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Total Holographic Characterization[™]: a Revolutionary Approach to Particle Analysis with Applications in the Pharmaceutical, Semiconductor, Food and Consumer Products Industries



Dr. Laura A. Philips -President & CEO, Founder Spheryx, Inc.

CEOCFO: Dr. Philips, your site indicates Spheryx is a revolutionary approach to suspension analysis. Would you tell us what you are doing?

Dr. Philips: Particles in suspensions exist in many different substances that you come into contact with every day. Anything you rub on your body or on any surface of your home, detergents, foods, pharmaceuticals, and even semiconductors are made with particles suspended in fluids. Spheryx's technology provides a powerful new way to characterize these particles for all of these industries. We call it Total Holographic Characterization[™]. Our technology will make better, safer and more consistent products for the benefit of our customers and consumers. All of these benefits deliver to the bottom line by reducing costs while supporting growing sales and profits.

CEOCFO: What would happen to the particles without the suspension and how are you able to make the suspension better?

Dr. Philips: We are focused on the enormous number of commercial and natural products that rely on keeping the right kind of particles suspended in fluids, or keeping the wrong kinds of particles from forming. One example would be proteinbased pharmaceutical products. The next big wave of pharmaceutical products is biologics. Unlike conventional pharmaceutical products, biopharmaceuticals are based on proteins, not chemicals. Manufacturing products based on proteins is challenging because proteins are less predictable than pharmaceuticals made by chemists in laboratories. Proteins have a tendency to aggregate, forming small particles that affect both stability and safety, and, ultimately, the cost of the product. As a result, many breakthrough drugs for treating diseases are put on the shelf because companies do not know how to control for protein aggregation. The FDA has issued guidance to the industry saying that protein aggregates in biologics are a safety hazard and a concern for the industry. They encouraged the industry to take on the challenge of detecting and monitoring for protein aggregates. In the very next sentence they acknowledge that there are not good tools to monitor protein aggregates. Total Holographic Characterization[™] can detect and monitor protein aggregates and then researchers can tweak either the product itself, or the suspension around it to eliminate potentially harmful protein aggregates. Instead of flying blind and not knowing whether you are forming protein aggregates, you now have this tool, a powerful tool for the pharmaceutical industry with this new wave of breakthrough biologic products.

CEOCFO: Are you creating the stabilizers?

Dr. Philips: No, we are not creating the stabilizers. We provide the tool that enables the pharmaceutical industry to study and determine the stability of their products. With each product it may be a different thing. The instability may be eliminated, for example, by a change in the buffer or a change in the packaging.

CEOCFO: How does the tool work and what are you measuring?

Dr. Philips: The tool uses a laser to measure the hologram of each individual particle in a device similar to a microscope. The suspension flows through a microfluidic channel and as each particle goes through the field of view its hologram is measured and then analyzed with proprietary, state-of-the-art hologram analysis software. The hologram captures the 3 dimensional details of the particle that encodes all of the information you need to determine the size, the composition, the symmetry, and the homogeneity of the particles, all in about 10 minutes.

CEOCFO: What are your first market targets and do you see it eventually becoming a standard?

Dr. Philips: Spheryx's technology is a dramatic departure from anything that is out there currently. Many of the existing technologies look at the entire bulk of the sample. They offer a sense of the overall properties of the sample, but have difficulty accounting for the complexity of many real-world products. We look at the individual particles and can distinguish subtle differences in the composition of individual particles even when they are the same size. Since it is so different from anything that anyone is used to seeing, we are talking first to people in R&D, where they will use it as a tool for innovation, both in products and processes. Once R&D embraces the technology, we anticipate it will become a tool for quality assurance when products move into manufacturing. Ultimately, we envision it becoming a powerful tool for manufacturing process control, where it will be used to monitor and control product production.

"It is pretty rare to find a revolutionary technology that offers solutions to such a variety of critical problems across such a broad array of industries. Spheryx's Total Holographic Characterization™ really is a game changer."- Dr. Laura A. Philips

CEOCFO: What has been the reception so far?

Dr. Philips: We have had an extremely positive reception to Spheryx's Total Holographic CharacterizationTM. Pharmaceutical companies are interested in using our technology to monitor protein aggregates, one of the largest issues currently in the biopharmaceutical arena, to ensure product safety and comply with FDA guidelines. We have also received a positive reception in the semiconductor industry. Highly polished wafers are used in the manufacture of integrated circuits. To ensure the wafers are flat and flawless, they have to be polished to incredibly high tolerances using slurries with very fine nanoparticles. However, much like the aggregates in proteins, agglomeration can occur in the slurries so that, instead of a nanoparticle, you end up with some large micrometer-scale agglomerates that can create deep scratches in the semiconductor wafers, rendering them unusable. This waste is an extremely expensive problem for the semiconductor industry. Therefore, if we can monitor the slurries as they are being fed onto the wafers for polishing, and assure that no large particles are in the mix, there will be enormous cost-savings to the semiconductor industry. We have also had a great reception from the consumer products sector. Many products that you use every day, such as laundry and dishwashing detergents and shampoos, are made of a complex mixture of individual components, all suspended in fluid. For example, with laundry detergent, in addition to the soap, you have softeners and perfumes that have to be released at precisely the right moment in the wash cycle so your laundry is consistently clean, soft and freshly scented as you pull it out of the dryer. It is not like the old days when pioneers made soap with fat and lye in a pot. These products are now very complex, created by a sophisticated process using mixtures and controls created by chemical and manufacturing engineers. Spheryx provides the tool necessary to monitor and control individual particles at the heart of these products during each step of the manufacturing process, ensuring the product is exactly the same every time.

CEOCFO: Where are you in the process and what are your next steps?

Dr. Philips: We are an early stage company. We are currently providing analytical services to customers who send their samples directly to us for analysis. At the same time, we are designing a beta instrument that we plan to introduce to the market by the end of this year. The beta program will focus on our existing customers and partners who understand the potential of our technology and are anxious to get it into their own hands. We will have a dozen or so beta instruments available by the end of this year (2016). We will work closely with those customers to monitor their reaction to the beta instrument and to gauge how they use it. We will refine the beta instrument based on this feedback, and then, by the end of 2017, we expect to have a production instrument available for sale broadly.

CEOCFO: Are you funded for your next steps? Are you looking for funding or partnerships?

Dr. Philips: As a startup company we are naturally always looking for funding and partnerships. We have 8 investors who invested in Spheryx at the beginning of last year, and an additional investor who joined us towards the middle of last year. In addition, we received funding from the National Science Foundation, a Phase I, Small Business Innovation Research (SBIR) grant that has enabled us to get to the point where we have two alpha version instruments in our facility for our analytical services business. We provided live demonstrations at the National American Chemical Society meeting in San Diego in March, where we garnered a great deal of interest. We recently applied for a follow-up Phase 2 SBIR grant from the National Science Foundation. We also were just awarded funding from the National Institutes of Health through a Phase 1 SBIR grant to focus on the protein aggregate issue. The combination of early stage Angel investors and Federal grants have gotten us to where we are now, and will see us through the current year. However, we are always interested in talking to potential new partners and investors.

CEOCFO: Are there competing ideas or technologies?

Dr. Philips: There are 400 different particles characterizations technologies out there according to one recent review article, so there are a great number of different technologies. Some of them have been around for a long time, and some are newer. Some do look at individual particles, but as far as we know, we are unique in our ability to look at not just the particle size, but particle composition as well. In mixtures of many different kinds of particles all together, we can tell the difference, based on their composition, between different particles, even when they are the same size. Distinguishing composition as well as size is our unique advantage, as it gives an additional dimension of information that can be so powerful.

CEOCFO: With so many potential uses, how do you keep from being scattered?

Dr. Philips: That is an excellent question and every early stage company has to be mindful of not getting too diffuse and being able to focus where the lowest hanging fruit is, to really keep your eye on what is the best and earliest opportunity for your company. At this stage, because we are providing analytical services, our technology is really a platform technology. There are modifications that can be made to optimize the technology for different applications, but we can provide a general research tool that has a very broad reach and applications across many different fields. Since the kinds of applications that we are talking about provide targeted solutions to large companies in key industries, and their wheels tend to grind rather slowly, we need to remember to be patient and resolute. To capture and maintain their interest, we have analyzed some samples for them and then they need to digest the results, have internal discussions, and then come back with the next iteration of discussions. So far, we have had the luxury of being able to pursue leads and opportunities across a wide variety of industries. However, as soon as we start being stretched too thin, we will focus on the opportunities that are most promising and offer the strongest partnerships available to us.

CEOCFO: Has your MBA from Cornell been helpful on the business side?

Dr. Philips: Absolutely! The PhD, the MBA and my business experience enable me to talk both science and business. Understanding the technology, being able to prioritize the experiments, assess the technical hurdles and understand the best opportunities from a technical perspective is critical. But I also have background in manufacturing, market analysis and strategic planning, all skills that help me build a successful company. In fact the SBIR grants that the NSF and NIH have awarded Spheryx require that the company have not only strong science but also a strong business strategy, so my education and experience are a great fit. When you are running a small company, you have a limited number of people so priorities and strategy are even more important. The MBA and the experience in business enables me to sort through the issues, whether it is putting in the right accounting system, or marketing the product effectively, or branding the company, or even designing the personnel systems to guide a high performance team. And of course you have to hire the right people. You need a breadth of business skills and technical skills to really move the ball as quickly down the field as possible.

CEOCFO: Put it together for our readers. With so many new technologies to consider, why is Spheryx so important?

Dr. Philips: It is pretty rare to find a revolutionary technology that offers solutions to such a variety of critical problems across such a broad array of industries. Spheryx's Total Holographic Characterization[™] really is a game changer. The ability to spot a technology and to have the depth of understanding is important, but it is also important to partner with the right creative genius, and I found him in David G. Grier, PhD; Chair of the Scientific Advisory Board and a Founder at Spheryx, who is a Professor of Physics at NYU. We exclusively in-licensed a dozen of his more than 50 patents and we are continuing to collaborate with him and his research group at NYU. It is just an explosion of possibilities. This technology is going to be successful. To be able to take something like this to market is a dream come true.

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



Spheryx, Inc.

For more information visit: www.spheryx.solutions