

SpectraScience Bringing Real-Time Diagnosis For A Treatable Cancer - CEO Hitchin Talks With Small Cap Pulse

A recent study by the American Cancer Society concludes that colorectal cancer incidence rates for males and females increased in 27 of 51 countries worldwide between 1983 and 2002.

An often overlooked fact is that colorectal cancer is preventable, and one-third of all colorectal cancer deaths could be avoided with simple screening.

SCP: SpectraScience has well documented the fact that the current gold standard for screening colorectal cancer (colonoscopies) can be significantly improved with the use of its WavSTAT platform. Is the word getting out?

Jim Hitchin: Yes, last year at this time, our focus was on making our product better known in the medical community and amongst distributors. Now, a year later, we are receiving more enquiries from physicians who would like to learn more about the WavSTAT and would like to run a trial. We are also getting more interest from the distribution channels overseas.

SCP: How many countries is the WavSTAT now distributed in?

Jim Hitchin: We are in six countries (soon to

be seven with France) in Europe now, and are talking with distributors in several other EU countries, as well as Latin America which we plan to announce in coming months.

SCP: Europe is a strategic focus for the roll-out of the WavSTAT platform. Why is that?

Colorectal cancer is the fourth most common cancer in men and the third most common cancer in women worldwide.

Jim Hitchin: Yes it is. First, the process of getting appropriate certifications and regulatory approval is faster, and enables us to move to commercialization quicker. In addition, we are able to use data collected in Europe for the purpose of supporting our regulatory applications here in the U.S.

Moving into Europe first actually is accelerating our approval process in the U.S. by gathering the study data quicker. We are seeing this with our esophageal application for the WavSTAT platform which is in trials here.

The importance of being able to add applications to the WavSTAT platform, in addition to colon cancer, cannot be understated.

From an investment perspective, physicians

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Distribution Channel Update - Recent Addition of Spain Distributor Expands Footprint to Seven European Countries

SpectraScience recently announced that it has secured distribution in Spain for its WavSTAT platform with SIM, a leading Spanish medical device distributor which is 75% owned by Pentax.

This expands SpectraScience's footprint in Europe to six countries, including Spain, Czech Republic, Austria, Germany, Italy and Greece.

Michel Vaudry, SpectraScience's VP of International Sales notes that the groundwork has been laid for an effective European sales campaign for the WavSTAT and awareness of the product has never been better.

"Last year, I was spending a significant amount of time knocking on the doors of physicians and distributors to tell them about

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LUMA Study Featured in Des Moines Register

Dr. Colleen Kennedy, primary investigator for the LUMA study at the university, said in the article that, "The hope is that LUMA will aid in the detection of pre-cancer so that we don't have as much cancer and also aid in the detection of cancer so that it's identified early when treatment is better."



CEO Hitchin Talks With Small Cap Pulse (Cont'd)

and clinics are able to better leverage their investment in our platform technology if they are able to screen for more cancers. For example, once they have the platform hardware, they will be able to add software for applications such as irritable bowel disease, stomach and lung.

From a distributor's perspective, they are able to sell greater value. It provides something of a razor-razorblade model which is proven in many other channels. It is appealing to distributors in this case as well.

SCP: Can you explain what the typical cycle is, or the process, for establishing a commercial market after you have established distribution?

Jim Hitchin: We received the CE Mark approval to sell our esophagus pre-cancer device internationally in January 2009. With that approval we begin building and then ramp up our sales efforts. But key to that is building our distribution channels, allowing them to demo the units and expose our technology to their customer base, and then create room in their annual budgets for purchase orders.

The process has some seasonality to it. At this time in 2008, we were working on upgrades to our technology to increase sensitivity and functionality. Heading into 2009, there was an increasing amount of uncertainty about the economy (for both Europe and U.S. customers) and this also created some headwinds for our sales efforts.

In terms of the cycle, we began announcing distributors in the second half of 2008 and started shipping units to them for trials allowing them to spread the word to their customer base.

Now, as I mentioned above, the word is getting out and more

prospective customers and distributors are familiar with the promise of optical biopsy, and in particular, of SpectraScience.

SCP: Is there also seasonality to the sales process in terms of when customers have a purchase mandate and spending power?

Jim Hitchin: Yes. Keep in mind that seasonality always results in more lumpiness for businesses in the ramp-up phase as the product gets more commercially established. Eventually revenues smooth out on a quarterly basis.

Our customers will be making buying decisions in the last quarter of the calendar year based on excess money available in the budget that needs to be spent or they will lose it until budgets get set for the next year.

Additionally, there is a budgetary process at year-end where decisions are being made about the coming year's spending and mandates.

An important factor to keep in mind, which I alluded to above, is that, as we roll out additional applications on our WavSTAT platform, distributors will be able to expand their sales efforts throughout the year.

An appealing characteristic of the WavSTAT platform technology is that it is scalable. You can add additional applications to the product with software modules (e.g., esophageal) which represents greater value to the distributor and to the customer.

The Promise of Optical Biopsy

One of the most powerful tools being added to traditional colonoscopy procedures around the world is the optical biopsy. By adding the power of an optical biopsy to a standard colonoscopy procedure, additional areas of concern, beyond the standard removal of large polyps, are now being analyzed and identified earlier.

How it Works

Upon contact with the WavSTAT probe, the tissue absorbs the safe laser light resulting in excitation of the tissue. The resulting autofluorescent signal is sent back via the same optical fiber and analyzed by a proprietary tissue recognition algorithm in the system's computer console. Within seconds a green "non suspect" or red "suspect" result is displayed on the console's screen. A green light represents normal tissue and a red light represents "suspect" tissue with dysplasia and/or cancer. An advantage of the system is that the margin of the lesion can be determined in real time and a physical biopsy sample can be taken using the same forceps from the exact same place where the optical biopsy is performed.



WavSTAT Optical Biopsy Forceps



Distribution Channel Update (cont'd)

the WavSTAT and now they are coming to us.”

Vaudry went on to comment on the “buzz” that is building in the industry, noting SpectraScience's recent presence at the Digestive Disease Week conference in Chicago, which attracted 16,000 GI doctors from around the world.

Vaudry said, “The Barrett’s specialist from France showed up at our booth and asked for a demo. After the demo he simply asked how soon he could get a WavSTAT in his hospital. This is a positive development as France represents a substantial market opportunity for our technology.”

SIM’s Consejero Delegado, Jose Manuel Ruiz, stated that, “We are pleased to be SpectraScience’s distribution partner and believe

there is significant market potential for this innovative gastro intestinal cancer diagnostic system. Our strategy is to be the leader in gastro-diagnostics and the WavSTAT Optical Biopsy System is an ideal fit with our PENTAX endoscopes. We see important benefits to our physicians, enabling them to quickly distinguish between normal and precancerous tissue in the GI tract and allowing for physical biopsy at exactly the same site and time that the optical biopsy is performed. More important, the WavSTAT objectively identifies the borders of tissue during surgery to determine if all cancerous tissue has been removed. This will prevent a second costly surgery.”



WavSTAT Optical Biopsy System



Michel Vaudry Talks To International Distributors at DDW

SpectraScience European Distributors

	Colon Cancer Rank Amongst Other Cancers as most frequent cancer	Colon Cancer Incidence (relative to other cancers)	Mortality Rate (rank amongst cancers and percentage based)
Czechoslovakia	#1	19.8%	#3 - 18.5%
Austria	#2	14.3%	#3 - 15.4%
Germany	#1	17.9%	#3 - 16.1%
Italy	#4	13.0%	#2 - 13.4%
Spain	#1	19.8%	#3 - 18.5%
Greece	#5	10.5%	#2 - 10.6%

Progress on Esophageal Application and LUMA Trial Study

SpectraScience is currently managing trials in the U.S. for its esophageal application at Boston University, University of San Diego, the University of Southern California, Minnesota Gastroenterology and the Mayo Clinic in Rochester.

Management has reported that enrollment in the esophageal trials has been moving forward, but not as quickly as had been anticipated. The Company has responded by identifying sites in Europe that have high Barrett’s esophageal rates that will qualify for its FDA trial.

The American Society for Gastrointestinal Endoscopy reported recently that the preva-

lence of GERD in the Western world is estimated to be 10% to 20%, with GERD defined as at least weekly heartburn and/or acid regurgitation. GERD is the third most common GI disorder in the United States, affecting 19 million adults and accounting for 4,590,000 outpatient visits and 96,000 hospitalizations annually.

The annual economic impact of GERD is estimated to be \$9.3 billion in 2009.

In addition to quality of life issues, complications of chronic GERD, such as esophageal stricture formation, Barrett’s metaplasia, and esophageal adenocarcinoma necessitate adequate diagnosis and treatment .

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About SpectraScience, Inc.

SpectraScience is a San Diego based medical device company that designs, develops, manufactures and markets spectrophotometry systems capable of determining whether tissue is normal, pre-cancerous or cancerous without physically removing tissue from the body. The WavSTAT® Optical Biopsy System uses light to optically scan tissue and provide the physician with an immediate analysis. With FDA approval for sale in the U.S. and the CE Mark for the European Union, the WavSTAT System is the first commercially available product that incorporates this innovative technology for clinical use. In addition, the Company's LUMA® Cervical Imaging technology has received FDA approval as an optical non-invasive system that is proven to more effectively detect cervical cancer precursors than conventional methods available today.

Our Vision

SpectraScience has the rights to significant intellectual property that supports our vision of a family of non-invasive cancer detection products that have multiple applications. Early detection of cancer and pre-cancer is key to prolonging life. All of us, at one time or another, will lose family and friends to the scourge of cancer. We are driven to make our technology available to catch cancer early, and save lives. We believe that the huge world-wide cancer diagnostic market will allow us to expand and ultimately become a major company dedicated to the well-being of our customers and their patients.

Heard It On The Street - Optical Biopsy More Advantageous Than Narrowband Imaging

A developing story in the cancer screening and diagnostics industry is that an increasing amount of attention is turning to optical biopsy as a more effective screening technique than narrowband imaging (NBI). Certainly, it's a valuable adjunctive tool to NBI. The advantage of an optical biopsy is that it gives an *absolute answer with high certainty*, whereas NBI provides a surveillance view that still requires interpretation, a physical biopsy and expensive pathology screening. Think about going through the colon, for instance, and touching what looks like suspicious tissue and getting a green light - real-time objective screening analysis. This enables the physician to keep moving through the procedure. It saves time and there is no bleeding compared to a physical biopsy, no risk of infection, and of course, it reduces the cost of pathology.

The bottom line is that more physicians and experts are recognizing that optical biopsy is a faster, more accurate screening for pre-cancerous dysplasia, while it lower risks to the patient and lowers cost to the physician and clinic. Consider the ability of a physician being able to do a Barrett's investigation in 10 minutes instead of 30 minutes. That gives the physician time to screen an extra patient and obtain more revenue!

LUMA Trial at University of Iowa on Track

The trial at the University of Iowa is expected to be complete in 2010, with analysis from the first year of the study being available in September.

Jim Hitchin, CEO of SpectraScience, said, "We are pleased with the progress of the University's study and look forward to the preliminary results this September. We are encouraged to see an increasing level of attention in the healthcare community related to the LUMA cervical imaging system. Each year precancerous cervical tissue goes undiagnosed in 200,000 American women. The LUMA system, which provides an *objective* method of screening cervical tissue, can help to dramatically reduce this number. We believe this will improve the quality of healthcare to the patient and reduce overall costs by avoiding the expense of treating later stage cancers."

