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SpectraScience (SCIE-OTC)

SCIE: Initial Roll-Out Taking Longer. Long-Term Outlook Still Intact

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	11/21/2012
Current Price (11/21/12)	$0.09
Target Price	**$0.15**

OUTLOOK

While we believe the various headwinds that SCIE has experienced during the initial roll-out will dissipate over time and the awareness-building and more focused sales efforts will eventually bear fruit, we think it's now clear that the runway to building the initial installed console base (which will then be fed the high-margin consumables) will be longer than previously anticipated. Our updated assumptions following Q3 2012 results largely reflects an approximate one-year extension (i.e.- delay) to the initial roll-out and related number of system placements. Important to note is that while this update to our model pushes back our estimated ramp in revenue, number of installed units and related volume of consumable sales by about one year, it does not change our fundamental outlook of the business, view of the viability of the revenue model, or expectations for the long-term opportunity of WavSTAT. This also assumes, of course, that SCIE continues to be successful in raising additional operating capital. Changes to our model have moved our price target from $0.30/share to $0.15/share and contributed to our rec moving from Outperform to Neutral. Our price target and recommendation are again subject to change which could be largely dependent on how revenue ramps and success in raising additional operating capital and shoring up the balance sheet.

SUMMARY DATA

52-Week High	**$0.24**
52-Week Low	**$0.04**
One-Year Return (%)	**N/A**
Beta	**1.28**
Average Daily Volume (sh)	**69,121**
Shares Outstanding (mil)	**108**
Market Capitalization ($mil)	**$13**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**4**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	$0 A	$0 A	$0 A	$27 A	$27 A
2012	$0 A	$310 A	$150 A	$270 E	$774 E
2013					$2,992 E
2014					$11,903 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.01 A	-$0.01 A	-$0.01 A	-$0.02 A	-$0.04 A
2012	-$0.03 A	-$0.05 A	-$0.01 A	-$0.01 E	-$0.09 E
2013					-$0.03 E
2014					-$0.02 E

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

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WHAT'S NEW....

Q3 10-Q / Conference Call

SpectraScience filed their 10-Q for the third quarter ending 9/30/2012 and held an investor call. Revenue came in well below our estimate. Despite SCIE's continued hard work behind the scenes which includes training the Pentax sales force and technical staff, increased awareness-building efforts via attendance at several key industry conferences, and their own sales and marketing efforts, revenue has yet to gain much traction. Management indicated that at least of a couple of issues have been a headwind - most notable of which may be that there is not yet an appropriate incentive structure in place for the Pentax reps relative to WavSTAT. This is expected to change - initially with SCIE offering sales incentives (which are to begin immediately) to the Pentax reps and then beginning in April 2013 (the start of Pentax's fiscal/budget year) SCIE may be able to roll these incentives back as Pentax will implement sales quotas for WavSTAT. Some of the other hindrances that management pointed to or at least appear to be factors and which are hopefully similarly short-lived, is that SCIE has been somewhat constrained in committing financial resources to headcount/projects that may further facilitate sales and the typical seasonal slowdown in Europe during the summer months.

While we believe the various headwinds will dissipate over time and the awareness-building and more focused sales efforts will eventually bear fruit, we think it's now clear that the runway to building the initial installed console base (which will then be fed the high-margin consumables) will be longer than previously anticipated. These updated assumptions are reflected in the changes to our financial model which largely reflects an approximate one-year extension (i.e.- delay) to the initial roll-out and related number of system placements. Important to note is that while this update to our model pushes back our estimated ramp in revenue, number of installed units and related volume of consumable sales by about one year, it does not change our fundamental outlook of the business, view of the viability of the revenue model, or expectations for the long-term opportunity of WavSTAT. This also assumes, of course, that SCIE continues to be successful in raising additional operating capital.

Q3 Results

Q3 revenue came in at $151k, down from $311k (-51%) in Q2 and about 55% less than our $332k estimate. While the revenue number was an obvious disappointment, a silver lining is that SCIE indicated these were largely not inventory stocking orders but instead related to end-use demand.

The other positive highlights were gross margin holding up strongly (48%) despite the relatively soft revenue and management continuing to do a good job in keeping a lid on operating expenses ($880k A vs. $1.3 million E) as well as cash burn. The significantly better GM (48% A vs. 16% E) and lower than estimated operating expenses resulted in operating income coming in substantially better than our estimate (-$807k A vs. -$1.3 million E), again despite the miss on revenue.

Net loss and EPS, which benefitted from $1.2 million in non-cash income related to the change in fair value of derivatives (which we don't model given its non-cash nature and required guesswork to do so), were $866k and ($0.01) versus our $2.5 million and ($0.02) estimates.

Cash

SpectraScience exited Q3 with $65k in cash and equivalents, down from $185k at the end of Q2. Cash used in operations in Q3 was $474k, down from $820k in Q2 and $1.1 million in Q1. During Q3 SCIE sold another $480k of convertible debt and $1.6 million in convertible debt and accrued interest was converted to equity. At the end of Q3 $1.4 million of convertible debt remained outstanding. About $884k of this debt was in default as of 9/30/2012 and the remaining will be due within 6 months from 9/30/2012. Management continues to look at financing alternatives and remains in discussions with investment banks to raise additional capital - while we feel confident that SCIE can raise additional operating capital, we also believe that they are attempting to do so in a way that reduces reliance on regular piecemeal raises. Nonetheless, the debt default is a concern (although this debt is convertible to equity at the holder's option) as is the meager cash balance.

BUSINESS

SpectraScience, Inc (SCIE) 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 made its debut in Europe at the 19th annual United European Gastroenterology Week in Stockholm, Sweden in October 2011 and launched near year-end. In June 2012 SpectraScience entered into an agreement with Pentax Europe GmbH, a European subsidiary of Tokyo-based optical giant Hoya Corporation, for a five year deal to be the exclusive distributor of WavSTAT for colon cancer in Europe as well as parts of the Middle East and Africa. In total, the distribution agreement covers 23 countries. 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 (including those sold by Pentax), 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.

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:

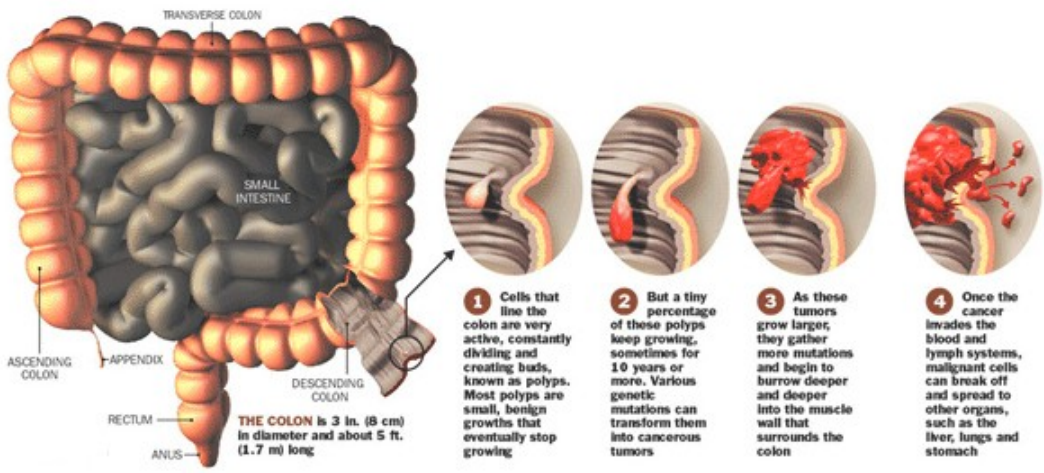
- **Early Detection is Key:** Treatment of colon cancer is most effective when the disease is discovered at an early stage. Regular screening is advised in order to increase the chances of finding and removing polyps before the become cancerous.
    - Over 90% of people diagnosed when the cancer is found 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

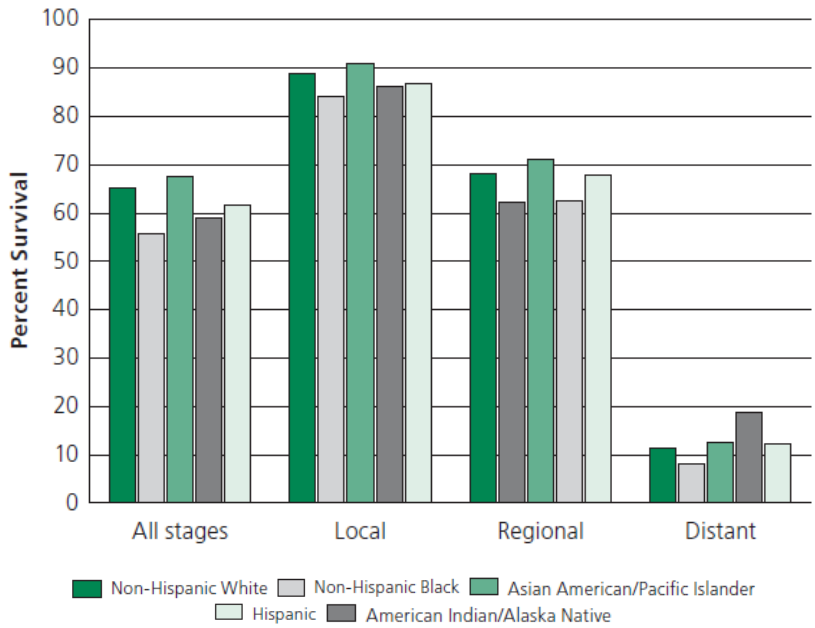
- Although the overall incidence rate of colon cancer has been declining, as has the rates in people 50 years of age and older, the incidence rate for those younger than 50 has actually been on the rise
- Despite a decline in the overall incidence of colon cancer, colon cancer screening is expected to 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.

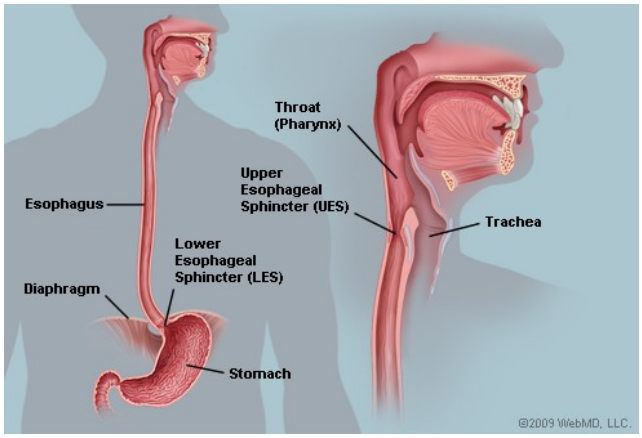
- **Flexible sigmoidoscopy:** similar to colonoscopy except sigmoidoscopy looks at only the rectum and lower part (~ final 2 feet) of the colon. It is generally recommended once every 5 years beginning at the age of 50 as a screening procedure. If suspicious areas are identified, a colonoscopy is typically 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

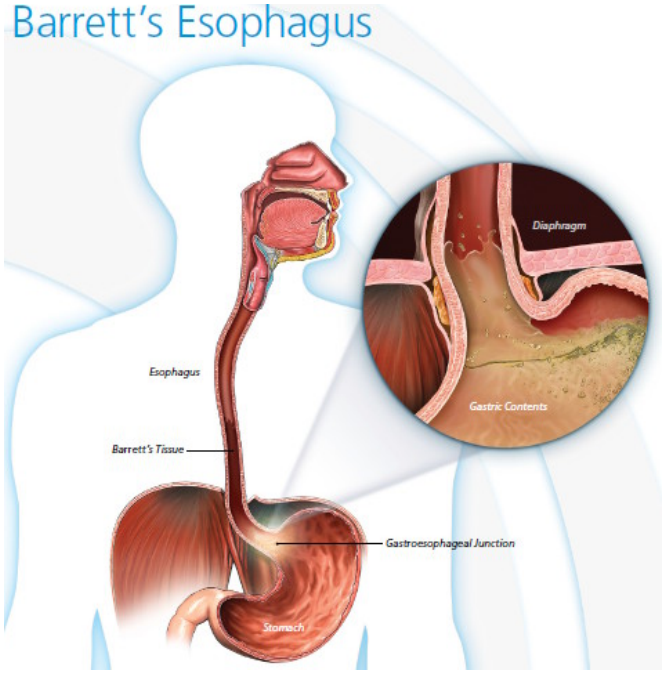
Esophageal cancer, especially in later stages, is often deadly as larger tumors tend not to be operable. Unfortunately, most people diagnosed with esophageal cancer are already in late stages of the disease as symptoms (i.e. - difficult and / or painful swallowing, hoarse coughing, coughing up blood) 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.



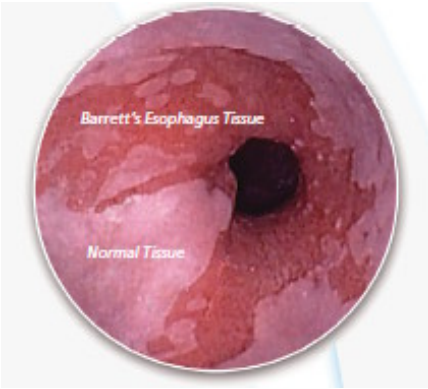
SOURCE: http://www.umcarizona.org/workfiles/gi/Barretts_Brochure.pdf

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



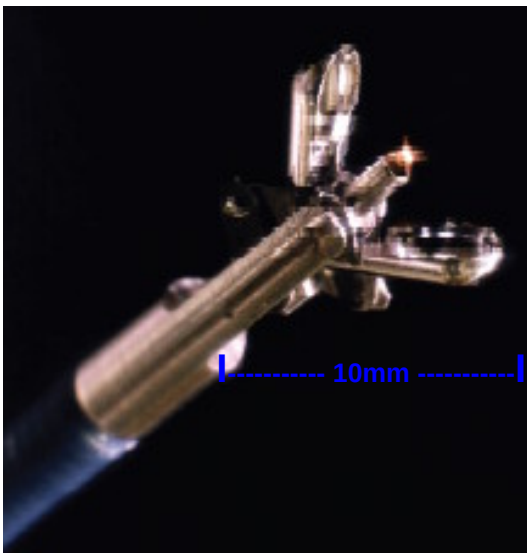
SOURCE: http://www.umcarizona.org/workfiles/gi/Barretts_Brochure.pdf

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.

PENTAX Distribution Deal Could Be A Big Win For SCIE….

In June 2012 they finalized an agreement with Pentax Europe GmbH, a European subsidiary of Tokyo-based optical giant Hoya Corporation, for a five year deal to be the exclusive distributor of WavSTAT for colon cancer in Europe as well as parts of the Middle East and Africa. In total, the distribution agreement covers 23 countries.

The agreement, which includes minimum annual purchase quotas of the WavSTAT instrument and forceps in each of the designated countries, provides that SCIE will sell WavSTAT and the forceps to Pentax for $30k per device and $825 per five-pack, respectively. Details of the minimum purchase agreement are confidential.

Pentax, through its Pentax Medical division, is one of the largest and most respected worldwide providers of gastroenterology devices including a variety of gastroscopes, colonoscopes, endoscopes, sigmoidoscopes and confocal laser microscopes. While (as we noted in our initiation report on SCIE) Pentax is considered a direct competitor to SpectraScience, they offer a leading line of cutting edge endoscopes which are compatible with SpectraScience's forceps which provides Pentax with a potentially valuable and appealing extension to their product portfolio. It also helps to further differentiate and expand their product offerings relative to major competitors including the likes of Olympus, Mauna Kea, and Fujinon. Pentax brings a very substantial distribution reach and potentially very valuable customer contacts and relationships that dwarf SpectraScience's current capabilities. And with initial expected gross margins on sales of the forceps to Pentax at around a healthy 40+% (and expected to grow with higher production), this deal with Pentax appears like it could be a big win for SCIE (and a nice addition to Pentax).

WavSTAT for the colon cancer application is already included in Pentax's trade show and industry conference marketing materials in Europe. It was also included in Pentax's booth at the United European Gastroenterology Week in Amsterdam in October.

SpectraScience/Pentax's current game plan is to initially roll out WavSTAT4 in Europe (via medical device distributors), the Middle East, and Africa 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%.

WavSTAT continues to be used in clinical studies. SpectraScience and Pentax will also be working together during the initial roll-out to demonstrate the efficacy and utility of WavSTAT in colon cancer to prospective customers.

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

OUTLOOK

Our Outlook is based on a number of assumptions and estimates which were gleaned through discussions with management, our own research and recent and ongoing developments. 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.

Our updated assumed timelines following Q3 2012 results had the effect of adding an approximate one-year extension (i.e.- delay) compared to our previous forecast to the initial roll-out and related number of WavSTAT system placements. Important to note is that while this update to our model pushes back our estimated ramp in revenue, number of installed units and related volume of consumable sales by about one year, it does not change our fundamental outlook of the business, view of the viability of the revenue model, or expectations for the long-term opportunity of WavSTAT.

Our near-to-mid term revenue and EPS estimates have materially changed, however. We now look for revenue of $3.0 million in 2013 growing to $30.4 million in 2015, changed from $10.1 million in 2013 to $56.4 million prior to our update. Our EPS estimates have moved to ($0.03) in 2013 and $0.01 in 2015 from ($0.03) in 2013 and $0.04 in 2015 (2013 EPS estimate did not change in part to also increasing the assumed share count).

OUR KEY ASSUMPTIONS

- **Additional Capital:** SpectraScience has been successful in raising capital as needed. We assume they continue to do so and are able to raise sufficient capital in order to continue to fund the roll out WavSTAT4 and get them the point of cash flow positive
- **Distribution:** with Pentax now onboard, OUS distribution is now in place - this was a very important and significant milestone for SCIE to hit. We assume U.S. sales / marketing (when eventually launched in the U.S.) is handled by third party distributor(s).
- **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:** commenced in Q4 2011 for colon indication. Assume begin detailing for esophageal some time in 2014. Bladder and lung indications in later years
- **U.S. Launch:** regulatory approvals via supplement to original PMA (software changes/updates currently ongoing) Assume U.S. launch commences in 2014 or 2015 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 falls with Pentax which has significant experience in international markets. 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

VALUATION

We continue to value SCIE using a comparable group consisting 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-2015 estimated sales, and price-to-2015 estimated EPS.

Based on these three metrics, SpectraScience is valued between $0.00/share and $0.29/share. Average valuation based of the three metrics is $0.13/share - which we round up to $0.15/share. We are moving our price target from $0.30 to $0.15 which reflects our updated timelines following Q3 2012 results which had the effect of adding an approximate one-year extension (i.e.- delay) to the initial roll-out and related number of WavSTAT system placements. This resulted in meaningful changes to our estimated near-to-mid term revenue and EPS estimates.

We are also moving our recommendation from Outperform to Neutral, reflecting our updated price target and additional risk from increasing stress to the balance sheet as a result of the diminished cash balance and current non-performing outstanding debt. Our price target and recommendation are again subject to change which could be largely dependent on how revenue ramps and success in raising additional operating capital and shoring up the balance sheet.

Ticker	Price/Book	Price/2015 Sales	Price/2015 EPS
GIVN	2.6	2.1	12.2
MELA	4.3	1.4	13.3
VRS.V	4.4	0.5	3.1
BCR	4.2	2.3	11.8
CNMD	1.3	0.9	12.1
Average	**3.4**	**1.4**	**10.5**

VALUATION BASED ON:				
	Price/Book	**Price/2015 Sales**	**Price/2015 EPS**	**AVG**
SCIE	$0.00	$0.29	$0.11	**$0.13**

FINANCIAL MODEL

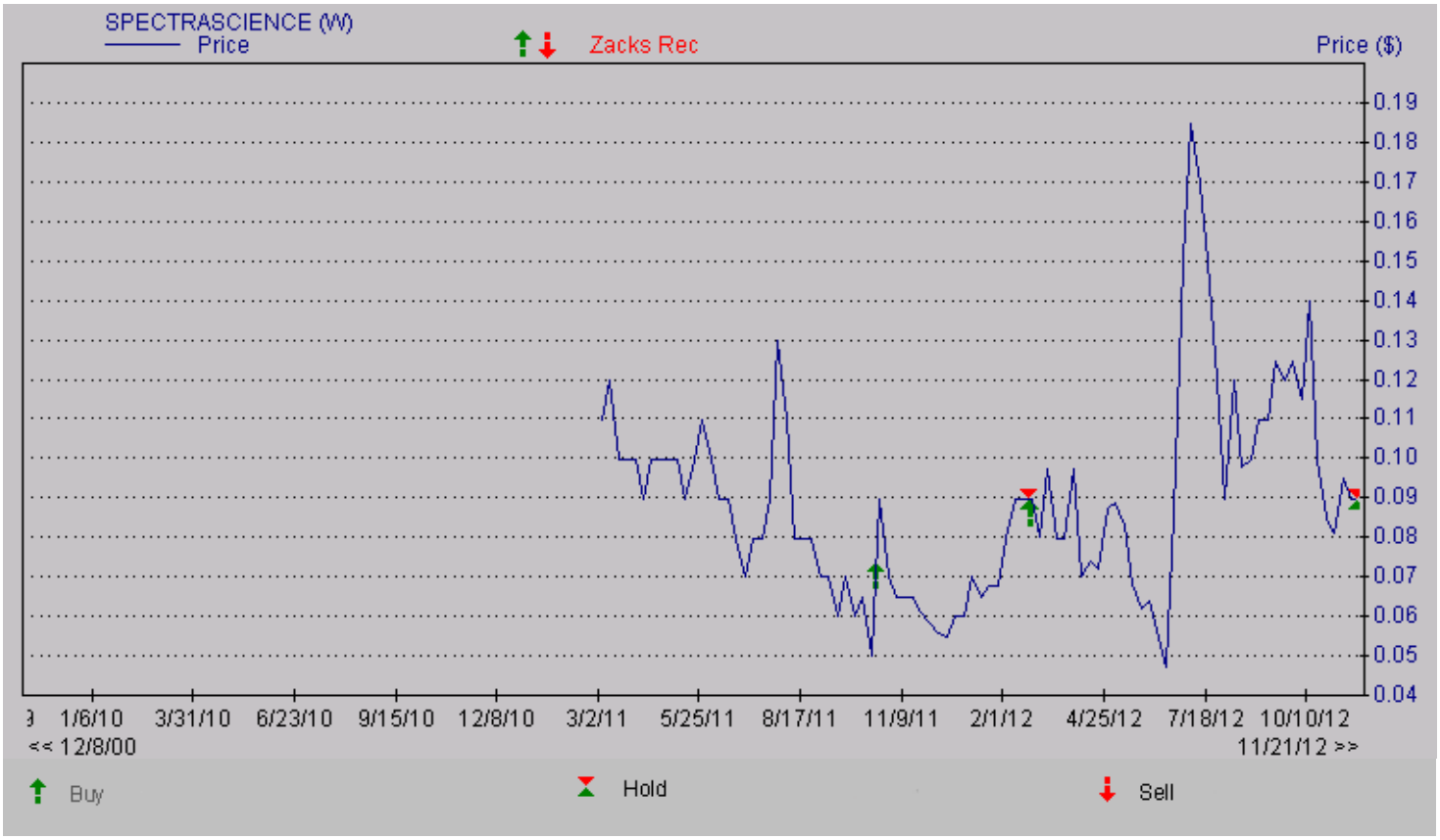
SpectraScience, Inc.

	2011 A	Q1A	Q2A	Q3A	Q4E	2012 E	2013 E	2014 E	2015 E
Revenue	$26.7	$0.0	$310.1	$150.8	$270.0	$730.9	$2,992.3	$11,903.4	$30,398.0
YOY Growth	*13.0%*	*#DIV/0!*	*-*	*-*	*909.9%*	*2633.8%*	*309.4%*	*297.8%*	*155.4%*
Cost of Goods Sold	$37.5	$0.0	$200.3	$77.9	$165.0	$443.2	$1,736.3	$6,073.4	$14,835.0
Gross Income	$10.7	$0.0	$109.8	$72.8	$105.0	$287.6	$1,256.0	$5,830.0	$15,563.0
Gross Margin	*-40.1%*	*#DIV/0!*	*35.4%*	*48.3%*	*38.9%*	*39.4%*	*42.0%*	*49.0%*	*51.2%*
R&D	$1,678.8	$380.3	$289.4	$236.0	$255.0	$1,160.7	$1,444.0	$3,822.0	$6,875.0
% R&D	*6279.4%*	*#DIV/0!*	*93.3%*	*156.5%*	*94.4%*	*158.8%*	*48.3%*	*32.1%*	*22.6%*
G&A	$2,509.3	$547.6	$652.8	$536.7	$704.0	$2,441.1	$2,587.0	$2,724.0	$3,728.0
% G&A	*9385.9%*	*#DIV/0!*	*210.5%*	*356.0%*	*260.7%*	*334.0%*	*86.5%*	*22.9%*	*12.3%*
Sales / Mktg	$568.8	$108.7	$132.1	$107.2	$124.0	$471.9	$721.0	$2,045.0	$3,695.0
% Sales / Mktg	*2127.4%*	*#DIV/0!*	*42.6%*	*71.1%*	*45.9%*	*64.6%*	*24.1%*	*17.2%*	*12.2%*
Operating Income	($4,767.6)	($1,036.6)	($964.4)	($807.0)	($978.0)	($3,786.0)	($3,496.0)	($2,761.0)	$1,265.0
Operating Margin	*-17832.8%*	*#DIV/0!*	*-311.0%*	*-535.3%*	*-362.2%*	*-518.0%*	*-116.8%*	*-23.2%*	*4.2%*
Other expense, net	($5.4)	$2,115.3	$4,563.5	$58.5	$1,194.0	$7,931.3	$1,341.0	$689.0	$128.0
Pre-Tax Income	($4,762.2)	($3,152.0)	($5,527.9)	($865.5)	($2,172.0)	($11,717.4)	($4,837.0)	($3,450.0)	$1,137.0
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	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($4,762.2)	($3,152.0)	($5,527.9)	($865.5)	($2,172.0)	($11,717.4)	($4,837.0)	($3,450.0)	$1,137.0
Net margin	*-*					*-*	*-*	*-29.0%*	*3.7%*
EPS	($0.04)	($0.03)	($0.05)	($0.01)	($0.01)	($0.09)	($0.03)	($0.02)	$0.01
YOY Growth	*-*					*-*	*-*	*-*	*-*
Diluted Shares O/S	108,034	108,041	108,041	117,153	169,000	125,559	190,000	218,000	227,000

Brian Marckx, CFA

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HISTORICAL ZACKS RECOMMENDATIONS



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