

Dear Fellow Shareholders,

Last week, you may have read that the U.S. Food and Drug Administration (FDA) is now accepting public comment for a Modified Risk Tobacco Product (MRTP) application submitted by Philip Morris International (PMI) for its IQOS system holder and charger. Although I would have been completely thrilled to hear of our own MRTP authorization for VLN[®], I was still pleased to hear this news. Forward movement on any MRTP application can only be interpreted as positive for public health and for the momentum of 22nd Century Group.

In addition to proposing a mandate to reduce the amount of nicotine content allowed in combustible cigarettes to “minimally or non-addictive levels,” the FDA’s [Comprehensive Plan for Tobacco and Nicotine Regulation](#) also calls for the development of less harmful nicotine products to further help smokers migrate away from combustible cigarettes, the most harmful form of nicotine delivery. Last week’s action on PMI’s application demonstrates that the FDA is still committed to its Comprehensive Plan and is working to advance MRTP applications.

Unlike PMI’s application, which is in the very early phases of the MRTP process and is just beginning scientific review, our MRTP application for VLN[®] King and VLN[®] Menthol King reduced nicotine content (RNC) cigarettes is in the final stages of review and is not impacted by any other MRTP applications or authorizations that the FDA is considering. The Tobacco Products Scientific Advisory Committee (TPSAC) has already completed its hearing, and the public comment period for our MRTP application has been closed for a little over a year now. The FDA has also already authorized our [Premarket Tobacco Product Application \(PMTA\)](#) for our reduced nicotine content technology and has determined that our product is “appropriate for the protection of public health.” What is more, the Center for Tobacco Products group that is reviewing our application is not the same group reviewing PMI’s application: the comprehensive review of our RNC products and the simple review of IQOS tobacco heating system require different scientific disciplines and different resources.

As I stated earlier this month when we shared our first quarter results, 22nd Century is fully prepared to launch sales of our VLN[®] cigarettes within 90 days of receiving MRTP designation, and we are currently in advanced discussions with potential independent, regional, and national distributors as well as retail partners to get our product in front of adult smokers looking to change their relationship with nicotine.

The FDA’s priorities may appear to be a bit mixed at times, but when taking a look at the big picture and the Agency’s actions, we are encouraged that the FDA remains committed to tackling smoking addiction and improving public health. There is evidence of significant progress being made on their Comprehensive Plan, considering their PMTA review of vaping products, development of pictorial health warnings, issuing an Advance Notice of Proposed Rulemaking to [ban the sale of menthol cigarettes](#), media reports that [nicotine reduction is coming back](#) on the FDA’s agenda soon, and Mitch Zeller’s own statement this past week at the Food and Drug Law Institute Annual Conference that, “a possible nicotine product standard that would reduce nicotine content in cigarettes remains under consideration and discussion.”

We strongly believe, based on the more than \$100 million of independent science conducted to understand the public health benefits of RNC cigarettes, that the mandate to cap the amount of nicotine in all combustibles is where the Agency’s focus should be, as this is how they can deliver the most significant positive impact on public health, saving millions of American lives across the country. It is important that the FDA give adult smokers a choice when it comes to smoking — a choice that is not available to them now when tobacco products available on the market today are addictive by design. We remain highly confident that our MRTP authorization is in the final stages of review and that FDA is actively advancing it. We will continue to do everything necessary to ensure adult smokers have the ability to choose our reduced nicotine content combustible cigarettes in the near future.

We have witnessed great positive momentum over recent weeks, and as we draw closer to MRTTP authorization for VLN® and a nicotine mandate from the FDA, 22nd Century and our technology may become a bigger target for Big Tobacco. We may see more strategically placed opinion articles and advertising by Big Tobacco to encourage the use of addictive tobacco alternatives that claim to be better for smokers – messages driven by a business model based entirely on ***maintaining*** tobacco addiction. While this messaging by Big Tobacco is disturbing to see for so many, it is important to remember that 22nd Century is at the forefront of the movement to ***eliminate*** tobacco addiction. As the only company with the technology for a viable combustible option to help adult smokers change their relationship and dependence on nicotine, we are in a position of strength to impact and shift the tobacco industry's paradigm rapidly and improve the lives of smokers everywhere.

Thank you for your continued support of 22nd Century and our important mission to reduce the devastating harm caused by smoking addiction. Please visit our [Press Release page](#) on the 22nd Century website and follow us on [Twitter](#) and [LinkedIn](#) to learn more about our Company and the important work we are doing in tobacco harm reduction and cannabis plant science.

James A. Mish
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