

**Oncoscope, Inc. is Using their Light-Based Technology to Identify Pre-Cancerous Tissue Long Before it Becomes a Significant Risk to Patients – With a First Target in Esophageal Cancer Where There is a Large Worldwide Market with Unmet Needs**

**Healthcare  
Optical Imaging  
(Privately Held)**

**Oncoscope, Inc.**

**324 Blackwell St., Suite 1120  
Durham, NC 27701  
Phone: 919-251-8030  
www.oncoscope.com**



**Perry A. Genova, Ph.D.  
President and CEO**

**BIO:**

Dr. Genova is an accomplished biomedical professional with expertise in medical and pharmaceutical product innovation and development. Previously, he served as Global Vice President and Dose Form Leader for Metered Dose Inhalers with GlaxoSmithKline in Evreux, France. From 1996 through 2006 Dr. Genova was Vice President of Biomedical Engineering at Kos Pharmaceuticals where he built an integral part of Kos' lung delivery franchise while serving as the Project Team Leader for Kos' Inhaled Insulin program. Dr. Genova

has authored over 30 scientific papers and presentations and has received 20 US patents to date. He has also been principally involved in a number of successful startup ventures including Quill Medical (acquired by Angiotech in 2006) and IEP Pharmaceutical Devices (acquired by Kos Pharmaceuticals in 1999).

**Company Profile:**

Oncoscope was founded in June, 2006 to develop clinical applications of discoveries in the field of optical imaging pioneered by Dr. Adam Wax at the Department of Biomedical Engineering of Duke University. These discoveries are known as Angle-resolved Low Coherence Interferometry (a/LCI) and arose from work supported by grants to Duke University from the National Cancer Institute, the National Science Foundation, and the Wallace H. Coulter Foundation.

In 2007, Oncoscope received exclusive, worldwide license rights from Duke University to a/LCI optical imaging technology and began developing clinical prototypes. In parallel, work continued at Duke University including animal and human clinical testing of a/LCI in esophageal tissue. The results of the first pilot study of 30 patients were presented in May 2009 at Digestive Disease Week in Chicago, IL.

Oncoscope recently completed its commercial a/LCI system prototype and has commenced clinical testing under a multi-center study sponsored by an SBIR grant from the National Institutes of Health. The first two clinical sites in this trial are The Center for Esophageal Diseases & Swallowing at

the University of North Carolina, Chapel Hill under the direction of Dr. Nicholas J. Shaheen and the Thompson Cancer Survival Center in Knoxville, TN under the direction of Dr. Bergein F. Overholt.

Since it was formed, Oncoscope has diligently pursued new and expanding patent rights across the field of optical biopsy. Broad U.S. patent claims were received in 2009 and several other key patent filings are pending in the U.S. and abroad.

**Interview conducted by:  
Lynn Fosse, Senior Editor  
CEO CFO Magazine**

**CEO CFO:** Dr. Genova, what is the basic idea behind Oncoscope?

**Dr. Genova:** Oncoscope has developed a device that can identify pre-cancerous tissue long before it becomes a significant risk to patients. We are using a light-based, non-invasive technology to look at fundamental cell morphology, which is the primary marker that pathologists use when diagnosing dysplasia or pre-cancer. Such early detection presents opportunities for treating pre-cancerous disease, such as those provided by ablation, long before it progresses to cancer.

**CEO CFO:** Has your approach been tried in the past?

**Dr. Genova:** That is a great question. There are four fundamental optical biopsy technologies: spectroscopy, confocal microscopy, optical coherence tomography (OCT), and then our technology, which is called Angle-resolved Low Coherence Interferometry (a/LCI). There are certainly com-

panies in the other three categories. In fact, we have identified 130 companies in the OCT category, but only Oncoscope has a/LCI technology. These other technologies either primarily do not see deep into the tissue or they produce images requiring interpretation. Oncoscope's technology profiles the full thickness of the epithelium and provides meaningful data in real-time to an attending physician to facilitate his or her biopsy decisions.

**CEO CFO:** How does your process actually work?

**Dr. Genova:** This device shines near-infrared light deep into the tissue to where the earliest manifestation of disease is presented as enlarged nuclear diameters. This light scatters off objects in the tissue; the angle that the light scatters is inversely proportional to the diameter of the object that scattered it. In other words, a small object will create a large scattering angle and vice versa. So, we are actually measuring scattering angles and by measuring scattering angles, we can determine the size of the object that scattered the light. Given that pre-cancerous tissue has enlarged nuclear diameters, if we see a preponderance of large scatterers or enlarged nuclear diameters, then we would suspect this tissue of being pre-cancerous or dysplastic.

**CEO CFO:** Are there particular areas of the body, particular types of cancer or are there uniform results in all cases?

**Dr. Genova:** The device works in epithelial tissue where about 85% of all cancers begin. These cancers include colon, cervical, bladder, lung, laryngeal, stomach, and esophageal cancer. Screening for these cancers cost \$25 billion in the U.S. annually, with the majority of these procedures and healthcare dollars focused on looking for cancers in the colon and esophagus. We have chosen first to focus on early esophageal cancer identification.

**CEO CFO:** Where are you in the proc-

ess of developing the technology and the equipment?

**Dr. Genova:** We have produced a number of these devices in our facility in Research Triangle Park, North Carolina, and have been engaged in the collection of data from two clinical sites. Data from this pilot study involve about 200 patients and 600 or so biopsies. The devices have demonstrated excellent operating performance in these clinical environments. We are currently preparing for a pivotal trial, which involves a number of activities around manufacturing the device in a commercial manufacturing environment and with a supply chain that is well controlled and supported by an appropriate quality system infrastructure.

**CEO CFO:** Would you tell us about your patent protection?

**Oncoscope has developed a device that can identify pre-cancerous tissue long before it becomes a significant risk to patients. We are using a light-based, non-invasive technology to look at fundamental cell morphology, which is the primary marker that pathologists use when diagnosing dysplasia or pre-cancer. Such early detection presents opportunities for treating pre-cancerous disease, such as those provided by ablation, long before it progresses to cancer. - Perry A. Genova, Ph.D.**

**Dr. Genova:** Oncoscope is a spinout from Duke University. We have exclusive license to several patent families from Duke University and we continue to support and prosecute them. I am proud to be working again with several individuals that were part of the team at Quill Medical. These professionals really understand that intellectual property is a key aspect of value when one looks at these entities from investment and acquisition perspectives. Therefore, we are very diligent in the prosecution of patents as well as the development and broadening of our patent foundation or portfolio. We have six patent families that are currently being managed. We continue to expand on these domestically and abroad.

**CEO CFO:** What is the financial picture like for Oncoscope?

**Mr. Genova:** We are a privately held company and have a solid history of financing the company through private investment and have procured federal grants from NIH and National Cancer Institute as well. Our progress thus far has been built upon having capital from these sources available to us. We plan to open a financing round this year to complete instrument development, which consists primarily of commercial manufacture, and our pivotal trial and regulatory filings necessary for commercialization in the U.S. and abroad.

**CEO CFO:** Has the medical community taken notice at all yet?

**Dr. Genova:** One of the first things I did after taking this job in 2009 was to identify a key opinion leader to advise the company's product development and strategic and clinical planning. Dr.

Nicholas J. Shaheen is a gastroenterologist at UNC Chapel Hill, which is about eight miles from Oncoscope, and is arguably one of the top gastroenterologists in the world specializing in esophageal diseases and, more specifically, in esophageal cancer. I reached out to Nick to establish a relationship and to see if he would support a technology like Oncoscope's

as well as the Company's mission. I also wished to know what other key opinion leaders thought of Oncoscope. Nick brought in a number of his contemporaries - gastroenterologists who are well known in this space of esophageal diseases. They have been advising and supporting us for over two years now. Therefore, in terms of these interactions, we have had a very warm reception from the gastroenterology community. We have also been published in Gastroenterology, a very prestigious journal. In addition, we have interacted with physicians in Europe, also at the key opinion leader level, and they have embraced the concept that we are putting forth. This support from the medical community is fundamentally important if we wish to improve the current paradigm for identifying pre-cancerous lesions in the esophagus, consisting of random biopsies. Physi-

cians and patients, who are well informed, certainly know that these random biopsy procedures are inadequate for accurately identifying early lesions. Therefore, they are desperate for and supportive of an effective early diagnostic tool like ours.

**CEO CFO:** What surprised you most as you have been developing the technology?

**Dr. Genova:** What has been most surprising to me is the number of people in our sphere who have been personally affected by esophageal cancer, a disease that is not widely understood to be very prevalent. In fact, we have an intern who just started helping us with some software development and analysis. He is a graduate student in biomedical engineering, who told me today that he lost a family member to esophageal cancer, as have I. This disease has impacted two of our board members and many other folks on Oncoscope's periphery. The difficulty in raising money through the venture community for a technology, as profoundly important and game changing as this one has been a bit of a surprise as well, but I think there are reasons for this. We are in the midst of a perfect storm in terms of the economy, healthcare reform, focus on cost containment, and an environment that is not warmly embracing medical device innovation in our country. So, perhaps on reflection, this comes as less of a surprise than at first blush.

**CEO CFO:** Do you see partnering in the future?

**Dr. Genova:** We certainly have had conversations since I came on board in the context of strategic partnerships. My focus during these interactions has been simply to inform would-be partners, to plant seeds, rather than to work towards getting a deal in place too early. I strongly believe that Oncoscope's team can build significant value ultimately to the benefit of shareholders, physicians, and patients alike. There have been some very encouraging and recent developments in our space, specifically in gastroenterology and esophageal cancer, that have proven the

market to be attractive and the field to be in need of innovation and worthy of investment. For example, the acquisition of BarrX by Covidien late in 2011 clearly illustrates that large multinationals have taken note of the severity of this disease and the promise of therapeutic and diagnostic technologies in this space. I would fancy a strategic relationship that could benefit both parties and, most importantly, provide beneficial outcomes for patients and physicians who are desperate for an effective early cancer diagnostic. Our plan is to broaden the opportunity into some of those other areas I mentioned earlier, for example colon IBD, cervical, and gastric cancer screening to name a few.

**CEO CFO:** Why should investors pay attention to Oncoscope today?

**Dr. Genova:** First and foremost, this is cancer, and cancer has not gone away, is not going away, and is associated still with high unmet need with regard to diagnosis. As we see incidence and mortality trends declining for some cancers like colon for example, these declines are occurring principally because of early diagnosis and intervention. Esophageal cancer is on the rise and is a significant killer with 96% mortality. In fact, it is the deadliest cancer known to man and is predicated on the most common upper GI disorder in Western society – GERD or reflux disease. The market is quite attractive from a financial perspective in the U.S., EU, and in Asia, where esophageal cancer presents an order of magnitude greater problem than we have here, in the U.S. Additionally, this is a platform technology applicable to screening for a wide spectrum of cancers. For these reasons alone, I believe Oncoscope is an opportunity that investors should consider. If we then look at comparables in the space (probably the most noteworthy is the BarrX acquisition that we suspect will wind up being about a \$400 million plus acquisition by Covidien) we find there are compelling exit scenarios. Further, although BarrX provides a 90% cure rate for a very deadly disease, its use is dependent upon on a wholly inadequate random biopsy procedure for locating

pre-cancerous lesions. Simply put, it lacks a companion diagnostic. I would therefore suggest that the commercial prospects for BarrX can benefit by finding more disease and that is really the promise of Oncoscope.

Oncoscope has an enormous market opportunity in the U.S. alone with over 6 million patients who are presently being monitored and need to be monitored in an ongoing way for the progression of this disease, which is called Barrett's Esophagus. Barrett's can progress to cancer in some of these patients but we do not know how to identify which patients will progress. Oncoscope's device provides a platform well grounded in biology that can risk stratify or identify those patients who may be developing cancer and send them to be treated with a technology like BarrX. In so doing, we are not only saving lives and saving cost, but we are growing the sales of the therapy as well. Therefore, if we were to look at the various boxes that need to be checked from an investment perspective, Oncoscope checks many of those boxes. For example, we have a large market desperate for an effective early cancer diagnostic. We have low risk from a regulatory perspective, we have low risk from a reimbursement perspective, and we have a solid development plan and a capable, experienced team. In addition, there are comparables in the space that I think are very attractive. When you look at the rest of the world, this is a big problem and we have a great opportunity to enter those markets as well.

Another compelling aspect of Oncoscope's device that appeals to many investors is that the technology is a platform that can screen for esophageal, gastric, colon, cervical, and laryngeal cancers, with only slight changes to the probe. Finally, Oncoscope is in a space where there have been solid acquisitions. Therefore, it is the right opportunity at the right time. As I have said, many of us have been touched by this disease, and, it turns out, we are not alone.



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