Transcript for ICW_Lynn_Kirkpatrick (1).mp3

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Hello and welcome to the DDW Podcast.

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Podcast covering topics around drug discovery and development,

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Pharma and biotech.

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I'm Megan Thomas, multimedia editor at DDW,

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and this episode is part of the “In conversation with” Series,

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where I speak with members of the drug discovery industry about their work

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and how it helps turn science into business.

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Today, I'm in conversation with Dr. Lynn Kirkpatrick,

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CEO of Ensysce BioSciences.

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As we all know, the opioid epidemic is one of the biggest issues

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in the United States today.

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As of late, it has been a crackdown to prevent overdosing

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and abuse of opioids, but it still leaves patients with a need

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for pain medication.

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Currently, Ensysce BioSciences is headed into Phase three clinical trials

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with a drug that improves the care and safety of patients

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by preventing the possibility of both abuse and overdose

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of prescription drugs.

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Today, Dr. Kirkpatrick talks about how they are developing the safer option

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to opioid painkillers and how it prevents abuse and overdose.

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Hello, Lynn, thank you for joining me today.

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The first question I have for you is,

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how has the company's Trypsin Activated Abuse Protection been developed

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in order to avoid recreational abuse?

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Well, let's first start talking about why we're developing TAAP

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and there's some very interesting numbers, obviously,

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in the US on people in pain.

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The CDC estimates approximately 20% or 50 million Americans

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suffer from chronic pain.

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And about 17 million people have severe high-impact chronic pain.

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Now, the American society also estimates,

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there's approximately 2 million people abusing opioids.

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So here we have dueling crisis, big numbers on both sides,

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and that's really why we're focused on the problem.

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When we began developing TAAP or Tripsin Activated Abuse Protection product

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we observed the market really was crowded

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in what we felt was a fairly primitive approach

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to limit abuse.

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And this is called abuse deterrent formulations.

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These are ADFs.

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And really, the key word is deterrent.

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The idea behind these is that there are physical means

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to reduce abuse or limit the rate of release of the opioids,

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such as a hard shell or a gel.

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As we know, unfortunately, the mechanisms,

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these physical mechanisms haven't really deterred abuse.

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We still have the problem because a lot of these can be broken.

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So I'm a medicinal chemist when I saw the smart chemical approach of Ensysce,

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I was immediately intrigued.

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Our TAAP or Trypsin Activated Abuse Protection,

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, the name says it all, their protection,

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is a chemical approach.

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They're engineered at the chemical level to reduce abuse.

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And we can apply them to opioids or, in fact, any drug that we apply these to.

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This chemical approach really makes the opioid inactive until it swallowed.

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And it's hard to break.

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So in contrast to the ADFs, we have the same pain relieving effects of opioids

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and harder to break and a few other advantages.

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The name Trypsin or TAAP, Trypsin is an enzyme in our small intestine.

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It's there to digest our protein products.

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And we need that to start the activation process to release the opioid.

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So the chemistry is actually responsible rather than the physical means

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to release the opioid slowly over time.

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And that means somebody can't take our product and chew it.

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They can't crush it to snort it and injecting won’t activate it

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because it has to be exposed to Trypsin.

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Our clinical data shows it works.

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You swallow the drug, the opioid is released,

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and we've shown actually an added benefit is that our products last longer than the ADFs.

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And this is critical because if you're prescribed a pain reliever to take twice a day

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and it's not lasting till your next product, you start self-medicating,

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potentially leading to additional problems.

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And that could be a potential reason why we have the problem today.

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Right now, we know the approach to STEM abuse by limiting opioids

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is really being wrongly applied.

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We're hurting those people who are in chronic pain.

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There was a really interesting article in the New York Times just recently

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describing the horrors that people in chronic pain are living with when they

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can't get access to the pain relievers.

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So really that's why we're developing these next generation of opioids.

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Great, thank you so much.

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That really does give us a great overview, great starting point there.

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So how has tap been developed in order to ensure overdose protection?

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Again, if we look at the numbers, we're losing actually two Americans

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every hour to prescription opioid overdose.

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And that's really why we're focusing.

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We believe we need a product not only for abuse protection, but overdose protection.

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And our approach, which we refer to as MPAR,

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multi-pill abuse resistant really, again the name says it all, people who take our MPAR products

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will still get that same pain relief, but it's designed to put the breaks on the release of the

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opioid if somebody consumes too much.

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It's a combination product of our TAAP opioid and a Trypsin inhibitor, which sounds a little

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counterintuitive.

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We refer to it as smart overdose protection.

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If you take your prescription, you get your pain relief.

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If you take too much, you're consuming more of the inhibitor of Trypsin.

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So it blocks the activation and protects from an overdose.

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And we've recently completed our clinical trial.

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We've demonstrated the concept works at the prescribed dose.

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One or two pills, the opioid is released.

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As you start dose escalating, either self-medicating or if you want to try and get high,

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with this more inhibitor, you're blocking the release and preventing the overdose.

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So here we have two distinct categories, our MPAR products and our TAAP products,

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and we're moving these both through the regulatory process in parallel.

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Thanks for that answer.

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So this treatment is anticipated to be the first FDA approved product to make opioid safer

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for patients with chronic severe pain with the promise of eliminating accidental and deliberate

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overdose. Could you please explain why this is so significant?

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Well, obviously, people are concerned to have opioids in the cabinet

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And about taking opioids.

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If like me, you take your medication and then a little bit later, you say,

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did I take my prescription and you double the dose.

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Here we have something that will prevent you from overdosing accidentally versus just trying to

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say I want to get high, I'm going to take a whole handful or on purpose, you take a lot of the

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medication. So in both cases, this product will prevent an overdose.

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Great, thank you so much. That really does give us a great overview.

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So my next question is the company's molecule, PF614, is currently in phase two clinical trials

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and fast track by the FDA. What are the next steps assuming success in the clinic?

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Well, we're really at a highly interesting and motivating time.

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We're stressing that so far all of our clinical data has been very supportive.

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We've shown a good safety signal, reduced abuse potential, we've shown efficacy,

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all highly positive. So in other words, we've had success, we've de-risked the programs,

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and we're currently presenting this full package of data to the FDA, discussing our plans for

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phase three, and that's scheduled for the end of January. This makes us poised to move into our

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pivotal trials in the second half of the year. And two things we've learned from our clinical

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studies that have some patient benefit, our TAAP analgesics and PF614 can be taken with or without

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food. And this is important if you're in pain and have no appetite, you can still get your pain

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really. As I mentioned previously, our longer half-life means that we can be prescribed twice a day.

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We have a 12-hour half-life. So with this twice a day dosing, people shouldn't have breakthrough

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pain before their second dose. So we believe this problem of self-medicating and the cycle that

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people get in having pain relief and no pain will be something for our product to have a benefit

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with. So we've shown PF614 is effective, it's safe, it delivers oxycodone whether it's taken

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with or without food, and our phase three program should be relatively low-risk. So this next

question

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I have, you actually probably feel like you've answered in parts specifically with relation to

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taking it with food, but how does the safety profile compare to other traditional opioids?

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We've already shown PF614 is effective and really the safety profile is identical to other opioids

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on the market. So with the added benefit, we believe of having less abuse potential. That really

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feels that PF614 is no different. We've shown it has effectively the same release profile as

oxycodone.

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We can substitute our product for oxycontin and should have no problem using PF614

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and being a safer product based on the abuse potential. Great, thank you so much. Now the next

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question I have for you is how have drugs in development progressed from animal models to

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human clinical trials? Well, we have two products in our pipeline, our lead product PF614, as

mentioned,

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a TAAP modified oxycodone has the same release profile as oxycontin. It's progressed through phase

two.

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We've shown efficacy and it's actually poised for the last stage of clinical development over

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the next two years. Our combination product, PF614-MPAR with overdose protection, has

demonstrated

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safety, it's demonstrated oxycodone delivery and overdose protection in our first clinical study.

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So now we're set to have a discussion with the FDA and try to move this as quickly as possible

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through development into clinical development. Great, thanks very much. And now this

next

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question is a broad one and possibly varying into philosophical, but do you think opioids are

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still the most effective treatment for patients with severe pain?

Well, certainly I do, but I think

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more importantly, the experts do as well. And there was really a reason why opioids have been used

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for 3,000 years to treat pain. They're fundamentally the only thing effective for some severe pain,

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not necessarily for all pain. That's why we have different classes, but obviously opioids need

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safety guardrails like cars need seatbelts. Have we cracked the code with TAAP and MPAR?

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Maybe we have an about to turn the corner. We believe we can deliver a safer opioid to help

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millions of people who struggle with pain daily and products that are safer should be used.

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Thank you very much. I'm interested to know if you've found that regulatory attitudes towards

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these sorts of drugs has put you in a position where you're up against a harder challenge or whether

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that's more of a public issue than it is a regulatory one and what your experience has been in this

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development process. Again, especially in the US and I guess in many countries.

I think there is an

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opiophobia. In some countries they don't prescribe opioids. For many reasons and certainly in the

US because

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of the opioid use over the last decades that have led to problems and the promise that other

products

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were safe and we're going to solve the problems of abuse and never did deliver a solution.

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Our products may be look too good to be true, but I can tell you I've seen the data. I know

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our products deliver an opioid, can treat pain and I really believe we have an advance in the field.

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We are moving our products through development and hopefully from our clinical trials we can prove

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that both to the public and to the regulatory bodies to get this product on the market and show

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people who are concerned about using opioids because all of the media and everything else that

there

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is a safer option. Great, thank you so much. It's a very exciting prospect and I wish you lots of luck

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and look forward to reading more results and updates from the company. Thank you for joining me

today.

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Thank you so much. Thanks for having me. We certainly love to talk about our products and really

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do believe a benefit for those people who are suffering from severe pain and we're working as

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quickly as we can to get this on the market.

Well that brings us to the end of this

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in conversation with episode. Thank you Lynn for your insight today and thank you to our audience

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