Zacks Small-Cap Research

October 20, 2011
Brian Marckx, CFA
bmarckx@zacks.com
Ph. (312) 265-9474

www.zacks.com
111 North Canal Street, Chicago, IL 60606

SpectraScience (SCIE-OTC)

SCIE: Near-Term Product Launch. Initiating At Outperform.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/19/2011
Current Price (10/19/11)	$0.07
Target Price	**$0.40**

OUTLOOK

WavSTAT4, SpectraScience's flagship product for the diagnosis of colon cancer, will be introduced at United European Gastroenterology Week during the fourth week of October 2011. The device offers advantages over competitive technologies, providing for a unique value proposition. Additional applications, including for the diagnosis of esophageal cancer, are expected to follow shortly after launch. WavSTAT4 could enter the U.S. market in 2014.

We are initiating coverage of SpectraScience with an Outperform rating and $0.40 per share price target.

SUMMARY DATA

52-Week High	**$0.21**
52-Week Low	**$0.03**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**61,240**
Shares Outstanding (mil)	**N/A**
Market Capitalization ($mil)	**$9**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**N/A**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	$11 A	$8 A	$3 A	$1 A	$24 A
2011	$0 A	$0 A	$0 E	$44 E	$44 E
2012					$3,561 E
2013					$15,424 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.01 A	-$0.03 A	-$0.02 A	-$0.01 A	-$0.07 A
2011	-$0.01 A	-$0.01 A	-$0.01 E	-$0.01 E	-$0.04 E
2012					-$0.04 E
2013					-$0.02 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

© Copyright 2011, Zacks Investment Research. All Rights Reserved.

KEY POINTS

- SpectraScience's WavSTAT Optical Biopsy System received FDA approval through the PMA (i.e. - most stringent) regulatory process for use during endoscopic screening in the year 2000. It has since been enhanced and the current version, called WavSTAT4, already has CE Marking and can be marketed in the European Union for diagnosis of all types of cancer. WavSTAT4 could receive FDA approval (via a supplement to the original PMA application) and launch in the U.S. in 2014

- Resulting in approximately 50k deaths per year, colon cancer is the 2nd leading cause of cancer-related death in the U.S.

- Key to reducing colon-cancer fatalities is accurate early-stage diagnosis

- Current standard of care can result in mis- or under-diagnosis (especially of small polyps which account for 85% of all polyps) which can result in cancerous polyps being overlooked and not biopsied - this can have fatal consequences. WavSTAT4 aims to take the guesswork out of colon cancer diagnosis and reduce the risk of overlooking cancerous polyps

- WavSTAT's patent-protected technology can instantly detect if tissue is normal, pre-cancerous or cancerous. WavSTAT's Laser Induced Fluorescence (LIF) technology transmits laser light and analyzes reflection from tissue to determine whether a polyp should be biopsied

- Designed to be used as an adjunct to colonoscopy, current top-line data from ongoing clinical trials has indicated that WavSTAT can increase a physician's ability to diagnose cancer by up to 40% and reduce false negatives by up to 93%

- WavSTAT provides a non-subjective diagnosis within one second. Diagnosis with competing devices require interpretation (i.e. - are subjective) and can take as long as 3 to 10 minutes

- With approximately 3.1 million colonoscopies performed in the U.S. each year and another 4.1 million in the E.U., SpectraScience's near-term market opportunity (estimated at ~ $1.5B) is enormous. In addition, the screening market is expected to grow by as much as 20% per year for the next 10 years

- SpectraScience's value proposition with WavSTAT is its greater accuracy compared to traditional screening methods and lower cost (as it reduces the need for costly physical biopsies) / greater speed relative to competing products - which can result in fewer colon cancer related deaths and lower overall health care costs

- WavSTAT4 is expected to make its debut in Europe this coming week (October 22 - 26) at the 19th annual United European Gastroenterology Week in Stockholm, Sweden

- Current timelines anticipate WavSTAT4 to launch in the E.U. in late 2011 for the diagnosis of colon cancer. SpectraScience hopes to begin marketing in the E.U. for other cancers, including esophageal, by mid-to-late 2012. Bladder and lung cancer applications could follow

- SpectraScience is in the midst of finalizing distribution agreements for sale of WavSTAT4 in the E.U.

- Launch in the U.S. could come by about mid-2014, targeting managed care organizations

- Razor / razor-blade business model. Current game plan will be to sell the system at cost and generate revenue / profit through sales of single-use disposable forceps

BUSINESS

SpectraScience, Inc has incorporated their proprietary and patent-protected technology into their WavSTAT Optical Biopsy System which can instantly determine if tissue is normal, pre-cancerous or cancerous, without the need for a physical biopsy. The WavSTAT Optical Biopsy System is classified as a Class III medical device and received FDA approval through the PMA (i.e. - most stringent) regulatory process for use during endoscopic screening in the year 2000. It has since been enhanced and the current version, called WavSTAT4, already has CE Marking and can be marketed in the European Union for diagnosis of all types of cancer. The system is expected to make its debut in Europe this coming week (October 22 - 26) at the 19th annual United European Gastroenterology Week in Stockholm, Sweden. WavSTAT4 could receive FDA approval (via a supplement to the original PMA application) and launch in the U.S. in 2014.

For colon cancer, SpectraScience's initial target market, WavSTAT is used and is compatible with flexible endoscopes, which are used during routine colonoscopy procedures. With over 3 million colonoscopies performed every year in the U.S. and another 4+ million in Europe, the procedure is one of the most common methods for colon cancer screening.

Until recently SpectraScience had also been pursuing the further commercialization of a cervical cancer diagnostic instrument, which was acquired (along with 34 patents and 28 additional patent applications) through the November 2007 purchase of Luma Imaging Corporation. Luma had developed and received FDA approval for an optical, non-invasive diagnostic imaging system called LUMA Cervical Imaging System (Class III device) that was proven to be more effective than traditional colposcopy diagnosis in the detection of cervical cancer precursors. However, in order to fully commercialize the LUMA system, it required further development, including additional and potentially costly and time-consuming clinical studies. As a result, SpectraScience recently shifted their focus and resources towards WavSTAT, which management believes holds the most opportunity (especially from a return on investment standpoint). The company subsequently began winding down their LUMA business and in 2010 wrote off the remaining fair value of the LUMA inventory. This freed up more operational and financial resources which have now been fully dedicated to the commercialization of WavSTAT. SpectraScience retained the intellectual property of LUMA for use in the development of future generations of the WavSTAT System.

TARGET MARKETS

COLON CANCER

While regular screening has helped reduce the overall incidence of colon cancer since the mid-1980's, current screening programs and procedures may not be enough as the disease remains the second leading cause of cancer death in the U.S., behind only lung cancer. It is the third most commonly diagnosed cancer (behind only prostate and lung), with approximately 5% of people developing colon cancer at some point in their lifetime. The American Cancer Society estimates that about 141k Americans will be diagnosed with the disease during 2011 and almost 50k will die from it. Over 1 million Americans currently have colon cancer.

There are two general types of colorectal polyps; hyperplastic and adenomatous. Hyperplastic polyps usually do not develop into cancer, while adenomatous polyps may develop into cancer. WavSTAT4 is powered to differentiate between these cancerous and non-cancerous polyps. Adenomatous polyps develop into cancer over an extended period of time - typically 10 to 15 years.

Colon cancer facts and statistics according to the American Cancer Society:

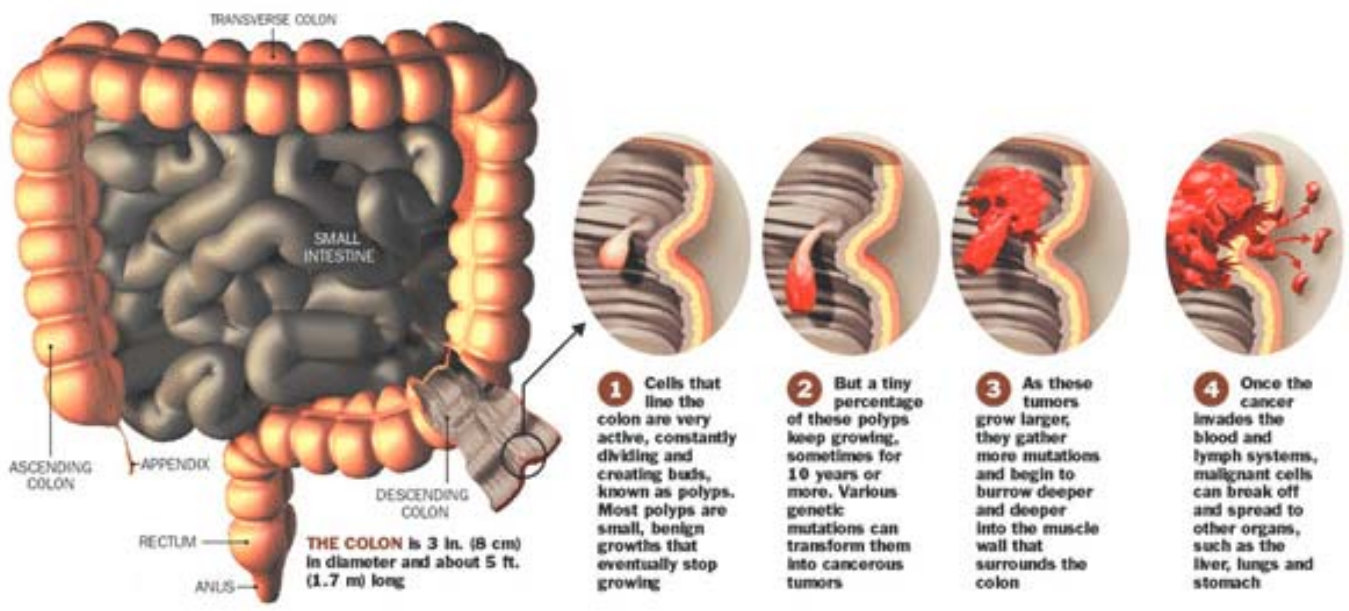
- **Early Detection is Key:** Treatment of colon cancer is most effective when the disease is discovered at an early stage. Regular screening is advised in order to increase the chances of finding and removing polyps before the become cancerous.
    - Over 90% of people diagnosed when the cancer is found early and has not spread from the colon or rectum (i.e. - local stage) survive for more than five years

- If the cancer is found after it has already spread to adjacent areas of the body (i.e. - regional stage), five-year survival falls to 69%
- If the cancer is found after it has already spread to distant organs in the body (i.e. - distant stage), five-year survival plummets to only 11%

- **Most Not Found Early:** The majority of colon cancer cases are not found until they have already spread
  - Only 39% of colon cancers are found at the earliest (local) stage
  - 37% are found at the regional stage
  - 20% are found at the distant stage

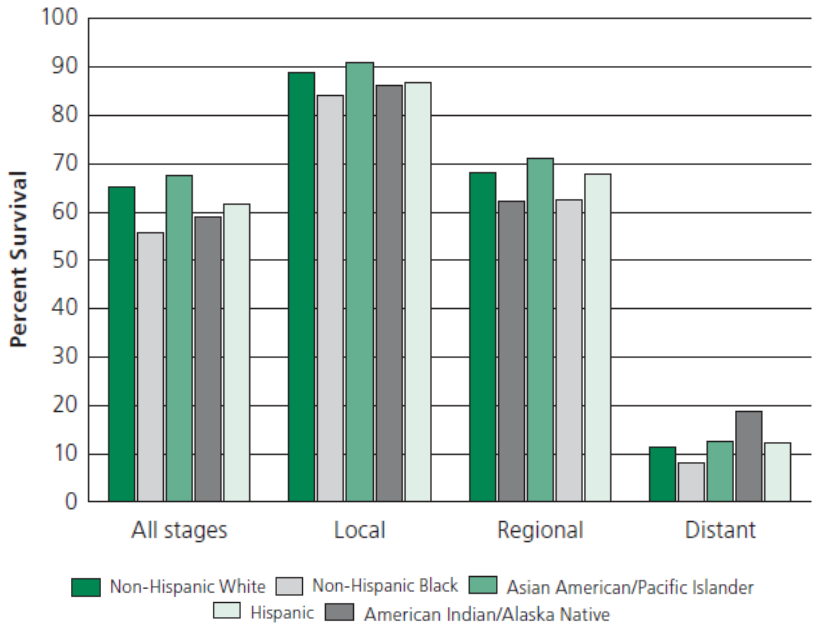
- **Usually Afflicts Older People:** Colon cancer rarely afflicts younger people and is usually (although not always) first discovered in middle-aged or older individuals
  - 90% of new cases and 95% of deaths from colon cancer are with people 50 years of age or older
  - Although the overall incidence rate of colon cancer has been declining, as has the rates in people 50 years of age and older, the incidence rate for those younger than 50 has actually been on the rise
  - Despite a decline in the overall incidence of colon cancer, colon cancer screening is expected to grow by as much as 20% per year over the next 10 years, largely as a result of significant growth in the proportion of the population over the age of 50

Stages of Colon Cancer



SOURCE: http://www.helpfulhealthtips.com/stages-colon-cancer/

5-year Colon Cancer Survival By Stage and Ethnicity (1999 - 2006)



SOURCE: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-028323.pdf. Altekruse et al.

SCREENING FOR COLON CANCER

Most polyps are found during regular screening and, as survival rates are highly inversely correlated to the degree of polyp progression (i.e. - stage), early detection is critical to reducing colon cancer related deaths. Several different health-related organizations publish colon cancer screening guidelines (or provide recommendations on the use of certain guidelines), including the American Cancer Society, the U.S. Preventive Services Task Force, the American College of Radiology, the American College of Obstetricians and Gynecologists, Centers for Disease Control and the American Academy of Family Physicians (among others). While there are slight differences between some of the various organizations related to the menu of tests recommended or screening frequency, there is a general consensus that the following screening methods provide value in the detection of colon cancer; colonoscopy, flexible sigmoidoscopy, double-contrast barium enema, and fecal occult blood test.

- **Colonoscopy:** a small flexible tube with a camera on the end is used to look at the interior walls of the rectum and the entire colon. During a colonoscopy, tissue samples may be collected and polyps removed so they can be biopsied. It is widely agreed that colonoscopies should be done as a screening procedure at least once every 10 years beginning at the age of 50 and as a confirmatory diagnosis when the results of another screening test are positive. Weakness of colonoscopies is that they can miss small polyps and diagnosis involves a significant amount of interpretive skill - this not only increases the risk that cancerous polyps are left to grow, it also can result in unnecessary biopsies from benign polyps being mistakenly suspected of being cancerous. WavSTAT directly addresses both of these weaknesses. While smaller polyps, in general, typically present a lower risk of cancer, as small (< 1 cm) polyps account for approximately 85% of all polyps, it's imperative that screening can accurately detect these. Approximately 3.1 million colonoscopies are performed in the U.S. each year, with another ~ 4.1 million performed in Europe.

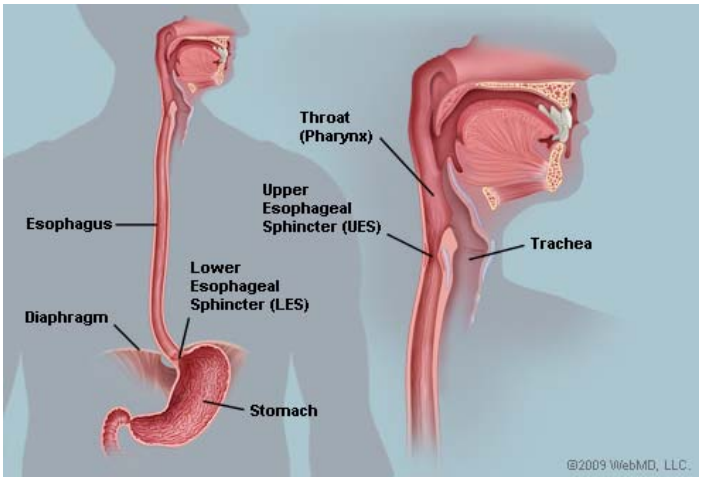
- **Flexible sigmoidoscopy:** similar to colonoscopy except sigmoidoscopy looks at only the rectum and lower part (~ final 2 feet) of the colon. It is generally recommended once every 5 years beginning at the age of 50 as a screening procedure. If suspicious areas are identified, a colonoscopy is typically ordered for supporting diagnosis and to remove any polyps. Weaknesses of flexible sigmoidoscopies are that they view only about 1/3 of the colon, they can miss small polyps, it involves subjective diagnosis and polyps can not be removed during this procedure.

- **Double-contrast barium enema:** patient receives an enema with barium sulfate, a contrast agent, followed by x-rays of the colon and rectum. The contrast agent highlights the intestines which allows the x-rays to pick up abnormal growths. If suspicious areas are identified, a colonoscopy is typically ordered for supporting diagnosis and to remove any polyps. The American Cancer Society recommends a double-contrast enema is done once ever five years beginning at the age of 50. Weaknesses of double-contrast enemas are that they can miss small polyps, false positives can be an issue and polyps can not be removed during this procedure.

- **Fecal occult blood test:** blood vessels of large polyps can be easily damaged by the passage of feces. The small amount of blood released into the feces is usually not visible by the naked eye but can be detected by a stool test. If the test comes back positive, a colonoscopy is needed to determine the cause of the bleeding. Fecal occult blood tests are generally recommended once every year beginning at the age of 50. Weaknesses of the test are that it can miss many polyps, can produce false positives and should be done frequently (i.e. - every year).

ESOPHAGEAL CANCER

Esophageal cancer (specifically Barrett's esophagus) is expected to be WavSTAT's follow-on target market. As its name implies, esophageal cancer is malignancy of the esophagus. The esophagus is a muscular tube, about 8 inches long, which connects the throat and the stomach. During swallowing, food goes from the mouth through the pharynx into the esophagus and finally into the stomach.



SOURCE: www.webmd.com

Esophageal cancer facts and statistics according to the American Cancer Society:

- **Incidence:** approximately 17k Americans diagnosed every year with esophageal cancer
- **Deaths:** esophageal cancer is the 10th leading cause of cancer-related death in the U.S. Approximately 15k die from the disease annually
- **Prognosis:** prognosis is usually poor as diagnosis typically is not made until later stages of the disease. The overall 5-year survival rate for esophageal cancer is only about 15% with most patients dying within the first year

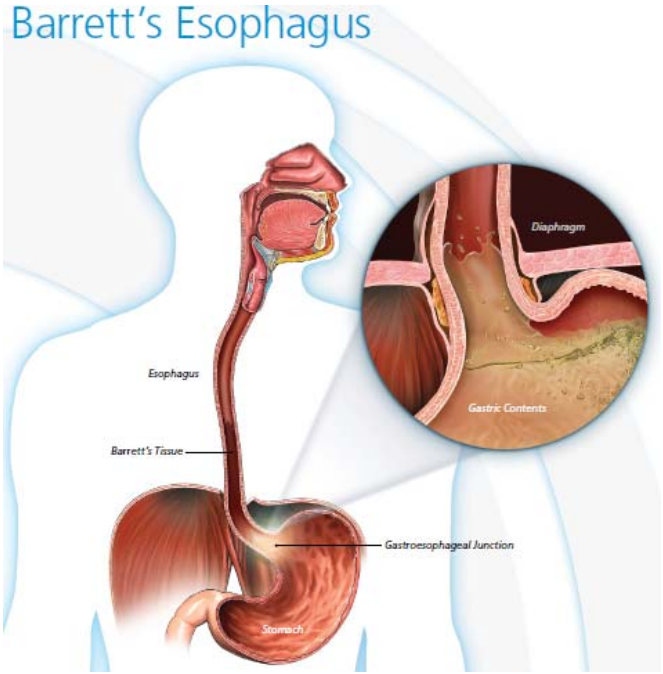
Esophageal cancer, especially in later stages, is often deadly as larger tumors tend not to be operable. Unfortunately, most people diagnosed with esophageal cancer are already in late stages of the disease as symptoms (i.e. - difficult and / or painful swallowing, hoarse coughing, coughing up blood) are often not apparent until a significant portion of the esophagus has become obstructed at which time the tumor has already matured.

There are two main types of esophageal cancer; squamous cell and adenocracinoma. Squamous cell accounts for about 90% of all esophageal cancer throughout the world and forms in cells in the upper ~ two-thirds of the esophagus. Its cause is often linked to tobacco and alcohol use.

Adenocracinoma accounts for approximately 65% of all esophageal cancer in the U.S. and forms in glandular cells found near the bottom ~ one-third of the esophagus. It is often linked to gastroesophageal reflux disease (i.e. - extreme and recurrent heartburn) and Barrett's esophagus.

Barrett's Esophagus / Dysplasia
SpectraScience expects to pursue an indication with WavSTAT for the diagnosis of high-grade dysplasia and esophageal cancer. Barrett's esophagus results when the lower part of the esophagus undergoes an abnormal change as it adapts to chronic exposure to stomach acid. The earliest stage of Barrett's Esophagus is called non-dysplastic and is characterized by normal flat cells being replaced by glandular cells. Barrett's Esophagus patients which have a precancerous change in the esophageal tissue are diagnosed as having dysplasia, the next stage of the illness. Depending on the progression of the dysplasia, it is either low-grade or high-grade. Patients with high-grade, or more severe dysplasia, are considered to have an increased risk of developing esophageal cancer.

Gastroesophageal reflux disease (GERD) can be a precursor to Barrett's esophagus with approximately 10% of people with chronic GERD eventually developing the ailment. It is estimated that between 2 million and 7 million Americans have Barrett's esophagus. While people who have Barrett's esophagus have somewhere between a 5 times to 40 times greater chance of developing esophageal cancer compared to the general population, it has been found that the overall cancer risk in patient's with Barrett's esophagus is very low (only about 1% to 5% of people with Barrett's esophagus develop esophageal cancer). In fact the most recent studies have indicated that Barrett's patients have the same life expectancy as the overall general population. Among those with Barrett's and high-grade dysplasia, studies have indicated between a 15% - 59% chance of developing esophageal cancer over a 5 to 8 year period.

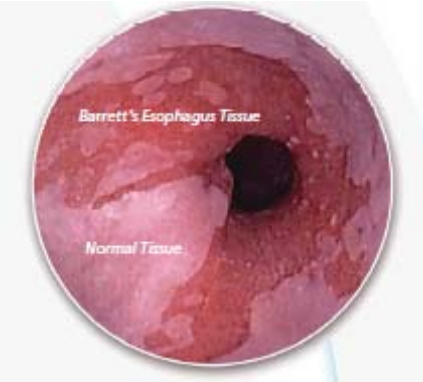


SOURCE: http://www.umcarizona.org/workfiles/gi/Barretts_Brochure.pdf

Screening for esophageal cancer / Barrett's esophagus
As opposed to colon cancer, there are no standard or routine screening tests for esophageal cancer. The most common testing procedure is with an upper endoscope (or esophagoscope) which is similar to what is used in a colonoscopy. During an endoscopy a flexible tube with a lens on the end is passed through the nose or mouth and down the throat into the esophagus. Some endoscopes have the ability to remove tissue samples for biopsy. Endoscopy is also typically used to diagnose Barrett's esophagus and while there are no set guidelines relative to screening, some recommendations suggest screening patients over 50 years old with a history of GERD. The endoscope can identify Barrett's tissue which is salmon colored compared to normal tissue which is pink.

Although there is no significant evidence showing that screening for Barrett's esophagus decreases esophageal cancer related deaths, the American College of Gastroenterology has stated that "patients with chronic GERD symptoms are those most likely to have Barrett's esophagus and should undergo upper endoscopy."

Barrett's tissue is salmon colored, normal tissue is pink



SOURCE: http://www.umcarizona.org/workfiles/gi/Barretts_Brochure.pdf

WavSTAT

SpectraScience's WavSTAT Optical Biopsy System uses laser-induced fluorescence to determine whether suspect polyps are cancerous or benign. Fluorescence is the radiation of absorbed light by certain substances. Light emitted by a substance is at a different wavelength than the absorbed light - the emitted light (fluorescence) spectra can be measured and provide information about the substance such as its chemical composition and structure. Fluorescence is used in a variety of scientific applications including mineralogy, gemology and biological detection.

WavSTAT uses a laser to produce ultraviolet light to stimulate fluorescence in tissue. The system then reads "spectral signatures" of the radiated light through application of a proprietary algorithm to determine whether the tissue is healthy or cancerous. The system consists of a mobile console which contains both the laser source and a computer to analyze the data from the tissue and optical forceps integrated with fiber optic cable. The forceps are attached to the end of an endoscope and are the working end of the system. The forceps are single-use disposables, sales of which represent an ongoing revenue stream for SpectraScience.

WavSTAT Optical Biopsy Forceps



WavSTAT4 Console



SOURCE: SpectraScience

The system transmits low-level laser light through the working channel of an endoscope and the forceps' integrated optical fiber to the tissue. After the laser transmits a signal, the light is turned off and auto-fluorescence spectra is collected and analyzed by the console. Within seconds the system provides a diagnosis which is displayed on the console with either a green (non-cancerous) or a red (cancerous) light - this non-subjective diagnosis is unique among competing technologies. If WavSTAT signals that the tissue is cancerous, it is biopsied to provide a definitive diagnosis. Data can then be printed or saved electronically. The forceps can be used to remove tissue suspected of being cancerous - the ability to diagnose and initiate treatment within the same procedure is another distinct advantage with WavSTAT. WavSTAT is compatible with existing endoscopic equipment. SpectraScience owns exclusive rights to eight U.S. patents covering the WavSTAT technology.

Launch Strategy
SpectraScience has spent the last several months making enhancements to the WavSTAT Optical Biopsy System to improve its ease of use and increase its diagnostic sensitivity. The enhanced version of the system, called WavSTAT4, is expected to make its debut in Europe this coming week (October 22 - 26) at the 19th annual United European Gastroenterology Week in Stockholm, Sweden. SpectraScience's current game plan is to initially roll out WavSTAT4 in Europe (via medical device distributors) for colon and esophageal cancers where they expect reimbursement will be more favorable than in the U.S. As there are no Current Procedural Terminology (CPT) codes providing for reimbursement of the use of WavSTAT, doctors will not be paid by Medicare and many private insurers in the U.S. The company hopes that once they can prove the benefits of WavSTAT4 in Europe, that they can then target managed care organizations in the U.S. such as Kaiser Permanente. Many managed care organizations do not necessarily follow Medicare's lead regarding reimbursement policy and have an interest in reducing health care costs. If WavSTAT4 can be shown to reduce the number of physical biopsies, that would be a potentially important value proposition for managed care organizations. Physical biopsies are relatively expensive procedures compared to optical biopsy with WavSTAT4, which means it has the potential to reduce overall costs related to cancer screening and treatment.

Indicated Uses
The WavSTAT Optical Biopsy System is classified as a Class III medical device and received FDA approval through the PMA regulatory process as an adjunct to gastroenterologist's in the diagnosis of colon cancer. It has since been enhanced and the current version, WavSTAT4, already has CE Marking and can be marketed in the European Union for diagnosis of all types of cancer. Prior to entering the U.S. market WavSTAT4 will have to receive FDA clearance - as WavSTAT4 is essentially an enhanced version of the already FDA-approved WavSTAT Optical Biopsy System, it is expected that approval could be attained through a relatively simple supplemental filing to the original PMA application. SpectraScience's current timeline has WavSTAT4 approved and in the U.S. market in 2014.

SpectraScience expects to pursue a follow-on indication for esophageal cancer / high-grade dysplasia in the future and believes this can also be accomplished for the U.S. market through a supplemental filing. Additional applications, including for diagnosis of cancers of the bladder, lung, stomach, breast, lymph system and skin could follow the esophageal indication.

SpectraScience's future goals also include incorporating scattering spectroscopy technology into WavSTAT to complement laser-induced fluorescence, potentially providing even greater accuracy and facilitating diagnosis of various types of cancer. As opposed to laser-induced fluorescence which looks at biochemical properties of tissue, scattering spectroscopy, which SpectraScience also holds patents on, examines the physical properties of tissue such as changes in its thickness and vascularity.

Clinical Trial Data
Results from a clinical trial titled *Distinguishing Neoplastic from Non-Neoplastic Colonic Polyps Using Laser-Induced Fluorescence* showed laser-induced fluorescence significantly improved physicians' diagnostic capabilities of colon cancer compared to colonoscopy alone. The study included 110 patients who were scheduled to undergo routine colonoscopy at one of five trial sites (which included the Mayo Clinic in Rochester, MN, Hennepin County (MN) Medical Center, Massachusetts General Hospital, and Minnesota Gastroenterology). 112 neoplastic polyps and 154 non-neoplastic polyps were removed and biopsied. Results showed that laser-induced fluorescence used as an adjunct to a physician's diagnosis identified neoplastic lesions with a sensitivity of 97% and specificity of 75%, both of which were statistically superior to the physician's diagnosis alone. The authors concluded that laser-induced fluorescence can accurately distinguish neoplastic from non-neoplastic tissues and may be a useful adjunct to endoscopy.

Preliminary data from an unrelated ongoing clinical trial indicated WavSTAT can increase a physician's ability to diagnose cancer by up to 40% and reduce false negatives by up to 93%. The full data set from the trial could be available during the first half of 2012.

WavSTAT4 Clinical Value Drivers

- Focus is small polyps (large polyps are typically always removed) which account for ~85% of all polyps and are most susceptible to being missed with traditional diagnostic methods
- As patient survival is correlated with finding cancerous polyps at earliest stage, WavSTAT4 can save lives
- WavSTAT4 may be able to reduce unnecessary biopsies and the cost, patient discomfort and risks associated with them
- Enables diagnosis and initial treatment (removal with forceps) during same procedure
- Reliable diagnosis at point of care can eliminate (at least for some patients) the 1 - 2 week wait time for a biopsy pathology report, affording greater convenience to the patient and providing physician with information needed for determining the patient's appropriate follow-on screening interval
- Red / Green indicator lights provide unambiguous diagnosis without the need for interpretation
- Almost instantaneous results (one second) means less time required for diagnosis
- Compatible with existing endoscopes - other than the WavSTAT4 system itself, no other equipment to purchase

COMPETITION

WavSTAT will compete against two distinct technologies; confocal microscopy and narrow band imaging. The leaders in these technologies are mostly very large, well-established imaging companies with significantly greater resources than SpectraScience. This poses obvious challenges for SpectraScience to gain market share.

Confocal laser microscopy uses very high magnification and resolution to provide histology. Its advantages over standard histology such as colonoscopy is that it provides a much greater level of detail. However, similar to standard endoscopic procedures, it requires a certain level of interpretation of the images to discern what is and is not suspicious tissue. This also means diagnostic time is longer than with WavSTAT4 which does not require subjective interpretation. SpectraScience estimates the average cost of confocal microscopes at about $140k (with no per-procedure costs).

Narrow Band Imaging uses two distinct bands of light, one blue and the other green. The narrow band blue light highlights microcapillary networks while the green light shows subepithelial vessels. When combined, they provide a high contrast image of the tissue surface.

Mauna Kea Technologies
Mauna Kea Technologies' Cellvizio is a probe-based confocal laser microscope. The microscope is inserted into the working channel of existing endoscopes. The original Cellvizio system (it has been enhanced over the years) received FDA 510(k) clearance in 2005. The system is FDA approved and CE Marked for use in the gastrointestinal (GI) and pulmonary tracts and has been commercially available since 2007. Cellvizio systems are currently installed in approximately 200 hospitals and research centers in and outside of the U.S. Annual sales of the system are currently about $8.3 million.

Olympus Medical
Olympus Medical is a subsidiary of Tokyo-based Olympus Corporation, a global imaging company and leader in digital cameras as well as life sciences imaging devices. Olympus Medical offers a variety of medical imaging tools including endoscope-based narrow band imaging products. Similar to confocal microscopy, Olympus' narrow band imaging products require a subjective assessment of the images for diagnosis. Olympus Medical is the dominant provider of narrow band imaging products.

PENTAX Medical Company
PENTAX Medical Company is a subsidiary of Tokyo-based optical company Hoya Corporation. Hoya's optical products include photographic filters, lasers and contact lenses. Along with a number of other GI devices, including a variety of gastroscopes, colonoscopes and sigmoidoscopes, PENTAX Medical offers a line of confocal laser microscopes. PENTAX Medical distributes its products all over the world. There is no publicly available unit placement information for their confocal microscopes.

Fujinon Inc.
Fujinon Inc. is part of Fujifilm Corporation, a wholly owned subsidiary of Fujifilm Holdings Corporation, another Tokyo-based imaging giant. Through its diverse network of operating companies, Fujifim Holdings has a major presence in color films, digital cameras and office copiers and holds a leading position in medical imaging products through its Fujifilm Medical business. Fujifilm Medical's endoscopy division carries a large line of GI products including colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes which are distributed all over the world. There is no publicly available unit placement information for their products, including for their endoscope-based confocal laser microscopes.

WavSTAT4 Competitive Value Drivers

- No upfront cost for hospital - SpectraScience will sell WavSTAT4 at cost to distributors who will likely lend the device free of charge. Revenue will be generated from sale of disposable forceps. Competitive systems require substantial upfront cost
- WavSTAT4's unambiguous diagnosis means;
  - less training required compared to competing systems which require interpretative skill
  - fewer unnecessary biopsies
- WavSTAT4's instantaneous diagnosis affords higher patient throughput - allowing hospital greater potential to maximize revenue
- Expandable (in the future) to other forms of cancer

FINANCIAL CONDITION

Cash
As of their most recent reporting period (6/30/2011) SpectraScience had $2.58 million in cash and equivalents. Cash used in operations was $1.19 million through the six months ending 6/30/2011. At this burn rate, the company has enough cash (as of 6/30/11) to operate for approximately 12 months. We, however, anticipate the cash burn rate to significantly increase in the near-term as SpectraScience ramps up production, manufacturing and related activities in preparation for the European launch.

Convertible Preferred Stock
The company has no debt but does have two classes (Series B and Series C) of convertible preferred stock outstanding. The majority of both classes were converted to common stock during 2010, the remainder outstanding consists of 2.59 million Series B with a liquidation preference of $517k plus accumulated dividends of $98k and 1 million shares of Series C with a liquidation preference of $200k.

The Series B are convertible into an equal number of common shares at a conversion price of $0.20/share. Dividends at a rate of 8% are payable in either cash or common stock, at the option of SpectraScience. The Series C are convertible into an equal number of common shares.

OUTLOOK

Our Outlook is based on a number of assumptions and estimates which were gleaned through discussions with management and our own research. Our Outlook also assumes that SpectraScience hits a number of significant milestones over the near-to-mid term and that the economics of WavSTAT4 and SpectraScience's business model work not only for SpectraScience, but also for distributors, hospitals, physicians, third-party payers, and potentially patients as well. Failure to hit some of these milestones (which we allude to below) or a break in the chain of the economics of their business model, could significantly alter SpectraScience's future.

SpectraScience's roll-out of WavSTAT4 is expected to kick off with introduction of the system at the 19th United European Gastroenterology Week in Stockholm, Sweden, taking place during the fourth week of October 2011 (i.e. - in about 1 week). General timelines put the system on the European market and generating revenue (albeit modestly initially) from the colon cancer application in late Q4 2011. Esophageal cancer diagnosis could follow beginning in the second half of 2012. Beyond 2012, additional applications could come online including bladder and lung cancer. If all goes well SpectraScience will enter the U.S. market with WavSTAT sometime in 2014. The U.S. roll-out is expected to follow a similar pattern, initially targeting colon, then esophageal and then potentially following with bladder and lung.

OUR KEY ASSUMPTIONS

- **Additional Capital:** SpectraScience will need to raise additional capital in the near-term. We assume they are able to raise sufficient capital in order to fund the pre-launch and launch of WavSTAT4
- **Distribution:** both E.U. and U.S. sales / marketing is handled by third party distributor(s). Initial agreements in place within the next few weeks to facilitate E.U. launch. Expect SpectraScience will look to bring on a major distribution partner over time which can handle worldwide (Europe and U.S.) sales
- **Revenue Model:** sell WavSTAT system to distributors at cost. Distributors place system at no charge to customer. Distributors purchase disposable forceps from SpectraScience and resell at higher price
- **E.U. Launch:** commences in Q4 2011 for colon indication. Esophageal in 2012, followed by bladder and lung indications in later years
- **U.S. Launch:** regulatory approvals via supplement to original PMA. Launch commences in 2014 for colon indication. Esophageal follows shortly afterwards. Bladder and lung indications are marketed in later years
- **Reimbursement:** currently unclear what degree of insurance reimbursement WavSTAT may enjoy in various parts of Europe. The onus to market the system where reimbursement may be most favorable will likely fall with international distributors. Reimbursement in the U.S. will likely be, at best, very spotty, at least initially. Expect SpectraScience to target managed care organizations where cost benefits of WavSTAT can be leveraged

Along with the assumptions above, our revenue model is based on our best-guesses relative to the rate of WavSTAT unit placements, selling prices of the forceps, and utilization (i.e. - forceps unit sales).

Unit Placements

As we assume a late Q4 launch of WavSTAT (in Europe), we model immaterial revenue through the end of the current year. We estimate approximately 30 WavSTAT systems placed through the first six months of 2012 but expect the system placement rate to begin to significantly pick up in the second half of that year, facilitated by the commencement of marketing for esophageal cancer (along with the initial colon indication). Our model assumes just over 100 systems are in use in Europe by the end of 2012. Our model assumes consistent growth in the placement rate throughout 2013, driven fairly equally between the colon and esophageal applications. We also think SpectraScience could be marketing for a bladder cancer indication in Europe by the tail-end of 2013 and model over 400 systems in place by the end of that year. U.S. launch could come in 2014, initially for colon and followed by esophageal in that same year. SpectraScience may also look to continue to expand into additional applications in Europe. Our model assumes SpectraScience tops just over 1,000 total units in service by year-end 2014.

Forceps
Until WavSTAT is on the market, the realizable price-point for the forceps will be unknown. Based on discussions with management, current expectations are that the colon forceps will be offered at a lower price-point compared to those for other indications (i.e. - esophageal, bladder, lung, etc). Colon clearly represents the low-hanging fruit and, being the initial target market, means SpectraScience / distributors may have an interest in sacrificing some margin in order to grab market share, maximize the unit placement rate and help spark utilization. The size of the colon cancer market also makes it one of the most attractive and, therefore, means even relatively low margins (~ 50% initially) can be highly profitable with even moderate utilization. Our model currently incorporates an assumption that SpectraScience sells the colon forceps (to distributors) in the $100 - $200 range (per unit) and ~ 2x to 3x that amount for the other applications.

Utilization
Our assumed utilization rate is arguably conservative at approximately 4 patients per device per week. We also note that we assume no increase in the rate of utilization as additional indications come online or with commercialization in the U.S. Using this assumed utilization rate, along with our estimated ~ 300 average number of units in service throughout 2013, equates to approximately 60k procedures with WavSTAT during that year. That is less than 1% of the more than 6MM combined colonoscopy and upper endoscopy (i.e. - esophageal cancer diagnostic) procedures performed in Europe each year.

REVENUE
Using the assumptions and estimates above, we think SpectraScience could generate $3.6 million in revenue in 2012, including $1.4 million from forceps. As the installed base grows and additional indications come online (the related forceps which we expect to carry higher price-points), revenue growth should significantly accelerate - which is reflected in our estimated revenue figures beyond 2012. We model revenue of $15.4 million in 2013, including forceps sales of $8.9 million, and $40.5 million in 2014, including forceps sales of $27.7 million.

GROSS MARGIN
Gross margin will be a function of realizable selling prices of the forceps (including an appropriate margin for distributors) and the related cost to manufacture them. The colon forceps will likely carry the thinnest margins compared to those for other applications. This is due to the expected lower selling price combined with the colon forceps requiring more optical fiber due to the longer tube used for colonoscopies compared to other procedures such as esophageal screening. Over time, we expect gross margin to widen significantly due to a combination of factors; an ever greater proportion of overall revenue will come from forceps sales (as opposed to WavSTAT system sales which we model to have a 0% margin), forceps margins from follow-on indications should carry a higher margin than those for colon, and higher production volumes should offer some economies of scale. SpectraScience may also have the opportunity to raise prices down the road. We model forceps margin of approximately 45% in 2012, growing to ~ 63% in 2013 and ~ 73% in 2014.

VALUATION

Our comparable group used to value SCIE consists of companies with early stage devices used in cancer diagnosis as well as companies involved in the manufacture of endoscopic products. Our valuation methodology uses the average of three metrics; price-to-book value, price-to-2014 estimated sales, and price-to-2014 estimated EPS.

Based on these three metrics, SpectraScience is valued between $0.23/share (based on an average 4.7x book value multiple) and $0.61/share (based on an average 1.6x estimated 2014 sales multiple). Our other metric, price-to-2014 estimated EPS, produced a value of $0.33/share. Average valuation based on these three metrics is $0.39/share - which we round up to $0.40/share. SCIE currently trades at $0.08, significantly below what we calculate to be fair value. We are initiating coverage of SpectraScience with an Outperform rating and a $0.40 per share price target.

Ticker	Price/Book	Price/2014 Sales	Price/2014 EPS
GIVN	2.7	2.1	16.4
MELA	7.2	1.9	12.4
VRS.V	8.6	1.1	4.8
BCR	4.0	2.2	10.0
CNMD	1.2	0.9	11.7
Average	**4.7**	**1.6**	**11.1**

	VALUATION BASED ON:			
	Price/Book	**Price/2014 Sales**	**Price/2014 EPS**	**AVG**
SCIE	$0.23	$0.61	$0.33	**$0.39**

KEY PERSONNEL

Michael P. Oliver
President and Chief Executive Officer
Mr. Oliver, has more than 20 years of experience in the medical device industry, and has been a member of four separate management teams that took over struggling medical device companies, increased their revenues and profitability and sold them to strategic buyers. In these companies Mr. Oliver served in the capacity of head of sales and marketing, and, in two cases held major operational responsibilities as well. Mr. Oliver received his MSA from George Washington University and his BS from the United States Naval Academy.

Jim Dorst
CFO and COO
Jim Dorst, Vice President of Finance and CFO joined the Company in December 2007. Mr. Dorst brings to the Company over 20 years of senior management experience in finance, operations, planning and business transactions. Prior to joining SpectraScience, Mr. Dorst was Chief Financial Officer of Aethlon Medical, Inc., a public medical device development company. Before joining Aethlon, Mr. Dorst was Vice President of Finance and Operations for Verdisoft Corporation, a developmental-stage mobile-software developer acquired by Yahoo, Inc. Previously, he held executive positions as SVP of Finance and Administration at SeeCommerce, COO/CFO of Omnis Technology Corp and CFO / SVP of Information Technology at Savoir Technology Group, Inc. (acquired by Avnet, Inc.). Mr. Dorst practiced as a Certified Public Accountant with Coopers & Lybrand (PricewaterhouseCoopers) and holds an MS in Accounting and a BS in Finance from the University of Oregon.

Michel G. Vaudry
Director of International Sales
Mr. Vaudry previously held the position of Technical Director at Hemotherapies, Inc., a Liver Dialysis manufacturer. Prior to Hemotherapies, he was the President of Medicare Industries, Inc., manufacturing Intensive Care equipment for neonates. At Medicare Industries, he also headed the Operations and Regulatory/Quality control Departments and set-up International manufacturing and research/development alliances. He was responsible for establishing ISO 9001 and CE marks for two companies. Previously, he moved from Europe to the US and held the position of VP International Sales for a major medical device manufacturer. Mr. Vaudry has a Bachelor of Science in Electronic Engineering and a Degree in Mechanical Engineering from the University of Caen, Normandy, France. He is fluent in French, English and conversational in Spanish and has some knowledge of spoken Arabic.

Glen Freiberg
Vice President of Regulatory Affairs & Quality Assurance
Glen Freiberg brings extensive regulatory experience to the Company. Prior to joining SpectraScience, Mr. Freiberg was Vice President of Regulatory Affairs and Quality Assurance at Alphatec Spine Incorporated. Prior to this he spent eight years with Gen-Probe, Inc. as Vice President of Regulatory, Quality and Government Affairs. Prior to Gen-Probe Mr. Freiberg held similar positions at Bard Diagnostic Sciences, Inc., ONCOR, Inc., Boehringer Mannheim Corporation, Curtin Matheson Scientific, Inc., The Coulter Corporation and The Upjohn Company. Mr. Freiberg also spent over four years as a Consumer Safety Officer with the U.S. Food and Drug Administration. Mr. Freiberg has held numerous board memberships and advisory positions in both trade groups and philanthropic organizations. He holds a BA in biological sciences and an MA in microbiology from the University of Colorado and has completed post-graduate work at various accredited institutions.

Mike Brady
Director of Engineering
Most recently Mr. Brady spent three years as a Senior Project Manager/ Systems Engineer. Prior to this he spent three years at Elgar Electronics where he managed several concurrent engineering projects. Before this, Mr. Brady spent thirteen years at leading medical device manufacturer Mallinckrodt/Nellcor Puritan Bennet, where he was a Senior Project Manger/Principal Electronic Engineer. Brady holds a BSEE degree from San Diego State University.

Todd Pinkowski
Director of Operations
Mr. Pinkowski brings over 23 years of extensive operations and production experience to the Company. Prior to SpectraScience, Inc. Mr. Pinkowski spent nine years with ResMed Corp. as Senior Manager of Technical Service and Manufacturing. Before this he spent 14 years as a Senior Production Supervisor with Infrasonics/Nellcor PB. Mr. Pinkowski began his career as an Aircraft Armament Systems Specialist with the U.S. Air Force.

FINANCIAL MODEL

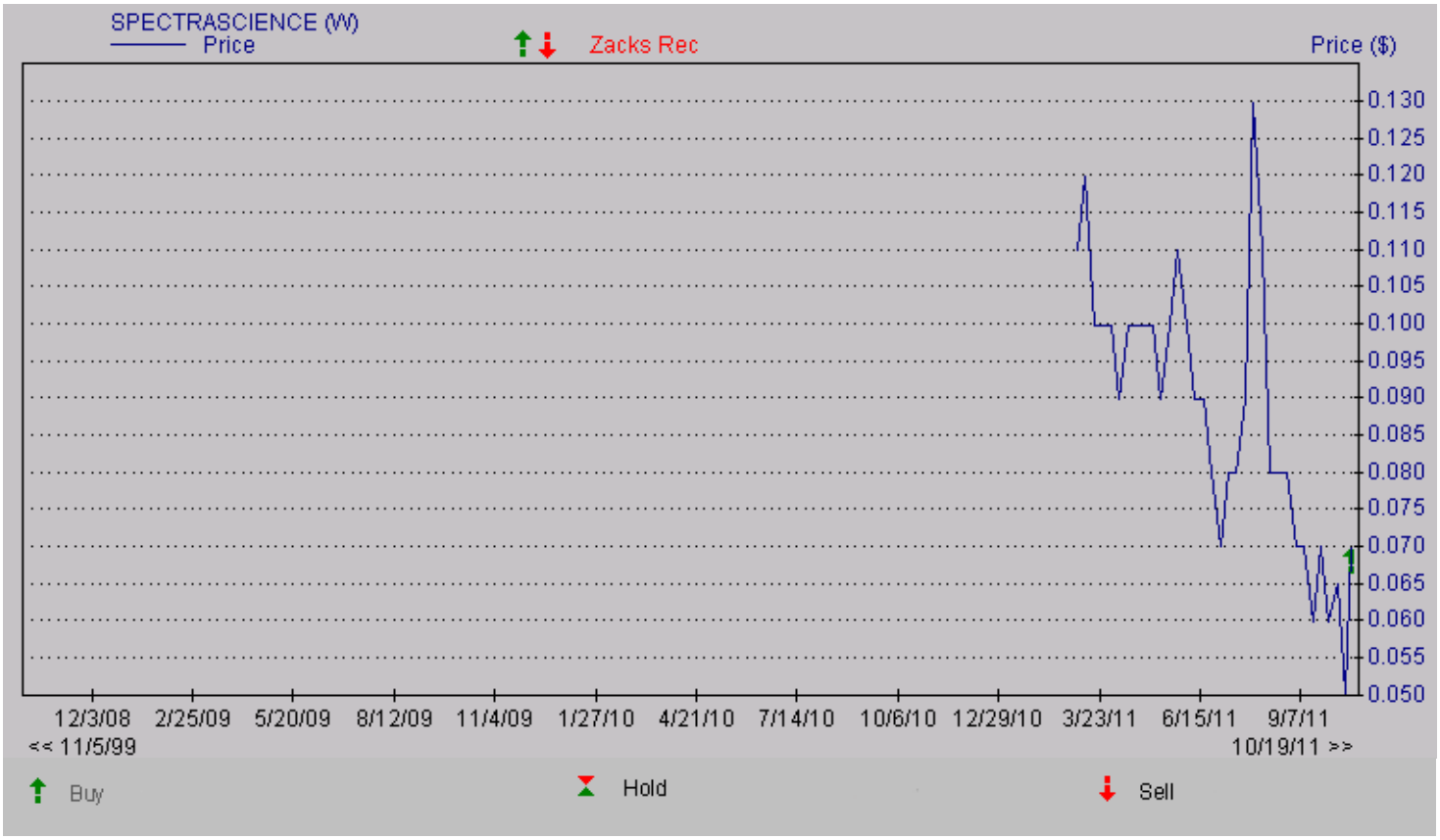
SpectraScience, Inc.

	2010 A	Q1A	Q2A	Q3E	Q4E	2011 E	2012 E	2013 E	2014 E
Revenue	$23.7	$0.0	$0.0	$0.0	$43.8	$43.8	$3,560.8	$15,424.2	$40,504.2
YOY Growth	*-85.8%*	-	-	-	*3407.2%*	*85.4%*	*8022.3%*	*333.2%*	*162.6%*
Cost of Goods Sold	$13.3	$0.0	$0.0	$0.0	$42.4	$42.4	$2,947.1	$9,842.7	$20,395.5
Gross Income	$10.4	$0.0	$0.0	$0.0	$1.4	$1.4	$613.7	$5,581.4	$20,108.6
Gross Margin	*43.9%*	-	-	-	*3.3%*	*3.3%*	*17.2%*	*36.2%*	*49.6%*
R&D	$2,065.6	$211.7	$288.6	$388.0	$551.0	$1,439.3	$2,626.0	$3,988.0	$7,845.0
% R&D	*8734.1%*	-	-	-	*1256.8%*	*3283.0%*	*73.7%*	*25.9%*	*19.4%*
G&A	$1,985.2	$547.1	$514.4	$481.0	$404.0	$1,946.5	$1,812.0	$2,100.0	$3,645.0
% G&A	*8394.0%*	-		-	*921.5%*	*4440.0%*	*50.9%*	*13.6%*	*9.0%*
Sales / Mktg	$417.3	$95.9	$158.6	$104.0	$113.0	$471.5	$845.0	$1,780.0	$3,600.0
% Sales / Mktg	*1764.5%*	-	-	-	*257.8%*	*1075.4%*	*23.7%*	*11.5%*	*8.9%*
Operating Income	($4,457.7)	($854.7)	($961.5)	($973.0)	($1,066.6)	($3,855.8)	($4,669.3)	($2,286.6)	$5,018.6
Operating Margin	*-18848.7%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-2432.8%*	*-8795.1%*	*-131.1%*	*-14.8%*	*12.4%*
Other expense, net	($359.1)	$0.2	($2.5)	($2.0)	($2.0)	($6.3)	$10.0	$100.0	$30.0
Pre-Tax Income	($4,098.6)	($854.8)	($959.1)	($971.0)	($1,064.6)	($3,849.5)	($4,679.3)	($2,386.6)	$4,988.6
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred dividends	$1,943.3	$0.0	$0.0	$0.0	$12.0	$12.0	$150.0	$100.0	$50.0
Net Income	($6,041.9)	($854.8)	($959.1)	($971.0)	($1,076.6)	($3,861.5)	($4,829.3)	($2,486.6)	$4,938.6
Net margin	-	-	-	-	-	-	-	-	*12.2%*
EPS	($0.07)	($0.01)	($0.01)	($0.01)	($0.01)	($0.04)	($0.04)	($0.02)	$0.03
YOY Growth	-	-	-	-	-	-	-	-	-
Diluted Shares O/S	92,447	108,019	108,041	108,050	108,070	108,045	128,000	130,000	170,000

Brian Marckx, CFA

© Copyright 2011, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Investment Research ("ZIR") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks SCR uses the following rating system for the securities it covers. Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution of Zacks Ratings is as follows on the 1035 companies covered: Buy/Outperform- 15.6%, Hold/Neutral- 77.3%, Sell/Underperform – 6.2%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2011, Zacks Investment Research. All Rights Reserved.