CEO CFO

COGNOPTIX

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Developing a Diagnostic Platform based on the Biomarker for the Detection of Beta Amyloid Proteins Responsible for the Formation of Plaques in the Brains of Alzheimer's Patients, Cognoptix, Inc. is well positioned to Change to the Course of Alzheimer's Disease by Detecting it Before Symptoms Arise

Healthcare
Alzheimer's

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Paul Hartung
CEO

BIO:
Paul is a longtime life sciences executive with a proven track record in launching successful startup businesses and leading Fortune 500 organizations. He has extensive experience in the laser and medical device industries, including managing manufacturing for Summit Technology, Inc., a leading developer of the LASIK procedure and other laser eye correction procedures. Prior to Cognoptix, Paul was Vice President of Operations at Winphoria Networks, a successful mobile communications startup acquired by Motorola. Before that he was Senior Director at 3Com Corporation, where he was involved in a number of mergers and acquisitions, and directed global operations and new product introductions. At Trumpf, he developed high power automated laser systems for industrial applications. As Director of R&D at Laser Fare Ltd., he developed new laser processing techniques for the medical device industry and other applications. Paul started his career as an Advanced Manufacturing Engineer at General Electric Company. He graduated from MIT with an MS Degree in Mechanical Engineering. He received the FW Taylor Award of the CIRP for his research.

About Cognoptix, Inc.:
Alzheimer's Disease has long been recognized as a growing diagnostic and therapeutic challenge, with current medical detection methods limited to invasive, expensive, and unreliable tests that are unable to catch Alzheimer's early enough to help doctors engage in preventive therapy.

A key obstacle to early and predictive diagnosis of Alzheimer's is the fact that no commercially available *in vivo* biomarker for the disease exists today. With an increasing patient population, as well as a growing pipeline of Alzheimer's therapies currently under development by major pharma companies, there is a large unmet need for effective predictive diagnostics and preventive intervention enablers, as well as for accurate tools for measuring the efficacy of new drugs in development.

To meet these emerging needs, Cognoptix was co-founded by Dr. Lee Goldstein and Dr. Leo Chylack of the Brigham and Women's Hospital in Boston, on the basis of a new and promising biomarker for the detection of beta amyloid proteins responsible for the formation of plaques in the brains of Alzheimer's patients.

Drs. Chylack and Goldstein and their research team discovered that they could detect beta amyloid aggregates in the lens of the eye and that those proteins could be measured and monitored with non-invasive tools, such as existing laser eye scanning technologies. Further research determined that suspect beta amyloid proteins could be detected in the eye prior to buildup of toxic plaques in the brains of genetically engineered Alzheimer's mice. Cognoptix is currently developing combined optical scanning devices and diagnostic agents based on these discoveries for clinical, commercial and academic research use. The company is actively forming and seeking new strategic alliances with pharma partners and academic institutes, while preparing its diagnostic platform for clinical use.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Mr. Hartung, what is the vision and concept of Cognoptix?
Mr. Hartung: Cognoptix is going to change the course of Alzheimer's disease by detecting the disease before

symptoms arise. We are the only company positioned to make this happen soon.

CEOCFO: What have you figured out that others have not?
Mr. Hartung: We found, for the first time outside of the brain, a protein that is associated with Alzheimer's disease that actually grows in the lens of the eye. We are able to non-invasively, inexpensively and easily, in the hands of the general practitioner, determine whether someone is at risk of developing the disease.

CEOCFO: Why were you looking for this protein and how did you find it there?
Mr. Hartung: The protein amyloid is a hallmark of Alzheimer's disease. It is one of the defining features of the disease and it is what forms plaque in the brain. The breakthrough discovery was that this protein actually grows in the eye as well. It was discovered in looking at human eye / brain pairs that there was a direct correlation between an unusual cataract, which is a clouding of the lens that forms in the cases of Alzheimer's patients, which did not exist in people who died of other natural causes and also of other neurodegenerative diseases. Once that discovery was made and further research was done on this, we looked at the problem of how early does this protein start to grow in the eye, and could be used as a way of forming early detection and disease monitoring. Therefore, we developed a drug / device combination product where the drug is something that gets applied the night before the procedure in the form of an ophthalmic ointment. This identifies the protein in the eye. We have a simple instrument that a general practitioner or the staff can use, which in a matter of minutes can take these measurements, non-invasively.

CEOCFO: Is the medical community aware as of yet? How do you get them to believe that it can be something as powerful and as simple?
Mr. Hartung: We have recently announced the formation of a top-notch clinical advisory board. The top researchers in the world in Alzheimer's disease have been aware of what we are doing for a number of years now. I think the general public is just starting to become aware of it. We have been very busy developing the technology and running it through preclinical and limited in vivo studies. We have gotten some very promising results from the clinical studies. We are ramping up our clinical studies to give us the data that we need in order to commercialize the product.

CEOCFO: Have you found many false positives? In general, how accurate is the test?
Mr. Hartung: First of all, I want to explain that the first application for our test is as an aid in the diagnosis of probable Alzheimer's disease. It will initially be used to help diagnose patients who are starting to display symptoms. At this point it is a very expensive process of elimination to determine whether or not someone truly has Alzheimer's disease. Unfortunately, forty percent of the cases today are treated by physicians without a proper diagnosis. Therefore, putting a tool in the hands of the physician early in the diagnostic process of Alzheimer's disease that provides valuable data in determining the course of either a further diagnostic workup or therapeutic intervention is very important. What we have found is that not all of the cases that have this build-up in the brain convert to symptoms. Not everyone who has a brain loaded with this protein actually displays the symptoms of Alzheimer's disease in their lifetime. However, the analogy that I like to draw involves a cholesterol test. If your cholesterol goes through the roof, do you wait until you have a heart attack to do something about it, or do you take measures to reduce your cholesterol? In the case of HIV and AIDS, HIV is detected before it converts to full blown AIDS. Unfortunately, with Alzheimer's disease it has been a disease defined by symptoms only, for many years. That was changed just a year ago. This is a very important time for Alzheimer's disease where the scientific community got together and made a clear recognition that the disease needs to be defined, not only by symptoms, but by underlying biological change. It is a disease. Changes occur in the body. The symptoms of the disease are the changes in cognition. However, the disease itself is the underlying biological change. That is what we are directly measuring with our technology.

"Cognoptix is going to change the course of Alzheimer's disease by detecting the disease before symptoms arise. We are the only company positioned to make this happen soon." - Paul Hartung

CEOCFO: What is the timetable as you move forward?
Mr. Hartung: We have a regulatory process that we are going through. We have finished one stage of human clinical trials. We are doing larger-scale trials this year and we expect, in 2014, to be conducting a pivotal study, which would take us all the way to market.

CEOCFO: How far will current funding take Cognoptix? Will you be looking for additional funding?
Mr. Hartung: Yes. We are beginning to raise funds. We expect to close financing in the first half of this coming year to fund our pivotal studies. We have funding that will enable us to get through the current set of clinical studies that we are conducting.

CEOCFO: You have considerable history in the life sciences industry. What have you learned in the past that you are able to bring to the table at Cognoptix to really aid in the process of development and commercialization?
Mr. Hartung: You have to embrace the issues and recognize that the development process with medical technology is not a linear process. You have to recognize that there are differences between human models and animal models. You are going to run into surprises along the way that you need to address. I think that the best qualities are to be persistent, tenacious, and passionate and remain a problem-solver.

CEOCFO: Why should investors and people in the business community pay attention to Cognoptix?

Mr. Hartung: We stand alone in providing the opportunity to change the course of the disease by putting a technology in the hands of the general practitioner at point of care to be able to not only identify a patient for treatment, but also do monitoring, post-treatment. The current technologies that are out there, for instance, PET imaging, which has been recently approved by the FDA, is a good technology, but it is very expensive and limited to a hospital environment. Therefore, there is a great need for a low cost point-of-care test for Alzheimer's disease and no one except Cognoptix has one at this point.

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