

Jim Datovech, President of LKC Technologies discusses their RETeval® a unique, handheld Electrophysiology Device used invasively or non-invasively in Neonatal to Geriatrics for Detecting Major Eye Diseases from Diabetic Retinopathy and Glaucoma to Vascular Macular Degeneration



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“We design, develop and sell ophthalmic devices using visual electrophysiology technology, which is a functional assessment of the retina, the optic nerve and visual cortex depending on the protocol used.”- Jim Datovech

CEOCFO: Mr. Datovech, what is the focus for LKC Technologies today?

Mr. Datovech: We are an ophthalmic device manufacturing company. We design, develop and sell ophthalmic devices using visual electrophysiology technology, which is a functional assessment of the retina, the optic nerve and visual cortex depending on the protocol used.

CEOCFO: How do you decide what to work on?

Mr. Datovech: Basically, there are a couple of ways. The first way is there is a society called the International Society for Clinical Electrophysiology of Vision, ISCEV, that publishes a series of standard protocols that are used to perform visual electrophysiology testing. Our devices basically conform to the specifications of ISCEV. Then we look at major unmet health diseases such as diabetic eye disease, diabetic retinopathy, macular edema and vascular macular degeneration, glaucoma; major eye diseases that cause major health difficulties that really impact healthcare systems in spending around the world. We ask if there is a way we can apply this technology to assist in managing those disease states either from aiding and diagnosing to management of treatment, to assessing length of treatment, and how we can apply this technology to those diseases to improve the outcomes for patients around the world.

CEOCFO: What is the market like? Are many companies in manufacturing and developing or are the two not often together in one organization?

Mr. Datovech: Those companies that are in visual electrophysiology are in the design development manufacturing and sale of the product. Most companies who make a device such as ours do the whole spectrum.

CEOCFO: *LKC has been around since 1976. Does it matter when doctors are looking to purchase? Do they look at history?*

Mr. Datovech: They look at a lot at history. Those who have experience with LKC understand that our products are known for their longevity, for their service, durability, stability and results over time. Secondly, they know they are going to get exceptional service when they need it on the device. The doctors on the one have I think have the trust and confidence in LKC. This is around the world. Given our longevity in this space, we have a very strong reputation and we are known worldwide even though we are not a large company. Secondly, I think they look for innovations for the ability to diagnose various disease states assisting diagnoses of various disease states, looking for companies that have use devices that have been used in research. In the last five years, the LKC devices have been references in over 400 peer review publications, so I think that people look for those types of affirmation on the quality of the product and also knowing that if they have read peer reviewed publications and want to have similar results, if it were done with our device, they know they are going to get those similar results when they do it on their patients or animal testing.

CEOCFO: *Would you give us an example of how your product is better?*

Mr. Datovech: If you take our **RETEval**® product, it is a unique, handheld, fully functioning electrophysiology device. It can test either on eyes that are dilated or undilated. It is the only device in the world that has this patented capability. You can either use an electrode that goes directly on the cornea of the eye or one of our unique and patented sensor strip electrodes that are skin based to fit just under the eye on the cheek and on the side of the head where a side burn is. It is a unique device that has incredible flexibility, portability, can be used invasively or non-invasively everywhere from neonatal up to geriatric use. It is a tremendous product that has expanded the use of electrophysiology, so that is an example.

CEOCFO: *Why would a doctor dilate if not necessary?*

Mr. Datovech: That is a good question. Some ophthalmologists will say they dilate everyone that comes in anyway because they want to look in the eye, and the **RETEval** device can be used on a dilated eye as protocols that are for dilated eyes. On the other hand, you could have a child who you say you do not know whether you need to have an electrophysiology testing or not, and typically those children are sedated or in an operating room for this type of testing. There has been quite some success of doing testing without dilation and without sedation on children, which is an amazing advancement.

CEOCFO: *What new products, concepts and improvements are you working on now?*

Mr. Datovech: We are working on two different things. One is we continue to enhance the **RETEval** product line. There are universities and other companies doing multicenter studies on being able to do differential diagnosis of mental health diseases, using retina responses, because the retina starts out in life as cerebral tissue and then separates off to form the retina and it is truly a window into the brain. Looking at differential diagnoses, there is a multicenter study underway, looking at autism and being able to diagnose it early. There are multicenter studies looking at drug addiction and drug dependencies, so it is not just looking at different retinal diseases but also systemic diseases and mental

diseases as well including those as well as traumatic brain injury. We are working on supporting universities and doctors around the world, doing research into these areas. The second is on our flagship product line, UTAS. We are in the process of enhancing that device into Windows 10 technology, advancing our amplifier technology to make the acquisition of these small, electrophysiology signals easier to gain and be more robust. We are looking at having our core technologies as well as the **RETeval** technologies.

CEOCFO *Has the role of the eye and the retina been known for a long time as potentially a source on some of these other diseases and has it not been looked at as much due to lack of instrumentation?*

Mr. Datovech: There have been publications that have shown the promise of this that have been out for several years. The issue is if you look at traditional electrophysiology and electroretinogram devices, you had to have a large device about the size of an office desk. It was a 40,000-70,000 dollar device and was typically in a hospital setting. The patient had to have their eyes dilated and have a corneal electrode placed directly on the cornea of the eye. In some cases, they had to be dark adapted for twenty minutes and then you had to have a trained technician administer the test and a trained physician to interpret the results. Even though there was some promise, the technology did not exist to allow that to really ramp up and be used universally. The **RETeval** device, being non-mydratic, non-dilating and non invasive, being able to do a test in any environment on anyone in just a few minutes, opens this technology to these new applications.

CEOCFO: *When you are at a conference, how do you stand out or does your reputation do that for LKC?*

Mr. Datovech: Number one I think is our reputation and name in the industry does help us stand out. Secondly, we sell directly in the US and North America as well as through partners. We also sell through distribution around the other countries in the world. We do a lot of marketing not only through ourselves but in cooperation with our distribution partners around the world. One of the ways that we differentiate ourselves is if you look at that last three or four years, there have been over 100 posters and presentations at ophthalmology meetings around the world on a **RETeval** device for example, which generates buzz and people wanting to understand more about what it might do in their environment and that leads to them to come to visit us at a meeting and learn more or visit our website and learn more, and generates more people utilizing the device. Some of it is organic, some of it is reputation and some of it is marketing related.

CEOCFO: *What have you developed that gets the most interest and what might you have that is not recognized for what it can do?*

Mr. Datovech: I would say that the one item that has been very well received. It is the use of the **RETeval** device in the pediatric population for being able to test children without sedation or dilation in a clinic setting without them having to make an appointment or travel. Sometimes people have to get on an airplane for these tests and this gives it the potential to be universally available. I would say that the pediatric use has been well received for the device. The one area that it has tremendous capability is in the area of assessing people with diabetes for diabetic eye disease. There is a specific protocol that has been developed that correlates very well with sight threatening

retinopathy to the gold standard. There will be a presentation at the ARVO (The Association for Research in Vision and Ophthalmology) meeting next year on how it is also predictive of those who will likely progress. If you fail the **RETeval** test, you are twice as likely to progress as assessing photographs. I think there is a tendency to use structure like photographs in assessing the damage of the retina versus utilizing something like **RETeval** which is a functional test in understanding the ischemic level of the retina and how that correlates and not only gives you an assessment of potential sight threatening retinopathy in the eye, but it also gives you a window into the future in terms of progression. That is the one area that I would love to see people begin to embrace because it truly offers capabilities that are not available through either a visual doctor looking at the retina through a dilated eye or taking retinal photographs and reading those.

CEOCFO: What is next?

Mr. Datovech: What is next with the **RETeval** device is the mental health diseases and being able to do differential assessment of mental health disease. One out of every three general practice visits is mental health related; people have a malaise, they do not feel well and cannot seem to get up in the morning and those types of things. When a doctor is assessing a pharmacological intervention, they have to make a very quick assessment if this person has depression or schizophrenia etc. There is no real easy objective way to do that and what is being studied is utilizing this technology to make an objective assessment as to which protocol treatment to start, which could have tremendous impact on millions of people around the world. The other thing that is next is looking at the people-ography capability of the device and assessing other diseases like traumatic brain injury and other concussions and those types of things.

CEOCFO: What should people remember about LKC Technologies?

Mr. Datovech: We have capability in our devices to make a difference in the outcome of patients through the use of functional testing of the retina, and structural testing with a dilated eye exam, which that is an OCT or a series of retina photographs to give you an idea of the structure, but it does not tell the whole story. The story is completed by understanding which cells are stressed, which cells are dying and what is happening within the retina itself from a cellular standpoint and a functional standpoint. Only then can you really complete the picture of what is happening in the eye. There is a capability of doing that now that is accessible, affordable and provides the repeatability to make that capability possible, anywhere for anyone where a patient needs their care.

