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Q&A with Chris Pulling, CEO of MicroOptx developing a novel, Miniaturized, Nano Fabricated Implant that Reduces Intra-ocular Pressure to treat Glaucoma and Slow the Progression to Blindness by Shunting Excess Fluid from Inside the Eye to the Surface of the Eye

Chris Pulling
Chief Executive Officer

MicroOptx
www.microoptx.com

Contact:
Chris Pulling
763-670-5600
cpulling@microoptx.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

"Intraocular pressures in the 10mm range can not only slow the progression to blindness, but stop it... If we accomplish what I know we can, I believe it is Nobel Prize worthy – it's that impactful!"- Chris Pulling

CEOCFO: ***Mr. Pulling, MicroOptx site shows, "The End is in Sight". What are you developing to get there?***
Mr. Pulling: We are developing a novel, miniaturized, nano fabricated implant to treat glaucoma. Today, current therapies for glaucoma are ever improving, but are really only able to slow the progression to blindness from glaucoma. They cannot stop it. The goal of today's treatments is to slow the progression to blindness enough to spare at least some vision through end of life. Despite best efforts, glaucoma is still the leading cause of irreversible blindness in both the United States and in the world. Therefore, there is clearly a lot of room for improvement and management of patients with glaucoma. It is estimated that there is somewhere between eighty million and one hundred million people worldwide with glaucoma. Many are from less developed countries with limited or even zero access to glaucoma treatments. In the US there are about three million people with glaucoma. Our technology is approaching the problem in a completely different way from everyone else.

CEOCFO: ***What is the approach at MicroOptx?***
Mr. Pulling: It is a tiny micro shunt that is implanted in the eye. It reduces intra-ocular pressure by shunting excess fluid from inside the eye to the surface of the eye.

CEOCFO: ***Before we discuss your solution would you give us a little information about glaucoma?***
Mr. Pulling: We are constantly producing a substance called aqueous humor that flows into the front of the eye. It provides lubrication to the front of the eye and also gives the front of the eye, just behind the colored part of your eye, a depth and structure. If it is constantly flowing in, it must also flow out at the same rate. As we age or maybe through genetics or injury, the native drainage network inside the eye becomes compromised, and the rate of outflow no longer keeps up with the rate of inflow. As a result, fluid begins to build up in the front of the eye and that causes an increased intraocular pressure. That pressure compresses the optic nerve on the back of the eye, causing permanent irreversible cell death, which leads to permanent irreversible vision loss. Therefore, the goal of glaucoma treatment is to reduce the pressure in the front of the eye to relieve pressure on the optic nerve. Several studies have shown that once that damage begins to the optic nerve, it is not enough just to get pressure back to a normal range - you have to get it below twelve millimeters of mercury to halt further damage to the optic and the progression to blindness. Normal range is fifteen to twenty millimeters. For instance, if someone is at a pressure of twenty six millimeters and they are able to get to maybe seventeen with conventional therapy that still a big improvement, but they are still losing vision.

CEOCFO: ***How are you addressing the situation?***
Mr. Pulling: We are addressing it by shunting that excess fluid from the front of the eye directly to the surface of the eye. It is a tiny implant very precisely engineered to achieve a rate of flow that will get intraocular pressure in the ten millimeter

range. We are able to do that because we are going to a surface of the eye. There is no resistance to outflow other than the resistance we engineer into the device. That is a very important distinction with our device compared with others to treat glaucoma. We know what the rate of aqueous flow into front of the eye is. We know what we want the pressure to be. Therefore, we have learned how to engineer the resistance to flow that achieves the desired pressure. Intraocular pressures in the 10mm range can not only slow the progression to blindness, but stop it. This concept was actually first contemplated in the early 1990s, and other companies have tried this approach in the past. However, no one has been able to do it yet without causing infections inside the eye, which is actually worse than the glaucoma you are trying to treat.

CEOCFO: ***What have you figured out that others have not?***
Mr. Pulling: The first thing, which is not a trade secret, is that other companies have tried a trans-corneal approach, which failed because the cornea does not heal very well – corneal tissue does not heal to the shunt and bacteria can enter the eye through the incision, around the device. We are going through the sclera, which has a more aggressive healing response. The space between the incision and the device is immediately closed due to a tight friction-fit and the elasticity of scleral tissue, and the device is fully healed in place shortly thereafter. On the inside of the device we are using advanced biomaterials – a super hydrophyllic hydrogel, specifically - that creates a hydration shell along the entire flow channel. Bacteria, proteins and things that try to attach to the walls of the flow channel are unable to – they cannot adhere to water. We have also maximized the shear stress of the laminar flow using advanced microfluidics. Think of a river where water is constantly flowing downstream. If something is trying to swim upstream, it can with a very slow current. However, as the current gets stronger and stronger it is just washed away. You never see ducks swimming up rapids in a river. The same concept applies here. The current - or the shear stress of laminar flow – that we have been able to create is twenty times the adherence strength of a MRSA bacteria, for example. If anything does enter the flow channel, it is immediately just washed away and goes back to the surface of the eye.

CEOCFO: ***What is involved in implanting the glaucoma implant?***
Mr. Pulling: It is rather simple. A small incision is made through the white part of the eye, very near where the white part of your eye meets the colored part of your eye. The incision is made in a similar location and in a similar manner as the incision used for cataract surgery, except our incision is about one third the size of a standard cataract surgery incision. Once the incision is made the device is simply grasped with a forceps and slid into the incision.

CEOCFO: ***Would this be done in a doctor's office?***
Mr. Pulling: Eventually, yes. It would be an in-office procedure.

CEOCFO: ***Why is it so much easier than people think? What is it about the eye that allows for ease of implantation?***
Mr. Pulling: I sometimes put eye drops in my eye, such as Visine or whatever. I do not like doing it. I do not know anyone who does! It is your eye! You get a little piece of debris in your eye and it hurts, even an eyelash. The eye is a sensitive area and you are awake during surgery. You see a knife approaching, or something like that, and it is scary. However, you look at advancements in laser surgery, such as Lasik, people are getting much more used to it. Even cataracts are done quickly and easily. They just numb the surface of the eye with local anesthesia and maybe give you a sedative to relax. If you watch a cataract surgery, it is not that easy to watch. However, if you are having one, it is often over before you know it with very little discomfort. You do not feel it and with the sedative you are not so nervous about it. That would be similar for us. We will numb the eye and administer a little bit of sedative. The incision and insertion are all done very quickly with little or no discomfort, bleeding, etc.

CEOCFO: ***Where are you today in development?***
Mr. Pulling: We are through the development phase. We have gone through a very rigorous, non-clinical testing program. We have had over eighty devices studied in animals in various animal studies. We have submitted an Investigational Device Exemption to the FDA to do a first human study. That IDE is approved and we are currently enrolling patients for that first human study. We will also be initiating a clinical trial in Germany in April. We are initiating a clinical trial in Chile in May.

CEOCFO: ***At what point would it be most appropriate for someone to have the implant?***
Mr. Pulling: The labeling that we will be seeking with FDA will be anyone with glaucoma who has not adequately controlled their intraocular pressure with medicated eye drops. It could be someone fairly early in the disease progression. It could also be for someone who has had glaucoma for a very long time and has tried many, many drugs and many, many procedures and are still going blind - anyone on the spectrum.

CEOCFO: ***What has the response been from the medical community?***
Mr. Pulling: Ophthalmologists are very excited about the prospect of what we are doing. Many of the physicians - actually, I would say all of them - have an immediate concern about communicating with the surface of the eye and providing a potential conduit for infection. The general feeling is, "Wow, if you can really do this without causing infections in the eye, this changes everything about how we treat glaucoma!" We have known that from the moment the idea was conceived; that we need to figure out a way to do this without causing infections. Virtually every aspect of the engineering and design of the device has been with a mind towards preventing bacterial encroachment and infection. In over 80 animal implants, we have not had a single positive bacterial culture or gram stain. We even conducted a bacterial challenge study, where a daily drop of a bacterial broth was dropped on the eye for two weeks after implantation – we observed 100% bacterial exclusion even under that extreme condition.

CEOCFO: ***Are there reimbursement codes in place? Do you fall under a standard category?***
Mr. Pulling: Reimbursement codes exist for certain, what are called MIGS devices; Minimally Invasive Glaucoma Surgical devices. Examples of those would be the Glaukos iStent®, which has been in the market for roughly five years. Alcon has the CyPass® Micro-Stent that has more recently been introduced to the US market. Allergan has XEN® Gel Stent available on the US market. Those technologies also fall under the same general category of a MIGS device. Ours does too. Each one of those devices have their own category three reimbursement code. Those implant procedures, though, are different from ours. They are implanting the device in what is called an *ab interno* approach - they enter the eye and insert the device into very specific region inside the eye. Their procedure codes are specific to their implant procedure. Ours is very different in that we are implanting the device from the outside of the eye (*ab externo)*, in a simplified procedure. There is a very general reimbursement code that I believe we could fall under. However, we will be seeking our own category three code. There is some talk that the AMA may be, in the not too distant future, condensing all the category three codes for all these different MIGS devices into a single category one code. If that happens, we would expect to be included in that code.

CEOCFO: ***Are you seeking funding or partnerships?***
Mr. Pulling: Yes. We have raised 7.5 million dollars since inception May of 2015. Our current financing will take us all the way through 2018 and maybe a month or two into 2019. We will be raising an institutional round of financing towards the end of this year. Once we have a little more human data in hand to help with that fundraising effort, presuming they are good data, we will be raising about $25 million to $28 million. That is what we will need to get from now through PMA approval in the US and early stages of commercialization.

CEOCFO: ***There are so many new ideas in health.. Would you address both the medical and the investment communities? Why does MicroOptx standout from the crowd?***
Mr. Pulling: It is a huge market. It is roughly six billion dollars a year in the US and well over ten billion dollars a year worldwide. Yet glaucoma remains, to a great extent, an unmet clinical need. It is the leading cause of irreversible blindness, despite all the recent investment and advancements. We have novel, breakthrough technology in a huge market with unmet need, and we have a leadership team with a demonstrated ability to bring novel technologies to market. In addition, we have aligned ourselves with some of the greatest medical minds in ophthalmology to serve on our Medical Advisory Board - providing input on what the device needs to be and do to make the impact that we think it can. I would also add that many of the people going blind from glaucoma are from parts of the world with very high rates of glaucoma and literally no treatments available to them. The medicated eye drops are too expensive. The current surgeries or implants are unattainable. They do not have the centers or expertise to perform procedures. This could eventually be something that is a very real, practical, feasible solution for those parts of the world, too. If we accomplish what I know we can, I believe it is Nobel Prize worthy – it's that impactful!

MicroOptx