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Issue: March 10, 2014
The Most Powerful Name in Corporate News

Improving Patient Safety and Cost through a Proprietary Biopsy System

Michael P. Oliver- *CEO*

SpectraScience's (PINK:SCIE) proprietary WavSTAT Optical Biopsy System assists the practicing gastroenterologist who uses a flexible endoscope to identify polyps that may be cancerous. Our system has the capability to immediately distinguish whether or not the tissue is cancerous with a 96% negative predictive value. The system uses laser-induced fluorescence and an optical fiber to transmit laser light via the flexible endoscope to the tissue. The auto-fluorescence from the tissue is then collected and returned to an optical detector for immediate analysis.

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

CEOCFO: ***Mr. Oliver, what is the concept at SpectraScience?***
Mr. Oliver: The driving concept of SpectraScience is to improve patient safety and help reduce total cost by providing a better, faster and less expensive way to distinguish potentially cancerous polyps from benign lesions in the colon.

CEOCFO: ***How are you going to do so?***
Mr. Oliver: SpectraScience uses laser-based technologies and the interaction of light and human tissue to differentiate between normal tissue and potentially cancerous tissues. We are seeking pre-cancers, and not cancer per se. The big advantage of our proprietary technology is that it provides an immediate analysis with a 96% negative predictive value, thus virtually eliminating the need for unnecessary biopsies. It takes just one second for our device to give an answer, and we can do it using a standard flexible endoscope without having to remove any tissue. The procedure causes no pain, while eliminating the expense and the complications sometimes associated with traditional biopsies. In addition, patients don't have to wait weeks for a report from pathology.

CEOCFO: ***Has light been used in the past?***
Mr. Oliver: The basic science of using laser-based light in this way was discovered decades ago. It is only with modern consumer electronics and the ability to have a great deal of computing power in a very small and inexpensive package that we have been able to optimize this technology.

CEOCFO: ***Please explain how it works.***
Mr. Oliver: What we do is simply place an optical fiber in contact with the tissue. The light is pulsed through the optical fiber and it excites certain amino acids and enzymes in the tissue. This light has only micro-joules of power, so it does not cut, burn or heat up the tissue. By exciting these amino acids and enzymes with a known wavelength of light, we know how they respond by absorbing some of this light. When we turn the light off, we are doing this in milliseconds, they are emitting a wavelength of light as the electrons in those amino acids and enzymes go back to their relaxed or normal states. Our technology captures those emitted photons of energy and makes an instantaneous analysis.The concentration, the number and the intensity of those photons, and the wavelengths at which they are emitted are essentially proxies for the presence and the concentration of the various amino acids and enzymes in the tissue. By knowing the concentrations of those constituents and those key biomarkers, we can determine where that particular piece of tissue is on the continuum from normal epithelial tissue to potential pre-cancer.

CEOCFO: ***Where are you in the process of development and/or commercialization?***
Mr. Oliver: We have received a ConformitéEuropéenne ("CE") mark, which indicates a product's compliance with EU legislation and allows the free movement of our products within the European Union. We are actively selling our products in Europe. Our initial indication under our CE marking is for the diagnosis of the very tiny, small and diminutive polyps and flat lesions that you might find during colorectal cancer screening. We have FDA approval in the United States for our third generation product. We are currently selling our fourth generation product, and we are in the process of communicating

with the FDA to demonstrate the clinical data that shows that our fourth generation product is equal to or better than our third generation product. We actually had a first generation product approved by the FDA approximately ten years ago.

CEOCFO: *Why was colorectal the first area of focus?*
Mr. Oliver: It is an enormous market, and our system can provide a significant financial benefit to the health care system. Today the standard of care during colorectal cancer screenings is to remove any of the small structures that are observed. When I say small structures, I am talking about things that are anywhere from 2 millimeters to 7 or 8 millimeters in size. These structures cannot be diagnosed by the physician with the optical equipment that they have today. The standard of care is to remove all of them when you see them. Depending on the study you look at and the physician to whom you speak, anywhere from 70 percent to 90 percent of these structures are benign. They are normal tissue. They are like freckles on the back of your hand. They are not cancers today, they will not be cancers tomorrow and they will not be cancers in 30 years. However, there is some percentage of those small structures that are analogous to moles. They could possibly become cancerous. Those are called adenomas, or in the case of the size that we are looking at, pre-adenomas. What we are doing is providing the clinician with a tool that allows him or her to discern between those that are benign today and will truly be benign – the freckles, so to speak – and those that are possibly moles that could become cancerous in the future. Those are the structures that should be removed and sent to pathology for evaluation. A study was done and published about two years ago in one of the medical journals, and it showed that the cost to the health care system for just the pathology associated with those benign biopsies taken in the United States was more than $1 billion a year.

CEOCFO: *Would your technology be used during a colonoscopy and then the doctor could decide whether something needs removal?*
Mr. Oliver: Yes. The doctor can make an immediate decision.

> **"The nice thing about our light-based technologies is that they are compatible with existing colonoscopy procedures that use flexible endoscopes; they reduce unnecessary biopsies, thus saving costs and enhancing patient safety; and they provide an immediate analysis with a 96% negative predictive value. In other words, our system is better, faster, safer, and less expensive than today's standard of care for a screening colonoscopy."**
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> **- Michael P. Oliver**

CEOCFO: *How do you battle the entrenched methods used today?*
Mr. Oliver: We believe that as the medical community sees the economic savings and safety benefits that we offer our system will ultimately sell itself. There are approximately 15 to 20 million colonoscopies performed in the United States annually, but are reimbursed by insurers at a low rate. Many of the pathologists with whom I have spoken have expressed a need for two things. One is to receive only those pathology samples that have clinical implications and meaningful pathology that really needs to be examined. Secondly, in viewing that, if they can reduce their workload in this relatively low-reimbursed situation, then they can take their team and pathology resources and use them to do more complex, interesting, challenging analysis at a higher reimbursement rate. It is really kind of a win-win for both the gastroenterologist who is performing the procedure and for the pathologist, who is at the back end of that analysis.

CEOCFO: *How is business in Europe?*
Mr. Oliver: Business in Europe is starting to take off. We also have a great partnership today for sales, marketing and distribution in Europe through PENTAX Medical, the second-largest manufacturer of flexible endoscopes. And we have completed the clinical validation of our product. Our product has demonstrated clinical efficacy in a statistically significant number of patients of 96 percent negative predictive value. We far exceed the industry guideline for products of this type in the lower GI. A clinical standard for what is called *in vivo* histopathology that was published by the American Society for Gastrointestinal Endoscopy sets a minimum 90 percent negative predictive value for any device or technology to be considered appropriate for inclusion into clinical practice.

CEOCFO: *What are the next steps for the company?*
Mr. Oliver: We are currently conducting an evaluation in eight European nations in which we are replicating our clinical data, and at the same time, gathering economic data in each of those countries about how much money specifically we can save in their particular health care systems. Once completed, the clinical investigators in each country will present to their approval authorities – both the validation of the clinical performance and the economic benefit of adopting our technology and making it the standard of care in their country. That is where we are today. That study is currently underway, and we expect to complete data collection in the second quarter with subsequent presentations to the various approval authorities. Some of that approval has to do with reimbursement depending on which country you are talking about and how it is incorporated into the schema in that country. Nonetheless, that is where we are going. We expect

coverage indications from many of the major markets in Europe in late 2014 and into 2015. Those indications will identify our product as the standard of care, which will then mean physicians and hospitals using our product and our technology will be covered, reimbursed or included in the DRG payment, depending on which nation they operate in. We believe our system will then become a routine part of doing colonoscopies in that jurisdiction.

CEOCFO: *Are you funded for what you are planning to do or will you be seeking funding or partnerships?*
Mr. Oliver: We continue to seek funding and partnerships. As I said, we currently have a great partnership with PENTAX Medical for sales, marketing and distribution in Europe. As we begin our US expansion, we will be looking for potential partnerships here. We are a small public company and have received funding individually by private individuals--high net worth individuals and occasionally a small venture fund or family fund. In order to accelerate our commercialization activities, we are continuing to seek additional sources of financing so that we can develop not only our GI indication, but also indications in other parts of the body. The technology is applicable to a number of other cancer indications.

CEOCFO: *Why SpectraScience?*
Mr. Oliver: SpectraScience has very strong intellectual property around a platform of technologies that use light to detect and diagnose cancer. As populations age we expect a steady increase in incidence. As many of the world's developing countries develop a larger, more viable middle class, you will begin to see increased demand on health care systems for cost-effective early detection and diagnosis. The nice thing about our light-based technologies is that they are compatible with existing colonoscopy procedures that use flexible endoscopes; they reduce unnecessary biopsies, thus reducing costs and enhancing patient safety; and they provide an immediate analysis with a 96% negative predictive value. In other words, our system is better, faster, safer, and less expensive than today's standard of care for a screening colonoscopy.

BIO: Michael Oliver, President and CEO, joined SpectraScience in November 2010. As a 30 year medical device executive he has a wide and varied background. His experience includes participation in management teams that took struggling medical device companies, increased their revenue and profitability and sold them to strategic buyers. In addition he consulted to some of the world's largest and best-known medical device companies on how to improve both revenues and profitability. He began his career with American Hospital Supply Corporation serving in a variety of sales, marketing and general management positions. Mr. Oliver received his MSA from George Washington University and his BS from the United States Naval Academy.

SpectraScience, Inc.
11568 Sorrento Valley Rd # 11
San Diego, CA 92121
858-847-0200
www.spectrascience.com