Dear Fellow Shareholders,

It has been an exciting year at 22nd Century Group as we accelerated our leadership position in plant genetics and laid a strong foundation for future success. We are leading the world in plant genetics research focused on the disruption of two large and valuable industries – the evolving area of tobacco harm reduction and the emerging, rapidly-growing, legal hemp/cannabis space.

The tobacco and cannabis industries are similar in many ways. Both are plant-based, highly regulated and consumer facing, but they also differ. Tobacco – under fire and dominated by just a few major players – is ripe for disruption. Cannabis – emerging, fast-growing, highly fragmented and undercapitalized – has yet to see real differentiation in its marketplace. We believe 22nd Century is well positioned to capitalize on these unique opportunities. By leveraging our strengths and expertise in plant genetics R&D, intellectual property, FDA regulation and consumer packaged goods, we have the ability to disrupt the global tobacco industry and position our Company for leadership in the legal hemp/cannabis industry. We have made significant progress in the past year in pursuit of this vision, which we believe will create meaningful value for shareholders and lead to positive change in the world.

Last year, we made major progress in our efforts to launch our highly disruptive very low nicotine content (VLNC) tobacco cigarettes. While our VLNC tobacco cigarettes look and smoke like conventional cigarettes, they contain 95% less nicotine than their conventional counterparts. We have spent several years and millions of dollars to develop our proprietary VLNC tobacco and related patents as well as to support and develop the enormous body of clinical science that studies the benefits of our VLNC tobacco cigarettes to adult smokers and for public health.

Our own research and that of leading independent researchers has confirmed that smokers who use our VLNC tobacco cigarettes – even smokers with no intention of quitting – reduce their nicotine exposure and dependence, smoke fewer cigarettes per day, experience reduced withdrawal symptoms, increase their number of smoke-free days and double their quit attempts – without demonstrating any compensatory behavior to obtain more nicotine.

We filed two applications with the U.S. Food and Drug Administration (FDA) in 2018 requesting authorization to introduce our reduced nicotine tobacco cigarettes to market under the brand name VLN® along with several marketing claims including “95% Less Nicotine.” We believe the substantial, independent science supporting these applications is compelling and clearly supports a product launch with a modified risk tobacco product authorization from FDA.

Last year FDA authorized the first of our applications, our Pre-Market Tobacco Product Application (PMTA) for our VLNC tobacco cigarettes, which was a major milestone in our efforts. This authorization occurred largely due to the efforts of our new regulatory science group, who have worked closely with FDA over the past year on our applications. This authorization is the first – and likely the only such authorization that will ever be – granted by FDA to any company for a combustible cigarette. In authorizing this application, FDA determined that the sale of our products is “appropriate for the protection of the public health because of, among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers.”

Our regulatory science team also successfully presented the second of our two FDA applications, which is a Modified Risk Tobacco Product Application (MRTPA), to FDA’s Tobacco Products Scientific Advisory Committee (TPSAC) earlier this year. Our presentation to TPSAC marked another important milestone in the FDA application review process, and we look forward to FDA’s upcoming decision about this second application.

Our tobacco R&D activities this year were focused on supporting not only the planned commercialization of our VLNC tobacco cigarettes but also the FDA’s proposed plan to reduce the nicotine content of all cigarettes sold in the U.S. to minimally or non-addictive levels. Our VLNC tobacco cigarettes already meet the FDA’s proposed product standard, and our ultimate success in tobacco will be enhanced by FDA implementing a rule requiring all cigarettes sold in the U.S. to have very low nicotine content. Our science and operations teams have also worked hard to refine our product design, tobacco growing practices and production processes to ensure we are able to
bring the highest quality VLNC tobacco cigarettes to market. This work included activities to further develop and commercialize our proprietary, non-GMO tobacco with 95% less nicotine in both bright and burley varieties. Our R&D activities are important to the continued development of our VLNC tobacco plants and IP as well as the eventual global marketing of our VLNC tobacco cigarettes.

While we are very pleased with our tobacco-related activities, we also took important steps to accelerate our work in legal hemp/cannabis. We continued to leverage our scientific assets and the expertise of our team in plant genetics and IP to create value in the emerging area of hemp/cannabis plant genetics. We are focused on the creation of proprietary hemp/cannabis plants with proprietary, unique and valuable cannabinoid profiles and other desirable agronomic traits. Of critical importance to our hemp/cannabis R&D this year was the formation of our exclusive, global, hemp/cannabis research partnership with KeyGene, a Netherlands-based company that is a leader in plant biotechnology.

Our first year of work with KeyGene focused on the development of hemp/cannabis plant research tools and genome knowledge. In a few short months, we have created one of the world’s first complete and high-quality maps of the entire hemp/cannabis plant genome. We are now completing annotations and adding genomic maps of new hemp/cannabis plant lines to create a proprietary, high-powered analytics and data visualization platform that will be key to our continued genetics discovery and plant development. KeyGene has already begun applying its proprietary knowledge of and tools for plant mutagenesis, transformation, regeneration, rapid-cycle speed breeding and metabolite quantification to our proprietary hemp/cannabis plants lines. This first year was thus an exciting start to a novel process in the world of hemp/cannabis plant genetics that is expected to yield proprietary, unique and valuable hemp/cannabis plants and IP for 22nd Century.

We also are building a portfolio of strategic partnerships in the hemp/cannabis space and took important steps to do so last year. We made our first investment in a platform company, Panacea Life Sciences, Inc. (Panacea), a vertically integrated, consumer-facing, hemp-derived CBD products company based in Golden, Colorado. Panacea has grown quickly with a wide variety of products and a strong leadership team, and we look forward to working with them to help accelerate their growth. We also added new leadership to our team to help drive our partnership activities. We believe that our strategic partnerships will position 22nd Century well to lead in the hemp/cannabis products space through the marketing of highly differentiated and legal cannabinoid products derived from our proprietary, unique and valuable hemp/cannabis plants and IP in development.

We also have exciting and compelling goals and plans for the coming year in both tobacco and hemp/cannabis.

We will continue to work toward a commercial launch of our VLNC tobacco cigarettes upon authorization of our MRTPA by the FDA. Our consumer research shows that an astounding 60% of smokers are interested in buying our VLN® cigarettes, and with over 34 million smokers in the United States and nearly 1 billion smokers worldwide, the commercial and public health opportunity for 22nd Century’s VLN® product is enormous. Our regulatory team will continue its work with FDA, and our science team, research partners and tobacco growers will continue to enhance and improve our VLNC tobacco and products.

We will continue to support efforts to advance the FDA’s proposed plan to reduce the nicotine content of all cigarettes sold in the U.S. to minimally or non-addictive levels. This is important, worthwhile and valuable work given the FDA’s plan to save millions of lives and prevent millions more people, especially youth, from ever becoming addicted to nicotine.

We will continue to pursue our strategies to leverage our scientific, regulatory and commercial capabilities and assets in the emerging and fast-growing hemp/cannabis space. With our research partner, KeyGene, we will continue our high-density genetic mapping and metabolic profiling of hundreds of hemp/cannabis plant lines, which will enable continued genetics improvements, new gene discovery and new plant design to create proprietary, unique and valuable hemp/cannabis plants for 22nd Century.
We look forward to Panacea’s continued success in the hemp CBD marketplace as they focus on driving growth of their branded products business, and we will continue exploring new strategic partnerships in our quest to become a leading plant-derived cannabinoid products company differentiated by proprietary, unique and valuable plant genetics and intellectual property.

Finally, last year we mourned the passing of our friend, colleague and Board member, Joseph A. Dunn, PhD. Joe’s contributions to 22nd Century over his many years of Board service were numerous and valuable. He will be long remembered by his family and his many friends as a kind, generous, warm-hearted, and fun-loving soul.

We thank you for your continued interest in and support of 22nd Century and the important work we are doing to create value and meaningful change in the world through plant genetics.

With warm regards,

Mike Zercher
President & Chief Operating Officer