KemPharm $KMPH Founder and CEO Discusses Why The Best Is Yet To Come and Answers YOUR Questions!

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(Note: Edited for flow by removing vocalization pauses and filler words.)

Dan Sfera (DS): All right Guru Nation and Clinical Research Circle, welcome back to another very special episode. Today I've got the CEO and founder, Dr. Travis Mickle, of KemPharm. Dr. Mickle co-founded KemPharm in 2006 with the discovery of the company's Ligand Activated Therapy prodrug technology. We're going to talk a little bit about that. I don't think the community understands the power of prodrug technology as well as some of the business implications in regards to patents and things like that.

As President and CEO, he oversees KemPharm's business and scientific strategy. Prior to KemPharm, Dr. Mickle was the director of drug discovery and CMC at New River Pharmaceuticals, where he was the principal inventor of Vyvanse, which is another prodrug of amphetamine for the treatment of ADHD. Today, Vyvanse is [leading the $]17 billion plus ADHD market. The success of Vyvanse, along with a robust pipeline of prodrugs targeting ADHD, pain and thyroid dysfunctions which Dr. Mickle was responsible for creating, led to New River Pharmaceuticals being acquired by Shire for $2.6 billion.

During his career Dr. Mickle has been granted more than 80 U.S. and European patents and has authored more than a hundred patent applications. So, Dr. Mickle received his PhD from the University of Iowa and his B.A. from Simpson College.

He is the founder of KemPharm and it's not that often that we have a CEO who's also the scientist and who's also done it before for another company; so proven track record. I always say bet on the jockey and maybe that's why KemPharm, by the way congrats to you and your team, KemPharm is so popular from all the biotechs. I've probably covered 30 biotechs this year, KemPharm is by far, probably gets more reactions than all the other 29 combined. And that's not, I'm not exaggerating either. So, I think some of that has to do with you, it *has* to do with you. Some of that's probably due to the technology. Some of it's probably because people think maybe the stock price is undervalued. Who knows? But let's talk first about your career. How does someone even get to the point where they can create this prodrug technology with Vyvanse and now with KemPharm. How do you even get to that point?

Dr. Travis Mickle (TM): Well, it did start with my education, so, going back to the University of Iowa, PhD was also in prodrugs; now specifically HIV prodrugs so things like

AZT and other drugs that were back in the 90s. We were focused on those types where once the drug is given it gets changed to actually become active but it's not dissimilar at all from what we do. So that concept was there. We have a team here that a few of those members were with me in grad school. So, part of that magic hasn't ever broken up as it were. We have that collective knowledge going way back into the mid-90s.

DS: Wow, okay, so, with Vyvanse can you just, i guess in a minute, kind of bring us through that process, because it's not like you can just go find people in this industry. People [who] have been working in this industry for decades have not been able to come close to coming up with something like Vyvanse or even remotely close to it. So, how have you done it here with Vyvanse and now with Azstarys. Time will tell what the market share of this will be, what the potential of this, we're going to talk a little bit about that, but how did you manage to do that?

TM: Some of it's being, you know, in the right place at the right time. I think when you know with my background in prodrugs and going to New River, they didn't have a completely dissimilar technology originally. But it was enough so that it needed to be changed. And so, just taking my background and saying, "okay why don't we focus on something that makes a little more sense and would be more straightforward." Prodrugs had kind of fallen out of favor really for the last few decades. It's an older technology or an older approach and so going back to it as a fundamental sort of idea of how we can improve amphetamine we listed out what what's bad about it and we say, "well make it less abusable, make it more consistent, give it a longer duration of action." I mean that addresses all the issues. And so, when we were able to discover the molecule, I think one of the tricks that folks underappreciate completely is: all right once you get it, how do you get it approved? And how do you prove out all those benefits? And that's where New River really taught me, you should know a little bit about everything, if not a lot about everything that's going on. So, while I was in charge of manufacturing I was also on the clinical team, the non-clinical, everything about it and so coming to KemPharm I knew the basis for all drug development

DS: Wow, see this is this for the hardcore Guru Nation that don't just care about stock…they care about careers and research. I always talk about being a generalist; here we have Travis, who is a perfect example. How important is being a generalist to you now that you're running KemPharm?

TM: Oh, it's imperative to be able to call BS on somebody; that vendor that's telling you they can't do something. Well, I've done it so I know you can do it. And to be able to really understand what each one of your employees and which of the disciplines is going through as they fight through, say, problem solving and be able to sit in front of the FDA and credibly tell them, "we did this and why we did this and what the scientific basis was." You don't have to be an expert in each one, but it helps to know as much as you can about each area.

DS: And right before we're about to go in a little inside baseball on Azstarys and KemPharm's pipeline, any potential catalyst coming up, any exciting things, I wanted to talk to you about your ADHD. Is this, is Vyvanse, is Azstarys, is this just a way for you to scratch your own itch or did you start working on this before the ADHD, for you personally?

TM: No I honestly, I didn't really recognize it in myself until maybe the last five or six years and that was more so due to my children. And this is very common nowadays: children get diagnosed and you're sitting there and you see the symptoms they have and you're like, "oh my goodness, that's my life. That's what I've dealt with and now I can see I don't have to deal with that anymore. I can try to overcome some of those things. You know at the same time treating it could be a crutch but also it could be a huge benefit to you to have ADHD. Just the creativity and the lack of focus sometimes can be good if you want to learn in a bunch of different areas. It has been at least for the last five, six years a real focus because I have a child on Vyvanse. I hope to switch him to Azstarys someday and so when you have those things in your daily life it's really meaningful to develop something that could potentially really help them.

DS: So this is super meaningful, super personal to you. Actually, that brings up a good point, maybe a good segue: on the last conference call you mentioned you were starting trials for the four and five-year-old age group for Azstarys. How long would a study like that typically take to be completed? I don't need like a start and end date specifically for you guys, but just typical length of time for this kind of study?

TM: Yeah, it was listed as one of the requirements and it's all public information at this point, but Corium is required to do a study in in four- and five-year-olds and we expected them to have to do that. They're fairly lengthy, it's hard to do these studies because four- and five-year-olds just without ADHD are difficult to deal with. And then you have to do blood draws and testing and all sorts of stuff. So, you know it's probably a couple years out before that's going to be on the label. I think that's actually fairly big for a product like this. If you're asking a physician to write a script for an eight- or nine-year-old and it's already approved in a four- and five-year-old it just gives that sense of safety, right? It's like every patient's gonna walk in my door, this can be safe for, something I can prescribe. And the next time there's a four- or five-year-old there that's going to be their option. But even when they're thinking for older ages, like if it if it's safe enough for a preschooler it should be fine for these older kids

DS: Yeah, so do you think the market is underappreciating, I mean, I know you can't comment come on the stock price, but, do you think this is overall just the underappreciated component of Azstarys' future?

TM: I do. I don't think a lot of people have really looked into, well number one, how many preschoolers are on these products? It's difficult to go and track the marketplace. We believe it's a few percent of the overall market. But if you get a few percent that's

hundreds of millions of dollars potentially. And if we're the first or one of just a few products that are listed for preschoolers that's a huge thing on top of six and up. I forgot about the rest of it.

DS: That's a good point. We're actually, we're hearing that Azstarys sales will begin in, around July, August. This scheduling came much earlier than expected so is it possible that sales will follow suit and being earlier?

TM: I couldn't say for sure because Corium is fully in charge of that. I know they want to get it out there as quickly as possible so there is no intentional delay. I think a lot of it is "hey you were planning for June because *nobody* in government goes faster." In this case they were almost two months ahead. And so, I still think that timing is about right. If they can squeak out a few extra weeks or a month earlier, I guarantee you they would do it.

DS: Yeah, yeah. Do you have any indications, I mean, are you dealing with Corium on a regular basis or have you just kind of licensed that out and now you're focused on the rest of the pipeline. In regards to the payor reception for Azstarys, is Corium going to be able to give payors enough of a differentiation to make them happy, do you think?

TM: So, we work hand in hand with Corium, so they don't have extensive experience with the scientific side. They had very little experience in manufacturing, I mean, we were the manufacturer for forever as far as managing third-parties to make this for us. (*That's great.*) And so, part of our services agreement is just that—is working with them. There's regulatory filings we still do for them and I meet with Perry literally three or four times a week on Azstarys-type products, issues and discussions. And I will tell you, yes, I mean they've done a lot of research, they've spoken to KOLs that talk to payors. The payor receptivity is the most surprising one for all of us. Big payors are reaching out to them to ask about clinical benefits. We've heard that scheduling is a big deal to them. They think that's great. I don't know if you know or are aware but most of these payors are being sued on the opioid side, right, for overprescribing or allowing the overprescription of these products. And here comes a Schedule II product that's 70 percent Schedule IV. (*Right*) Well, if all my other ones are Schedule II, why would I block the less abusable version? Why would I cause an issue with the less abusable version when I'm already being sued on the other side for over prescribing issues or blocking safer alternatives?

DS: Yeah, I guess that brings up to another question: so how you personally see the SDX Schedule IV, like, how do you think it actually helps Azstarys, which is still a Schedule II?

TM: It's not as big as the Schedule IV will be for our pipeline products that use SDX, because it's still a Schedule II product and so it still has the same difficulties. Now when a salesperson, and this is just hypothetical I can't tell you for sure exactly what the sales message will be, I don't think it's fully formed yet, but they're going to go into an office, on the front of the label it says that SDX, the 70 percent component, is Schedule IV. In section 9 it says right there it's Schedule IV. So, we already know from our physician research and

they've had some feedback, that's a big differentiation not just for payors, right, but also physicians. They have the same liability with the DEA. They have the same accountability with parents and patients, so, we know that that's a big deal.

DS: In regards to the rest of the pipeline, so we have the substance use disorder. Can you talk a little bit about this particular drug?

TM: Yeah, this all came out of some work that we actually did. When I was at New River we filed an IND for cocaine dependence and with using Vyvanse to treat that. And I don't think that program ever really went anywhere when it went to Shire. But this kind of bubbled up over the last few years when we saw our abuse liability data from the clinical studies. We were shocked at just how really little abuse could happen with the product and how high you could push the dose without causing real issues. And so, when you think about like opioid use disorder, you have products like suboxone, and generics, methadone. They're there to wean people off of their addiction. There's nothing for stimulant use disorder, and there's actually more people that enter treatment for stimulant use disorder than opioid use disorder, and nobody talks about that. And so…

DS: Why do you think that is? Yeah, I don't really, I didn't know this. This is something new that I've learned.

TM: Yeah, we did some preliminary work. You can go to SAMHSA—one of the government organizations. They do an annual report on this, specifically on treatment and so forth. And it's about 450,000 people enter treatment a year: about 400,000 for stimulant use disorder, about 400,000 for opioid use disorder. Now why that is, I think stimulants come in so many different forms from prescription like amphetamine and methylphenidate, phentermine and others. But also, when you think about methamphetamine and cocaine, these are things that can be very problematic. And because there's no treatment a lot of these are recycled patients *(Right).* These are folks that have been in treatment for like three or four times before they finally may kick the habit as it were.

DS: As somebody who does clinical research I own research sites, Travis. And we've actually done some opioid addiction studies and the patients…they bounce around treatment to treatment, study to study, it's very tough to do this kind of study. Have you received any special designations or priority review for KP879 or do you think this would be a given with the potential and the need, *the need* for this kind of thing?

TM: Yeah, we have not received anything to date. We, of course, pass that along as soon as we possibly could. The things that I think are meaningful, fast track is nice for shareholders and investors, they get to see that, but it doesn't really help us in clinical development. It's breakthrough therapy and I think once we have some of our initial clinical data, which we hope to start about mid-year and get some at least preliminary data by the end of the year if not sooner. That's going to be big for being able to make that argument. Because then the agency has to work with you, you can submit early even when

studies aren't fully completed, and that would be great for patients. They really need this product and there's nothing available.

DS: Yeah, a lot of people who don't work in clinical research don't understand, and mostly investors, fast track doesn't mean anything really. The clinical trials are still the same. You still have the same issues with recruiting patients, keeping the patients in the study. These are tough studies but this is why there's a huge need—the tougher the problem, the bigger the potential on it. With GPC [Gurnet Point Capital] having an option on 879, what is the ultimate hold that they have in negotiating for a partner? Are they going to get the last call on any offers? Sometimes we see a party with an ongoing ROFR drag out negotiations. What's your thoughts on this?

TM: We've learned through good and bad experiences you can't be tied down too hard. They had a valid right to have some sort of right of first negotiation on the product because SDX is a major component in their licensed product, right? (*Right*) So, when we negotiated this, when we actually worked it out, we said, "okay after the first study let's do a right of first negotiation and that will go on for some time period." If you pass or we can't come to any terms, none of those have been set yet either. That's another big thing is, we can ask for something ridiculous if we really want to keep it. And if they match it, that's great, we'll take it. But at the end of the day, it does switch to a ROFR. But that's not forever, it's a one-time thing, somebody else can come in and do it. We are free to develop it and commercialize it as we see fit without ever asking them again. And it does expire when the NDA is finally accepted, not approved, but that initial FDA acceptance.

DS: Okay. In regards to the substance use disorder study I read somewhere that there was some talk, and a lot of drug companies are doing this now, where they're utilizing AI, artificial intelligence, to search for patients or even to develop the protocol. Is there anything like this that KemPharm is doing, or looking into?

TM: I think with this patient base there's enough folks that we can easily recruit. A lot of people go into treatment, I mean opioid, already from your experience with opioid use disorder; it probably wasn't terribly difficult to find folks for that.

DS: It was tough to keep them in. That was the problem—retention. Not so much recruitment [but] retention, and also finding the patients that are not just in it for the money. It's very hard as a research site to differentiate "this patient truly wants to get better" versus "this patient just wants to get paid." Because you get paid for your participation just so they can go out and do the opposite of what the study is trying to do. So, that's the tough part. I don't think people understand this. You have to be in research to understand this. If you're an investor it's not that simple. You can't just use AI and then find candidates and all of a sudden it's like magic, they fall out of the sky. This is not how it works. This is why this is an epidemic in this country.

TM: Well, you have to work with the right clinical sites too. Folks that really, like you, understand the ins-and-outs of the disease and the patients that are going to be coming in your door (*Yeah*). Oftentimes we do a lot of human abuse liability trials in the past, you have to distinguish between the casual abuser, the professional study taker—which those are actually sometimes the better ones. And you got to find which sites have those and which ones don't.

DS: Yeah, and so this is why it's good to have a generalist as the CEO of the company. By the way, I have a few sites that might be good fits for this if and when you guys start doing site selection. When are you planning site selection anytime soon or like even started to look at this?

TM: Yeah, we're starting to look into the next study. This first one is very much exploratory: we're looking at pharmacokinetics at high doses, we're looking at stimulant-like effects at high doses and feeling high. We want these folks to feel something but not feel high, right? So, we've got to find that right dose and we're very lucky to know so much about SDX already; it makes it a lot simpler. But this is not like treating ADHD with an ADHD drug. This is treating stimulant addiction with an ADHD drug.

DS: Completely different. When do you think, do you think the data will be released this year, for this?

TM: Yeah, by end of the year we should have at least interim data if not sooner. Now I'm still narrowing down the exact like timing of everything. And it's all about recruitment right now. How many folks can we get into the clinic and get PK draws and get everything analyzed by the end of the year.

DS: You're using one clinic right now?

TM: Yeah, no, it's a small study because it's mostly PK.

DS: Okay. Is it fair question to ask if you've been answering a lot of phone calls from other companies voicing interest in, and at least talking to you about 879 or it's too early for this?

TM: I was shocked after, right after the approval I got so much inbound interest in really our entire pipeline. It was great, you know? It's almost an affirmation after you get something approved where folks finally realize, "oh, hey maybe they're for real." So we have a lot of interest; it's really nice.

DS: I think you would be great, this is just way out of left field, and I do want to get five minutes here to ask questions from the community. I think you would be great to be a vlogger, because you've done this already with Vyvanse. First of all, not everybody does that in a career, it's very rare to achieve that. And now you're trying to do it again with

Azstarys and with substance use disorder. It would be cool if you were able to do a vlog, like a weekly vlog, "hey this is what happened". Because a lot of people out there, you're gonna inspire a lot of researchers who are looking to get into the biotech space. And maybe they have an idea or passion and they want to create something but they can see the work that goes into it. Because this is not something, this is 2021, this is not something that just happened last year. This has been since 2006 for you, right, with KemPharm and then even previously with Vyvanse so just something I wanted to put out there. I got a question here: you opened the door to speculation on something big when you mention Alzheimer's in a recent podcast. They're saying, "would you like to repeat that here today?" [Laughter]

TM: I think I just was listing off a bunch of different opportunities that we're looking at. I mean each one of these is pretty big opportunities. So, you know behind KP879 we've already talked about KP1077 for idiopathic hypersomnia, right? This is a rare unmet area and no treatment options really available. I think Xywav from Jazz just got approval. And so people think this is a big market and Jazz became a multi-billion dollar product, company, off of just one product treating narcolepsy. You can really do a lot in that space. And then beyond that, other psychiatric, neurological diseases and Alzheimer's just happened to be one I listed off. It's certainly very attractive.

DS: So the point is: this platform can, you're basically, the company has a lot of options. This is like a long-term. KemPharm is set for the long-term with this technology.

TM: Right. We literally have dozens of candidates we could boil to the top. It's usually about resource allocation and finding the right ones that are going to be the highest value at that moment. Right? To work in abuse-deterrant opioids. Well maybe that didn't work out but now ADHD is certainly very hot still. And then moving beyond that into rare diseases. We could work in oncology, we could work in any area because the technology can just be applied to anything.

DS: Right. For the Azstarys studies, were you guys using a CRO or were you doing everything in house yourself?

TM: No, we manage everything here. We're actually pretty small team. We use a CRO for every other, everything.

DS: Okay, you use the CRO.

TM: Yeah (*Okay*). We do all of our own drug discovery. So, everything on that side is kept in-house because that's the secret sauce--the trade secrets. Folks that have all the science behind it (*Yeah*) and we don't want that going out to the general public at all.

DS: You don't want the nosy CROs going in there and then talking to your competitors, "hey, this is what they're doing." But for the monitoring of the study the CRAs you're using a CRO for this.

TM: We are, yes.

DS: Okay. Another question I got: what do you want to tell the long-term KemPharm holders and believers? This, the community is very strong; there's something, there's a secret sauce there to what you guys are doing with the marketing; I don't know if it's intentional or not. But what message do you have for the long-term investors?

TM: Well, certainly I'm the longest. [Laughter] I was the first. I put money in that's still underwater at this point, at very early stages and extremely high risk. And continue to do so all along the way. I really believe in the company. At the same time, one of the things that we have always focused on, is to try to find an opportunity for M&A; whether that's us getting bigger by acquiring somebody else or the opposite—getting acquired by somebody bigger than us. Or other strategic options; there's lots of ways to return value to shareholders. We've had to fix a lot of problems first. We had to get through huge debt overhang, get relisted, bring in some capital and,yeah, it was painful; it was really painful for me. But at the same time that's necessary to be able to grow and build a good company that somebody will actually *want* to be a part of.

DS: So how important is that for you, Travis, to be able to be in control and build and achieve more with this company? You said there's a lot of potential here, a lot more that you can do from the technology, right?

TM: Right, absolutely. Now, look, at some point my goal has always been to find that value for shareholders. So, it's important to me to do that only in that it serves what the best needs of the company and shareholders are. So, we chase down value and try to create as much as possible. I enjoy it, I'd love to keep doing it, but I can do it after that too. We can create something else and we can do it all over again for folks. So, that's something that I'd like to see KemPharm shareholders really see that upside.

DS: So, in your opinion the best is yet to come. Azstarys is just the beginning for KemPharm.

TM: It is. We got to get this product launched. We're working diligently with Corium and Apadaz started last year. It's very, very slow; opioids are very difficult to be in. But all of this is just inching forward and as I said, there's good things coming in on the business development side and we're just really excited about all the different opportunities.

DS: This is awesome. So, yeah, I really appreciate your time, Travis, I know you gotta go. We're gonna have to do a part two sometime; I'll bring the rest of my team on when you can, maybe in a couple months or so. I'll talk to your team in the background because we

have three other people who analyze these biotechs with me and they're all blown away by just the amount of reception that that your company garners. And I think a lot of that has to do with you and your background. And a lot has to do with what we've touched on in this interview with the potential for the technology going forward, so. Any last words for the audience out there? This is a strong KMPH group out there online.

TM: Yeah, I mean I greatly appreciate the support. Not so much the negative parts but that always comes with the attention that you can receive. I mean this is a great company; we've really built it in the last few years back again, to be just that, to be a multi-billion-dollar company. That's our goal, that's our board's goal, you know, stay tuned. It does take a little bit of patience to get there but we're gonna go as fast as we can.

DS: Okay, good good good. Thank you, Travis, very much. Thank you everybody for watching and listening. We're gonna do part two soon, guys, so be patient. Thank you very much. Bye-bye (*Yeah*).