

SafeRX Pharmaceuticals Founder/CEO Dr. Michael Presti on Solving a Critical Dimension of the U.S. Opioid Epidemic

In an interview with CEOCFO Magazine, SafeRX Pharmaceuticals Founder/CEO Dr. Michael Presti discusses their alcohol resistant opioids

LENOX, MASSACHUSETTS, US, August 24, 2021 /EINPresswire.com/ -- [CEO CFO Magazine](https://www.ceocfo.com/), an independent business and investor publication that highlights important technologies and companies, today announced an

interview (<https://www.ceocfointerviews.com/saferxpharmaceuticals21.html>) with Dr. Michael Presti, Founder/CEO of Lenox, MA based [SafeRX Pharmaceuticals](https://www.saferxpharmaceuticals.com/), sharing his thoughts on their alcohol resistant opioids OxARO™ IR and MethARO™ IR. “The reality is that this isn’t like COVID,



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Dr. Michael Presti

there is no vaccine on the way and there will never be any single “silver bullet” solution to the opioid epidemic. But SafeRx is developing a solution to a previously unaddressed dimension of this crisis responsible for nearly one-quarter of fatal prescription overdoses- the combination of opioids with alcohol.”

An accompanying video (<https://youtu.be/zgW3qyMdnfl>) further details the SafeRX Pharmaceuticals’ alcohol resistant opioids platform.

Asked by CEOCFO Magazine’s Senior Editor Lynn Fosse if

the danger of combining opioids with alcohol been looked at before, Dr. Presti responded, “Well, the hazard of combining alcohol with opioids is certainly well-established in the medical community, and in a survey SafeRx recently conducted among Pain Medicine specialists, 100% of respondents either “agreed” or “strongly agreed” with the statement, “The risk of prescription opioid overdose is significantly increased in patients who consume alcohol with their medication.” So certainly, the standard of care is to provide education about these risks and to

advise all patients prescribed an opioid to avoid concurrent alcohol consumption."

In the interview Dr. Presti explained how their opioid products work, "Our Alcohol-Resistant Opioid (ARO) platform of products represent 2-in-1 pills, referred to as "fixed dose combinations" that contain, in addition to one of four prescription opioids of choice, a medication called disulfiram- an enzyme blocker that interferes with alcohol metabolism but generally has no other perceptible effects in the body. So if the medication is taken as directed without alcohol, the opioid component exerts its typical analgesic profile and the disulfiram component remains effectively inactive. But if alcohol is consumed with the medication, the disulfiram component interferes with the breakdown of an intermediate in the alcohol metabolism process, causing a rapid accumulation of this toxic intermediate called acetaldehyde."

Dr. Presti continues, "What happens is that since that acetaldehyde- which is basically the stuff that hangovers are made of- can no longer be processed in the normal way with the enzyme blocker on board, it accumulates very quickly, and within minutes induces a very noxious constellation of effects. This is referred to as the disulfiram alcohol reaction, which is characterized by flushing, sweating, dizziness, throbbing headache, and nausea and vomiting. And at that point, it becomes pretty hard to keep drinking! So in a nutshell these ARO products will give patients a very straightforward choice: take the medication without alcohol as directed by your doctor, or drink; you can no longer do both."



Dr. Michael Presti, Founder/CEO, SafeRX Pharmaceuticals



Explaining where they are in the process, and the advantages they have in gaining FDA approval, Dr. Presti tells Lynn, "We have initiated our correspondence with the FDA and brought in industry consultants to help finalize our regulatory strategy. There is a pathway and a legislative policy that we intend to leverage in order to get these drugs FDA approved and on the market on a much more expedited timeline than would be typical for a new chemical entity. And there are a couple of reasons behind that. First, because all the active pharmaceutical ingredients included in these products are already individually approved by the FDA for their intended functions, by pursuing an FDA new drug application pathway called a 505(b)(2), we can pull forth those prior agency findings of safety and efficacy. This markedly narrows the scope of new studies that we need to perform to gain FDA approval for these new combination products."

Asked if SafeRX Pharmaceuticals was funded for the next steps Dr. Presti told CEOCFO, "As CEO, fundraising is always top-of-mind. We raised a few hundred thousand dollars of seed capital from family and friends- mostly old med school buddies- to get things rolling last year. And we recently opened an equity crowdfunding campaign aiming to raise another \$5 million with which, by leveraging those accelerated regulatory pathways just described, within 2 ½ years we believe we can achieve FDA approval of our first ARO product, MethARO™. And although this crowdfunding strategy is atypical within the pharmaceutical sector, we felt that because the opioid epidemic has become such a scourge throughout the country, this opportunity would resonate broadly within those injured communities as a bridge to becoming part of a solution to the crisis. And, given our modest anticipated capital requirements, we think we can get there without institutional money, which will help to preserve operational autonomy and commitment to our mission. So we're really excited to be one of the first pharmaceutical companies to pursue this form of fundraising. And because SEC regulations limit the scope of public statements I can make pertaining to that online offering, I can't get into the details here. But I encourage all of your readers to check us out at <https://www.investinsaferx.com/>, and to consider a financial investment. Because together Lynn, we can win this fight!"

Contact:

Lynn Fosse

Senior Editor

CEOCFO Magazine

352-431-3400

lf@ceocfomail.com

Lynn Fosse, Senior Editor

CEOCFO Magazine

+1 352-431-3400

[email us here](#)

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