales, general, and administrative | 20 | — |
| Research and development | 650 | 605 |
| Total amortization expense | $ 680 | $ 615 |

During the year ended December 31, 2022, the Company incurred impairment charges of $1,488, primarily related to write-down of tradename, as a result of a shift in strategy and changes in expected future cash flows for certain contracts supporting the associated tradename (see Note 19). During the year ended December 31, 2021, the Company incurred a charge of $78 related to a write-down of our trademarks, as a result of abandonment of the trademark as it no longer aligned to Company strategic objectives.

The impairment charges are included in Other operating expenses, net on the Company’s Consolidated Statements of Operations and Comprehensive Loss.

Estimated future intangible asset amortization expense based on the carrying value as of December 31, 2022 is as follows:

| | 2023 | 2024 | 2025 | 2026 | 2027 | Thereafter |
|---|---|---|---|---|---|---|
| Amortization expense | $ 1,667 | $ 1,657 | $ 1,516 | $ 1,261 | $ 1,111 | $ 3,800 |

**NOTE 7. – INVESTMENTS & OTHER ASSETS**

The carrying value of the Company’s investments at December 31, 2022 and 2021 consisted of the following:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Panacea Life Sciences Holdings, Inc. common stock | $ — | $ 2,340 |
| Aurora stock warrants | — | 5 |
| Change Agronomy Ltd. ordinary shares | 682 | — |
| Total investments | $ 682 | $ 2,345 |

***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. 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. 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.

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 originally 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.

*Panacea Investment – Settlement Agreement:*

On December 31, 2022, the Company and Panacea Life Sciences Holdings, Inc. entered into a settlement agreement in which the Company agreed to forfeit and return all PLSH common stock outstanding with a fair value of $229 and reduction to the face value of the Promissory note receivable of $500, in exchange for resolution to all contractual requirements from the June 30, 2021 Promissory Note Exchange Agreement and Securities Exchange Agreement surrounding the investment and business relationship. The total charge of $2,789 recorded in connection with the settlement agreement and change in fair value during the year ended December 31, 2022 is included within Realized (loss) gain on Panacea investment on the Consolidated Statements of Operations and Comprehensive Loss and is comprised of change in fair value and write-off of PLSH common stock of $2,340 and extinguishment of note receivable of $500 less adjusted discount of $51.

As of December 31, 2022, the total carrying value of the Company's investment in Panacea is outlined below:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Panacea Holdings common stock | $ — | $ 2,340 |
| Promissory note receivable | 3,410 | 3,741 |
| Total | $ 3,410 | $ 6,081 |

***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 8 for additional information on the fair value measurements.

***Investment in Change Agronomy Ltd.***

On December 10, 2021, the Company 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 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 equated to approximately 1.8% of CAL's total equity.

In accordance with ASU 2019-04, a foreign currency-denominated equity investments that are measured using the measurement alternative are nonmonetary items that should be remeasured using their historical exchange rates. Accordingly, for the year ended December 31, 2022, there is no foreign currency exchange gain or loss recorded in the Consolidated Statement of Operations and Comprehensive Loss related to the investment in Change Agronomy Ltd.

During the years ended December 31, 2022 and 2021, respectively, there were no impairment triggering events identified for investments.

## NOTE 8. – FAIR VALUE MEASUREMENTS AND SHORT-TERM INVESTMENTS

**Assets and Liabilities Measured at Fair Value on a Recurring Basis**

Fair value measurement standards apply to certain financial assets and liabilities that are measured at fair value on a recurring basis (each reporting period). For the Company, these financial assets and liabilities include its short-term investment securities and equity investments. The Company does not have any nonfinancial assets or liabilities that are measured at fair value on a recurring basis.

.The following table presents information about our assets and liabilities measured at fair value at December 31, 2022 and 2021, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

| | Fair Value December 31, 2022 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets** | | | | |
| Short-term investment securities: | | | | |
| Money market funds | $ 10,163 | $ — | $ — | $ 10,163 |
| Corporate bonds | — | 7,031 | — | 7,031 |
| U.S. treasury securities | — | 999 | — | 999 |
| Total short-term investment securities | $ 10,163 | $ 8,030 | $ — | $ 18,193 |
| Investments: | | | | |
| Change Agronomy Ltd. ordinary shares | $ — | $ — | $ 682 | $ 682 |
| Total investments | $ — | $ — | $ 682 | $ 682 |

| | 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 |
| Investments: | | | | |
| Panacea Life Sciences Holdings, Inc. common shares | $ 2,340 | $ — | $ — | $ 2,340 |
| Aurora stock warrants | — | — | 5 | 5 |
| Total investments | $ 2,340 | $ — | $ 5 | $ 2,345 |

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. The Company classifies its money market funds within Level 1 because it uses quoted market prices to determine their fair value. The Company classifies its commercial paper, corporate notes, certificates of deposit, and U.S. government bonds within Level 2 because it uses quoted prices for similar assets or liabilities in active markets and each has a specified term and all level 2 inputs are observable for substantially the full term of each instrument.

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

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 change in fair value for the years ended December 31, 2022, and 2021 were losses of $2,112 and $6,761, respectively.

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, 2022.

| | |
|---|---|
| Fair Value at January 1, 2022 | $ 5 |
| Unrealized loss on Aurora stock warrants | (5) |
| Investment in Change Agronomy Ltd. ordinary shares | 682 |
| Fair Value at December 31, 2022 | $ 682 |

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, 2022 and 2021:

| | Available for Sale Debt Securities December 31, 2022 | | | |
|---|---|---|---|---|
| | Amortized Cost Basis | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Corporate bonds | $ 7,143 | $ — | $ (112) | $ 7,031 |

| | 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 |

The following table sets forth a summary of the Company's available-for-sale debt securities at amortized cost basis and fair value by contractual maturity as of December 31, 2022 and December 31, 2021:

| | Available for Sale Debt Securities | | | |
|---|---|---|---|---|
| | December 31, 2022 | | December 31, 2021 | |
| | Amortized Cost Basis | Fair Value | Amortized Cost Basis | Fair Value |
| Due in one year or less | $ 7,143 | $ 7,031 | $ 8,286 | $ 8,280 |
| Due after one year through five years | — | $ — | $ 30,357 | $ 30,201 |
| | $ 7,143 | $ 7,031 | $ 38,643 | $ 38,481 |

The Company recognized interest income on short-term investment securities recorded in Interest income, net on the Consolidated Statement of Operations and Comprehensive Loss during the years ended December 31, 2022 and 2021 of $546 and $483, respectively.

**Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis**

Fair value standards also apply to certain assets and liabilities that are measured at fair value on a nonrecurring basis. The Company's non-recurring fair value measurement as of December 31, 2022, consisted of the fair value of impaired indefinite-lived intangible asset that was determined by utilizing the relief from royalty method with Level 3 inputs, including royalty rate of 1.0% and discount rate of 24.5%.

During the years ended December 31, 2022 and 2021, the Company did not have any other financial assets or liabilities measured at fair value on a nonrecurring basis.

**NOTE 9. – NOTES AND LOANS PAYABLE**

The table below outlines our notes payable balances as of December 31, 2022 and 2021:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Insurance loans payable | $ 780 | $ 596 |
| Vehicle loans | 128 | — |
| Total current notes and loans payable | $ 908 | $ 596 |
| | | |
| Bridge loan | $ 2,814 | $ — |
| Vehicle loans | 187 | — |
| Total long-term notes and loans payable | $ 3,001 | $ 596 |

*Insurance loans payable*

During the second quarter of 2022, the Company renewed its Director and Officer ("D&O") insurance for a one-year policy premium totaling $2,394. The Company paid $400 as a premium down payment and financed the remaining $1,994 of policy premiums over ten months at a 3.25% annual percentage rate. Additionally, during the third quarter of 2022, the Company expanded its D&O coverage as a result of the acquisition of GVB, resulting in an additional premium down payment of $90 and financing of $168, under the same terms as the original one-year policy.

During the second quarter of 2021, the Company renewed its 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.

The Company also has other insurance loans payables related to pollution, and general liability for GVB.

*Vehicle Loans*

The Company has various vehicle loans with monthly payments ranging from $0.5 to $2.1, interest rates ranging from 0% to 11%, and maturity dates ranging from March 2023 to September 2026.

*GVB Bridge Note*

In connection with the acquisition of GVB (see Note 2), the Company assumed the outstanding principal balance of 12% secured promissory note in the principal amount of $4,250 ("GVB Bridge Note"). On October 31, 2022, the Company repaid $1,899 (outstanding principal of $1,750 and accrued interest of $149). The remaining outstanding principal of $2,500 and accrued interest was refinanced and has a maturity date of May 1, 2024 (see Note 21).

Accretion of non-cash interest expense amounted to $0 and $7 for the years ended December 31, 2022 and 2021, respectively.

Estimated future principal payments to be made under the above notes and loans payable as of December 31, 2022 are as follows:

| | |
|---|---|
| 2023 | $ 908 |
| 2024 | 2,935 |
| 2025 | 59 |
| 2026 | 7 |
| Total | $ 3,909 |

## NOTE 10. – CAPITAL RAISE AND WARRANTS FOR COMMON STOCK

*2022 Capital Raise*

On July 21, 2022, the Company and certain institutional investors (the "Investors") entered into a securities purchase agreement (the "Securities Purchase Agreement") relating to the issuance and sale of shares of common stock pursuant to a registered direct offering (the "Registered Offering" and, together with the Private Placement (as defined below), the "Offerings"). The Investors purchased approximately $35,000 of shares, consisting of an aggregate of 17,073,175 shares of common stock at a purchase price of $2.05 per share, subject to certain restrictions. The net proceeds to the Company from the Offerings, after deducting the fees and the Company's offering expenses, were $32,484. The Offerings closed on July 25, 2022.

Pursuant to the Securities Purchase Agreement, in a concurrent private placement, the Company issued and sold to the Investors warrants (the "Warrants") to purchase up to 17,073,175 shares of common stock (the "Private Placement"). The Warrants are exercisable immediately upon issuance at an exercise price of $2.05 per share of common stock, subject to adjustment in certain circumstances, and expire on July 25, 2027.

*2021 Capital Raise*

On June 7, 2021, the Company and an 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.

*Warrant Exercise*

During the first quarter of 2021, the Company's warrant holders exercised 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. The following table summarizes the Company's warrant activity since January 1, 2021:

| | Number of Warrants |
|---|---|
| Warrants outstanding at January 1, 2021 | 11,293,211 |
| Exercised | (11,293,211) |
| Issued | — |
| Warrants outstanding at December 31, 2021 | — |
| Exercised | — |
| Issued | 17,073,175 |
| Warrants outstanding at December 31, 2022 | 17,073,175 |

## 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, 2022 and 2021 amounted to $200 and $171, 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** | **2023** | **2024** | **2025** | **2026** | **2027 & After** | **Total** |
| Research Agreement | KeyGene | Hemp / Cannabis | Contract fee | $ 2,524 | $ 2,058 | $ 1,589 | $ 1,302 | $ 328 | $ 7,801 (1) |
| License Agreement | NCSU | Tobacco | Minimum annual royalty | 325 | 100 | 100 | 100 | 1,000 | 1,625 (2) |
| Research Agreement | NCSU | Tobacco | Contract fee | 99 | — | — | — | — | 99 (3) |
| Sublicense Agreement | Anandia Laboratories, Inc. | Hemp / Cannabis | Annual license fee | 10 | 10 | 10 | 100 | — | 130 (4) |
| Research Agreement | Cannametrix | Hemp / Cannabis | Contract fee | 667 | 666 | — | — | — | 1,333 (5) |
| License Agreement | Cannametrix | Hemp / Cannabis | Minimum annual royalty | — | — | 75 | 100 | 1,900 | 2,075 (6) |
| Growing Agreements | Various | Tobacco | Contract fee | 242 | — | — | — | — | 242 (7) |
| Consulting Agreements | Various | Various | Contract fee | 1,195 | 746 | — | — | — | 1,941 (8) |
| | | | | $ 5,062 | $ 3,580 | $ 1,774 | $ 1,602 | $ 3,228 | $ 15,246 |

(1) Exclusive agreement with the Company in the field of the Cannabis Sativa L. plant. 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. On March 30, 2022, the Company and KeyGene entered into a new Framework Collaborative Research Agreement for a term of three years at an aggregate cost of $1,830 in the field related to the hops plant.

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 stated fields of each agreement. The Company has also granted KeyGene a license to commercialize the Results outside of each field and KeyGene will pay royalties in varying amounts to the Company relating to KeyGene's commercialization of the Results outside of each field.

(2) The minimum annual royalty fee is credited against running royalties on sales of licensed products. 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) On August 19, 2022, the Company entered into a one-year Sponsored Project Agreement with NCSU for continued research of tobacco alkaloid formation.

(4) 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.

(5) On March 11, 2022, the Company expanded its research agreement with Cannametrix for hemp/cannabis product development, formulation, and validation for a three-year period at an aggregate cost of $2,000.

(6) The minimum annual royalty fee is credited against running royalties from the sales of goods or services based on Project IP and/or Background IP.

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

(8) General corporate consulting agreements.

***Insurance recoveries*** – In connection with the Grass Valley fire, the Company has recorded $5,000 asset as Insurance recoveries on the Consolidated Balance Sheets and as income offsetting property, plant and equipment and inventory casualty losses in Other operating expenses, net in the Statement of Operations and Comprehensive Loss (see Note 19). The insurance recoveries related to property, plant and equipment of $3,500 is a non-cash investing activity. Additional business interruption insurance coverage with limits of $15,000 remains pending as of December 31, 2022, and will be recognized as income when all contingencies have been resolved.

***Litigation*** - The Company is subject to litigation arising from time to time in the ordinary course of its business. The Company does not expect that the ultimate resolution of any pending legal actions will have a material effect on its consolidated results of operations, financial position, or cash flows. However, litigation is subject to inherent uncertainties. As such, there can be no assurance that any pending legal action, which the Company currently believes to be immaterial, will not become material in the future. In accordance with applicable accounting guidance, the Company establishes an accrued liability for litigation and regulatory matters when those matters present loss contingencies that are both probable and estimable. In such cases, there may be an exposure to loss in excess of any amounts accrued. When a loss contingency is not both probable and estimable, the Company does not establish an accrued liability. As a litigation or regulatory matter develops, the Company, in conjunction with any outside counsel handling the matter, evaluates on an ongoing basis whether such matter presents a loss contingency that is probable and estimable. If, at the time of evaluation, the loss contingency related to a litigation or regulatory matter is not both probable and estimable, the matter will continue to be monitored for further developments that would make such loss contingency both probable and estimable. When a loss contingency related to a litigation or regulatory matter is deemed to be both probable and estimable, the Company will establish an accrued liability with respect to such loss contingency and record a corresponding amount of related expenses. The Company will then continue to monitor the matter for further developments that could affect the amount of any such accrued liability.

*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 January 14, 2021, the Court granted the motion, dismissing all claims with prejudice. The Plaintiffs filed a notice of appeal on February 12, 2021 to the Second Circuit Court of Appeals. On May 24, 2022, after briefing and oral argument, the Second Circuit issued an order affirming in part, and reversing in part, the District Court's dismissal order. The Second Circuit affirmed the District Court's dismissal of the claims relating to the non-disclosure of stock promotion articles, but reversed the District Court's dismissal order of the claims alleging the non-disclosure of an SEC investigation. The Second Circuit noted in its opinion, however, that the District Court had not addressed certain arguments raised by the Company and Messrs. Sicignano and Brodfuehrer in the Motion to Dismiss the Amended Complaint as to these remaining claims, and remanded the case to the District Court to address these arguments for the dismissal of the remaining claims. On August 8, 2022, the Company and Messrs. Sicignano and Brodfuehrer filed a renewed motion to dismiss the remaining claims in the Amended Complaint to address the arguments not previously addressed by the District Court. On September 22, 2022, Plaintiffs filed a brief in opposition to the motion. On October 12, 2022, the Company and Messrs. Sicignano and Brodfuehrer filed a reply brief in further support of the motion. On January 6, 2023, the District Court denied the motion to dismiss, and the case will proceed forward on the remaining claims. No trial date has been set. The parties have scheduled a mediation during March 2023.

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 remaining 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). On May 3, 2019, the Court ordered the *Mathew* case stayed. This stay was applied to the Consolidated Action pursuant to the Court's August 15, 2019 Order Consolidated Related Shareholder Derivative Actions and Establishing a Leadership Structure. As a result of the Court's denial of the renewed Motion to Dismiss the Amended Complaint, the May 3, 2019 stay will be lifted. No trial date has been set. 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 brought the action derivatively alleging that the director defendants supposedly breached their fiduciary duties by allegedly allowing the Company to make false statements. The Complaint sought 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 August 3, 2022, Plaintiff dismissed the case with prejudice by filing a stipulation of discontinuance with the Court. This dismissal was not pursuant to a settlement.

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 Broccuto 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 Broccuto and Wayne cases consolidated and stayed pursuant to a joint stipulation from the parties. On June 27, 2022, the Court ordered that the stay continue until thirty (30) days after the District Court rules on the renewed Motion to Dismiss the Amended Complaint in the Noto Class Action case. As a result of the Court's denial of the Motion to Dismiss the Amended Complaint, the June 27, 2022 stay will be lifted. No trial date has been set. The parties have scheduled a mediation during March 2023. 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, 2022 and 2021, 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, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands, except for per-share data) | |
| Net loss | $ (59,801) | $ (32,609) |
| Weighted average common shares outstanding - basic and diluted | 192,837 | 156,208 |
| Net loss per common share - basic and diluted | $ (0.31) | $ (0.21) |
| | | |
| Anti-dilutive shares are as follows as of December 31: | | |
| Warrants | 17,073 | — |
| Options | 4,912 | 5,171 |
| Restricted stock units | 4,033 | 3,165 |
| | 26,018 | 8,336 |

## NOTE 14. – ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The following table is a summary of the components and activity of Accumulated Other Comprehensive Income (Loss) ("AOCI") as of and for the year-ended December 31, 2022 and 2021, respectively:

| | Years Ended December 31, 2022 and 2021 | | | | |
|---|---|---|---|---|---|
| | Corporate securities/ investments | Foreign Translation Adjustment | Pre-tax Amount | Tax | Net of Tax Amount |
| **Balance at January 1, 2021** | **$ 74** | **$ —** | **$ 74** | **$ —** | **$ 74** |
| Unrealized loss on short-term investment securities | (236) | — | (236) | — | (236) |
| **Balance at December 31, 2021** | **$ (162)** | **$ —** | **$ (162)** | **$ —** | **$ (162)** |
| Unrealized loss on short-term investment securities | (316) | — | (316) | — | **(316)** |
| Foreign currency translation | — | 1 | 1 | — | 1 |
| Reclassification of realized losses to net loss | 366 | — | 366 | — | 366 |
| **Balance at December 31, 2022** | **$ (112)** | **$ 1** | **$ (111)** | **$ —** | **$ (111)** |

## NOTE 15. – EQUITY BASED COMPENSATION

*Stock Compensation Plan*

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, 2022, the Company had available 4,461,984 shares remaining for future awards under the 2021 Plan.

*Compensation Expense*

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

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Sales, general, and administrative | $ 5,307 | $ 3,821 |
| Research and development | 182 | 163 |
| Total RSUs and stock option compensation | $ 5,489 | $ 3,983 |

*Restricted Stock Units ("RSUs")*. We typically grant RSUs to employees and non-employee directors. The following table summarizes the changes in unvested RSUs from January 1, 2021 through December 31, 2022.

| | Unvested RSUs | |
|---|---|---|
| | Number of Shares | Weighted Average Grant-date Fair Value |
| | in thousands | $ per share |
| Unvested at January 1, 2021 | 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 |
| Granted | 3,535 | $ 1.96 |
| Vested | (2,306) | $ 2.11 |
| Forfeited | (361) | $ 2.39 |
| Unvested at December 31, 2022 | 4,033 | $ 2.13 |

The fair value of RSUs that vested during the years ended December 31, 2022 and 2021 was approximately $4,505 and $5,262, respectively, based on the stock price at the time of vesting. As of December 31, 2022, unrecognized compensation expense for RSUs amounted to $4,189 which is expected to be recognized over a weighted average period of approximately 0.8 years. In addition, there is approximately $1,310 of unrecognized compensation expense that requires the achievement of certain milestones which are not yet probable.

*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 January 1, 2021 is as follows:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| | in thousands | $ per share | | |
| Outstanding at January 1, 2021 | 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 | | |
| Exercised | (150) | 1.16 | | |
| Forfeited | (100) | 1.39 | | |
| Expired | (9) | 2.76 | | |
| Outstanding at December 31, 2022 | 4,912 | $ 1.67 | 2.3 years | $ — |
| | | | | |
| Exercisable at December 31, 2022 | 4,812 | $ 1.65 | 2.2 years | $ — |

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 2022. The following assumptions were used for the year ended December 31, 2021:

| | 2021 |
|---|---|
| Risk-free interest rate (1) | 0.54 % |
| Expected dividend yield (2) | — % |
| Expected volatility (3) | 87.92 % |
| Expected term of stock options (4) | 4.09 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.

As of December 31, 2022, there is approximately $190 of unrecognized compensation expense for stock options that requires the achievement of certain milestones which are not yet probable.

**NOTE 16. – INCOME TAXES**

The following is a summary of the components giving rise to the income tax (benefit) provision for the years ended December 31, 2022 and 2021:

| | 2022 | 2021 |
|---|---|---|
| Current: | | |
| Federal | $ — | $ — |
| State | 14 | — |
| Foreign | — | — |
| Total current provision | $ 14 | $ — |
| | | |
| Deferred: | | |
| Federal | (11,319) | (7,566) |
| State | (4,978) | (1) |
| Foreign | (24) | — |
| Total deferred benefit | (16,321) | (7,567) |
| Change in valuation allowance | 15,873 | 7,581 |
| Total income tax (benefit) / provision | $ (434) | $ 14 |

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

| | 2022 | 2021 |
|---|---|---|
| Statutory federal rate | 21.0 % | 21.0 % |
| Other items | (0.6) | (0.5) |
| Stock based compensation | (0.8) | 2.7 |
| Research and development credit carryforward | — | 0.1 |
| State tax, net of federal benefit | 8.3 | — |
| 162(m) limitation | (0.6) | — |
| Valuation allowance | (26.6) | (23.3) |
| | | |
| Effective tax rate | 0.7 % | — % |

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

| | 2022 | 2021 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carry-forward | $ 39,806 | $ 24,859 |
| Inventory | 694 | 104 |
| Stock-based compensation | 1,167 | 1,326 |
| Investment in Panacea Life Sciences, Inc. | 79 | 1,320 |
| Investment in Aurora Cannabis, Inc. | 53 | 46 |
| Start-up expenditures | 175 | 177 |
| Research and development credit carryforward | 1,205 | 1,192 |
| Accrued bonus | 537 | 411 |
| Severance liability | 151 | 50 |
| Allowance for doubtful accounts | 89 | — |
| Research and development costs | 1,521 | — |
| Operating lease obligations | 672 | 365 |
| Capital loss on investment | 2,209 | 107 |
| Capitalized legal fees | 178 | — |
| Other | 106 | 18 |
| | $ 48,642 | $ 29,975 |
| Deferred tax liabilities: | | |
| Machinery and equipment | (757) | (254) |
| Patents and trademarks | (356) | (373) |
| Operating lease right-of-use assets | (638) | (362) |
| Other intangible assets | (2,470) | (259) |
| | (4,221) | (1,248) |
| Valuation allowance | (44,652) | (28,779) |
| | | |
| Net deferred taxes | $ (231) | $ (52) |

The Company has net operating loss ("NOL") carryforwards of approximately $120,023 as of December 31, 2022 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 2030. As of December 31, 2022, the Company has a research and development credit carryforward of approximately $1,205 that begins to expire in 2030. The Company generated a capital loss carryover of approximately $9,271 as of December 31, 2022, that begins to expire 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. The valuation allowance increased by $15,873 and $7,581 for the years ended December 31, 2022, and 2021, respectively.

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, 2022.

**NOTE 17. – SEGMENT AND GEOGRAPHIC INFORMATION**

The Company organizes its business into two reportable segments: (1) Tobacco and (2) Hemp/Cannabis. This segment structure reflects the financial information and reports used by the Company's management, specifically its Chief Operating Decision Maker, to make decisions regarding the Company's business, including resource allocations and performance assessments. This segment structure reflects the Company's current operating focus in compliance with ASC 280, *Segment Reporting*.

The Company defines segment income from operations as revenues, net less cost of goods sold and expenses attributable to segment-specific selling, general, administrative, research, development, and other operating activities. The remaining unallocated operating and other income and expenses are primarily administrative corporate overhead expenses such as corporate personnel costs, equity compensation, investor relations, strategic consulting, research and development costs that apply broadly to the overall plant science platform, and that are not allocated to reportable segments. Unallocated corporate assets consist of cash and cash equivalents, short-term investment securities, prepaid and other assets, property and equipment, and intangible assets. Transactions between the two segments are not significant.

The following table presents revenues, net by segment for fiscal years ended December 31, 2022 and 2021:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Tobacco | $ 40,501 | $ 30,905 |
| Hemp/cannabis | 21,610 | 43 |
| Total revenues, net | $ 62,111 | $ 30,948 |

The following table presents income from continuing operations for the Company's reportable segments for fiscal years ended December 31, 2022 and 2021:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Tobacco | $ 5,753 | $ 2,527 |
| Hemp/cannabis | 15,870 | 624 |
| Total segment operating loss | 21,623 | 3,151 |
| Unallocated operating expenses | 35,483 | 25,261 |
| Operating loss | 57,106 | 28,412 |
| Hemp/cannabis other (income) expense, net | 227 | - |
| Unallocated other (income) expense, net | 2,902 | 4,183 |
| Loss before income taxes | $ 60,235 | $ 32,595 |

(1) In the fourth quarter of 2022, the Company recorded pre-tax charges and other expenses of $4,799 related to the Grass Valley fire. These charges were included in Other operating expenses, net as described in Note 19.

The following table presents depreciation and amortization expense for the Company's reportable segments for fiscal years ended December 31, 2022 and 2021:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Tobacco | $ 606 | $ 546 |
| Hemp/cannabis | 1,475 | 37 |
| Total depreciation and amortization included in segment operating loss | 2,081 | 583 |
| Unallocated depreciation and amortization | 777 | 665 |
| Total depreciation and amortization | $ 2,858 | $ 1,248 |

The following table presents total assets for the Company's reportable segments as of December 31, 2022 and 2021:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Tobacco | $ 15,748 | $ 10,746 |
| Hemp/cannabis | 65,965 | 2,266 |
| Total reportable segments | 81,713 | 13,013 |
| Unallocated assets | 32,938 | 62,942 |
| Total assets | $ 114,651 | $ 75,954 |

The following table presents capital expenditures for the Company's reportable segments for fiscal years ended December 31, 2022 and 2021:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Tobacco | $ 650 | $ 461 |
| Hemp/cannabis | 2,549 | - |
| Total reportable segments | 3,198 | 461 |
| Unallocated expenditures for long-lived tangible assets | 459 | 286 |
| Total expenditures | $ 3,657 | $ 745 |

***Geographic Area Information***

For the years ended December 31, 2022 and 2021, substantially all third-party sales of product are shipped to customers in the United States. Additionally, as of December 31, 2022, and 2021, substantially all long-lived assets are physically located or domiciled in the United States.

## NOTE 18. – REVENUE RECOGNITION

*Tobacco*

The Company's tobacco reportable segment revenues are derived primarily from contract manufacturing organization ("CMO") customer contracts that consist of obligations to manufacture the customers' branded filtered cigars and cigarettes. Additional revenues are generated from sale of the Company's proprietary low nicotine content cigarettes, sold under the brand name VLN®, or research cigarettes sold under the brand name SPECTRUM®.

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the product to a customer. For certain CMO 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. Tobacco revenue from the sale of the Company's products, which include 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, 2022 and December 31, 2021. Excise taxes recorded in Cost of Goods Sold on the Consolidated Statement of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021 was $12,619 and $10,135, respectively.

*Hemp/Cannabis*

The Company's hemp/cannabis reportable segment revenues are derived primarily from a CBD wholesale extracts and bulk ingredient distillate or isolate. Additional revenues are generated from private/white label contract manufacturing.

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the product to a customer. Revenue is recorded at the estimated amount of consideration to which the Company expects to be entitled. For certain sales where the company licenses its formulations for hemp-based products, it recognizes revenue once the products have been sold to customers by the licensee.

When applicable, the Company pays imports duties in the various countries to which it sends products to and bills the customer for such import costs. The Company recognizes the import duties as part of revenue in accordance with ASC 606.

There are no material sales provisions or volume discounts that provide variability in recording revenue amounts.

*Disaggregation of Revenue*

The Company's net revenue is derived from customers located primarily in the United States and is disaggregated by major product line because the Company believes it best depicts the nature, amount, and timing of revenue and cash flows. Revenue recognized from Tobacco products transferred to customers over time represented 74% and 68%, for the year ended December 31, 2022 and 2021, respectively. Revenue recognized from Hemp/cannabis products transferred to customers over time represented 4% and 0%, for the year ended December 31, 2022 and 2021, respectively.

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Tobacco | $ 40,501 | $ 30,905 |
| Hemp/cannabis | 21,610 | 43 |
| Total revenues, net | $ 62,111 | $ 30,948 |

The following table presents net revenues by significant customers, which are defined as any customer who individually represents 10% or more of disaggregated product line net revenues:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2022 | | 2021 | |
| | Tobacco | Hemp/cannabis | Tobacco | Hemp/cannabis |
| Customer A | 21.69 % | * | 26.00 % | * |
| Customer B | 19.55 % | * | 27.04 % | * |
| Customer C | 23.31 % | * | * | * |
| Customer D | * | * | * | 10.81 % |
| Customer E | * | * | * | 81.01 % |
| Customer F | * | 12.03 % | * | * |
| Customer G | * | 11.29 % | * | * |
| All other customers | 35.45 % | 76.68 % | 46.96 % | 8.18 % |

*Less than 10% of product line's total revenues for the period.

*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) relate 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, 2022 | December 31, 2021 |
|---|---|---|
| Unbilled receivables | $ 354 | $ 178 |
| Deferred revenue | (831) | (119) |
| Net contract assets (liabilities) | $ (477) | $ 59 |

During the years ended December 31, 2022 and 2021, the Company recognized $59 and $77 of revenue that was included in the contract asset balance as of December 31, 2021 and 2020 respectively.

## NOTE 19. – OTHER OPERATING EXPENSES, NET

The components of "Other operating expenses, net" were as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Grass Valley fire: | | |
| Fixed asset write-offs | $ 5,550 | $ - |
| Inventory charges | 3,998 | - |
| Compensation & benefits | 195 | - |
| Professional services | 36 | - |
| Lease obligations | 20 | - |
| Insurance recoveries | (5,000) | - |
| Total Grass Valley fire | 4,799 | - |
| Acquisition costs | 1,046 | - |
| Impairment of intangible assets | 1,488 | 78 |
| Impairment of inventory | 237 | - |
| (Gain) loss on sale or disposal of property, plant and equipment | (368) | - |
| Total other operating expenses, net | $ 7,202 | $ 78 |

*Grass Valley Fire*

In November 2022, there was a fire at our Grass Valley manufacturing facility in Oregon, which manufactures bulk ingredients, primarily CBD isolate and distillate.

We recognized fixed asset write-offs and inventory charges of $5,550, $3,998, respectively, related to property destroyed in the fire in the fourth quarter of 2022. The associated lease ROU asset and lease liability were also written-off, with remaining lease obligation of $20 being recorded for December rent. We have incurred certain fees for various professional services in 2022 in connection with the assessment of the fire and the efforts to rebuild and resume operations. Further, we incurred $195 of compensation and benefits in 2022 for Grass Valley manufacturing employees, subsequent to the fire. In connection with the Grass Valley fire, we have recognized anticipated insurance recoveries deemed probable

of collection of $5,000 in 2022 related to our ongoing insurance claim for property damage, which the corresponding receivable is recorded as Prepaids and other current assets on the Consolidated Balance Sheet as of December 31, 2022.

Additional business interruption insurance coverage with limits of $15,000 remains pending as of December 31, 2022, and will be recognized as income when all contingencies have been resolved.

*Acquisition Costs*

During 2022, acquisition costs include $1,046 primarily related to the acquisition of GVB Biopharma and consist primarily of professional fees and others costs.

*Other general charges*

During 2022 and 2021, the Company recorded other impairment charges in connection with intangible assets subject to amortization that are periodically reviewed for strategic importance and commercialization opportunity prior to expiration and we recorded an impairment charge for the tradename intangible asset impacted by changes to expect future cash flows of $1,453.

Additionally, the Company recorded an inventory write-down in the fourth quarter in connection with unavoidable casualty from a weather event that resulted in hemp/cannabis crop loss.

**NOTE 20. – QUARTERLY REVENUE AND EARNINGS DATA – UNAUDITED**

| | Three Months Ended | | | |
|---|---|---|---|---|
| | December 31, 2022 (1) | September 30, 2022 | June 30, 2022 | March 31, 2022 |
| Revenues, net | $ 19,206 | $ 19,383 | $ 14,477 | $ 9,045 |
| Gross profit (loss) | $ (646) | $ 619 | $ 892 | $ 309 |
| Net loss | $ (26,283) | $ (13,102) | $ (11,498) | $ (8,918) |
| Net loss per common share - basic and diluted (2) | $ (0.12) | $ (0.06) | $ (0.06) | $ (0.05) |

| | Three Months Ended | | | |
|---|---|---|---|---|
| | December 31, 2021 | September 30, 2021 | June 30, 2021 | March 31, 2021 |
| Revenues, net | $ 7,960 | $ 7,811 | $ 8,371 | $ 6,806 |
| Gross profit | $ 231 | $ 292 | $ 448 | $ 515 |
| Net loss | $ (13,964) | $ (9,440) | $ (4,174) | $ (5,031) |
| Net loss per common share - basic and diluted | $ (0.09) | $ (0.06) | $ (0.03) | $ (0.03) |

(1) In the fourth quarter of 2022, the Company recorded pre-tax charges and other expenses of $4,799 related to the Grass Valley fire. These charges were included in Other operating expenses, net as described in Note 19.

(2) The quarterly per share data in this table has been rounded to the nearest $0.01 and therefore may not sum to total year-to-date EPS.

**NOTE 21. – SUBSEQUENT EVENTS**

*Acquisition of RX Pharmatech Ltd*

On January 19, 2023, the Company acquired RX Pharmatech Ltd ("RXP") a privately held distributor of cannabinoids with 1,276 novel food applications with the U.K. Food Standards Agency ("FSA"). RXP's products include CBD isolate and numerous variations of finished products like gummies, oils, drops, candies, tinctures, sprays, capsules and others. The Company paid $200 in cash and $450 in stock and may pay up to an additional $1,550 of contingent earn out over the next three years based on specified conditions being met. The Company expects to determine the preliminary purchase price allocation prior to the end of the first quarter of 2023.

*Insurance Recoveries*

During the first quarter of 2023, the Company received $5,000 of casualty loss insurance recoveries from the Grass Valley fire.

*New Senior Secured Credit Facility*

On March 3, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with each of the purchasers party thereto (each, including its successors and assigns, a "Purchaser" and collectively, the "Purchasers") and JGB Collateral, LLC, a Delaware limited liability company, as collateral agent for the Purchasers (the "Agent"). Pursuant to the Purchase Agreement, the Company agreed to sell to the Purchasers (i) 5% Original Issue Discount Senior Secured Debentures (the "Debentures") with an aggregate principal amount of $21,052,632 and (ii) warrants to purchase up to 5,000,000 shares of the Company's common stock, par value $0.00001 per share (the "Common Stock"), for an exercise price of $1.275 per share, a 50% premium to the VWAP on the closing date (the "JGB Warrants"), subject to adjustments as set forth in the JGB Warrants, for a total purchase price of $20,000,000.

The Debentures bear interest at a rate of 7% per annum, payable monthly in arrears as of the last trading day of each month and on the maturity date. The Debentures mature on March 3, 2026. At the Company's election, subject to certain conditions, interest can be paid in cash, shares of the Company's common stock, or a combination thereof. The Debentures are subject to an exit payment equal to 5% of the original principal amount, or $1,052,632, payable on the maturity date or the date the Debentures are paid in full (the "Exit Payment"). Any time after, March 3, 2024, the Company may irrevocably elect to redeem all of the then outstanding principal amount of the Debentures for cash in an amount equal to the entire outstanding principal balance, including accrued and unpaid interest, the Exit Payment and a prepayment premium in an amount equal to 3% of the outstanding principal balance as of the prepayment date (collectively, the "Prepayment Amount"). Upon the entry into a definitive agreement that would effect a change in control (as defined in the Debentures) of the Company, the Agent may require the Company to prepay the outstanding principal balance in an amount equal to the Prepayment Amount. Commencing on March 3, 2024, at its option, the holder of a Debenture may require the Company to redeem 2% of the original principal amount of the Debentures per calendar month which amount may at the Company's election, subject to certain exceptions, be paid in cash, shares of the Company's common stock, or a combination thereof.

The JGB Warrants are exercisable for five years from September 3, 2023, at an exercise price of $1.275 per share, a 50% premium to the VWAP on the closing date, subject, with certain exceptions, to adjustments in the event of stock splits, dividends, subsequent dilutive offerings and certain fundamental transactions, as more fully described in the JGB Warrant.

*GVB Bridge Loan*

On March 3, 2023, the Company executed a Subordinated Promissory Note (the "Subordinated Note") with a principal amount of $2,864,767 in favor of Omnia Ventures, LP ("Omnia"). The Subordinated Note refinanced the 12% Secured Promissory Note with a principal amount of $1,000,000 dated as of October 29, 2021 payable to Omnia (the "October Note") and the 12% Secured Promissory Note with a principal amount of $1,500,000 dated as of January 14, 2022 payable to Omnia (the "January Note", and together with the October Note, the "Original Notes"), which were

assumed by the Company in connection with the acquisition of GVB Biopharma. The maturity date of the Subordinated Note is May 1, 2024.

Under the terms of the Subordinated Note, the Company is obligated to make interest payments in-kind (the "PIK Interest"). The PIK Interest accrues at a rate of 26.5% per annum, payable monthly. The Company is not permitted to prepay all or any portion of the outstanding balance on the Subordinated Note prior to maturity.

In connection with the Subordinated Note, the Company issued to Omnia, warrants to purchase up to 675,000 shares of the Company's Common Stock (the "Omnia Warrants"). The Omnia Warrants are exercisable for seven years from September 3, 2023, at an exercise price of $0.855 per share, subject, with certain exceptions, to adjustments in the event of stock splits, dividends, subsequent dilutive offerings and certain fundamental transactions, as more fully described in the Omnia Warrants.

**Item 15(b). 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 |
|---|---|
| 2.1 | Reorganization and Acquisition Agreement between the Company and GVB Biopharma (incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed with the Commission on May 18, 2022). |
| 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 (incorporated by reference to Exhibit 4.1 to the Company's Form 10-K filed on March 1, 2022) |
| 4.2 | . Form of Warrant (incorporated by reference from Exhibit 4.1 to the Company's Form 8-K filed with the Commission on July 25, 2022). |
| 4.3* | Form of Original Issue Discount Senior Secured Debentures dated March 3, 2023 |
| 4.4* | Form of JGB Warrant |
| 4.5* | Form of Omnia Warrant |
| 10.1†† | 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). |
| 10.1.1 | 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). |
| 10.2 | 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). |
| 10.3† | 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). |
| 10.4† | 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). |

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| 10.5††† | 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). |
| 10.6† | 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). |
| 10.7† | 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). |
| 10.8† | 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) |
| 10.9† | 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). |
| 10.10† | 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). |
| 10.11† | 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). |
| 10.12††† | 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). |
| 10.13 | 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). |
| 10.14† | Employment Agreement between the Company and R. Hugh Kinsman (incorporated by reference to exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Commission on June 15, 2022). |
| 10.15†* | Employment Agreement between the Company and John J. Miller dated November 11, 2022 |
| 10.16† | 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) |
| 10.17†* | Employment Agreement between the Company and Peter Ferola dated September 20, 2022 |
| 10.18* | Securities Purchase Agreement dated March 3, 2023 with each of the purchasers party thereto and JGB Collateral, LLC, a Delaware limited liability company, as collateral agent for the Purchasers |
| 10.19* | Subordinated Promissory Noted dated March 3, 2023 |
| 21.1* | Subsidiaries |
| 23.1* | Consent of Freed Maxick CPAs, P.C. |

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| 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.

**Item 16. Form 10-K Summary.**

None.

**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 9, 2023 By: /s/ James A. Mish
James A. Mish
Chief Executive Officer and Director
(Principal Executive Officer)

Date:March 9, 2023 By: /s/ R. Hugh Kinsman
R. Hugh Kinsman
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 9, 2023 By:/s/ Nora B. Sullivan
Nora B. Sullivan
Director

Date:March 9, 2023 By:/s/ Richard M. Sanders
Richard M. Sanders
Director

Date:March 9, 2023 By:/s/ Clifford B. Fleet
Clifford B. Fleet
Director

Date:March 9, 2023 By:/s/ Roger D. O'Brien
Roger D. O'Brien
Director

Date:March 9, 2023 By:/s/ Dr. Michael Koganov
Dr. Michael Koganov
Director

Date:March 9, 2023 By:/s/ Anthony Johnson
Anthony Johnson
Director

Date:March 9, 2023 By:/s/ Lucille S. Salhany
Lucille S. Salhany
Director