Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Mr. Buckland, why did you start Bioptigen? What is the concept?

Mr. Buckland: The company started as a spin out of Duke University based around a technology called optical coherence tomography, or OCT, that allows us to see into biological tissues with very high resolution. Bioptigen has focused on ophthalmic imaging, and this is in fact the largest market for OCT imaging systems globally. Our company is among the pioneers of a generation of technology called spectral domain OCT that allows very high resolution images of internal tissue structures to be taken at video frame rates. This opens up a new set of applications and opportunities for the diagnostic and research imaging. When we started, our objective was simply to provide the highest quality imaging of its kind to the ophthalmic research market. Our technology is analogous to ultrasound in that it sees in the tissue in three dimensions but uses light waves instead of sound. The potential applications had not been fully developed, so we decided to look ahead taking what we learned from the research market into new clinical opportunities. That was the origin of the company, and since that point, we have grown into new segments and established a solid reputation for delivering the highest performance systems.

CEOCFO: What are you working on today?

Mr. Buckland: Basically, what we are doing is imaging the eye and particularly imaging the retina and the cornea of the eye. For the retina of the eye, we are really interested in looking at the tissue so that physicians and researchers can diagnose and develop new treatments for all the major eye diseases from macular degeneration to diabetic retinopathy and glaucoma. The structures of the eye happen to be finely layered tissues, so the ability to separate all the different layers of the tissues and know what each of the layers is responsible for and how it is responding to disease states is critically important. Before our type of technology, one could only see the surface – a photograph of the tissues – but could not see what is underneath the photograph.

CEOCFO: Have alternate methods been tried in the past?

Mr. Buckland: This particular technology is unique in its ability to see fine tissue structures, really at the cellular level, completely non-destructively. Ultrasound has the advantage of being able to see very deeply, for example allowing us to see a developing baby in a womb. But ultrasound does not see fine structures like the layers of a retina. The first generation of OCT was useful and provided the value of seeing the details of the retina, but imaging was slow and resolution was still limited. The advantage of our particular implementation is that we can get a full image of the retina in three dimensions in just three seconds. That is really what is unique. We can see about 100 times finer detail with OCT than what you can see with ultrasound, and this always clinicians and researchers to really see the earliest manifestation of disease and to follow progression in the eye in a way never before possible.

CEOCFO: What equipment is needed?

Mr. Buckland: The equipment includes an engine that houses a broadband light source – a super LED – and optics for creating an interference pattern with light scattered from the eye. Light is delivered to the eye via a handheld scanner.
unique to Bioptigen that scans the light through the pupil of the eye back onto the retina. The interference signal is collected with a custom spectrometer and proprietary signal processing transforms the signal of reflected light into a three dimensional image of the tissue structure. The light power is non-hazardous at the level of illumination that we use. That is basically the instrument. The system now is FDA cleared. In fact, it is the only system of its kind that is explicitly FDA-cleared for pediatric applications, including for the imaging of neonates and preemies. Clinically, pediatric ophthalmology is our target application and our specialty.

CEOCFO: Why is that the target market for you?  
Mr. Buckland: We serve the ophthalmology research market and the pediatric ophthalmology market. In particular pediatric ophthalmology is a critically underserved market. There are specific childhood diseases of the eye, just as there are system diseases of childhood. Young children are not good candidates for imaging with equipment designed for adults. In the adult market, the patient is cooperative and they can come into the clinic, sit in front of an instrument, get their eye scanned, and the physician can then get to report and compare that report against normal data for an adult patient. A young infant cannot be imaged that way. Furthermore and there is no normative data for the young infants. Therefore it was our objective to develop an instrument that could be brought to the patient rather than the patient having to come to the instrument, and appropriate to imaging the features of the eye relevant to childhood diseases of the eye. That is what we have done. We have the only portable instrument of this kind in the world today.

CEOCFO: When would an ophthalmologist be called in? In what kinds of conditions would your tools be useful?  
Mr. Buckland: Let’s start with premature babies. When babies are born prematurely their eyes have not finished developing. The premature eye is susceptible to a particular disease called retinopathy of prematurity that presents a major for blindness in the premature child. It is essential to identify at-risk infants. Appropriate imaging can help the physician make appropriate treatment decisions. The clinical community is now developing methodologies to use our equipment to assess the risk and progress of retinopathy of prematurity. Another risk to the pediatric eye is a tumor called a retinoblastoma. Caught early, retinoblastoma is treatable. Left un-treated, it can lead to blindness or loss of an eye, and can metastasize to the unaffected eye. Retinoblastoma is observed at a very early stage with our equipment. Another application is forensic analysis of trauma. For example, shaken baby syndrome will lead to particular damage to the eye. The ability to observe the structural damage to the eye helps forensically in identifying whether a baby is subject to shaken baby-type trauma.

CEOCFO: Where are you in the commercialization process?  
Mr. Buckland: We are commercial. We have been commercial for research applications since 2007. We received FDA clearance for the pediatric application in 2012. We sell direct, domestically and internationally, though we are now establishing distribution partners. We have our system in more than 100 sites in 15 countries today.

CEOCFO: Why would every lab and clinic not have one?  
Mr. Buckland: OCT is still evolving as standard of research, and is not yet a standard of care in pediatric ophthalmology. The pediatric community is continuing active research on how the technology is best used in the clinical care of infants. Right now, the user base consists of lead adopters in the top institutions in North America, Europe, and India. We are working to broaden the use of this technology through collaborations with our lead adopters who are advocating through publications and presentations internationally.

CEOCFO: How have your previous experiences played into that strategy? What have you learned in the past?  
Mr. Buckland: We are developing new markets with new technology. This combination always presents risks, and has high potential for reward. The technology base is being validated in adult diagnostic applications, so we don’t carry the burden alone. In any case, it is rewarding to solve hard problems and to see the benefits to the patients – the children – from our efforts to build the market for pediatric imaging with our technology.

CEOCFO: What type of training is involved for the doctor?  
Mr. Buckland: We have on our staff a clinical photographer who came to us from the Department of Ophthalmology at Columbia University. Ours is a handheld imaging system, so there is a certain amount of skill and training that has to
come to bear to teach both doctors and nurses to use the system. Once they get the handle on how to image with a handheld device, they are able to extract beautiful images, and analyze these images as an aid in their diagnosis.

**CEOCFO: What is the plan for the next year or so?**

**Mr. Buckland:** We are continuing the expansion into the pediatric market, but there is another growth opportunity that has become apparent as an extension to the pediatric market. Many children are imaged under anesthesia simply because they cannot be fully treated or examined awake. When they are examined under anesthesia that brings them into the operating room. Once we are in the operating room, there tends to be a collaboration between the pediatric ophthalmologist and a surgeon. This engagement of ophthalmologists and retinal surgeons has brought our system into the surgical realm. Our next area of development is therefore in surgery, specifically in image-guided surgery of the eye. There is tremendous potential for OCT before, during and after surgery for all patients, not just for infants. We see applications in retinal, cornea transplants and cataract surgery. Doctors need to see more detail, in more depth as they perform precision procedures on the eye. Intrasurgical imaging is a much larger opportunity than pediatric imaging alone. It is our intention to support and continue to develop the technology and market for the pediatric community, and to develop our next generation systems around image-guided surgery for ophthalmology.

**CEOCFO: Put it all together for our readers. Why pay attention to Bioptigen?**

**Mr. Buckland:** Bioptigen is a recognized brand for delivering the highest quality OCT imaging to the ophthalmic research and pediatric communities. We are serial innovators, pioneering the commercialization of high performance OCT in two market segments, delivering the first FDA-cleared OCT product for Pediatric imaging. Bioptigen is leveraging our experience and technology to address critical needs in surgical visualization with our new intrasurgical OCT platform for better care for the patient and growth for Bioptigen.

**BIO:** Eric co-founded Bioptigen, for which he has acted as principal investigator on multiple federal grants and received a Frost & Sullivan Award for Excellence in Research in Ophthalmology. Eric has 25 years experience in the development and commercialization of optical technologies. He earned his BS/MS in Physics from North Carolina State University and his PhD in optics from the University of Rochester and has been awarded more than 30 US patents.