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<<Bri>Cheng, Analyst, Cantor Fitzgerald>>

Good afternoon. Thanks for joining us today at our Annual Global Healthcare Conference. I'm Brian Cheng, I'm the Senior Biotech Analyst here at Cantor. Today we have the management team from KemPharm. Joining us is their CEO, Travis Mickle. Travis, nice to meet you. The floor is yours.

<<Travis C. Mickle, President, Chief Executive Officer, Chairman and Co-Founder>>

Thank you, Brian. Thanks everyone for joining today. Just to start with the obligatory cautionary note if you don't want to read all this, you can always go to our website and look under the Investor Relations tab.

So, just to kick it right off what KemPharm is really found over the last few years, there has been two camps, one folks that are unfamiliar, or just new to the story, as well as folks that have been time shareholders and supporters of the organization. But I think it's good to start with kind of a fresh look every once in a while.

So, what is KemPharm? Fundamentally, we are a specialty pharmaceutical company. We focus on drug development and drug discovery in the CNS space. Today we now have our second approved product, was approved back in March and then for the treatment of ADHD. Both of these medications also have commercial partners.

And how we create value and how we create these opportunities, starts from our platform technology, which is known as LAT. And also, is leveraged extensively by our experiences in drug development, in the CNS space.

As you can see from this slide, the management team has a lot of experience in both corporate development, as well as drug development with experiences ranging across the Board, but again, heavily in the CNS arena. You can see there the three different products the team, Sven Guenther, our EVP of Research; and myself were at New River Pharmaceuticals, where we discovered, developed and invented the product Vyvanse, which is now a multi-billion-dollar product for the treatment of ADHD.

Now, the technology behind what was developed around Vyvanse is not to as similar from what we do here at KemPharm. We refer to LAT project technology. Again, it's a fairly straightforward type of approach. We take an approved, active, something that's known to work. We make a chemical modification to that, or re-engineer it at the molecular level.

Once it's administered as directed, it comes back off with just the normal human metabolic processes. So, you get exact same drug back, but at the same time you get some sort of benefit.

So, we can change the pharmacokinetics, we can change the metabolism, we can change how the actual product is delivered as far as organ delivery, site delivery, just the list of possibilities goes on and on.

What's nice about this approach? It allows you a couple of benefits. Number one, it's starting with the same active and ending with the same active. So, reliance on a 505(b)(2) is very typically the case. Also, when we attach something to this new drug or old drug we refer to as a ligand, it's generally recognized as safe. So, we're not adding in regulatory burden where there doesn't need to be one. So, the new molecule gets composition of matter-based patents, sometimes NCE status. And at the same time, you get all the benefit of a 505(b)(2). A little bit of a situation where you get your cake and eat it too. Formulation type regulatory development path on top of the fact that you are going to get strong composition of matter with a new molecule that was created.

So, we've been fairly successful. This is just a kind of a snapshot of our products and product candidates. I don't list APADAZ here. Just in abundance of space. ADHD, I mentioned AZSTARYS the product was just approved back in March. It was officially launched by our partner in late July. We're looking to start to collect on those royalties and sales milestones next year. Of course, sales will start this year, but royalties we don't expect will be very high in the very early days. So, we'll kind of look forward to next year as the best potential time for that.

We also licensed KP484 at the same time. The determination of whether or not, or when that will be developed, will be made by our partner in that case.

And I will spend a fair amount of time later on in the discussion is related to kind of the bottom two columns or rows, stimulant use disorder, hyper idiopathic hypersomnia, these two candidates are derived from the same prodrug. And what we're doing right now is exploring the different opportunities. And we're really seeing that there are a number of different opportunities that could be at play here for that prodrug. It happens also to be the same prodrug that was in the AZSTARYS product, and has some very interesting properties, which I'll cover later.

At this time too we're also evaluating our preclinical pipeline. We've spent most of the last few years with a financial restructure of the organization, but as well, focused on the approval of our ADHD product. And now we're finally able to actually spend some resources and time delving into what we actually have as far as preclinical candidates go. So, it's a great opportunity for us.

What's nice about KemPharm? We have this technology, right, we have the two approved products, but they are both licensed. So, we're not taking on the commercial risk, we're not taking on the commercial cost at this time. But you can see from this list and we have a fair amount that's already able to drive value for our shareholders.

So, AZSTARYS of course, I've mentioned, that was actually partnered with an affiliate of Gurnet Point Capital. Of course, this is a large private equity fund located in Boston. They own a number of various organizations. One of them happens to be Corium, which is the commercial partner in this case, which they assigned those rights to. At the same time, they licensed AZSTARYS, they licensed KP484, they received a Right of First Negotiation, Right of First Refusal for any of our project containing what's known as SDX or methylphenidate pro drugs, that we may develop in

other indications. Also, ROFR, ROFN after our amphetamine pro drug. And then of course, last but not least, we also have a partnership in place on our pro drug of hydrocodone known as APADAZ that's partnered with KVK Tech.

It launched late last year through a very early-stage pilot program. I can just touch on that briefly here. That particular product, that particular program is focused on more of a replacement strategy with education. Hey, look, this is a product in APADAZ that may secure some benefits when it comes to the potential for abuse or may be less abusable. The data suggest one thing the label is a clear that there's unknown, whether that would work or not, but it's also provided at no additional cost. So, it costs the same as a regular hydrocodone acetaminophen. So, you are able to do that, sort of switch out approach with physicians. And we believe using an educational approach where you actually provide, the opportunity to learn more, do research with the product is one way to take it to market.

So again, this is more for the folks that are new to the story. The company has really evolved over the last 15 years of its existence starting, basically with a technology focused and moving now into our next phase of our genesis, which is product and revenue based focused. We still have the platform technology, we still have our expertise, we now have the two products, and now we're looking to the next step.

So, you see the examples I gave in the pipeline are really unmet niche areas or rare diseases in the CNS space. So, you can kind of see where we're going, where we want to be. A lot of organizations have made the leap to commercial at that stage. That's something we're considering, but something, I think, could very well happen if we have the right opportunities in front of us and the right pipeline of product candidates.

So, for those that aren't new to the story as much, and just wants to hear some highlights, commercial launch back in July, mentioned that. The one thing that is nice about AZSTARYS, we got long-lived patents, we're sitting here in 2021, and all expire in 16 years, still eligible for patent term extension and other benefits as well.

The project behind AZSTARYS was actually scheduled as a Schedule four. It was a brand-new pro-drug never made before. And so, it had to go through a formal scheduling decision, DEA and FDA agreed that it should be Schedule four. We believe this provides us a lot of benefit for this product.

Great cash position. For the first time in our history, we actually have a solid financial position to sit on. Cash on hand \$132 million. We had net income in the second quarter, and we just expect things to continue to improve as we bring in royalties and sales-based milestones on our two products.

And then what's kind of beyond that we initiated in the middle of this year an SDX trial looking at just some high-level effects, as well as mostly pharmacokinetics. We expect to get the data back before the end of the year. Once that's available, that will tell us the development path for SDX related compounds.

And then I mentioned before KVK Tech has kicked off this educational campaign, with Sure Med compliance known as the perspectives and care that should be expanding in the future in the next coming quarters.

So let me jump in a little bit to what is AZSTARYS and how do we believe it's better. ADHD of course is, very large and growing market. We actually see that the market research here shows that a \$175 billion was prescribed back in 2019 with continuous growth. Methylphenidate accounted for a big portion of that. Most of those are generic drugs but certainly a few branded products. When we started on this endeavor, we saw that there was three unmet needs, physicians overwhelmingly agreed, duration of action for methylphenidate products was very lackluster, abuse was still a huge concern, and most of them also came back and said, hey, look onset of action would be great. And of course, all three of these would be ideal. And that's where we really undertook the development and moved forward with the AZSTARYS.

So, what is AZSTARYS, that I've been actually speaking about it for quite a while now. This is our pro drug of d-methylphenidate used in the treatment of ADHD. It's 70% of the pro drug that's also co-formulated with 30% immediate release d-methylphenidate component. The immediate release gives you early onset. The pro-drug has the extended-release properties, the lower abusability, and so forth. When you put them all together and you look at the label, these are just some highlights that you can point to here indicated for the treatment of ADHD and patient six years of age and older. Can be administered with, or without food You can open it up the capsules, sprinkle on apple sauce and water and take it that way, or take them whole they are very small capsules. SDX is a Schedule IV compound the first and only methylphenidate-based Schedule IV.

What's interesting are kind of like the third to last in the last bullets here, these are the real differentiations, I believe for the product itself. Number one, on safety and side effect profile, when we did a 12-month study with AZSTARYS there really was no clinically significant changes in height or weight. There was a very small change over time to the negative where growth didn't go up as much as it should have, but it wasn't clinically significant at all. And we're hearing some of that feedback from patients and physicians who have prescribed it. It's quite a novel approach. Most of the concern with patients and parents, especially is the lack of eating and in a growing child that can be problematic.

And then the other point, the last bullet here, focused on how this product works across the day in the label. And I'll show this in a second. We saw differences in the LS Mean across from 30 minutes to 13 hours. So, this is a once a day, full day, sort of ADHD treatment option. Of course, there's no generic equivalent. The pro-drug makes it an NCE. And as I mentioned, there is some PTE and pediatric exclusivity possible as well. So, very long-lived product.

If I look a little bit at the market itself and what the need was, and you can compare that against the AZSTARYS profile, you can see highlighted here in the red, some of the real differentiation Adderal XR does not have a duration that's indicated, Vyvanse starts at about an hour and a half. Focalin XR starts early, but it doesn't last as long, it goes out to 12, and Concerta from 2 to 12. This is consistent with all the feedback we've heard from physicians for year-over-year, doing research, speaking to KOLs very consistent. Products like AZSTARYS will do better because they

are superior to the ones that are currently available. And we'll continue to kind of beat that drum and see how the clinicians and physicians actually see how well this does in their patients.

So, I'm not going to go through this in detail at all. This is just kind of expanding upon the highlights that I provided earlier. AZSTARYS, of course, again, is indicative for six and up that's across the age gaps of pretty much everybody. Administration, I spoke about already. This is the actual language from the label regarding the changes in height and weight. You can see there for yourself either here or if you go to the label itself, what those changes were and how they are not significant over the course of a year. Most of the changes were an initial decline in the first four months, and then rapidly get back to normal after that.

This is the efficacy data. So, this is the change in the SKAMP score across the day. SKAMP is a raider train, so they actually set these children up in a classroom setting, give them tests, have a schedule of when they're going to write them and each one of these time points, of course, is one of those rating days rating them hours, time points across the day. And you can see here across from half hour to 13 hours, we have differences throughout the entire time course. And I think qualitatively we've heard as well that the product does last throughout the entire day and does well within the individual's day, as far as when does it start to work and when does it start to wear off.

So, I'll turn a little bit now to the commercial launch. As I mentioned before, Corium in this case is an affiliate of Gurnet Point Capital. Corium is the commercializing party. They wanted to start as in the United States back in July. Initially it's going to be a focus launch, a few states, a few select prescribers within those states. And this is really due to what we all know is an industry standard. All new products get at least a six-month NDC block. And that's just the nature of the game. They have told us the pair discussions are ongoing and that they are going very well. They're not having a lot of push back. They'll see that they should make some good progress, but it's going to have to follow that typical timeline, post six months of launch.

Some positive signs that we have heard from payers and – our prescribers and patients is that, they believe in the clinical profile. They see it in their day to day. They know what's going on. We can see from our tracking data that prescribing is going through and getting repeat prescribing with the same physicians, as well as refills with the same patients. One kind of pushback or issue that we've all kind of seen it seems like Texas and Florida were probably the states where the focus of the launch where initially, of course, that's where also where the Delta variant of COVID-19 happened to be in its peak levels in July, August, September.

So many of the doctor's offices were closed to new patients, or certainly not to salespeople. So, we have heard that this is opening back up, of course, things are starting to level back off and, and go back to a state of normal. And we hope that that continues to kind of open up the opportunities for Corium. Of course, this is a huge deal for us. We're here to support Corium and provide whatever they need. And we believe that this is a much bigger opportunity than even we thought initially.

So, I'm just very briefly on the license agreement with Commave. This is entered back into September of 2019. They again sign the commercial rights to Corium. Corium has led their CEO is former head of the Neuroscience Business Unit at Shire. The team that really brought Vyvanse to market and made it the multi-billion-dollar ADHD treatment that it is, this deal is worth to us in

regulatory and sales milestones up to \$590 million. It's a significant amount. We believe most of its attainable. It's not those biobucks that most folks get. We really see that it is a real opportunity here for KemPharm shareholders. And you can see the other numbers there. I think what's meaningful is that on top of the sales milestones we have royalties that will be paid from the high-single-digits to the mid-20s in U.S. net sales.

So, I'm going to turn back to a little bit of science here. Talk about SDX's pro-drug and methylphenidate, and I really want to kind of hit home here. Having a schedule for methylphenidate is highly valuable. There are so many opportunities for methylphenidate-based products, now with a completely different pharmacokinetic profile, that's not reproducible, something that's inherently already now a schedule for product really means that the opportunities for SDX are huge. So, we're taking our – this opportunity to really explore what those are going to be. So, what are the indications that make sense here? What's the value proposition?

How much clinical risk is there, and where we see is that, hey, there's at least at face value there's two great opportunities, stimulant use disorder, idiopathic hypersomnia and I'll cover each of these in a second. And this provides us an opportunity to take the data that we should be able to achieve here by the end of the year. And from that to be able to determine commercial value, timing, costs and determine which path should be first. Second, maybe which one is the one to go with altogether, and then provide some more guidance around what product we're going to develop? But as of right now we're exploring both opportunities.

So let me touch on KP879. So, this is an SDX theoretical product for the treatment of stimulant use disorder. There's currently nothing to treat stimulant use disorder. And you can see from the prevalence data for abuse that was issued by SAMHSA. This is a huge issue, and it's in fact actually bigger and surprisingly so when I saw this data than opioid abuse, and those people seeking treatment, that's a bigger market than opioid abuse. And I don't think it's something that gets as much attention, of course not as many people die, but it's still a huge life changing problem and a societal issue for all of us.

KP879 for the treatment of SUD, again this is just as SDX very gradual blood levels, low of usability. There is a lot of work that has to be done here. I'll be very frank because nobody's been successful in developing a treatment for stimulant use disorder or cocaine addiction or methamphetamine addiction or any of these subsets of stimulant use. So, in this particular case, there is a fair amount of clinical risk. So, we have to evaluate that as we consider what path to go forward with.

When we look at the other opportunity KP1077, this is a rare disease. Typically, this is one you could imagine a company like KemPharm being able to afford a salesforce and feel that, and be able to monetize the asset entirely itself. About 37,000 patients, there's nothing approved for the treatment of excessive daytime sleepiness in idiopathic hypersomnia. Xywav was just approved as a GHB sodium oxybate product typo there, no big deal. Typically, stimulus are used off label, but there's nothing to control septum through 16 hours, nothing to allow for kind of IRR as needed, and then abuse remains an issue of concern and why modafinil has been used so heavily in this narcolepsy IH space is because of just the concern of addiction and abusability. So that's really what we're looking at when we think about a product like a 1077.

Here in this case, certainly fast-track eligible I don't know if a breakthrough designation is in the case, but I think it's a possibility, so we'll certainly try. And then all the benefits of moving forward, as you could highlight from the slide with our pipeline, we have an opportunity to right into a Phase 2, Phase three 3 study early next year, and so that's certainly very attractive. We know that product like methylphenidate does treat sleepiness in these disease states. So, I think there's a little less clinical risk here, so you can hear by my emphasis, this might be the more attractive option, but we'll wait to see the data in fact.

And then briefly I'll touch on the financial results and leave a little bit of time for a couple of questions. Second quarter was actually marked by again another quarter of net income. And this is certainly a nice trend to see, getting revenue of 12 million net income of 6.2 certainly is positively driven by mostly for \$10 million milestone payment for DA scheduling as SDX, and then a service fee revenue of \$2 million. We received that for consulting with Corium and Commave. This is kind of where we've come on the last, I'd say 18 months.

The organization, if you didn't know us last year was not listed on the NASDAQ, we were on OTC. We had about \$70 million in debt, less than \$5 million in cash. And now you can see there's been a complete financial transformation, just remarkable set of transactions able to take place and capitalize on the approval and get us in a position now where we can actually really grow the story and move into the next stage of our existence. Looking at cash 132 million as of June 30th you can see the rest of the details there. This is to move the company forward in our internal development opportunities, as well as look at some external opportunities for the first time, looking to bring in more candidates in the clinical phase so that we can kind of fill that pipeline up nicely in CNS.

So, looking ahead and just to kind of wrap up, everybody will be watching intently on the commercial launch of the AZSTARYS. We have that SDX trial. We should have that wrapped up soon and be able to report in the fourth quarter for year-end the results there and the path forward with that as well. Nice cast position allows us to really think about all the opportunities, external, internal, moving things up from the preclinical. And then knowing that you're going to have licensing revenue and royalties in sales milestones moving into future years is helpful as well. I think that puts us in a solid position that many organizations just don't have right now.

So, with that, I believe that's the end of my formal presentation. Brian, if you had a few questions, happy to answer them.

<< Brian Cheng, Analyst, Cantor Fitzgerald>>

Yeah, that'd be great. So, thank you so much for going through a story. So, as you said you have made a lot of progress over the last 12 months. You now have ongoing stream of revenues coming in with AZSTARYS and also you also have a number of assets in the pipeline as well. So where do you think is the most underappreciated part of your story today?

<<Travis C. Mickle, President, Chief Executive Officer, Chairman and Co-Founder>>

I think the appreciated part is maybe the totality of the story. Folks focus on AZSTARYS right, because that's interesting to them. Folks, they — while they're here, there's an interesting pipeline behind there, there's SUD or IH or all of that, and they forget that every part of that is a component to the story, right. We have revenue, solid cash, the launch of the product. We also have APADAZ and then our pipeline of assets. So, I think that's where things are a little bit underappreciated right now is just looking at the company as a whole, as opposed to one part.

<<Bri>Cheng, Analyst, Cantor Fitzgerald>>

Okay. And I guess if you were to pick one catalyst that investors should focus on for the next six to twelve months; what would it be?

<<Travis C. Mickle, President, Chief Executive Officer, Chairman and Co-Founder>>

I think as far as big catalyst in the next six to twelve months, it's the SDX trial and the data we should get out and then what product do we move forward with next year? Where do we take this? How quickly can we get to an NDA from there? I think it will be a fairly quick program, whatever we pick.

<<Bri>Cheng, Analyst, Cantor Fitzgerald>>

Great. Then we'll definitely look forward to that. And that concludes the presentation for today. Travis, thank you so much for joining us.

<<Travis C. Mickle, President, Chief Executive Officer, Chairman and Co-Founder>>

Yes, thank you, Brian. Thanks, Cantor for inviting us.