

Cognitive Disorder Evaluation Products



K.C. Fadem
Founder, President & CEO

Neuronetrix, developer of the COGNISION™, is a leading neurotech company focused on providing physicians and scientists with accurate and meaningful information about brain processing. This information is critical in the understanding of complex brain function, diagnosis of cognitive disorders, and evaluating the effects of pro-cognitive therapies.

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

CEOCFO: Mr. Fadem, what is the concept at Neuronetrix?

Mr. Fadem: We are developing products that are used to evaluate cognitive disorders; disorders ranging from Alzheimer's disease to traumatic brain injury to schizophrenia, ADHD, and dyslexia. These disorders impact the brain's ability to process information.

CEOCFO: This is an area where testing has not been very effective; so what is the approach you are taking at Neuronetrix?

Mr. Fadem: The problem comes down to understanding what is meant by information processing in the brain. Historically psychometric testing is used field to evaluate these disorders. Psychometric testing is based on asking patients a series of questions. Physicians try to determine whether or not there is some information processing impairment based on the patient's responses. In late-stage or very severe cases of say, schizophrenia, it can be quite obvious that somebody may have some cognitive disorder. But for mild cases of Alzheimer's or some other early-stage

diseases, it is very difficult to try to ascertain whether or not somebody has a pathologic disorder just based on responses to a series of questions. What Neuronetrix is doing is using electro-physiologic techniques to measure the electrical activity in the brain as it performs a series of tasks. These tasks are designed to evoke fundamental types of information processing steps in the brain. Then we record the electrical activity from the brain as it is performing these tasks in order to get a very precise measure of normal or abnormal brain processing. The tasks are based on a series of stimuli, either auditory or visual. They can be quite simple. For example, the patient may be asked to listen to a series of tones and respond to a specific tone. The sequence of tones is designed in such a way to force the brain to do a number of fundamental information processing steps. We then record the electrical activity of the brain and compare the recording to databases that we have developed. This type of cognitive testing is unrelated to any language.

CEOCFO: Has a similar process been tried in the past?

Mr. Fadem: Absolutely. We did not invent any of this underlying science. Electroencephalograms and event-related potentials (ERPs) have been around since the nineteen thirties. It has been clear that the brain produces EEGs as a part of its normal functions. But ERPs are quite complicated and the equipment that has been used in the past to perform these kinds of tasks has been very difficult to use, especially in a clinical environment. In the past in order to get the interpretation, an expert looked at these electro physiologic wave forms and just tried to determine whether or not they looked "normal or not. "By comparison, we have developed an easy-to-use and automated device which can be administered by anyone in a doctor's office. The test does not have to take place in a hospital. We use advanced pattern recognition algorithms that automatically extract the features of interest. The computer itself does all the scoring. We have taken a complicated and difficult-to-use technology and turned it into a practical automated easy-to-use system.

CEOCFO: What do you understand about the process that allows you to have something that works?

Mr. Fadem: That is a very insightful question. I can tell you that there is no magic. The magic was in our willingness to go in and just beat down all of the little nails that are sticking up. There were just so many areas that made this difficult. People were never able to get it out of the research laboratory. This kind of technology is used quite commonly in academic research labs all over the world for doing all kinds of cognitive research. However, we set out to make it a practical and cost effective system for the physician. What was required was to go through the entire process and hyper-automate every step and use good industrial design and human factors engineering to develop a total system that was

useable by the physician. There was not one particular place where we solved one problem in order to have a successful system. We had to go through the whole process from end to end to automate and make it more efficient and useable.

CEOFCO: Is it the sum total of all the responses that helps you come up with the indication or could someone score a ten (for example) in one area and that will immediately jump out and say yes there is a problem?

Mr. Fadem: Excellent! What we are measuring are specific cognitive domains. For instance we can probe attention, memory, executive function and a number of other cognitive domains. We can find out how you are performing in various cognitive domains. Different diseases may manifest as different cognitive impairment. Memory impairments can present in a range of disorders. We are not necessarily diagnosing Alzheimer's per se but we are, as part of the test, evaluating the brain's ability to store information in short-term memory and quickly retrieve that information. This deficit is frequently impaired in people with Alzheimer's disease. The overall pattern of cognitive impairments may point to a specific diagnosis.

CEOFCO: Where are you in the development and commercialization process?

Mr. Fadem: It is available for limited types of use. It is not available yet for use by a clinician to diagnose disease in their office. It is available and is being used by pharmaceutical companies where there is a need for to measure cognitive performance. These measures are used to select recruits for clinical trials. They are used to measure the effectiveness of their drug that is proposed to increase cognitive performance.

CEOFCO: Are the members of the medical community aware and should they be at this stage?

Mr. Fadem: They are aware and they certainly need to be aware. This is something they have been screaming for--the ability to evaluate early-stage patients. For example if I am a 67 year-old male and I lose my keys every once in a while and I go see my doctor, the neurologist hates to tell the patient they do not know if they have a disorder or if it is normal aging. They do not like sending patients home with an uncertain evaluation. Patients do not feel very good when they leave in a situation like that. In addition, clinicians do not like to have their patients leave not feeling very good. Clinicians are looking for a product that can give them an objective measure of cognitive ability. They cannot buy the system yet. But it is important that they are aware of the system's capabilities. Most clinicians try to stay up on the current scientific and clinical literature so they know how to manage their practices moving forward.

"In order to make our system simple to use, there is a tremendous amount of technology behind the scenes. When you look at our product, you do not see everything that is behind the scenes and all the development that had to go in to it; completely new kinds of electronics, web-based database systems and very sophisticated pattern recognition algorithms." - K.C. Fadem

CEOFCO: Is there much skepticism or do the players understand?

Mr. Fadem: There is skepticism but I do not believe the skepticism is in the underlying technology. The skepticism is rooted in whether someone can put all the pieces together, can reliably perform this test and get good results, and do it in a timeframe and ease-of-use level that can make it profitable for a physician to do it. In other words, if this were a test that took two hours to perform, it never would be profitable for a clinician. If it were not profitable for a clinician, it would be completely useless. I think there has been skepticism in whether somebody really can take this complex test and make it easy enough to use and reliable enough that they can do it in a profitable way.

CEOFCO: What are the next steps?

Mr. Fadem: We have just recently completed recruiting for our pivotal study. It turns out in devices you do not have the term pivotal like you do in pharma. But this is equivalent to a pivotal study where we are going to publish our ability to discriminate early-stage Alzheimer's patients who have been very well diagnosed and characterized from age matched normal controls. We hope to submit to a publication within the next few months. We have recently submitted for a 510-k and we need to get through the FDA process. That could take anywhere from three to six months. At that point, we will be entering the market selling this product to clinicians for the purpose of evaluating patients with cognitive disorders.

CEOFCO: How will you be handling the marketing?

Mr. Fadem: We are a small company and this is a huge market opportunity. It does not make sense long-term for us to manage the whole marketing process for this product. As a small company, in order to maximize market share, we intend to partner with a larger company. It is our long-term goal to have one of the strategic device companies as a marketing partner for this product.

CEOFCO: Do you have the funding in place now for the next steps or will you be seeking some attention there?

Mr. Fadem: We will be raising additional funding at the beginning of Q-2 or the end of Q-1. That will be the money necessary to initiate the clinical rollout.

CEOCFO: *What have you learned personally from previous experience that has been most helpful for you with this venture?*

Mr. Fadem: I have been through this a number of times but I keep learning the same lesson. The lesson is that things take longer and are harder and require more money than you ever think they do at the beginning.

CEOCFO: *Why pay attention to Neuronetrix?*

Mr. Fadem: This is a completely untapped market of providing a physiologic measure of cognitive impairment. It is an enormous market opportunity which is a multi-billion dollar market in Alzheimer's alone. This does not include other CNS diagnostic markets such as schizophrenia, traumatic brain injury, ADHD and the others. This is a completely open market and we have a product that meets the market's requirement. It is profitable for the physicians to do these tests and there is nobody else in place currently that we have to beat to the market. We are going to be the first one there with a product that addresses an enormous market opportunity.

CEOCFO: *Final thoughts?*

Mr. Fadem: The architecture of the product is very simple from the perspective of the customer. They have to easily learn how to use it and it has to be inexpensive. They have to be able to run the test in a few minutes and they have to get good, reliable results. In order to make our system simple to use, there is a tremendous amount of technology behind the scenes. When you look at our product, you do not see everything that is behind the scenes and all the development that had to go in to it; completely new kinds of electronics, web-based database systems and very sophisticated pattern recognition algorithms. It is by definition intended to be a simple presentation of a very sophisticated solution.

BIO: KC Fadem, inventor of the COGNISION™ System, has extensive experience in the medical device industry. In 1993, Mr. Fadem founded Val-U-Med, Inc., a medical device development and distribution company headquartered in Atlanta, GA. While at Val-U-Med, Mr. Fadem developed a number of innovative surgical instruments, including an endoscopic device for Guidant Corporation for use in saphenous vein harvesting.

In 1996, Mr. Fadem sold Val-U-Med to LifeQuest Medical, Inc., a public company based in San Antonio, TX. As Director, EVP, and COO of LifeQuest Medical, Mr. Fadem managed the development and market introduction of more than 20 surgical products, resulting in over \$24 million in annual sales. In 1997, Mr. Fadem founded Surgical Visions I, Inc. (SVII) to fund the development of two innovative surgical devices; the PneumoSleeve™ and Protractor™. Mr. Fadem holds several patents for a variety of medical devices.



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