Transcript of My Eyes My Life Interview with Sydnexis CEO: Perry Sternberg.

Interviewer- Ayaan Seshadri:

Introduction Ayaan: Welcome, welcome, welcome to the My Eyes My Life channel to all our listeners and to Mr. Perry Sternberg, the CEO of Sydnexis. As you all know, MyEyesMyLife is a youth-organized movement focused on undiagnosed childhood myopia or near-sightedness. Our youth ambassadors, volunteers, and I go to preschools and elementary schools in our local areas and teach the teachers about the signs and symptoms of myopia that they may encounter in their classrooms, as the littlest kids are, well, too little to be able to articulate these themselves.

Nursery through fifth grade classroom teachers are in a unique position to flag myopia early and have the children treated sooner than they would have normally. And in this, halt its progression with early intervention. Sydnexis is one of the only drug makers for childhood myopia. And like My Eyes, My Life, Sydnexis focus too is entirely on children and their nearsightedness. Now you may wonder, what does it mean to be a drug maker for a disorder that's treated by wearing glasses or contacts? What is this drug, to be specific, eye drops doing in the land of glasses? Well, that is today's conversation. We believe what you'll learn today will change the way in which children are treated for myopia. So what are we waiting for? Let's introduce our guest. Mr. Schoenberg comes to Sydnexis after being the head of commercial sales for many high growth, large market sized products at some of the biggest pharma companies out there, including Shire Pharmaceuticals, now Takeda, the maker of ADHD drugs, the famous eye health company Bosch and Lawn, Novartis Ophthalmology, and Merck. His undoubtedly well-honed drug marketing skills will be exactly what Mr. Sternberg needs to deploy at the Nexus for the imminent commercial launch of CID-101 in the European Union and United States, as childhood myopia is now as rampant a disorder as can be. Prior to that, Mr. Sternberg is a graduate of Penn State University. Go Nittany Lions! Welcome, Mr. Sternberg.

Perry Sternberg: Thank you. Go Lions. Thank you.

Ayaan: Before we get into the next, can you tell us about the incidence and prevalence rates of myopia? Why does the disorder affect children first?

Perry Sternberg: Happy to do so. And thank you again for the opportunity to come and speak to My Eyes, My Life. What a remarkable organization, what you and everyone's doing out there for kids that suffer from myopia. So, to answer your question, today, there's roughly 28 million patients in the United States who suffer from pediatric progressive myopia. And by 2032, we estimate about 30 million patients in the US will suffer from

pediatric progressive myopia. And only about 11 million of the 30 million will be seeking treatment options. So this is a disease that is growing, not just in the US, but worldwide.

Ayaan: Absolutely. Thank you so much for that, Mr. Sternberg. What is myopia control? Everyone knows when you can't see afar, you wear glasses. Can you please explain to our viewers what myopia control means?

Perry Sternberg: Yes. Another fantastic question. So you hear a lot about myopia control or symptoms of myopia. It is well known out there that glasses help the symptoms of myopia.

And so, you know, a lot of people think about the way you help myopia or help control myopia is by putting glasses on. And it allows you to manage the symptoms of myopia. But the truth of the matter is myopia is a disease. It is actually classified as a disease. And what you need in addition to glasses are agents that help to modify the disease. So,what I look at is myopia control is not just controlling the symptoms of myopia, but it's actually modifying the disease of myopia.

Ayaan: Absolutely. And is myopia control only for children?

Perry Sternberg: No- myopia control is across the board, even going in adults. But the biggest part of myopia control is for pediatric progressive myopia.

Myopia starts young in age, and when it happens young in age, it progresses fast as well. So the majority of myopia is pediatric progressive myopia, and what you and My Eyes My life are doing out there to educate everyone is critically important. Yeah.

Ayaan: Thank you for explaining that myopia control is really a multi-year treatment plan that improves the slope of that graph of annual vision loss from myopia. We know that at least 25 % of myopic kids in the United States are not getting diagnosed on time. But for the remaining 75 % who do get diagnosed, how many have already have myopia control programs in place, not just wearing glasses every day?

Perry Sternberg: Its another fantastic question. So I would actually say you have an issue with the 25 % and you also have an issue within the 75%.

The truth of the matter is that myopia progresses young in age and as early in that progression when you start losing of diopters of vision, you lose them quickly. So the 25 % that have some type of myopia control mostly have symptoms of myopia control. They don't actually have the disease control. And of course the 75 % hasn't even got any myopia control. So what I always say with myopia, what you want to do is you want to catch them young in age and early in the disease process. And if I can say it again, young in age and early in the disease process. If you're able to do that, you can slow this disease down, minimize any back of the eye complications, and most importantly, save diopters of vision

because once you lose diopters of vision, you never get them back. And so again, young in age, right? And early in the disease, that's the time to treat. And so what you're doing, getting out there, educating at the schools that you're going to is exactly what we need.

Ayaan: Absolutely. Thank you for that. And what are the treatments available currently for myopia control in particular?

Perry Sternberg: Yeah, so the most important one is behavioral modifications. And what I say about behavioral modifications is outside, sunlight, that is great. Stay away from the devices all the time on computers. Back off the devices. So behavioral modifications. Keep the kid outside, keep them away from the devices. And when I say devices, meaning all the time on the computers. Of course, today we're on computers you and I, but not the 24 hours a day on the computers. The second is device options. And those come from glasses to help symptoms to products like Ortho K contact lenses that start around eight, nine, and 10 (years of age). But remember, remember again, myopia starts progressing young in age so you want to get them when they're four, five, six and slow that disease down. And what doctors will do is they'll use a non-FDA approved product called Atropine and they'll compound Atropine to try to slow that disease down. So (what we have now is)it's multifactorial behavioral modifications, a non-FDA approved product and device options.

Ayaan: Interesting. And now to focus a little bit more directly on your work at Sydnexis. Mr. Sternberg, where will your product, SYD-101 fit in? Tell us a little bit about low dose Atropine drops. How do they work and what is their mechanism of action?

Perry Sternberg: Yeah, so first I'll state that we are not approved yet. We're actually submitted our application to the US Food and Drug Administration for review. But pending approval, we would have the first and only FDA approved RX product for physicians to utilize if they feel it's the right choice to bring on and help control myopia. So compounding atropine is used out in the market. It's not FDA approved. Doctors do it because they believe they need to control the disease early in age and early in that progression. But we ran a large clinical study of over 852 patients, four years in duration, and pending FDA approval, we will have the first and only low dose atropine that doctors will be able to use for patients that they feel is appropriate to help start modifying the disease. So remember we would be a disease modification agent. We would be slowing down that progression. Glasses, device options, right? They control the symptoms. But what we would be doing is we would be slowing down that progression. And it's so critically important because remember with myopia, if both parents are myopes, you have a one in two chance of being myopic yourself. If one parent is myopic, you have a one in three chance. And if neither parent are myopic, you have a one in four chance. So what you want to do is you want to get these high risk kids and get them treated early in age and early in progression with a

disease modifying agent. And then as they get older, bring on the device options and other therapeutics as well.

Ayaan: Absolutely. And how low dose is low dose atropine? And where did the idea of Atropine drops even come from? Was higher dose Atropine used for other diseases in the past?

Perry Sternberg: Yeah, so another fantastic question. So atropine is an FDA approved product at a 1% concentration and it's a dilation product. It's used in eyecare all the time. If you put a 1 % concentration atropine in a child's eye, they will be dilated for two weeks. So they'll walk out and their eyes will be wide open and they'll be dilated- you can't do that. But doctors knew that atropine also had a role in slowing down myopia progression. And so what they did is they went ahead and they used and very common, this is what doctors do when there's not an FDA approved product, they will go ahead and they will get products compounded, non-FDA approved products, and they lowered it down to a 0.01%, 0.02%, a 0.03 % (concentration) because the safety profile is much better. The dilation is not that big. What you want to avoid is going up too high in the dose and it's because of the dilation and then the side effect issues that go with it. So, we will be a low dose atropine. We will be a novel formulation of it, all pending FDA approval. It will be one drop given in the evening. So think about it as a kid, they brushed their teeth, they take their myopia eye drop and they go to bed. And so that's the way that it would be treated to start modifying the disease.

Ayaan: Interesting. And since the concept of low dose atropine is already a proven concept in the Far Eastern nations where it's approved and myopic children use it routinely there, why has it never been approved in the USA. What did it take for Sydnexis to come along?

Perry Sternberg: Yeah, so, you know, the truth to the matter is doctors knew that atropine played a role in it to get a product approved in the United States. You had to do a large clinical trial. This is in a pediatric population and it should be a large clinical trial because you want to think about not just the efficacy, but the safety because a child could be on this for years, years and years. Some companies tried to get atropine approved, but unfortunately they were not successful in their clinical trials. We as the Sydnexis have a unique formulation of Atropine. We just completed our four years of clinical trial. Over 850 patients. It's the largest ever myopia trial done for a disease modifying agent. 50 % larger than any other trial ever done. And we believe that we have some exceptional results from the trial. Again, it's under review and FDA makes their final decision. But again, we believe that we did everything that the FDA asked us to do and created a very large, robust, and well-controlled clinical trial.

Ayaan: Absolutely. And you had mentioned just now the formulation that Sydnexis has your website opens with the banner formulation matters. So in a sort of high level sense, what is your specialized formulation?

Perry Sternberg: Yeah, so I'll leave it at a high level formulation matters. And so what it is what you want to worry about with formulation for myopia control and for kids eyes is that you got to keep a formulation of a product at near neutral pH, meaning that you don't want to drop the formulation pH too low because it's kind of like putting acid in a kid's eye. And a 1 % formulation of atropine allows you to stay at that near neutral pH, but the 1 % gives you the dilation issues at a kid's eye. So, when you start lowering down the concentration of atropine, you also impact the pH, right? That keeps near neutral pH. And so, our formulation allows us to lower down the concentration of atropine yet keep that near neutral pH. So, it's a novel formulation. Formulation clearly matters because you have to be able to have a very safe product for the children to take the product (compliantly) in order to get the efficacy benefits from the product. You can't get efficacy benefits if you're unable to take the product from a safety side.

Ayaan: Absolutely. And are there other atropine drops on the market or in clinical trials as of right now? Mr. Sternberg?

Perry Sternberg: So there are, as we know, the non-FDA approved products (are there). So compounding atropine that doctors go ahead and talk with the parents and try to get their understanding and the reasons to compound a non-FDA approved product. But there are no other FDA approved products on the market right now. We would be the first one pending FDA approval. There were a few other products in development. Unfortunately, they hit some clinical hiccups. So, we don't anticipate that they will be on the market anytime soon. So, we believe towards the end of this year, pending FDA approval, we would be the first one to market for this disease that actually needs help in slowing that progression down early in age, right? And early at that disease progression. So...Let's keep our fingers crossed. Most important is, you know, what I always tell my company is our job is to go out there and try to help people. And if we can offer one product and if the physician feels it's the right choice for their patient, then we made a difference. And so when you look at over 30 million patients in the US and growing, right, if we as a company can make a little bit of difference, just like what you're doing at My Eyes, My Life, then I think it takes all of us together to get children diagnosed, young in age, early in their progression, and to get products that allow doctors the options to treat their patients.

Ayaan: Absolutely. Thank you for that, Mr. Sternberg. And to pivot a little bit, we have a lot of budding scientists that tune into and support our work here at My Eyes, My Life.

So, to ask a little bit of a biotech 101 question, since myopia control is a new diagnosis or indication in the words of the FDA, would you be able to tell us a little bit about the phase one, phase two, phase three clinical trials that would be required for FDA approval and what's to this journey was there?

Perry Sternberg: Yeah, so another fantastic question. Whenever you're dealing with the pediatric population, FDA has two major questions. One is the product efficacious, but most importantly, is it safe, right? We're talking a pediatric population and we're talking myopia that progresses over years. So, you have to be able to show safety long-term on the product. So our study was a very large study over 850 patients in 47 sites across the US and Europe. It was a four-year study. Two-year data allowed us to submit in the EMEA, three-year data in the US, and then a fourth year of follow-up of the patients to make sure that we're monitoring any adverse reactions and side effects that could occur from the product. So as you can imagine, a very large study, right? And we had over 850 patients enroll in this study during the time of COVID. And so we were able to keep the parents engaged who were able to keep their children on the medication for this very important study. And I call this a landmark study in the world of Bio 101 or Pharmaceutical 101. This is a very large study. It's a landmark study - we had myopia patients in the study from the ages of three to 14. And you think about that, a four year study. That means a three-year-old is a seven-year-old, a 14-year-old is an 18-year-old when they complete the study. So, we have data on myopia from all ages, from three to really 18. And so landmark study, and that's what the FDA wanted and I agree with the FDA. Right? This is a pediatric population. Let's make sure that the product works effectively and it's safe to be used. Absolutely. Both incredibly important.

Ayaan: in your press releases as part of the Sydnexis, you've indicated that there's six months to your FDA approval date for SYD-101, which is coming up in around October. And if approved, when approved, who do you market to? Would you have to create partnerships with stores that sell glasses or do you go directly through optometrists and opticians? How do you get parents to understand the difference between myopia treatment and myopia control?

Perry Sternberg: Yeah, so, you know, pending FDA approval latter part of this year, we plan to be out on the market the beginning of next year, again, pending FDA approval. If we get approved and we're out beginning of next year, the ultimate decision maker in this is parents and physicians, right? And so we will be marketing and educating physicians directly. So that is pediatric ophthalmologists, general ophthalmologists, and optometrists, those physicians that have an interest in myopia.

And there are doctors that really understand myopia and I call them myopia specialists. They have a deep interest in helping children that are young, that are suffering from this disease to get it under control. So we will bring this product right out to the physicians. At the same time we will do education initiatives across the board. Talking with someone like yourself through My Eyes, My Life is a fine example where we want to get out and let parents know, let children know that there are options to talk with their health care provider about. what's interesting about myopia today, if we just take a step back, is that everyone is well aware we got to slow this disease down from industry organizations to optometry organizations, pediatric ophthalmology organizations. Insurance companies even say, hey, listen, myopia control, you know, it's an epidemic - we got to slow it down to the government that is actually putting vision tests in place in schools. And even large tech companies like Apple, who has put a myopia app on their phone saying back away from your phone, right? So everyone knows that our younger age population kids are experiencing myopia and we gotta control this disease. And I say this over and over. Once you lose a diopter of vision, you never get it back. So our goal is ultimately cure it, but I'm not here today to say that we cured it, but we're in second best place, I would say. We're slowing that progression down. We're keeping you from going to a severe myope and maybe keeping you at a mild or moderate myope. And so with everyone, with work together from doctors, people like yourself, your organization, industry organizations, insurance companies, government, tech companies, and pharmaceutical companies we can all go out there and make a difference in this disease.

Ayaan: Absolutely. And as part of your process, in bringing the product to market pending FDA approval, what do you need to do? (Is it) television ads on kids' channels or something else? Give us an understanding of how one builds awareness and uptake for the first medicine for myopia?

Perry Sternberg: Yeah, fantastic question. So again, pending FDA approval. You know, you would always look at the best ways to get out to kids and to their parents. And so one way to do it is TV ads for sure. I think in today's world, and I am a marketer by training, the world of digital and targeted marketing, right? So is probably the most effective way to go. Channels like yours, how you get out. Also since it is for to kids, right? So I'm not sure if large TV ads is the most effective way, but there are great ways to get out to the pediatric population, to the parents that have kids that suffer from myopia. And so we will, as a company, look at ways that we bring information in a fully balanced way.

So the answer to your question is yes, we will do it, but we'll do it in a very targeted manner. Today, I find that kids can actually show me I'm a little bit old, the best ways to actually get information and that's the way we want to communicate with them.

And obviously, again, a decision is always from our side, a health care professional's decision. An eye care doctor makes the final decision if they feel the product is right for the patient and the parent in this case. And so again, education across the board is critically important.

Ayaan: And finally, Mr. Sternberg, I asked how My Eyes, My Life can be the most beneficial for raising awareness of undiagnosed childhood myopia or of myopia control amongst those who have already been diagnosed.

Perry Sternberg: Yeah, so I got to say, you know, hats off to you and to My Eyes My Life organization. So I've been in the industry for 35 years in the healthcare industry. I started at Sydnexis just about a year ago. So, August will be a year. And I got to tell you, since being here, there's many things that have impressed me, but what truly impressed me is what you're doing here today. I was actually floored by it when you and I first got on the call. Thrilled to be chatting with you and to My Eyes, My Life organization, because this is the way we want to help people. It's exactly what you're doing. You gotta go out, you gotta educate them. You gotta let them know what is out there and what they can do about it and how you can make a difference. I gotta say I've been in the organizations. I worked for a lot of great companies, like you said at the beginning. Very few things have truly impressed me. A lot of things impressed me. Very few things truly impressed me. This this is one of them and so hats off to you and My Eyes My Life organization. And as we chatted about I'll flip it back over to you and to your organization Let me know what I can do to help you do what you're doing each and every day because you're making a difference. If you can impact one person that is one more person that then than the day before

And so for me, that's a huge impact. So congratulations to you.

Ayaan: Thank you so much. I'm so grateful to have had the opportunity to speak with you today, Mr. Sternberg. And clearly the work that Sydnexis is doing has great potential to trailblaze the future of myopia control at a pediatric level. Well, thank you for your time. It was great speaking with you.