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Q&A with Dr. Sean McCafferty, President and CEO of Intuor Technologies, LLC developing products for the Optics and Ophthalmic space with their flagship CATS Tonometer Prism™ Improving the Accuracy of Pressure Measurement in the Eye for Detecting Glaucoma



Dr. Sean McCafferty, MD, FACS, MS
President and Chief Executive Officer

Intuor Technologies, LLC www.intuortec.com

Contact: Nannnon Roosa, PMP, CPA, CMPE Chief Operating and Financial Officer 520.975.4550 nroosa@intuortec.com

Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine

CEOCFO: Dr. McCafferty, what is the concept behind Intuor Technologies, LLC?

**Dr. McCafferty:** Intuor Technologies is an ophthalmic and optic development company that takes our conceptual ideas in both industries, develops the intellectual property, performs the research and development, produces the prototypes, and, in some cases, markets the finished product. We are currently developing several innovative products. Our overall development criteria is that our products that are simple, effective, and clinically pragmatic. Intuor Technologies solve problems that exist either in ophthalmology or in the optic space.

CEOCFO: Are people coming to you with ideas and you are helping develop, or are you creating ideas at Intuor? What are the logistics?

**Dr. McCafferty:** As an ophthalmologist, I have the benefit of being an end user of these products. Therefore, the genesis of several of these products are from my colleagues' and my understanding the problems that exist out there and then developing a solution for them. Therefore yes, it is in conjunction with both me, as an end user, and the colleagues around me that enables me to come up with the IP for the solution.

**Ms. Roosa:** I think Sean's background is the reason he is able to develop these ideas. He has an undergraduate degree in mechanical engineering. He is also a graduate from Ohio State Medical School and a board-certified ophthalmologist. Additionally, he also earned a Master's in Optical Science from the University of Arizona. Therefore, his perspective on the world is one that seeks to solve real problems. When many of us encounter something that does not operate as well as it should, most of us would say, "Okay, we will work around it." When Sean looks at the same situation, he squints his eyes while thinking of a solution, and then says, "I think I can fix that." Therefore, I think his education background (the mechanical and optical engineering combined with the MD) provides him a very unique perspective on the world. As I said, Sean thinks of the solution when he encounters a problem.

CEOCFO: Are there some common challenges in ophthalmology and optics that are longstanding and that need to be addressed or is it from small increments or specific situations that enable you to come up with an answer? Dr. McCafferty: There are some major things, both in optics and in ophthalmology, that we consider the Holy Grail. One is a lens on the inside of the eye that is able to change its focal distance; currently we place an intraocular lens (IOL) on the inside of the eye during cataract surgery. Unfortunately these IOLs are unable to change focal distances, typically requiring patients to use reading glasses to see up-close. Over the last twenty years there has been a concerted effort to create a truly accommodating IOL to five diopters, which is the accommodation – the ability to be able to change our focal

distance – like we did in our twenties. However, all progress has occurred in minor increments, because there are many challenges to developing an accommodating IOL. Likewise in optics (non-medical application), the ability to create a lens that can change its focal distance and actually change the shape of the lens has been an emphasis of development for the probably the last forty or fifty years. Two of our innovative products relate to these concepts. Some of our products are targeted toward smaller incremental changes. For example, our flagship product, the CATS Tonometer Prism™, improves the accuracy of pressure measurement on the inside of the eye. This measurement enables clinicians to detect glaucoma and other disease processes. Measuring pressure is probably the second most important metric in an ophthalmologist's or optometrist's patient examination. There has been no change in this technology over the last sixty years. In this time, it is well-documented and understood that there are errors inherent in our ability to measure the pressure in a human's eye. To address this problem, we modified the existing tonometer prism to significantly improve its design so it is significantly increases the accuracy of the pressure and the variations between people. As a result, based on numerous scientific studies, our CATS Tonometer Prism™ provides eye care clinicians the data necessary to detect glaucoma earlier and also reduces the number of people who are being treated for glaucoma unnecessarily.

"Combining scientific knowledge and real-world oriented solutions, Intuor Technologies is developing solution-based products that are simple to use, effective, and pragmatic for the optics and ophthalmic industries."- Dr. Sean McCafferty, MD, FACS, MS

### CEOCFO: How does it actually measure the pressure? What is the adjustment that you were able to make?

**Ms. Roosa:** Have you gone to the eye doctor where they put the drops in your eye and you see this circle of light come forward? That is what we are talking about – measuring intraocular eye pressure (IOP).

**Dr. McCafferty:** The only way to truly measure the pressure in someone's eye is to place the pressure transducer right inside the eye via a needle. For obvious reasons, that is not going to happen in your normal clinic. Therefore, we have to infer what the pressure is on the inside of the eye from external measurements performed during an eye examination. Dr. Goldman, inventor of the Goldmann tonometer, discovered the idea of flattening the surface of the eye with a prism to a certain degree, a certain diameter. If you know the amount of force used, what are using to flatten it, and the area, then you can then determine the pressure. It is a relatively simple concept. The difficulty comes in with the assumption that everyone is the same. However, the truth is that children are not the same as adults. People who have had refractive surgery are not the same those who did not have surgery. Many people have very thin corneas or very thick corneas, corneal scarring, and various disease processes. All of these factors create errors inherent in this measurement process, because our eyes all develop differently from each other. Therefore, we redesigned the prism to correct for these errors. We created a new surface for the tonometer prism which significantly reduces the difference between two people so that eye-care clinicians can measure the same pressure on the inside of the eye, despite the difference that we have in the way that we are built.

# CEOCFO: Has the medical ophthalmological community been looking for a better way? Do they recognize that the standard is not as good as it could be?

**Dr. McCafferty:** Goldmann tonometry IOP errors are a well-accepted problem. Even Dr. Goldman, sixty years ago, acknowledged errors in measuring eye pressure. The ophthalmic community has been attempting, literally for sixty years, to come up with a better way of how to measure the intraocular pressure. There are several devices out there which infer the pressure externally though very complex mechanisms — at a substantial cost as well — but were ultimately unsuccessful in the clinical environment. However, no innovation, until now, has been able to improve upon the original Goldman design. To address this problem, we developed a modification for the Goldman design which will sell at roughly the same cost as the Goldman design, but vastly improves upon the original design.

### CEOCFO: Intuor received a recent FDA clearance. What happens now?

Ms. Roosa: One thing I wanted to say is that all of our products must conform to our design philosophy; our products must be simple to use, effective, and clinically pragmatic. This is very much the case with the CATS™ tonometer prism. The current reusable prism fits on the Goldman tonometer and should be replaced every three years. To adopt our prism, the clinician simply replaces the current prism with the CATS™ prism, and then the physician can continue to measure eye pressure in the same manner as before. Therefore, the only change is replacing the prism, and how the clinician measures intraocular pressure, interacts with the patient, and measurement technique remains exactly the same.

#### CEOCFO: It appears to be very simple!

**Ms. Roosa:** We design products that work effectively in a clinical setting. That is an advantage of Sean being clinician; we are not going to market something that is not going to work for eye care clinicians. To have a successful product, you

have to understand the business of medicine and interact within those constraints. The eye care clinician simply takes off the old prism, replaces it with the CATS™ prism, and s/he is good to go. Based on scientific studies, our CATS Tonometer Prims™ increases the intraocular pressure measurement accuracy for 50% of the population.

**Dr. McCafferty:** It is a clinically significant increase in the clinician's ability to be able to measure the intraocular pressure, which affects the doctor's decision making process.

**Ms. Roosa:** Right. If someone has a problem like glaucoma, then you can detect it earlier and get them on glaucoma drops – saving their eyesight. That is our whole goal: to improve and preserve eyesight. This tonometer is used in the United States and on a worldwide basis. Therefore, this change we are talking about will increase the accuracy of the intraocular pressure measurement and improve eye care globally.

### CEOCFO: What are your next steps? How do we go from you made it to everybody having it at the end of the three year period?

**Dr. McCafferty:** We have received notice of FDA clearance on March 9<sup>th</sup> of this year, so are cleared for sales and marketing in the United States. We will be pursuing our CE mark this fall. We are doing some minor design revisions to reduce our costs and increase our margins. In additionally, we will also be applying for expanded FDA claims, above and beyond the existing claims that exist for pretty much all tonometers, so that we can differentiate ourselves in the marketplace as well.

**Ms. Roosa:** We have FDA clearance on a reusable prism, and we are also developing a disposable version. We are developing plans for scaling manufacturing as well.

## CEOCFO: Are you looking for partners, funding or investments? Where do you stand from the business side? Ms. Roosa: We are doing great from the business perspective.

**Dr. McCafferty:** We are proceeding on a number of fronts. We are continuing our commercialization efforts to bring the product to market ourselves. Another avenue that we are considering is the potential for strategic partners to bring us to market via a number of deal structures to include sale of IP and licensure. Those partners include some companies already in this space, as well as others in the broader ophthalmic community as well. We are pursuing all options to get this product to market and available for clinician use.

### CEOCFO: Is the Intuor name known in the ophthalmology community or is each product stand alone?

**Dr. McCafferty:** Intuor Technologies was founded about four years. We certainly have been presenting in the ophthalmic conference space on a regular basis and publishing in peer-reviewed journals. Therefore, many people are aware of us. Are we necessarily a household name? No. However, certainly I have been personally working on the products for many years, actually decades. At this point in time, I would not say Intuor is a household name, but it is known among the developers and key opinion leaders in the ophthalmic space.

#### CEOCFO: Would you lay out the plan? What should we expect a year from now?

Ms. Roosa: As far as the next steps; we are pursuing several different options. We are looking for partners and seeking investment, as well as planning for market entry and distributing the product ourselves. Right now, I just want to make sure that all those options are on the table. In a year, we will have more focus on which option we will pursue, depending on what happens with the partners with whom we are interacting. By that time, if the IP is not acquired, then we will certainly be in production and the device will be available for sale. We will also be pursuing intellectual property in the optics and the intraocular lens fields. We are evaluating a number of options at this point, but we are very excited with our FDA clearance on our CATS™ Tonometer Prism product.

### CEOCFO: Why is Intuor Technologies, LLC an important company?

**Dr. McCafferty:** Combining scientific knowledge and real-world oriented solutions, Intuor Technologies is developing solution-based products that are simple to use, effective, and pragmatic for the optics and ophthalmic industries.

