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Long Nightscope short the criminals.

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On today's show, my guest is the CEO of Ensysce BioSciences, Dr. Lynn Kirkpatrick.

0:00:42 --> 0:00:48 Ensysce

BioSciences trades on the NASDAQ under the trading symbol EMSC.

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ENSYSCE BioSciences is a biotech company committed to stemming the prescription drug abuse epidemic.

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They are developing first in class and uniquely innovative solutions in oral drug delivery.

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Their proprietary TAP (TAAP) and M-PAR, (M-P-A-R) technologies, improve the care and safety

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of patients by preventing the possibility of both abuse and overdose of prescription drugs.

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Their mission is to revolutionize the safety and oral delivery of medicines for areas of

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high unmet need.

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I'd like to welcome onto the podcast Dr. Lynn Kirkpatrick.

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Thanks so much for joining me today.

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Thank you so much for having me, Matthew.

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Absolutely.

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Lots to cover here.

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Let's just dive straight in.

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Please give us a brief overview of Ensysce BioSciences.

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For our audience, I usually like to paint a picture of a company from the ground floor

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up.

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Let's start with that overview

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Sounds good.

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Ensysce BioSciences is a clinical stage company.

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As you mentioned, we're using two highly novel technology platforms using the acronyms

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TAAAP and MPAR, applying these to known therapies to improve drug safety as well as drug

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We have applied TAAP and MPAR to a number of different drug classes, but we are focused

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initially on the opioid class of medications in order to stem the crisis that, as we know,

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has resulted in thousands of deaths over the last few decades.

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By using known therapies, we believe we can really develop new drugs more quickly at reduced

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costs, and we can use them to expand our product pipeline over many therapeutic indications.

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But our initial focus in the opioid class, we've developed our lead product we refer to

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as PF-614.

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This is an oxycodone TAAP product, and all of our clinical trials have shown it works

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exactly how it's designed, and I'll go into that as we discuss.

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But PF-614 delivers oxycodone and pain relief only when it's swallowed in what's called

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an extended release fashion, or slowly over time, and it provides proven pain relief for

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a 12-hour period, which is different than other products that are marketed currently.

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Yeah, thank you for that.

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So let's go ahead and get into the nitty-gritty of the science behind the TAAP and MPAR

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technology a little bit further and explain if you can, from a very basic level, what it

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is that's actually at work in the technology that's active in both TAAP and MPAR.

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Great.

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I appreciate that our approach we refer to as TAAP, where trypsin in activated abuse protection

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is what we as a team call clever chemistry.

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We chemically modify a drug, in this case, oxycodone, to make it inactive, and it's inactive

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unless it's swallowed.

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And it uses the body's own enzyme, a digestive enzyme called trypsin, to start an activation

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process releasing oxycodone for absorption and providing pain relief.

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Now why is this important?

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Obviously, when the drug is inactive, unless it's swallowed, it removes the ability to

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administer the drug through inhalation or snorting or injection to remove those pieces of

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abuse protection.

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It also, with its slow release, gives us a true twice a day product.

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And part of the problem with some of the pain medication now, even though they're marketed

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twice a day, they're not lasting twice a day.

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So PF614 has advantages not only through the TAAP chemical modification, but also in its

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performance in the body.

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Now with MPAR, multi-pill abuse resistance, this takes the protection one step further.

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MPAR is a combination of our TAAP ProDug with a small molecule that is able to inhibit

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trypsin, or a triysin inhibitor.

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Now it sounds a little counterintuitive, but this trypsin inhibitor adds overdose protection

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to our TAAP ProDrug.

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So these M-PAR drugs, they're designed to deliver the medication if you take your prescription,

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which we believe will be one or two pills twice a day.

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The if you take more than your prescription, say three or four at a time, you're taking

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also more trypsin inhibitor.

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So it blocks the trypsin, this enzyme, which is used to activate and release the drug

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when you've taken too much.

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And it only kicks in when you take more than the prescribed dose.

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So we call it smart overdose protection.

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Now we've applied M-AR to PF614.

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So we have PF614 MPAR.

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We show, we've already shown clinically, it does exactly what it's designed, deliver the

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pain medication at one or two dose levels, but at three or more it blocks that activation.

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The excess material is excreted unchanged and overdose is averted.

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So what we believe TAAP and MPAR do is make opioids safer.

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And the beauty of the platforms is that they can be applied to other medications that may

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have a safety issue, may have a delivery issue, may have to work in the gut where they're actually absorbed.

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So it gives us lots of opportunity in our development, hypothetically.

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Thank you.

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A segment of our audience is always looking for clinical trial data and returns, right?

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So when do you anticipate phase three trials and ultimately the potential commercialization

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of PF614?

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Well, over the last 18 months we've been working diligently to complete all the work we

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need to get to phase three.

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I'd say we're poised for phase three.

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We're there now.

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We have a meeting scheduled with the FDA in January to discuss our plans and that is called

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an end of phase two meeting.

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And we believe we're on track with our plans to start conducting our phase three trials

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in 2024 and still file our NDA to commercialize then after review.

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So we're pushing forward trying to keep our timeline going but very excited about moving

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into our phase three studies.

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So you recently announced a strategic partnership with Oncozenge

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If I'm pronouncing that right, Oncozengea Swedish-based pharma company.

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How does this partnership differentiate and expand your mission to create pain therapies

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and treatment options that are safer, opioid alternatives?

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And then does the partnership signal any concerns on the development of PF614 and the

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upcoming phase three clinical trials that we just alluded to?

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We're really excited about this new opportunity.

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It adds another product in our pipeline to treat pain.

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And as

actually

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you mentioned, our TAAP and MPAR technology has been applied to opioids but we can

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apply those to other therapies.

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So we have a focus on other opportunities outside of opioid products.

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Bupizenge which is the product we are working on with Oncozenge gives us another

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tool in our war chest to treat pain outside of the opioid class.

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It's for cancer patients with a debilitating complication called oral mucositis.

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It's often experienced with patients undergoing chemo and radiation.

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And really this pain-relieving product has been extensively evaluated in clinical trials,

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phase two trials in head and neck cancer patients.

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It's been shown to be effective.

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It's moving towards phase three and commercialization in Europe.

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We've become a US partner.

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Happy to use our team to move this forward through IND enabling studies to get it through

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the FDA and into trials here in the US.

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So certainly we don't have any problems or concerns about PF614 moving through the

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clinic.

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As I mentioned, it's performed beautifully today.

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We're just using our expertise to develop and progress what we believe to be a game-changing

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treatment option in another therapeutic indication.

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Well, we've covered a lot of ground today and there's certainly a lot more to get into

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in future conversations.

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But before we conclude, I want to give you a chance to speak to the audience and give

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us one last takeaway for anybody who's just now getting associated with ENSC and care

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to learn more.

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What are some good resources for people or anything you want to direct people to in particular?

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Well, certainly we do have some information on a website.

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We have a video there to which describes tTAAP and M-AR and some of our clinical data more

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extensively.

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But what I really like to add this time is I've put together my team at Ensysce with vast

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experience, not only experience in developing drugs, but also into launching new products

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and pain products specifically.

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So we're very excited about moving PF-614 through to commercialization being able to launch

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our product.

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And I really truly believe I have a team that can do that.

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My guest today has been the CEO of Ensysce Biosciences, Dr. Lynn Kirkpatrick

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Trades on the NASDAQ, under the trading symbol ENSC.

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For more information on the company, you can visit them online at ENSYSE.com.

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Dr. Kirkpatrick, I'd like to thank you so much for coming on the show today and I look

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forward to having you back with us for another update very soon.

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Thank you very much.

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Stock Day encourages all listeners of this program to do their due diligence and research

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of an investment professional.