SpectraScience
INNOVATIONS IN CANCER DETECTION

SpectraScience, Inc.
11568 Sorrento Valley Road, Suite 11
San Diego, CA 92121
Telephone: (858) 847-0200
Fax: (858) 847-0880
www.spectrascience.com/

Ticker (Exchange)	SCIE (OTC)
Recent Price (08/05/2015)	$0.02
52-week Range	$0.01 – $0.05
Shares Outstanding	~196.8 million
Market Capitalization	~$3.9 million
Average 3-month Volume	73,656
Insider Ownership +>5%	8.2%
Institutional Ownership*	0.36%
EPS (Qtr. ended 3/31/2015)	($0.01)
Employees	9

*Source: S&P Capital IQ

SCIE One-Year Stock Chart

The WavSTAT® Optical Biopsy System

Company Description

SpectraScience, Inc. ("SpectraScience" or "the Company") is commercializing advanced, minimally invasive diagnostic products using light-based technologies that improve a physician's ability to diagnose cancer while lowering the cost of diagnosis. The Company's lead platform—the WavSTAT® Optical Biopsy System—is in the final stages of a multicenter, 1,200-patient European study and is poised to commence sales in Europe and potentially Saudi Arabia in 2016. The current WavSTAT4 product is initially targeted to the colorectal cancer screening market where recent **colonoscopy†** guidelines have created opportunities for new, improved diagnostic technologies. SpectraScience is further evaluating the potential of its technology in an array of additional indications and using a combination of next-generation, light-based technologies.

Key Points

- Up to 80% of colorectal biopsies performed are estimated to be identified as normal, non-cancerous tissue. Replacing these invasive physical biopsies with an optical biopsy, as WavSTAT4 does, reduces risks to patients and may lead to a healthcare cost savings of over $1 billion in the U.S. alone.
- WavSTAT4 has been designed for ease of integration into the current standard of care. It entails essentially the same process as how physicians screen for cancer today, and is compatible with existing **endoscopes**. SpectraScience merely adds a layer of diagnostic interpretation and confidence by notifying physicians that, at a particular tissue location, they do not need to take a physical biopsy that they otherwise might have performed.
- Tissue that WavSTAT4 finds to be precancerous or cancerous returns a red "suspect" icon. Unlike the traditional method of visual inspection, there is no ambiguity to the result and no need for physician interpretation.
- SpectraScience's patent portfolio in the field of optical methods to detect cancer, cancer precursors, and tissue abnormalities includes 34 U.S. utility patents, seven U.S. design patents, 25 foreign counterpart patents, and an exclusive license to the Massachusetts General Hospital's optical forceps patent.
- The Company's leadership has extensive experience in the medical device industry, specifically in the areas of strategic management, engineering, manufacturing, global sales, and marketing.
- SpectraScience had a cash position of $69,955 at March 31, 2015, and inventory valued at $283,883.

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Executive Overview

SpectraScience, Inc. ("SpectraScience" or "the Company") is advancing a novel technology toward commercialization that has shown to improve physicians' diagnostic capabilities in an array of indications, while lowering the cost of diagnosis and minimizing the number of invasive biopsies performed on patients. The Company's lead product platform is called the WavSTAT4 Optical Biopsy System, which holds a **CE Mark** in the European Union for use in detection of all cancer types as well as has received regulatory approval in Saudi Arabia. An earlier version of the technology platform was cleared for sale in the U.S. as a medical device to aid in endoscopic screening of the colon (a technique for identifying colorectal cancer and precancerous conditions). Upon making significant enhancements to the product's software and user interface, SpectraScience anticipates filing an updated **Premarket Approval (PMA)** application in the U.S.

A clinical validation study of WavSTAT4 is currently ongoing at hospitals and clinics in countries across Europe, including the UK, Italy, Germany, France, Sweden, Denmark, the Czech Republic, Poland, and Belgium. This trial has enrolled approximately 1,200 patients, and data collection is expected to be complete in the third quarter 2015. Data from the study is hoped to replicate earlier clinical findings of WavSTAT4's diagnostic abilities—which included a favorable **negative predictive value (NPV)** of 96%—as well as demonstrate WavSTAT4's economic benefits and value as part of the standard of care for routine endoscopies to key opinion leaders and physicians throughout Europe.

Subsequent to the end of the trial, SpectraScience intends to begin commercializing its WavSTAT4 platform initially in the UK, Germany, and Saudi Arabia. The Company has already purchased inventory sufficient to fulfill initial orders and maintains a non-exclusive distribution agreement with PENTAX Europe GmBH for the sale of WavSTAT4 in international markets. Product manufacturing occurs at both SpectraScience's California headquarters as well as through U.S. OEMs, with final assembly performed by SpectraScience. The Company reports that the FDA has reviewed its manufacturing processes and Standard Operating Procedures and that SpectraScience is authorized to manufacture the equipment in its current facility, which holds **ISO 9001** and other global quality certifications (Source: SpectraScience's Form 10K filed with the U.S. Securities and Exchange Commission [SEC] on March 20, 2015).

SpectraScience's initial target application of WavSTAT4 is the colorectal cancer screening market, for which the device has been designed to overcome limitations in current screening methods. Clinical results have further suggested potential for WavSTAT4 in bladder cancer as well as in other oncology indications. SpectraScience in particular views the esophageal screening market as an additional opportunity, as endoscopes are the typical diagnostic tool of choice for both colorectal and esophageal screening.

The WavSTAT® Optical Biopsy System in Colorectal Cancer Screening

SpectraScience's WavSTAT4 platform applies an established light-based technology, called laser-induced **fluorescence** (LIF) **spectroscopy**, for the differentiation of normal, precancerous, or cancerous tissues in the lower gastrointestinal (GI) tract. In doing so, the technology enables the real-time diagnosis of precancerous colon **polyps** (≤5 mm) during colonoscopy, without requiring that the physician physically biopsy the abnormal tissue and send it to a pathology laboratory for analysis. WavSTAT4's algorithm is capable of performing pathologic analysis onboard the system and displaying immediate results for physicians on screen as they move the endoscope over the suspect colorectal tissue. LIF has been validated in literature as a successful diagnostic technique for detecting colorectal and lung cancers as well as characterizing dermal lesions and atherosclerotic plaque, and has been noted for its high **specificity** and **sensitivity** for discriminating between **dysplasia** and healthy (no dysplasia) tissue (Source: *Zeitschrift für Medizinische Physik*, February 2012, 22(1):40–47). A complete explanation of how LIF spectroscopy functions begins on page 19.

The real benefit of WavSTAT4 stems from aiding physicians' own visual determinations of whether a diminutive polyp (under 5 mm) should be removed from a patient or not. Large polyps are removed as a matter of standard practice, as the larger the polyp, the greater the risk of its becoming cancerous. However, the smaller polyps are found in approximately half of adults undergoing colorectal screening (Source: *Gastrointestinal Endoscopy*, 2011, 73(3):419–421); yet macroscopic differentiation between a hyperplastic (benign) and an adenomatous (precancerous) polyp during colonoscopy is notably difficult (Source: the UK's National Institute for Health Research [NIHR] Horizon Scanning Centre, University of Birmingham, *Technology Alert*, February 2015). Diminutive polyps are very rarely malignant (Source: *Gastroenterology Hepatology*, 2012, 8(2): 128–130), and it has been estimated that pathologists find up to 80% of tissue removed during colonoscopies to be just normal tissue.

As a result, the standard of care for colonoscopies has recently been revised to account for the benefits of *not* removing every diminutive polyp observed in the colon or rectum. The American Society for Gastrointestinal Endoscopy's (ASGE) most recent Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) guidelines for colorectal cancer screening now state that polyps under 5 mm in size that are believed to be hyperplastic (normal tissue) can be left in the patient and do not need to be removed if the diagnostic technology in use provides a greater than 90% negative predictive value (NPV) when used with high confidence for adenomatous histology (Source: *Gastrointestinal Endoscopy*, 2011, 73(3):419–421). Importantly, a study of WavSTAT4 conducted by Dr. Helmut Neumann, a professor of molecular endoscopy and interventional endoscopy, and a specialist in internal medicine and gastroenterology at the Department of Medicine at Germany's University of Erlangen-Nuremberg, found that adding SpectraScience's technology to the screening colonoscopy procedure could increase the colonoscopy's NPV to 96%—well above the 90% NPV threshold recommended under PIVI guidelines (Source: *Gastrointestinal Endoscopy*, 2013, 77(5S):AB463). Similar data showing a 95.4% NPV in diminutive colorectal polyps (and up to an NPV of 98% in distal colorectal diminutive polyps) was presented at Digestive Disease Week (http://www.ddw.org/) held in Washington, D.C. during May 2015 (Source: *Gastrointestinal Endoscopy*, May 2015, Vol. 81, Issue 5, Supplement, Page AB158).

Impacts and Opportunities

A study published in *Endoscopy* in 2011 found that being able to avoid performing pathologic laboratory assessment on diminutive polyps would lead to a savings in healthcare costs of over $1 billion in the U.S. alone (Source: *Endoscopy*, 2011, 43(8):683-91). It would further alleviate strain on overburdened pathologists by removing the normal colorectal tissue from the queue and ensuring that the tissue examined by pathologists is truly tissue of consequence, in that it is likely to be precancerous or cancerous. Moreover, physical biopsies present known risks to patients of bleeding and **perforation**, which could be reduced by minimizing unnecessary biopsies.

Thus, WavSTAT4 may have an important position in the colorectal cancer screening market, as well as in screening for esophageal and bladder cancers, going forward. (The Company's recent data in bladder cancer is presented on page 23 and opportunity in esophageal cancer is on pages 26-27.)

The preferred method of screening for colorectal cancer today is a colonoscopy (Source: *American Journal of Gastroenterology* 2009; 104:739–750), which the U.S. Preventive Services Task Force (USPSTF) as well as many European agencies recommend that every adult between the ages of 50 and 75 undergo at least every 10 years. Colonoscopies may be more frequent for patients displaying risk factors for colorectal cancer or who have previously been identified as having colorectal polyps or other dysplasia (abnormal tissue). Improving screening programs for colorectal cancer is an important initiative worldwide. In the U.S., where colorectal cancer is the third most common cancer but the second-leading cause of cancer-related death, the National Colorectal Cancer Roundtable (NCCR) has recently undertaken an initiative called "80% by 2018" aiming for screening rates of 80% of the at-risk population by 2018.

In Europe, colorectal cancer is the second most common cancer as well as the second-leading cause of cancer-related death. Due in part to insufficient screening processes, the mortality rate of colorectal cancer remains high globally, with this tumor type accounting for 8.5% of all cancer-related deaths worldwide. Without improvements to the screening and diagnostics processes, this figure will likely continue to increase, as colorectal tumors are far more prevalent in older adults (over age 50)—a population group that is dramatically increasing in number (Source: *World Population Ageing 2009* from the United Nations' Department of Economic and Social Affairs, Population Division). To this end, World Cancer Research Fund International predicts that there could be 2.4 million cases of colorectal cancer diagnosed annually worldwide by 2035—an increase of one million more patients each year over current rates.

Headquarters and Employees

SpectraScience, Inc. was incorporated in Minnesota in 1983 as GV Medical, Inc. The Company's name was formally changed to SpectraScience in October 1992. Today, the Company includes wholly owned subsidiaries Luma Imaging Corp., SpectraScience International, Inc., and SpectraScience (UK) Ltd. It trades as "SCIE" on the OTC.QB.

As of March 2015, SpectraScience had nine employees (five full-time and four part-time). Five individuals work in manufacturing and engineering, one in sales and marketing, and three in finance and administration, with SpectraScience utilizing outside consultants for other financial, regulatory, software development, and design engineering work as necessary.

Growth Strategy

SpectraScience's lead initiative at present is driving adoption of its WavSTAT4 Optical Biopsy System per the commercialization strategy outlined below.

(1) Market WavSTAT4 initially in the EU, followed by promotion to U.S. **managed care organizations**

- Targeting European markets first is intended to enable SpectraScience to accomplish the following: collect post-marketing data for U.S. regulatory purposes; maximize the technology's design flexibility before submitting a supplemental PMA to the U.S. FDA; and develop a rationale for U.S. reimbursement.

(2) Pursue global partners for further development of SpectraScience's diagnostic technologies in an array of indications, including those affecting the colon, esophagus, stomach and bowels, bladder, prostate, lungs, pancreas, brain, and lymph nodes

SpectraScience's pipeline of future applications for WavSTAT4, which includes its use in screening programs for additional tumor types beyond colorectal cancer and the Company's plan to capitalize on multiple light-based technologies in one diagnostic product, is detailed on pages 26-27.

Figure 1 describes the Company's strategies for continued expansion.

Figure 1

SPECTRASCIENCE'S GROWTH STRATEGIES OVER THE NEXT 12 MONTHS

▪	Market and sell the WavSTAT4 Optical Biopsy System colon cancer diagnostic application through an existing non-exclusive distribution agreement with PENTAX Europe GmbH and other distribution channels in the European Union
▪	Complete country-specific evaluation trials (ongoing) to demonstrate the effectiveness and cost benefit of WavSTAT4 in each relevant European jurisdiction
▪	Coordinate the creation and publication of scientific papers and presentations related to the country-specific evaluation trials to support widespread education and adoption of WavSTAT4
▪	Pursue the introduction of WavSTAT4 in other international markets, in particular China, Saudi Arabia, and India
▪	Begin meeting with the FDA toward the preparation and submission of a supplemental PMA filing with the FDA and plan for additional clinical trials to support eventual approval for sale in the U.S.
▪	Begin design and planning for the next generation of multi-modal fluorescence and broadband spectroscopy systems at the Company's facility in San Diego, California
▪	Continue to expand and refine the Company's intellectual property portfolio

Source: SpectraScience, Inc.

Financing

During 2014, SpectraScience raised approximately $2.4 million in funding, following the receipt of over $1.8 million in funding during 2013. As of March 31, 2015, the Company had a cash balance of approximately $69,955, and will have to raise additional cash to provide working capital to execute its present business plans. SpectraScience also continues to be funded on a short-term basis primarily by existing investors.

Milestones

Recent Milestones

SpectraScience has achieved several key milestones over the past year, as the Company has sought to educate global markets on the benefits of its WavSTAT® Optical Biopsy System as confirmed through clinical studies.

- Purchased inventory for approximately 30 WavSTAT4 consoles, which is anticipated to fulfill initial orders expected from the UK and Germany following the completion of current European trials

- Expanded the WavSTAT4's MORDIS study to include the St. James University Hospital in Leeds, England, as providing the UK's National Health Service (NHS) with clinical validation of WavSTAT4 will likely assist SpectraScience in driving UK adoption of its technology

    - Based on the evaluation of WavSTAT4 at St. James University Hospital in Leeds, England, the NHS's National Institute of Health Research (NIHR) published a *Technology Alert* in early 2015 informing the UK's NHS hospitals that the WavSTAT4 Optical Biopsy System was available. The *Alert* is available at the following link: http://www.hsc.nihr.ac.uk/topics/wavstat4-optical-biopsy-system-for-colorectal-canc/.

    - NHS clinical validation through the WavSTAT trial in the UK, which was conducted in collaboration with the Colorectal Therapies Healthcare Technology Co-operative (HTC) based at St. James Hospital, also enables SpectraScience to enter into the National Institute for Health and Clinical Excellence (NICE) MedTech evaluation program. NICE offers guidance on use of medical technology across the NHS.

- Received regulatory approval for WavSTAT4 in Saudi Arabia, a country believed to have a globally advanced medical delivery system with rapid adoption of technologies to improve care, increase patient safety, and lower costs

- Appointed Rand Mulford (biography on page 13) to the Company's Board of Directors

Potential Milestones

Over the coming 12-24 months, SpectraScience's primary goal is the creation of revenue, which may be facilitated by accomplishing the milestones listed below.

- Completing the data collection phase of the MORDIS evaluation in the late third quarter 2015 followed by data validation and statistical analysis, with the potential for publication by mid-2016

- Completing analysis of the MORDIS data and beginning to use the results to drive sales of WavSTAT4 in certain markets, including the UK and Germany, in early 2016

- Launching a sales campaign in Saudi Arabia in 2016

- Going forward, filing a supplemental PMA to allow the sale of the WavSTAT4 in the U.S.

Intellectual Property

SpectraScience believes that it holds among the largest patent portfolios of its kind in the field of optical methods for detecting cancer, cancer precursors, and tissue abnormalities, which functions as a significant barrier to entry for potential competitors. This includes 34 issued U.S. utility patents, seven U.S. design patents, and approximately 25 foreign counterpart patents, as well as an exclusive license to the Massachusetts General Hospital's U.S. patent for optical forceps (Patent #5,843,000: "Optical Biopsy Forceps and Method of Diagnosing Tissue").

In 2007, SpectraScience acquired LUMA Imaging Corp. LUMA had previously held FDA clearance for an optical, minimally-invasive diagnostic imaging system to detect cervical cancer precursors using a technology similar to the WavSTAT system. In the acquisition, SpectraScience obtained approximately 30 issued U.S. patents, certain foreign patents, and 28 patent applications. While the Company has opted to focus on its own development of WavSTAT, the patents and applications from LUMA may have utility in future generations of SpectraScience's platform and further provides the Company with a broad suite of fluorescence-based intellectual property and know-how.

In addition, SpectraScience holds registered trademarks to "WavSTAT" and "SpectraScience," protects its software and graphics through copyrights, and maintains confidentiality and invention assignment agreements that help to protect aspects of the Company's technologies that are trade secrets and proprietary know-how.

Figure 2 (page 9) summarizes SpectraScience's U.S. issued patent portfolio.

Figure 2

A SELECTION OF SPECTRASCIENCE'S INTELLECTUAL PROPERTY

Patent Name	U.S. Patent Number
Optical Biopsy Forceps	5,762,613
System for Diagnosing Tissue with Guidewire	5,601,087
Method of Diagnosing Tissue with Guidewire	5,439,000
Guidewire Catheter and Apparatus for Diagnostic Imaging	5,383,467
Optical Biopsy Forceps System and Method of Diagnosing Tissue	6,066,102
Optical Biopsy Forceps	6,129,683
Optical Biopsy System and Methods for Tissue Diagnosis	6,174,291
Optical Forceps System and Method of Diagnosing and Treating Tissue	6,394,964
Spectral Volume Microprobe Analysis of Materials	5,713,364
Spectral Volume Microprobe Arrays	6,104,945
Spectroscopic System Employing a Plurality of Data Types	6,385,484
Spectral Volume Microprobe Arrays	6,411,835
Systems and Methods for Optical Examination of Samples	6,411,838
Spectral Data Classification of Samples	6,421,553
Optical Methods and Systems for Rapid Screening of the Cervix	6,427,082
Substantially Monostatic, Substantially Confocal Optical Systems for Examination of Samples	6,760,613
Fluorescent Fiberoptic Probe for Tissue Health Discrimination and Method of Use Thereof	6,768,918
Method and Apparatus for Identifying Spectral Artifacts	6,818,903
Spectral Volume for Microprobe Arrays	6,826,422
System for Normalizing Spectra	6,839,661
Optical Probe Accessory Device for Use In-Vivo Diagnostic Procedures	6,847,490
Methods of Monitoring Effects of Chemical Agents on a Sample	6,902,935
Optimal Windows for Obtaining Optical Data for Characterization of Tissue Samples	6,933,154
Methods and Apparatus for Displaying Diagnostic Data	7,136,518
Colonic Polyp Discrimination by Tissue Florescence and Fiberoptic Probe	7,103,401
Optical Methods and Systems for Rapid Screening of the Cervix	7,127,282
Methods and Systems for Correcting Image Misalignment	7,187,810
Image Processing using Measures of Similarity	7,260,248
Methods and Apparatus for Processing Spectral Data for use in Tissue Characterization	7,282,723
Methods and Apparatus for Characterization of Tissue Samples	7,309,867
Fluorescent Fiberoptic Probe for Tissue Health Discrimination	7,310,547
Methods and Systems for Correcting Image Misalignment	7,406,215
Methods and Apparatus for Calibrating Spectral Data	7,459,696
Unique Methods and Apparatus for Evaluation of Image Focus	7,469,160

Source: SpectraScience, Inc.'s Form 10-K filed with the SEC on June 27, 2014.

Company Leadership

Executive Management

Figure 3 summarizes the Company's executive leadership, followed by brief biographies.

Figure 3
EXECUTIVE MANAGEMENT

Michael P. Oliver	President, Chief Executive Officer (CEO), and Director
Lowell Giffhorn, CPA	Chief Financial Officer (CFO)
Hughes Wielemans	Director of Business Development – Europe
Mike Brady	Director of Engineering
Todd Pinkowski	Director of Operations

Source: SpectraScience, Inc.

Michael P. Oliver, President, Chief Executive Officer (CEO), and Director

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 an M.S.A. from George Washington University and a B.S. from the U.S. Naval Academy.

Lowell Giffhorn, CPA, Chief Financial Officer (CFO)

Mr. Giffhorn joined SpectraScience in September 2013. He brings to the Company more than 20 years of senior management experience in finance, operations, planning, and strategic planning. Prior to joining SpectraScience, Mr. Giffhorn was CFO of Patriot Scientific Corp. (PTSC-OTC) and Sym-Tek Systems. He was instrumental in helping to raise more than $20 million in public equity. Mr. Giffhorn practiced as a Certified Public Accountant (CPA) with Arthur Young (Ernst & Young) and holds an MBA and a B.S. in accounting from the University of Illinois.

Hughes Wielemans, Director of Business Development – Europe

Mr. Wielemans has over 20 years of experience in sales, marketing, and management while working for multinational medical device companies and distributors in Europe. Most recently, he was the director of sales and marketing for USGI Medical, Ltd. in Europe. Prior to this, he was the country manager for Bariatric Solutions Gmbh in Belgium. Mr. Wielemans spent three years as the director of sales and marketing for Covidien Belgium (acquired by Medtronic plc [MDT-NYSE]). Before this, he worked as European product director and manager for six years with Tyco Healthcare. Mr. Wielemans attended the Institut Catholique des Hautes Etudes Commerciales, Brussels, Sciences Economiques.

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 13 years at medical device manufacturer Mallinckrodt/Nellcor Puritan Bennett, where he was a senior project manager/principal electronic engineer. Mr. Brady holds a B.S.E.E. 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, Mr. Pinkowski spent nine years with ResMed Inc. (RMD-NYSE) as senior manager of technical service and manufacturing. Before this, he spent 14 years as a senior production supervisor with Infrasonics/Nellcor Puritan Bennett. Mr. Pinkowski began his career as an Aircraft Armament Systems Specialist with the U.S. Air Force.

Board of Directors

The Board of Directors oversees the conduct of and supervises the Company's management. Figure 4 provides a summary of Board members, followed by detailed biographies.

Figure 4
BOARD OF DIRECTORS

Michael P. Oliver	President, Chief Executive Officer (CEO), and Director
Mark McWilliams	Chairman of the Board
Sheldon L. Miller	Director
Stanley Pappelbaum, M.D.	Director
F. Duwaine Townsen	Director
Rand Mulford	Director

Source: SpectraScience, Inc.

Michael P. Oliver, President, Chief Executive Officer (CEO), and Director

Biography on page 10.

Mark McWilliams, Chairman of the Board

Since June 2007, Mr. McWilliams has served as the CEO of Medipacs, Inc., a development-stage infusion pump company. From December 2003 to November 2005, Mr. McWilliams was director of cell imaging and analysis at Beckman Coulter after the sale of Q3DM to Beckman in December 2003. He was president, CEO, and director of Q3DM, a life sciences startup that raised several angel and venture capital funding rounds, from October 2001 to December 2003. Previously, he was founder and COO of Medication Delivery Devices (MDD), an alternate care infusion systems company that was acquired by Baxter Healthcare in 1996. Mr. McWilliams served as a vice president of R&D at Baxter Healthcare for three years following the sale of MDD. Prior to MDD, he served as product development manager at the founding of Block Medical, where he was responsible for bringing the company's first two FDA-approved products rapidly to market. Block was sold to Hillenbrand Industries in 1991. He previously worked for Hughes Aircraft, Vacuum General, and Martin Marietta. Mr. McWilliams brings his expertise in managing and growing small technology companies and his strong network of contacts within the medical devices industry to the Board of Directors. He earned an M.S.M.E. from the Massachusetts Institute of Technology, a B.S.M.E. from Northeastern University, and holds eight utility patents.

Sheldon L. Miller, Director

Mr. Miller has been a litigator and expert counsel for more than 40 years and in private practice for more than 30 years. He has operated the Law Office of Sheldon Miller, PC for the past 30 years. He was a member of the Board of Governors of the American Trial Lawyers Association from 1977 through 2009 (longest tenure in history). From 1979 through 1992, he was the president of the Mediation Tribunal Association in Wayne County (Detroit), Michigan. In 1971, he pioneered the concept of mediation and was the first mediator on behalf of the Plaintiff's Bar in the State of Michigan. Mr. Miller was also the first to prosecute and articulate the concept of "comparative negligence" in the State of Michigan. Mr. Miller graduated from Wayne State University Law School in Detroit in 1961. Mr. Miller brings his considerable experience in legal risk analysis and responsibility to the Board of Directors.

Stanley Pappelbaum, M.D., Director

Dr. Pappelbaum has been managing partner of Pappelbaum, Turner & Associates, a national healthcare consultancy company that advises hospital, medical group, health insurance, and governmental healthcare clients, since 2000. Dr. Pappelbaum joined Scripps Hospital in 1996 as chief transformational officer in charge of creating and implementing Scripps' strategic vision of the future. In 1997, he was promoted to executive vice president and chief operating officer and, in 1999, was promoted to president and CEO when the hospital reached annual revenues of over $1 billion. From 1985 to 1995, he was the managing partner of Professional Health Consulting Group, a national company of physician executives that analyzed and managed change for complex not-for-profit healthcare systems clients throughout the U.S. From 1969 to 1984, Dr. Pappelbaum taught and practiced pediatric cardiology at the University of California, San Diego and at San Diego Children's Hospital, where he was chief of pediatric cardiology from 1972 to 1978. Dr. Pappelbaum completed his undergraduate work at McGill University in Montréal and received an M.D. from the University of British Columbia Faculty of Medicine in Vancouver. He completed his residency in pediatric medicine at Montréal Children's Hospital of McGill University and did graduate studies in cardiovascular physiology and a fellowship in pediatric cardiology at the University of California, Los Angeles. He also was awarded an Alfred P. Sloan Fellowship at the Massachusetts Institute of Technology, where he earned a Master's degree in management (health option). Dr. Pappelbaum brings his intimate knowledge of the healthcare industry and familiarity with recent changes in the healthcare environment to the Board of Directors.

F. Duwaine Townsen, Director

Mr. Townsen co-founded and has been the managing partner of EndPoint Late-Stage Fund of San Diego since 1999. This fund invests exclusively in late-stage life science companies. Mr. Townsen co-founded the Ventana Growth Funds in 1982 and served as the group's managing partner directing investments in early and middle stage life science, high technology, and telecommunications companies. Prior to this, Mr. Townsen was the CEO and chairman of Kay Laboratories, Inc., a medical device company, where he led the company through a successful IPO in 1978 and subsequent sale to American Hospital Supply Corporation in 1981. Following his public accounting experience, Mr. Townsen became a founder and CFO of Oceanographic Engineering Corporation and guided the company to profitability and its sale to Dillingham Corporation in 1967. Mr. Townsen serves as a director on the board of Sequal Technologies, a privately held, high technology company and has held numerous directorships at private and public companies, some of which included Agouron Pharmaceuticals, Inc., Brooktree Corporation, Cymer, Inc., and Maxim Pharmaceuticals, Inc. Mr. Townsen began his career with Arthur Young & Co. after graduating from San Diego State University. Mr. Townsen brings his specific public accounting environment and public markets experience to the Board of Directors, as well as his deep expertise related to corporate governance and fiduciary responsibility issues.

Rand Mulford, Director

Mr. Mulford is an independent consultant with a depth of experience in assisting organizations in developing overall strategy and conducting corporate financing and development programs. For the past five years, Mr. Mulford has successfully completed a variety of projects including managing M&A transactions, developing strategy for companies in therapeutic antibodies, cell-based therapy for eye diseases, prescription drug distribution, and developing a potential cure for AIDS. Previously, Mr. Mulford had joined with two other partners to found a specialty pharmaceutical company. Before that, he was executive vice president for strategy with Chatham Capital and Forest Health Services, a for-profit chain of hospitals. For two years, he worked with a venture capital firm working directly with four portfolio companies. His corporate experience includes group vice president of planning and control for a petrochemical company, head of corporate planning at Merck, CFO of a human tissue company, COO of a drug discovery company and president of its subsidiary—a research chemical company, COO of a diagnostics company, chairman of the Board of a medical device company, and head of corporate development at a biopharmaceutical company. Mr. Mulford started his business career with the consulting firm of McKinsey & Co. in the Chicago office. During an eight-year period, he served approximately 20 clients working on a variety of issues primarily related to strategy and organization. He obtained a bachelor's degree in engineering with honors from Princeton University in 1965. For the next five years, he served as a naval officer in the nuclear submarine program. Subsequently, he earned an MBA with high distinction at Harvard Business School.

Core Story

SpectraScience, Inc. ("SpectraScience" or "the Company") has developed a platform for determining whether bodily tissue is normal, precancerous, or cancerous without having to physically remove a tissue or cell sample from the body. Nearly 20 years of research and development (R&D) have gone into SpectraScience's WavSTAT® Optical Biopsy System, which is a medical device in the U.S. for which early product iterations have received FDA clearance. The Company's WavSTAT4 Optical Biopsy System, initially launched to European markets in 2011, holds a CE Mark for sales in the European Union (EU), regulatory approval in Saudi Arabia, and may pursue a supplemental Premarket Approval (PMA) filing in the U.S. The device is designed to fit seamlessly into the current standard of care for screening for and diagnosing colorectal cancer, with the aim of simplifying, accelerating, and improving the safety and accuracy of current colorectal cancer detection worldwide. By enabling real-time diagnostics within the context of a routine colonoscopy, the WavSTAT4 may also help alleviate the burden on laboratory pathologists while reducing healthcare costs.

SpectraScience is initially working to increase adoption of the WavSTAT platform in colorectal cancer, though the technology is believed to be applicable in detection of a multitude of tumor types including esophageal, lung, skin, stomach, prostate, and bladder cancers.

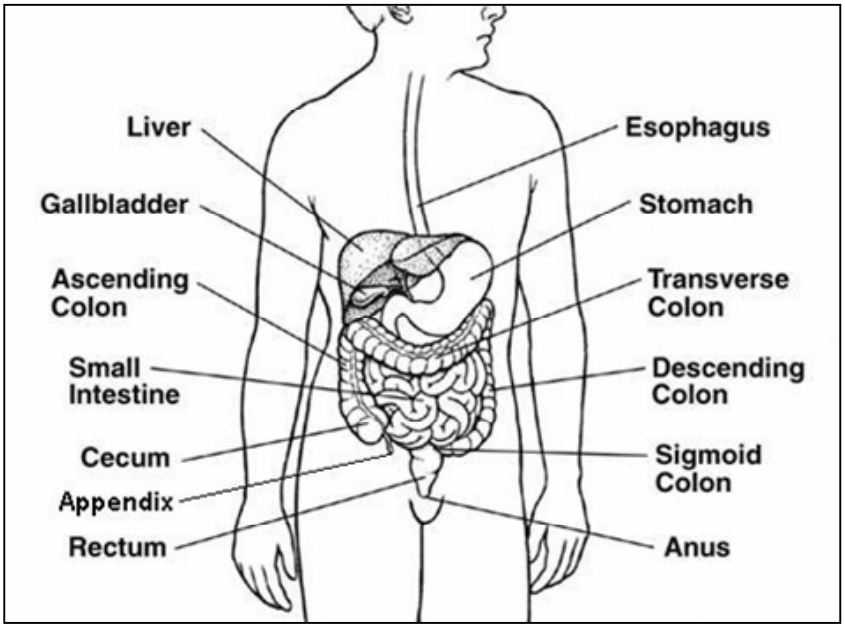
COLORECTAL CANCER

Colorectal cancer includes cancers that originate in either the colon or the rectum, as illustrated in Figure 5. The colon, which entails most of the large intestine, and the rectum are the final stages of the digestive system. After energy and nutrients have been removed from food by the stomach and small intestine, the colon absorbs the remaining fluid from the food and passes it to the rectum as solid waste where it is held before exiting the body through the anus.

Figure 5

THE DIGESTIVE SYSTEM

Colorectal cancer originates in either the colon (transverse, ascending, descending, sigmoid) or the rectum.



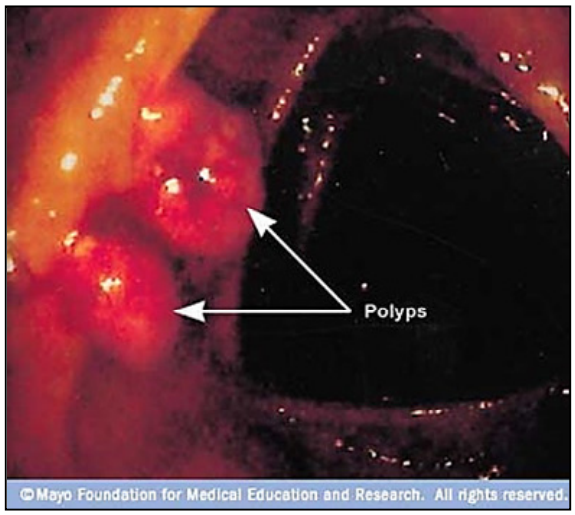
Source: American Cancer Society.

A colorectal tumor often begins as a small clump of cells attached to the interior lining of the colon or rectum. This growth, which in itself is not cancerous, is referred to as a "polyp" (as shown in Figure 6). Polyps produce virtually no symptoms, and patients may never know they are there.

However, the primary cause of concern with polyps is that, over time, they can become malignant. Figure 7 depicts the progression of a benign **adenoma**, which is a type of polyp that has a higher likelihood of becoming cancerous, from a small growth to a colorectal tumor. Adenomas are slow-growing and small adenomas may remain benign throughout a patient's lifetime. The larger they are upon discovery by a physician impacts the physician's assessment of that patient's risk of developing colorectal cancer from the polyps. It is estimated that over 95% of colorectal cancers develop from adenomas (Source: the Johns Hopkins Colon Cancer Center's "From Polyp to Cancer"). Accordingly, the presence of adenomatous polyps (adenomas) is considered a precancerous condition.

Figure 6

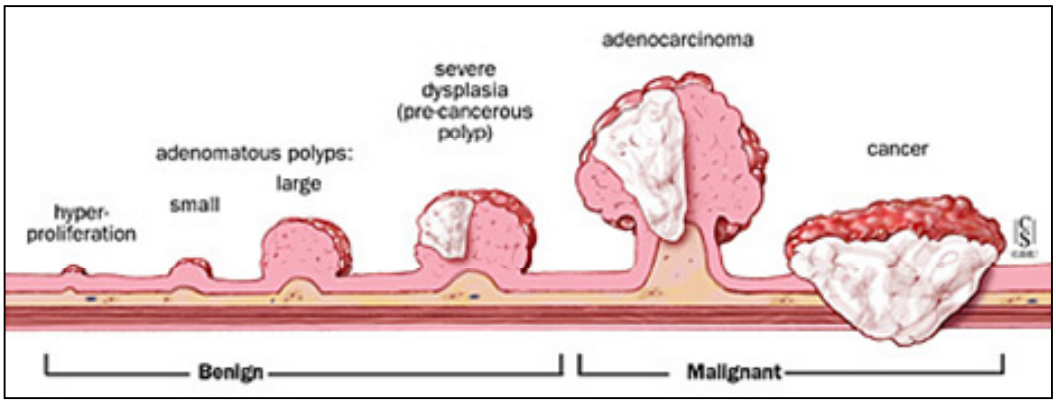
SMALL POLYPS INSIDE THE COLON



Source: the Mayo Clinic.

Figure 7

PROGRESSION FROM POLYP TO CANCER



Source: the Johns Hopkins Colon Cancer Center.

Another indicator of potential colorectal cancer is any dysplasia visible on the lining of the colon or rectal walls. Dysplasia entails a collection of abnormal cells and/or inflammation that may be due to a history of **ulcerative colitis** or **Crohn's disease**, among other conditions. To date, these cells would need to be biopsied and examined under a microscope in order to determine if the dysplasia is benign or malignant.

Other forms of colorectal cancer include tumors that begin in specialized hormone-producing intestinal cells ("carcinoid tumors"), tumors that start in the colon wall's **interstitial cells of Cajal** ("gastrointestinal stromal tumors"), tumors of immune system cells ("lymphomas"), and tumors that begin in blood vessels or within the colorectal wall's muscle and connective tissue ("sarcomas") (Source: the American Cancer Society).

With adenomas, which are by far the most common form of colorectal cancer, the tumor begins in the lining, or wall, of the colon or the rectum. As tumors advance, they grow from the innermost layer of the wall, through the colon and rectum's muscle and fibrous tissue layers (these muscles in the colorectal wall are what contract to move the contents of the intestines along), to the outermost layers of connective tissue covering the colon. When colorectal cancer is diagnosed and staged, it is evaluated based on the extent of its progression through the colorectal wall and/or its spread to other areas of the body (lymph nodes and other organs). An early stage colorectal tumor has likely not advanced beyond the inner lining or muscular layers of the colorectal wall and has not yet spread to distant sites or nodes. In contrast, a late-stage colorectal tumor has likely either grown through the entire colorectal lining or, if it has not breached the colorectal wall, has already spread to multiple nearby lymph nodes or at least one distant organ.

For all cancer types—colorectal included—a patient's likelihood of survival is highest when the tumor is caught and treated at its earliest stages, before it has spread to secondary sites in the body. Figure 8 illustrates the impact of early detection using the five-year relative survival rates for colorectal cancer patients. For both colon and rectal cancers, patients whose tumors were Stage I at diagnosis had a dramatically better prognosis for survival than patients who were not identified until the later stages.

Figure 8

COLORECTAL CANCER SURVIVAL RATES, BY STAGE AT DIAGNOSIS

(Data is based on outcomes of people diagnosed from 2004-2010.)

Survival rates for colon cancer, by stage	
Stage	5-year Relative Survival Rate
I	92%
IIA	87%
IIB	63%*
IIIA	89%*
IIIB	69%
IIIC	53%
IV	11%

*These numbers are correct : patients with stage IIIA or IIIB cancers had better survival than those with stage IIB cancers.

Survival rates for rectal cancer, by stage	
Stage	5-year Relative Survival Rate
I	87%
IIA	80%**
IIB	49%**
IIIA	84%
IIIB	71%
IIIC	58%
IV	12%

**These numbers are correct: survival was better for some stage III cancers than for some stage II cancers.

Source: the American Cancer Society's summary of data from the National Cancer Institute's SEER database.

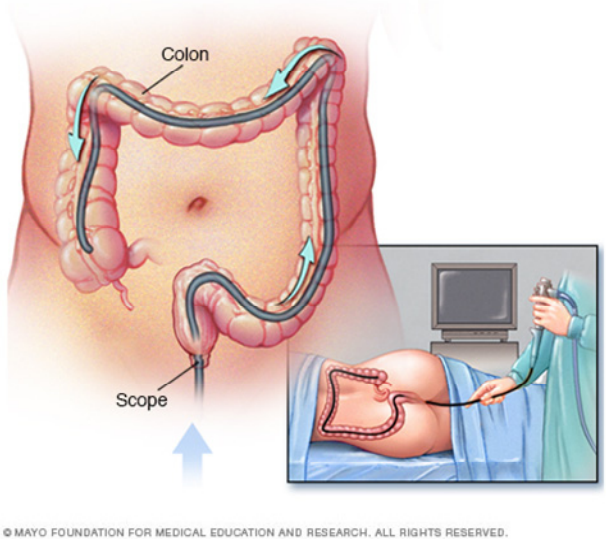
Colorectal Cancer Screening

The U.S. Preventive Services Task Force (USPSTF) as well as many European agencies recommend that every adult between the ages of 50 and 75 undergo routine colorectal exams. This typically entails a colonoscopy every 10 years, a **sigmoidoscopy** (similar to a colonoscopy but targeted to the lower [sigmoid] colon and rectum) every 5 to 10 years, or fecal occult blood tests (FOBT) every year. The FOBT is a test of consecutive stool samples to look for hidden blood particles that are not visible to the naked eye. Blood in the stool could be a sign of polyps or cancer. To date, the preferred method of screening for colorectal cancer is a colonoscopy (Source: *American Journal of Gastroenterology* 2009; 104:739–750).

In a colonoscopy, a physician inserts a tool called an endoscope through the rectum to reach the colon (as illustrated in Figure 9 [page 17]). Endoscopes are widely used devices that allow physicians to look inside body cavities. In any endoscopic procedure, a physician will insert an endoscope through a body opening, and using the light and camera attached to the device, be able to visually examine the tissue at the end of the endoscope. As a result, any colonoscopy currently performed is subject to the skill of the practitioner due to the degree of visual inspection and judgement required.

Figure 9

COLONOSCOPY



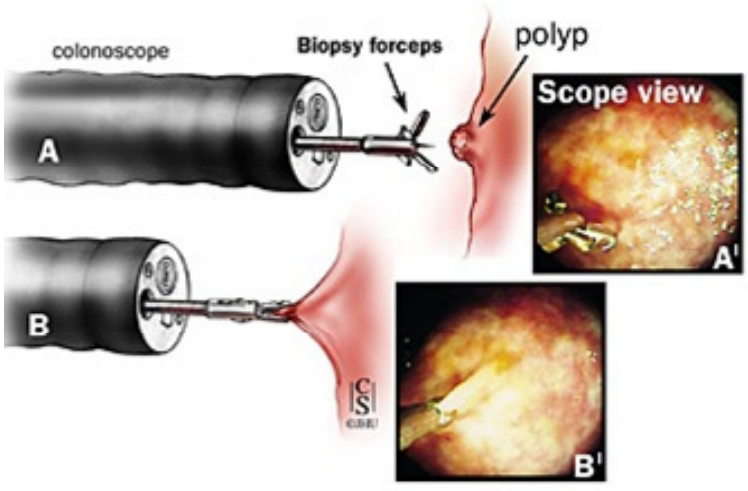
Source: Mayo Foundation for Medical Education and Research.

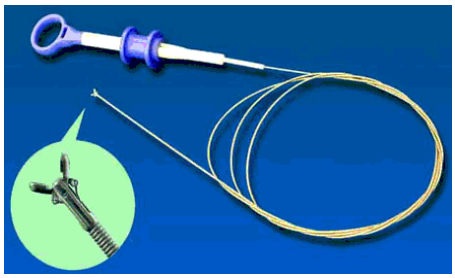
Endoscopes are designed with a narrow channel (or opening) that runs the length of the device. In a conventional endoscopy/colonoscopy procedure, tiny forceps used to perform a biopsy can be inserted through this channel, enabling the physician to extract a tissue sample from the patient for further analysis (as shown in Figure 10). If a polyp or dysplasia is detected during the colonoscopy, it can be removed by the physician and sent to a laboratory for a determination of whether the tissue is benign or malignant. SpectraScience's lead product for colorectal cancer screening uses this same working channel of the endoscope to feed the Company's optical biopsy forceps into the colon, as detailed on the accompanying pages.

Figure 10

PERFORMING A COLONOSCOPY WITH A BIOPSY

Endoscopic View of Biopsy Forceps | **Endoscope with Biopsy Forceps Attachment**





Sources: Johns Hopkins Medicine Gastroenterology and Hepatology and Crystal Research Associates, LLC.

THE WAVSTAT® OPTICAL BIOPSY SYSTEM

The WavSTAT4 is the fourth iteration of the WavSTAT® Optical Biopsy System. It aids physicians by immediately classifying polyps (that the physician has not already decided to remove) as either benign, and thus not needing removal and subsequent pathology, or malignant. The WavSTAT4 is an optical biopsy that can be performed and interpreted at the time of cancer screening, without requiring the physician or patient to wait on results from a pathology lab—a process that can take several weeks or more. Thus far, optical biopsy has been found to be a safe method that does not greatly increase the examination time and can provide the endoscopist with crucial information concerning the tissue both during examination and when scheduling patient follow-up (Source: *Anticancer Research*, November 2009, 29(11):4737–4739). Being able to determine an appropriate follow-up interval for patients is important for close monitoring of any suspect conditions.

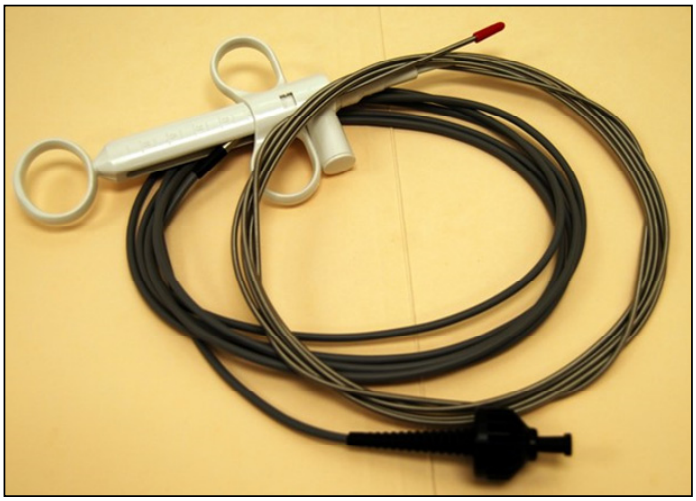
To perform an optical biopsy, the WavSTAT4 system employs low-level ultraviolet (UV) laser light to scan and illuminate the target tissue in a method known as laser-induced fluorescence (LIF) spectroscopy (detailed on page 19). The UV light is transmitted to the tissue via an optical fiber built into SpectraScience's optical biopsy forceps. The Company's forceps are very similar to traditional biopsy forceps (as described on page 17) with the exception that they also include the UV light-transmitting optical fiber. SpectraScience's optical biopsy forceps (shown in Figure 11) are inserted into the colon through the working channel of an endoscope. The other end of the optical forceps attaches to SpectraScience's proprietary WavSTAT4 mobile console.

Figure 11

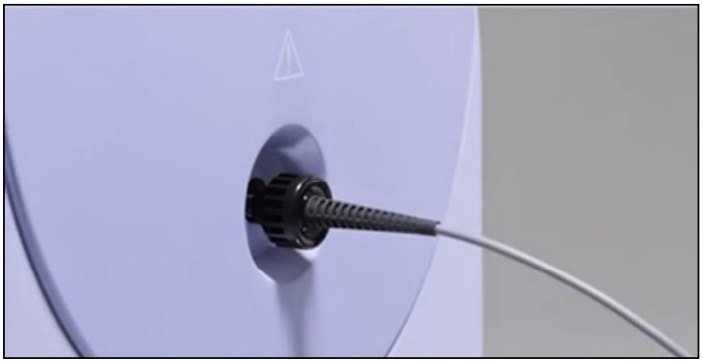
THE WAVSTAT4 OPTICAL BIOPSY SYSTEM

WavSTAT4 Console

SpectraScience's Optical Biopsy Forceps



Optical Biopsy Forceps Plug Into WavSTAT Console



Source: SpectraScience, Inc.

SpectraScience designed WavSTAT4 with ease of deployment in mind. The console is mobile and can be moved from one procedure room to another within a physician's office, outpatient clinic, or hospital. It is also equipped with a touchscreen and the capability to interface with other screens, including most major endoscope diagnosis monitors. All data is recorded and saved to both flash memory and an internal hard drive.

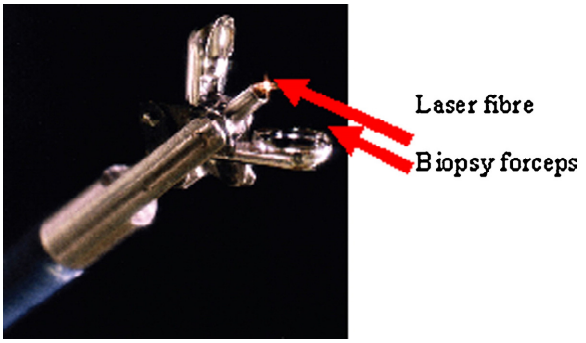
Laser-Induced Fluorescence (LIF)

WavSTAT4's ability to distinguish between adenomatous (precancerous) and hyperplastic (benign) polyps stems from the machine's underlying technology using LIF spectroscopy. Spectroscopy is the study of the interaction between matter and electromagnetic radiation. By examining the absorption, emission, or scattering of electromagnetic radiation, scientists can make determinations about the physical properties of the source matter. In LIF spectroscopy, researchers excite the target matter, e.g., colorectal tissue, by penetrating it with a specified wavelength of UV laser light. After being "excited" (or stimulated) by the laser, certain molecules in the colorectal tissue will emit a native fluorescence as they "de-excite" or return to a normal state. Fluorescence entails the emission of light as a result of bombardment by electromagnetic radiation, such as X-rays or UV rays. Importantly, fluorescence emitted by healthy tissue has been found to be measurably different from that emitted from abnormal (or potentially precancerous) tissue (Source: *Photodiagnosis and Photodynamic Therapy*, March 2015, 12(1):76-83). Moreover, LIF has been validated in literature as a successful diagnostic technique for detecting colorectal and lung cancers as well as characterizing dermal lesions and atherosclerotic plaque, and has been noted for its high specificity and sensitivity for discriminating between dysplasia and healthy (no dysplasia) tissue (Source: *Zeitschrift für Medizinische Physik*, February 2012, 22(1):40–47). A summary of key clinical findings relevant to the WavSTAT® Optical Biopsy system specifically is provided on pages 22-23.

When a polyp or lesion is detected during a colonoscopy, physicians using the WavSTAT4 would thread the optical biopsy forceps/fiber (as shown in Figure 12) through the endoscope. As with standard biopsy forceps, the physician can then grasp the polyp with the optical forceps and, depressing a foot pedal, send pulses of UV laser light through the optical fiber to the target tissue. WavSTAT4 then collects and analyzes the fluorescent signal that is returned in order to characterize the molecular makeup of the tissue, including its amino acids, enzymes, structural proteins, and so on, and make a determination of either healthy ("not suspect") or precancerous or cancerous ("suspect"). WavSTAT4 pulses the laser light at a very low power through the optical fiber. SpectraScience has stated that it is using a known wavelength of light—337 nanometers, which has been shown to be capable of creating endogenous fluorescence in epithelial tissue in the bowel (Source: *Journal of Urology*, 1996, 156(5):1597–1601)—but delivered with a power too low to burn, cut, or even warm the tissue/patient.

The Company's optical biopsy forceps are intended to only be single-use attachments (i.e., practitioners would use new forceps for each patient). Thus, SpectraScience anticipates being able to build a recurring revenue stream from the sale of the forceps akin to the razor/razor blade sales model, whereby the WavSTAT4 console is the "razor" and the forceps the "blades."

Figure 12
OPTICAL BIOPSY FORCEPS WITH OPTICAL FIBER



Source: Figure 1 from Photodiagnosis and Photodynamic Therapy, March 2015, 12(1):76-83.

System Interpretation and Display of Results to Physician

As the physician guides the endoscope with the optical fiber over the patient's tissue, the emitted florescence is collected, measured, and analyzed by SpectraScience's proprietary software algorithm onboard the WavSTAT4, with results available to the physician or WavSTAT4 operator within one second. The WavSTAT4's internal computer and proprietary analysis software deciphers the tissue's spectral data and displays the results in an unambiguous format on screen.

As illustrated in Figure 13, when the system detects normal tissue, the physician is shown a green "not suspect" icon on the console screen. Tissue that WavSTAT4 finds to be precancerous or cancerous returns a red "suspect" icon. Unlike the traditional method of visual inspection, there is no ambiguity to the result and no need for physician interpretation.

Figure 13

WAVSTAT4 DIAGNOSTIC OUTPUT: "NOT SUSPECT" OR "SUSPECT"

- A definitive, instant diagnosis
- Not subjective; requires no interpretation
- Could significantly reduce the costs of follow-on procedures

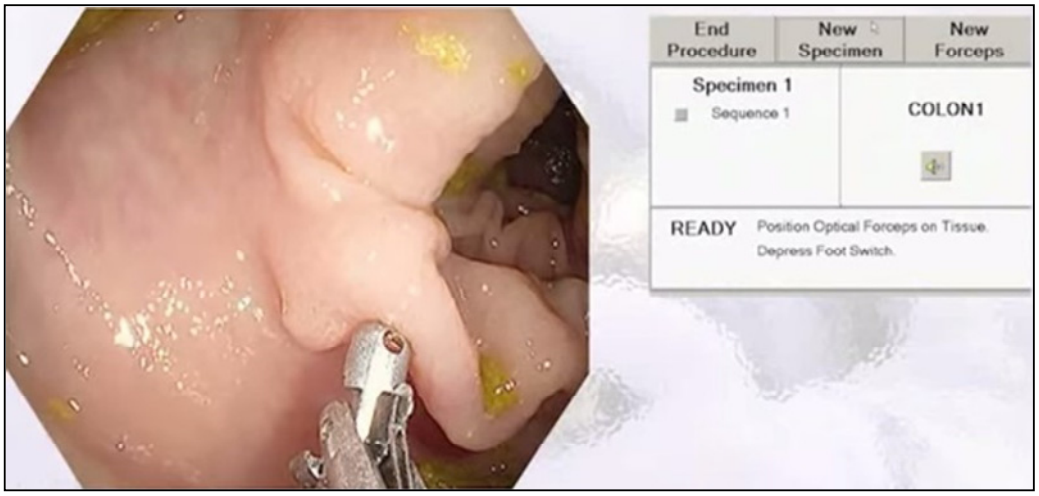
Source: SpectraScience, Inc.

Figure 14 (page 21) depicts a loose illustration of performing an optical biopsy inside the colon using WavSTAT4 and SpectraScience's optical biopsy forceps. If the system or physician identifies a polyp as suspect, the physician is able to biopsy the polyp as usual for further histopathologic analysis without requiring additional surgical tools. The optical biopsy forceps from SpectraScience are capable of performing both the optical and physical biopsies.

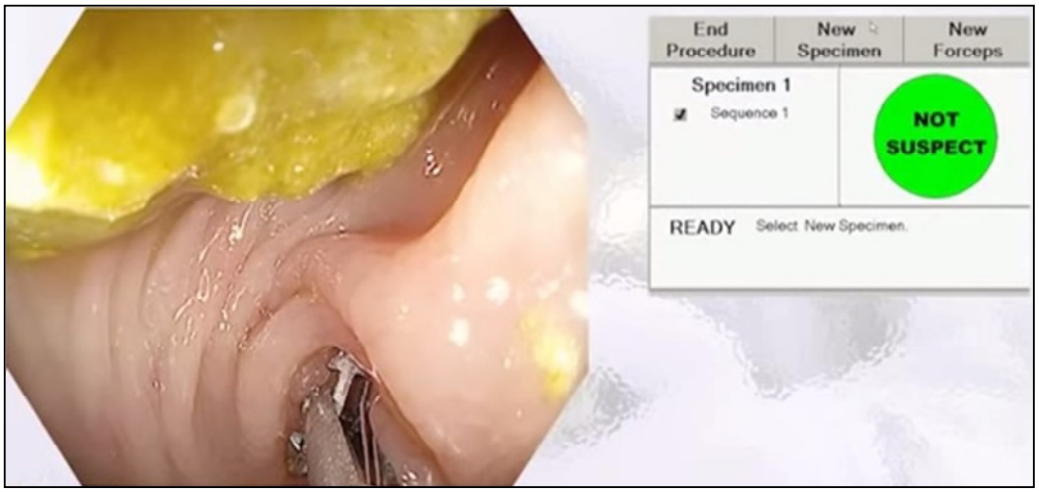
Figure 14

PERFORMING AN OPTICAL BIOPSY USING WAVSTAT4

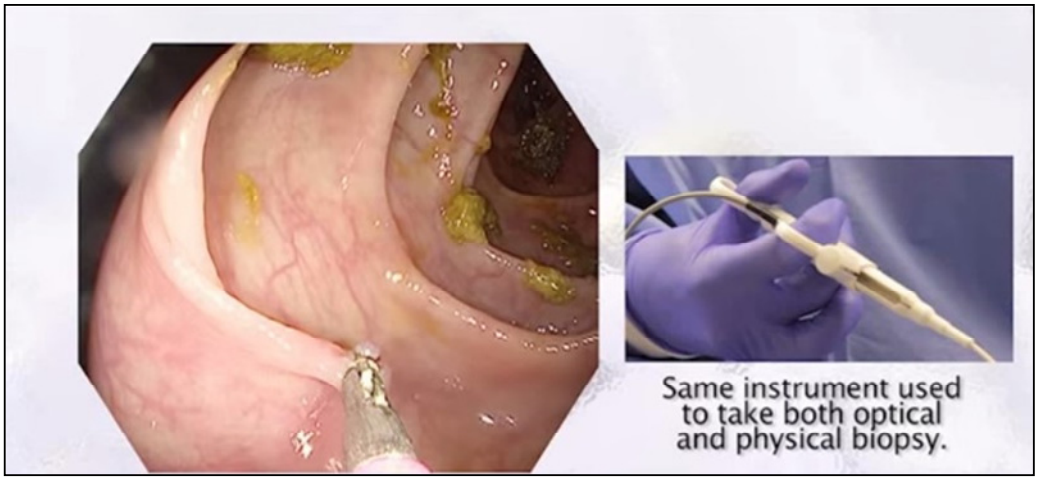
Position Optical Forceps on Tissue; Depress Foot Switch



System Displays Diagnostic Result



"Suspect" Tissue can be Immediately Biopsied/Removed Using the Same Optical Forceps



Source: WavSTAT4 YouTube Video available at https://www.youtube.com/watch?v=Ux_ij3_l0cg.

Clinical Data Obtained Using the WavSTAT® Optical Biopsy System

2013 Pilot Study by Dr. Helmut Neumann

Dr. Helmut Neumann, a professor of molecular endoscopy and interventional endoscopy, and a specialist in internal medicine and gastroenterology at the Department of Medicine at Germany's University of Erlangen-Nuremberg, performed the pilot study of the updated WavSTAT4 platform. The results of the study have been summarized in a published abstract in *Gastrointestinal Endoscopy* (2013, 77(5S):AB463). Dr. Neumann and his team found that adding SpectraScience's technology and optical biopsy forceps (with attached UV optical fiber) to the screening colonoscopy procedure could increase the colonoscopy's negative predictive value (NPV) to 96%—well above the 90% NPV threshold recommended under PIVI guidelines (as detailed on page 28).

Altogether, the pilot study examined 122 colorectal lesions using both the WavSTAT4 optical biopsy followed by conventional histopathological evaluation (requiring a physical biopsy). Roughly 20% of the suspected lesions were found to be adenomatous, which have a significantly higher likelihood of developing into colorectal cancer than hyperplastic (benign) polyps and lesions. Dr. Neumann's study suggests a sensitivity, specificity, and accuracy of WavSTAT4 of 81%, 84%, and 83%, respectively, in predicting adenomatous histology, as well as a **positive predictive value** of 50% and an NPV of 96% relating to the **in vivo** diagnosis of adenomatous tissue (Source: *Gastrointestinal Endoscopy* 2013).

The 96% NPV achieved with WavSTAT4 in Dr. Neumann's study is in contrast to earlier iterations of the WavSTAT platform. WavSTAT4 has a new, improved algorithm, which is the heart of its decision-making process, as well as improved user software and hardware enhancements that enhance fluorescent signal capture. The additional R&D work that SpectraScience put into WavSTAT4 is evident in its enhanced predictive values, which exceed ASGE guidelines, in comparison to, for example, a prior WavSTAT3 study that showed a lower NPV insufficient (Source: *Endoscopy*, January 2015; 47[1]:56-62, which was published using 2011 data from the WavSTAT3).

Data Presented at Digestive Disease Week in May 2015

Most recently, another study of WavSTAT4 was presented at Digestive Disease Week (http://www.ddw.org/) held in Washington, D.C. during May 16-19, 2015. Researchers from the Department of Medicine I, University Hospital Erlangen, Germany, conducted a WavSTAT4 optical biopsy as well as conventional histology on 142 diminutive colorectal polyps (an explanation of which is given on page 28). The study's objective was to assess whether WavSTAT 4 can accurately predict polyp histology according to the new ASGE PIVI statement outlined on page 28. Results showed that the overall accuracy of WavSTAT4 for prediction of adenomatous polyp histology was 84.1% with a sensitivity, specificity, and NPV of 81.5%, 85.2%, and 95.4% (Source: *Gastrointestinal Endoscopy*, May 2015, Vol. 81, Issue 5, Supplement, Page AB158). NPV increased to 98% for diagnosis of distal colorectal diminutive polyps as not being adenomatous. Moreover, the data support the correct prediction of onsite surveillance intervals with an accuracy for WavSTAT4 of 89.6% versus recent histology-based U.S. guideline recommendations, as well as the same or narrower surveillance intervals predicted by WavSTAT4 versus histology.

Based on the research presented at DDW 2015, researchers were able to conclude that WavSTAT4 had sufficient diagnostic accuracy to enable physicians to leave distal colorectal polyps in place without resection or to resect and discard them without pathologic assessment, thereby potentially leading to reduced costs and risks associated with the redundant removal of diminutive colorectal polyps (Source: *Gastrointestinal Endoscopy*, May 2015).

Additional Studies

An earlier study conducted during 2007-2008 at Thomayer's Teaching Hospital in Prague, Czech Republic, found that WavSTAT had been able to correctly identify 54 polyps consisting of 52 adenomas and 2 hyperplastic polyps. The results were confirmed through histopathological examination, which matched the optical biopsy's data 100%. One adenomatous polyp in this study was only confirmed through histopathological evaluation as it could not be examined with the optical biopsy due to its friable mucosa (easily crumbled mucosa). The study's authors concluded that the specificity and sensitivity of the WavSTAT platform was 100% in this trial, where no tissue was misidentified (Source: *Anticancer Research*, November 2009, 29(11):4737–4739).

Figure 15 illustrates SpectraScience's data from an earlier study of WavSTAT4, which also demonstrated the product's ability to improve upon current screening methods by reducing false negatives (reducing the frequency of tissue being characterized as healthy when, in fact, it was not).

Figure 15

WAVSTAT4 HAS SHOWN TO REDUCE FALSE NEGATIVES

	Endoscopist*	Add WavSTAT*
Sensitivity	56.2%	96.9%
False Negative	43.8%	3.1%

Source: SpectraScience, Inc.'s data from AMC, Netherlands, 2012.

Platform Technology Validated in Bladder Cancer

More recently, a team of investigators led by Dr. Omar Aboumarzouk of the UK's Ninewells Hospital and Medical School Department of Urology published results of a pilot study using a specially modified WavSTAT III console and WavSTAT optical biopsy forceps to improve the diagnosis of bladder cancer. Researchers performed in vivo LIF spectroscopy (at a wavelength of 405 nanometers) on patients' bladder walls before taking biopsies. Results showed a statistically significant difference in both fluorescence intensity and wavelengths between benign and malignant bladder tissue, indicating that malignant bladder tissue emits a measurably different amount and wavelength of fluorescence versus benign tissue (Source: *Photodiagnosis and Photodynamic Therapy*, March 2015, 12(1):76-83). Thus, LIF spectroscopy and WavSTAT may have utility in bladder cancer diagnostics as well. This could be a key development in bladder cancer screening, as it is reported that non-muscle invasive bladder cancer can be missed during white light endoscopy (a standard of care in endoscopy screening today) in up to 50% of cases (Source: *Photodiagnosis and Photodynamic Therapy*). Urologists typically biopsy representative random samples of tissue in the bladder and the integration of an optical biopsy may help reduce such random sampling by indicating which areas have a malignant or benign fluorescent signature.

Ongoing MORDIS Study

An additional confirmatory marketing evaluation of WavSTAT4 is currently ongoing across multiple European countries, reaching over 1,200 patients. Study sites include St. James University Hospital in Leeds, UK, as well as locations in Italy, Germany, France, Sweden, Denmark, the Czech Republic, Poland, and Belgium. Additional sponsors and collaborators are listed in Figure 16. The objective of these studies is multifaceted, including replicating Dr. Neumann's finding of a 96% NPV, measuring the economic benefit of incorporating WavSTAT4 into cancer screening processes, and working toward acceptance of a WavSTAT optical biopsy as part of the standard of care going forward. SpectraScience anticipates completing the MORDIS study and subsequently submitting for approvals in each country.

Figure 16

MORDIS STUDY COLLABORATORS

Policlinico Universitario Gemeli, Italy
European Institute of Oncology, Italy
Institut des Maladies de l'Appareil digestif, France
European Georges Pompidou Hospital
Catholic University Hospitals Leuven, Belgium
Innere Medizin I Interdisziplinäre Endoskopie Universitätsklinikum Tübingen, Germany
University of Erlangen-Nuremberg, Germany
Copenhagen University Hospital at Herlev
SKANE University Hospital Malmö, Sweden
Institute for Clinical and Experimental Medicine

ClinicalTrials.gov Identifier: NCT01980134

Source: ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT01980134).

Potential Competitive Advantages

There are a number of benefits to incorporating WavSTAT4 into colonoscopy/endoscopy procedures—in colorectal cancer screening and potentially in screening for a number of other cancers as well. SpectraScience's competitive advantages in the cancer diagnostics market may stem from the ability of its platform to do the following: (1) integrate easily with current procedures; (2) reduce the number of biopsies performed on diminutive colorectal lesions (e.g., hyperplastic polyps) that could be resected and discarded (or even left **in situ**) without adverse clinical impact; (3) increase patient safety by reducing risks of bleeding and perforation from unnecessary biopsies; (4) reduce healthcare costs; and (5) improve the diagnostic capabilities of screening endoscopies performed in other countries where it is allowable for a nurse endoscopist to perform the procedure (as WavSTAT4 eliminates the need for subjective physician interpretation of diminutive polyps). Figure 17 summarizes a selection of SpectraScience's perceived competitive advantages based on results shown in the Company's clinical studies.

Figure 17

POTENTIAL COMPETITIVE ADVANTAGES TO THE WAVSTAT4 OPTICAL BIOPSY

▪ Minimally invasive versus a physical biopsy where tissue is cut out of a patient and sent to a pathologist for examination
▪ Significantly improves the physician's diagnostic accuracy in determining whether small polyps in the colon are pre-cancerous or cancerous
▪ Improves patient survival rates by earlier detection and treatment of cancers, and more importantly pre-cancers, by more accurately identifying cancers or pre-cancers the physician may misdiagnose
▪ Improves the patient's quality of life by providing an immediate analysis of the tissue, thereby eliminating the anxiety of waiting several days to hear the pathology results
▪ Diagnostic results with WavSTAT4 are available to the physician within one second versus prolonged laboratory analysis, thereby enabling the physician to diagnose and treat the patient during the same endoscopy procedure with the same biopsy instrument—potentially reducing the need for scheduling a second expensive endoscopy for treatment purposes
▪ Significantly reduces the number of physical biopsies performed and reduces the number of unnecessary follow-on endoscopies performed
▪ Reduces the number of misdiagnosed patients, thereby eliminating the need for more costly advanced treatments such as surgery, chemotherapy, and/or radiation
▪ Essentially the same process as how physicians screen for cancer today, and is compatible with existing endoscopes; SpectraScience is not asking doctors to do anything different, other than notifying them that, at a particular tissue location, they do not need to take a physical biopsy that they otherwise might have performed
▪ Less expensive for healthcare payors
▪ Device can also be used by nurse endoscopists, providing them with the same diagnostic capability as expert physicians. This is a critical benefit in countries where screening colonoscopies are often performed by nurse endoscopists.

Source: SpectraScience, Inc.

Regulatory Clearances and Approvals

U.S.

SpectraScience received a **510(k) clearance** from the U.S. Food and Drug Administration (FDA) for its disposable and reusable optical biopsy forceps in 1996. Under Section 510(k) of the federal Food, Drug, and Cosmetic Act, manufacturers of medical devices must notify the FDA at least 90 days in advance of marketing a medical device. This is known as a Premarket Notification or a 510(k) application, through which the manufacturer must demonstrate to the FDA that the new device is substantially equivalent (meaning that it is at least as safe and effective) as a device already on the market before the FDA will clear the new device for sale (Source: FDA).

SpectraScience believes that the WavSTAT4 system itself is a Class IIb medical device in the U.S. and is thus subject to more stringent regulatory review than Class I but not as strict of a review as Class III devices. All medical devices to be sold in the U.S. must satisfy general controls, including listing the product with the FDA, manufacturing in accordance with **Good Manufacturing Practices (GMP)**, and labeling in accordance with labeling regulations. Class I devices are often simple in design with minimal potential for harm to the user (e.g., elastic bandages, examination gloves). Class II devices, such as powered wheelchairs, some pregnancy test kits, and surgical drapes, are subject to special controls, such as special labeling requirements, mandatory performance standards, and postmarket surveillance. A Class III device is usually one that sustains or supports life, is implanted, or is high risk, including pacemakers and breast implants.

WavSTAT was first cleared for use by the FDA in 2000, following the Company's 1998 Premarket Approval (PMA) submission for use of the product during endoscopic screening of the colon. A PMA is a scientific review to ensure a device's safety and efficacy, in addition to meeting general controls. SpectraScience has continued to refine and optimize its platform technology since its initial regulatory clearance, adding features based on outcomes of clinical studies. Subsequent iterations of WavSTAT (WavSTAT2 and WavSTAT3) were cleared by the FDA in 2001 and 2002. The WavSTAT4 entails multiple enhancements from prior iterations, including an improved algorithm that provides greater sensitivity, specificity, and NPV as well as a more user-friendly interface and more advanced software. SpectraScience anticipates filing a supplemental PMA for its WavSTAT4 following the receipt of sufficient financing. Previous generations of the WavSTAT have been discontinued.

Europe

SpectraScience has obtained the ISO 9001 and **EN 13485:2003** certifications and the CE Mark, enabling the sale of its WavSTAT medical devices within the European Union. The Company reports that it has held the quality certifications and CE Mark authorization since the year 2000, and that its CE Mark covers the sale of WavSTAT for aiding in the detection of all cancer types in addition to colorectal cancer.

SpectraScience first introduced the WavSTAT4 in Europe in late 2011, and in mid-2012, entered into a non-exclusive distribution agreement with PENTAX Europe GmBH for the sale of WavSTAT4 in international markets. Validation studies in the European market are ongoing, and SpectraScience aims to achieve sales beginning in the UK and Germany during 2016.

Saudi Arabia

In 2014, SpectraScience received regulatory approval for the WavSTAT4 in Saudi Arabia, a country believed to have a globally advanced medical delivery system with rapid adoption of technologies to improve care, increase patient safety, and lower costs. At present, the Company is in the planning process of launching a sales campaign in Saudi Arabia potentially in the first quarter 2016.

Manufacturing

WavSTAT4 manufacturing for clinical trials and studies occurs at SpectraScience's San Diego, California, facility. Production of the disposable optical biopsy forceps has been outsourced to U.S. OEM manufacturers, with final assembly performed by SpectraScience. The Company reports that the FDA has reviewed its manufacturing processes and Standard Operating Procedures required to build the WavSTAT systems and that SpectraScience is authorized to manufacture the equipment in its current facility, which holds ISO 9001 and other global quality certifications (Source: SpectraScience's Form 10K filed with the U.S. Securities and Exchange Commission [SEC] on March 20, 2015).

Future Applications and Developments

The WavSTAT4 Optical Biopsy System is currently being deployed for colorectal cancer screening. However, this is a platform technology believed to offer considerable medical benefit in screening patients for an array of cancer types, as demonstrated by recent results validating WavSTAT4 in non-muscle invasive bladder cancer (detailed on page 23). SpectraScience has stated that it views additional opportunities for its core technology specifically in esophageal cancer as well as potentially for lung, skin, stomach, prostate, and bladder cancers.

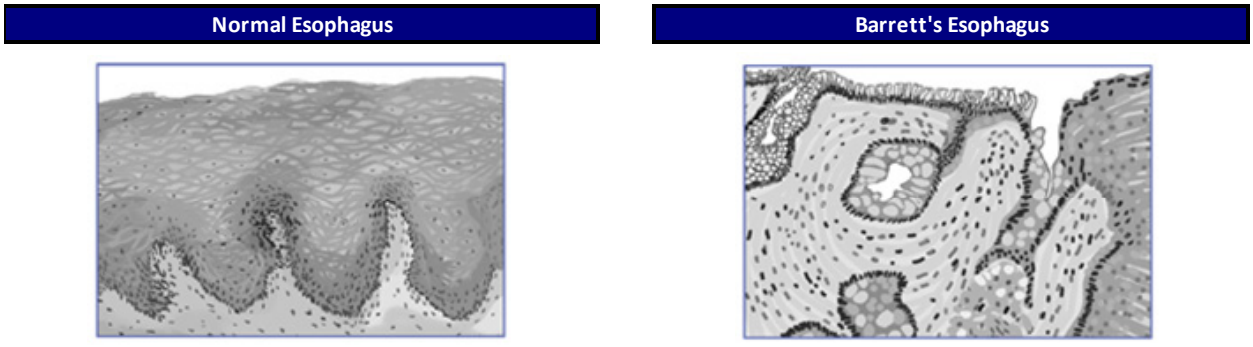
Esophageal Cancer

In 2013, **Current Procedural Terminology (CPT®)** codes went into effect for an optical endoscopy in the esophagus (upper GI tract). CPT codes, which identify medical services for reimbursement by healthcare payers, are maintained and copyrighted by the American Medical Association (AMA) as the standard for reporting physician and other services on standard transactions. While there is not yet an established CPT code for optical biopsies in the lower GI tract (colon and rectum), SpectraScience believes that the availability of reimbursement for esophageal optical biopsies suggests that healthcare providers are accepting of a new, minimally invasive approach.

In particular, SpectraScience perceives an unmet need for its technology in the diagnosis of a rare cancer called esophageal adenocarcinoma. This cancer of the esophagus develops in people who have a condition known as Barrett's esophagus, wherein the lining of the esophagus is atypical and contains tissue similar to intestinal tissue (illustrated in Figure 18). Barrett's esophagus is estimated to affect 1.6% to 6.8% of people, and men more often than women (Source: the National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK]). A person's risk of developing Barrett's esophagus is increased by the presence of gastroesophageal reflux disease (GERD), which is more commonly understood as acid reflux or chronic heartburn.

Figure 18

ILLUSTRATION OF THE DIFFERENCE IN TISSUE STRUCTURE IN BARRETT'S ESOPHAGUS



Source: the NIDDK's "Diagnosis of Barrett's Esophagus."

Barrett's esophagus may take many years to develop into esophageal cancer, but before it does, it usually displays precancerous cells or dysplasia in the Barrett's tissue. As in colorectal screenings, physicians diagnose Barrett's esophagus and any ensuing cancer using a GI endoscopy with biopsy. This procedure poses the same risks as colorectal cancer endoscopy: physicians' random sampling of tissue may miss precancerous or cancerous spots, and having to take multiple biopsies of the esophageal tissue is highly invasive and could lead to bleeding or perforation. The NIDDK states that physicians must biopsy at least eight areas of the esophagus (SpectraScience estimates based on the Company's research that the number of physical biopsies performed during the same esophageal endoscopy is in reality as high as 20) due to the difficulty of finding and diagnosing dysplasia in Barrett's tissue, which does not reflect all the tissue in the esophagus.

Esophageal endoscopies where WavSTAT4 may be beneficial are performed for patients who have GERD (to look for the development of Barrett's esophagus), for patients who have been diagnosed with Barrett's esophagus (to monitor progression to a precancerous dysplasia on an annual basis), and for patients who have shown dysplasia (to check for cancer every three to six months, depending on the grade of dysplasia). As with any cancer, early detection of precancerous esophageal conditions can significantly improve patients' quality of life and prognosis.

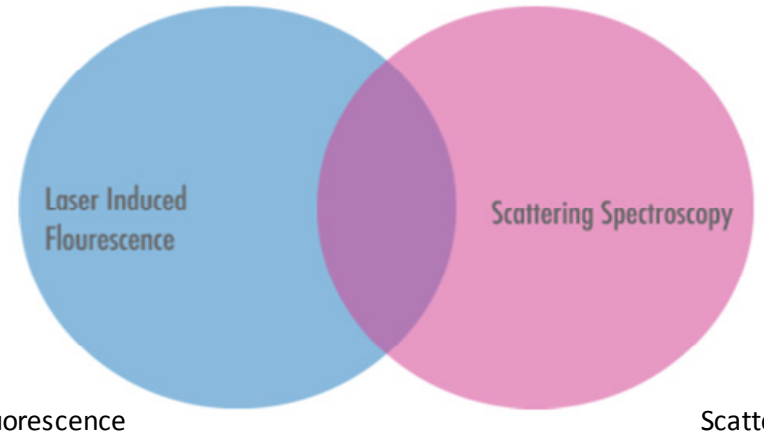
New Technologies

In addition to the LIF spectroscopy technology used in the current WavSTAT4 product, future WavSTAT products are anticipated to encompass additional light-based technologies to complement LIF spectroscopy. One of these is called scattering spectroscopy (SS), which targets the physical properties of tissue, such as its vascularity, epithelial thickness, and cell nuclei, rather than the biochemical properties of tissue identified by LIF (e.g., molecular makeup). SpectraScience reports that it holds intellectual property for the use of SS, and that this optical technology could be developed as both a complement to LIF or as a stand-alone product. As with LIF, SS is also intended to complement current endoscopic procedures and is intended by the Company to be used anywhere endoscopes are used for diagnostics.

Figure 19 illustrates the combination of LIF and SS, which SpectraScience believes may provide the optical blend of light-based technologies for diagnostics in many different types of cancer.

Figure 19

A "MULTI-MODAL" FUTURE FOR WAVSTAT: EMPLOYING COMPLEMENTARY TECHNOLOGIES FOR IMPROVED CANCER DETECTION AND DIAGNOSIS



Laser-Induced Fluorescence

LIF targets the chemical properties of tissue and can identify changes in amino acids, enzymes, and structural proteins that are characteristic of diseased tissue.

Scattering Spectroscopy

SS targets the physical properties of tissue and can detect changes in vascularity, epithelial thickness, and cell nuclei characteristic of diseased tissue.

Source: SpectraScience, Inc.

MARKET OPPORTUNITIES

Need for Improved Colorectal Cancer Screening Technologies

Diminutive (very small) polyps under 5 mm in size are extremely common, with the American Society for Gastrointestinal Endoscopy (ASGE) stating that these tiny adenomas and polyps are found in approximately half of adults undergoing colorectal screening (Source: *Gastrointestinal Endoscopy*, 2011, 73(3):419–421). However, it is the adenomatous polyps that are larger than 5 mm that are most likely to lead to cancer, and not the hyperplastic (benign) polyps that have virtually no chance of becoming cancerous. Unfortunately, macroscopic differentiation between a hyperplastic and an adenomatous polyp during colonoscopy is notably difficult, as evidenced by the low sensitivity (56.2%) and high rate of false negatives (43.8%) when performed by an endoscopist alone (as shown in Figure 15 on page 23) (Source: the UK's National Institute for Health Research [NIHR] Horizon Scanning Centre, University of Birmingham, *Technology Alert*, February 2015). Thus, the standard of care has been to resect and submit to a pathologist every polyp or suspect dysplasia seen during a colonoscopy, due largely to the inability of the physician to adequately discriminate between those small polyps that are hyperplastic and those that are pre-adenomas (precancerous). Altogether, diminutive polyps, even adenomas, are very rarely malignant (Source: *Gastroenterology Hepatology*, 2012, 8(2): 128–130). As a result, to date it is estimated that approximately 80% of tissue removed during colonoscopies is ultimately found to be just normal tissue.

There are two primary reasons why many researchers and physicians have critiqued the process of "cut-and-test-everything":

(1) performing unnecessary pathologic analysis on hyperplastic tissue considerably increases healthcare costs; and

(2) physical biopsies present known risks of bleeding and perforation, which could be reduced by minimizing unnecessary biopsies.

A study published in *Endoscopy* in 2011 found that not performing pathologic assessment for diminutive polyps would lead to a savings in healthcare costs of over $1 billion in the U.S. alone (Source: *Endoscopy*, 2011, 43(8):683-91). In response to these key findings, the ASGE's most recent Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) guidelines for colorectal cancer screening now have allowances for removing colorectal polyps under 5 mm in size from the patient and discarding these without sending them to a pathology lab. Moreover, the PIVI guidelines now also state that polyps under 5 mm in size that are believed to be hyperplastic (normal tissue) can be left in the patient and do not need to be removed if the diagnostic technology in use provides a greater than 90% negative predictive value (NPV) when used with high confidence for adenomatous histology (Source: *Gastrointestinal Endoscopy*, 2011, 73(3):419–421).

As a result, SpectraScience believes that WavSTAT4 may have an important position in the colorectal cancer screening market going forward. WavSTAT4 is designed to enable healthcare payors to realize the savings of forgoing unnecessary biopsies and laboratory tests and to save patients from the risks of numerous invasive biopsies that ultimately remove normal, healthy tissue. SpectraScience's technology has shown to be capable of distinguishing between adenomatous ("suspect" in terms of its potential to become cancerous) and hyperplastic ("not suspect") colon polyps under 5 mm in size. Larger polyps are removed as a matter of standard practice, but as noted in the PIVI guidelines, these smaller polyps that are found in roughly 50% of colonoscopy patients do not need to be removed if there is a reliable method of confirming that they are not cancerous.

To that end, SpectraScience's WavSTAT4 Optical Biopsy System has been found to provide an NPV of 95% to 96%, as presented at Digestive Disease Week in May 2015 (details of the data are provided on page 22). This is a key finding for the Company's technology, as it signifies a high level of confidence in the technology's ability to correctly diagnose tissue as not cancerous. PIVI guidelines state that a diagnostic technology must have at least a 90% NPV in order to leave a polyp under 5 mm in size in place (i.e., to avoid removing the polyp). With a new technology such as SpectraScience's optical diagnosis, physicians may be able to confidently avoid removing certain lesions that have been diagnosed as "not suspect." Accordingly, WavSTAT4 is anticipated to help reduce

biopsy costs and the risks associated with unnecessary polyp removal and tissue biopsies (Sources: *Gastrointestinal Endoscopy*, 2013, 77(5S):AB463; and *Gastrointestinal Endoscopy* Supplement, May 2015, 81(5):AB158).

Colorectal Cancer Burden

U.S.

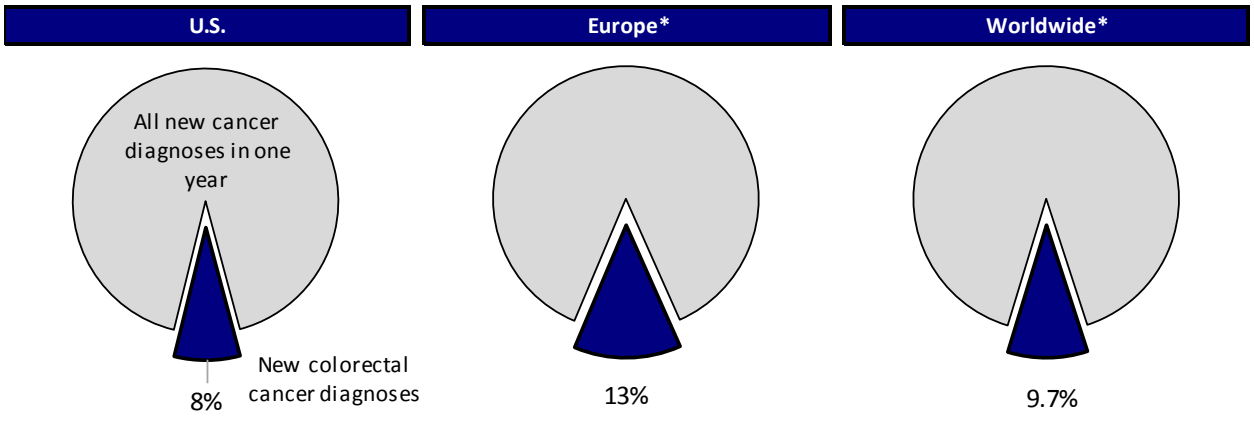
Colorectal cancer is the third most common cancer in the U.S. in both men and women, behind prostate and breast cancer (the most common cancers affecting men and women, respectively) and lung and bronchus cancer. It is also the second-leading cause of cancer-related death in both sexes, though its mortality rate is declining due to advancements in screening enabling earlier detection as well as improved treatments. Nevertheless, greater awareness and more frequent screening is still needed. The U.S. Department of Health and Human Services' (HHS) Assistant Secretary for Planning and Evaluation (ASPE) estimates that 60% of colorectal cancer deaths could still be prevented with regular testing of adults age 50 years and older, yet current screening rates are low. To this end, the National Colorectal Cancer Roundtable (NCCR) has recently undertaken an initiative called "80% by 2018" aiming for screening rates in the U.S. of 80% by 2018. Believing that one-third of adults over age 50 have not yet been screened for colorectal cancer as appropriate, the Centers for Disease Control and Prevention (CDC) has also implemented a "Screen for Life: National Colorectal Cancer Action Campaign" geared toward education and public service announcements.

An individual's lifetime risk of developing colorectal cancer is estimated at 1 in 20, or 5% (Source: the American Cancer Society [ACS]). The ACS has forecast 132,700 new cases of colorectal cancer to be diagnosed in the U.S. during 2015, composed of 93,090 new cases of colon cancer and 39,610 new cases of rectal cancer. As of 2011, there were over 1.1 million people in the U.S. living with colorectal cancer, with less than 65% of patients expected to survive more than five years (Source: the National Cancer Institute's SEER Stat Fact Sheets: Colon and Rectum Cancer). Estimates of the direct costs of colorectal cancer care in the U.S. vary, but as of 2010, were valued at roughly $14 billion (Source: CDC).

Figure 20 illustrates the proportion of annually newly diagnosed cancer patients who suffer from colorectal tumors in the U.S., Europe, and globally. Details for Europe and worldwide follow on page 30.

Figure 20

COLORECTAL CANCERS REPRESENT A SIGNIFICANT PROPORTION OF ANNUAL NEW CANCER DIAGNOSES



** Total diagnoses does not include skin cancers.*

Sources: the U.S. National Cancer Institute's SEER Stat Fact Sheets: Colon and Rectum Cancer, GLOBOCAN 2012, and Crystal Research Associates, LLC.

Europe and Worldwide

Rates of colorectal cancer in Europe, and the rest of the world, are on par with the frequency of the disease in the U.S. Globally, there are an estimated 1.4 million new cases of colorectal cancer annually, representing nearly 10% of the new cancer diagnoses made worldwide each year (Source: EuropaColon, www.europacolon.com/). Due in part to insufficient screening processes, the mortality rate of colorectal cancer remains high globally, with this tumor type accounting for 8.5% of all cancer-related deaths.

As colorectal tumors are far more prevalent in older adults (over age 50), their incidence is rising in part due to the globally aging population. Nearly two billion people over age 60 are expected to be alive worldwide by 2050—almost triple the 700 million people over 60 who were alive in 2009 (Source: *World Population Ageing 2009* from the United Nations' Department of Economic and Social Affairs, Population Division). To this end, World Cancer Research Fund International predicts that there could be 2.4 million cases of colorectal cancer diagnosed annually worldwide by 2035—an increase of one million more patients each year over current rates.

Colorectal cancer is the second most common cancer afflicting European citizens, with over 447,000 new diagnoses and nearly 215,000 fatalities due to the disease each year (Source: GLOBOCAN 2012). As in the U.S., colorectal cancer is the second-leading cause of cancer-related death in the EU. Additionally, a recent study published in *Lancet Oncology* found that the annual economic burden of colorectal cancer in the European Union (EU) totaled €13.1 billion as of 2009, representing approximately 10% of the EU's costs of cancer (Source: *Lancet Oncology*, Nov. 14, 2013, (12):1165-74).

Competition

SpectraScience operates in a highly competitive medical device industry characterized by rapid technology development and widespread work targeting oncology innovations. Within this industry, there is a subset of firms and institutions working specifically to apply spectroscopy (light-based) techniques to new modes of optical cancer diagnosis and imaging in addition to other medical specialties. These potential competitors to SpectraScience may include fully integrated medical device companies, emerging companies, universities, and public and private research institutions. However, to the Company's knowledge, it has few direct competitors in applying LIF spectroscopy for the differentiation of normal, pre-cancerous, or cancerous tissues in the GI tract.

Importantly, the WavSTAT diagnostic platform may be complementary to many current and in-development detection modalities, including blood and stool tests for detecting cancer such as Exact Sciences Corp.'s (EXAS-NASDAQ) Cologuard, a stool-based DNA test to detect colorectal cancer approved by the FDA in August 2014. When patients show to be positive for cancer markers in blood, stool, or other scan, they next proceed to a colonoscopy, where the specific polyp or lesion causing the result needs to be diagnosed.

The summaries following Figure 21 on pages 32-34 are not intended to be an exhaustive collection of potential competitors to SpectraScience; however, they are believed to be representative of the type of competition the Company may encounter as it seeks to further commercialize its WavSTAT4 Optical Biopsy System.

Figure 21

A SELECTION OF POTENTIAL COMPETITORS

	SpectraScience	Mauna Kea Technologies	Olympus Medical	Fujinon
Procedure Type	**Endoscope Based**	Probe Based	Endoscope Based	Endoscope Based
Technology	**Laser Induced Fluorescence**	Confocal Microscopy	Narrow Band Imaging	Confocal Endomicroscopy
Costs	**$0 capital cost ~$200 per procedure**	$125K capital cost $400+ per procedure	$125-150K capital cost	$125-150K capital cost
Results	**Suspect/Not Suspect Objective**	Interpretive Subjective	Interpretive Subjective	Interpretive Subjective
Lengthens Procedure?	**No**	Yes	Yes	Yes
Diagnostic Interval/Specimen	**One Second**	Three to Ten Minutes	Three to Ten Minutes	Three to Ten Minutes
NPV	96%	95%	82%	84%

Source: SpectraScience, Inc.

Caliber Imaging & Diagnostics, Inc. (LCDX-OTC)

Caliber I.D. is a medical device company that designs, manufactures, and markets point-of-care cellular imaging systems, allowing physicians to review tissue in vivo on a cellular level, aiding in the detection and diagnosis of skin cancer. Caliber I.D.'s Rapid Cell ID technology enables scientists and physicians to perform optical biopsies and characterize intact normal and abnormal cellular architecture that is otherwise invisible to the naked eye. The company developed VivaScope®, a suite of imaging products that provide physicians with a cellular-level view of the patient's skin at the bedside, allowing for immediate tissue characterization. In addition, the technology platform includes offerings for the analysis of both skin lesions during examination as well as excised surgical tissue for preparing the microscope slides used in traditional pathologic examination of tissue. Caliber I.D. also offers VivaNet® telepathology, facilitating the transfer of images from the point of capture to another physician, pathologist, or other diagnostic reader for near real-time collaboration with remote specialists. The company was formerly known as Lucid, Inc. and changed its name to Caliber Imaging & Diagnostics, Inc. in August 2012. Caliber I.D. was founded in 1991 and is headquartered in Rochester, New York.

FUJIFILM Corporation (FUJIY-OTC)

Fujifilm provides imaging, information, and document solutions worldwide. It operates through three segments: imaging solutions, information solutions, and document solutions. The information solutions segment's offerings include equipment and materials for medical systems, including diagnostic imaging and information systems for healthcare facilities. Fujifilm's medical solutions combine advanced imaging technology and products in the field of radiography, mammography, ultrasound, and endoscopy. The company was founded in 1934 and is headquartered in Tokyo, Japan.

Guided Therapeutics, Inc. (GTHP-OTC)

Guided Therapeutics, Inc., a medical technology company, focuses on developing medical devices based on its patented biophotonic technology that utilizes light for the early detection of cancer. The company's first product is the LuViva® Advanced Cervical Scan, a non-invasive device used to detect cervical cancers instantly and at the point of care. The system works by scanning the cervix with light, then analyzing the light reflected or emanating from the cervix. In a multicenter clinical trial with women at risk for cervical disease, the technology was able to detect cervical cancer up to two years earlier than conventional modalities. LuViva® is in use in Canada, Latin America, Europe, Asia, and Africa and is under PMA review by the FDA. The company believes that the LuViva® platform technology can be applied to other forms of carcinoma, including esophageal cancer, head and neck cancer, anal cancer, colorectal cancer, and skin cancer. Guided Therapeutics has already conducted human testing with the technology on patients at risk for esophageal cancer with positive results. The company was formerly known as SpectRx, Inc. and changed its name to Guided Therapeutics, Inc. in February 2008. Guided Therapeutics was founded in 1992 and is based in Norcross, Georgia.

Mauna Kea Technologies SAS (MKEA-Paris)

Mauna Kea is a global medical device company focused on endomicroscopy and optical biopsy-based systems. The company designs, develops, and markets tools to visualize and detect cell abnormalities in real time during standard endoscopy procedures. Mauna Kea's flagship product, Cellvizio®, is a probe-based confocal laser endomicroscopy (pCLE/nCLE) solution that performs high-resolution microscopic imaging of internal tissues. Cellvizio® generates optical biopsies in a minimally invasive manner, providing physicians with an instant real-time diagnosis of any area of interest detected during endoscopic procedures. Clinical trials have demonstrated Cellvizio®'s ability to help physicians more accurately detect early forms of diseases and make immediate treatment decisions. Cellvizio® has 510(k) clearance from the FDA and a CE Mark in the EU for use in the gastrointestinal tract and the urinary and respiratory systems, for endoscopic exploration of the biliary and pancreatic ducts, and for fine-needle aspiration procedures. The company was founded in 2000 and is based in Paris, France.

MELA Sciences, Inc. (MELA-NASDAQ)

MELA Sciences is a medical device company that designs and develops software-driven technology for the early detection of skin cancer. The company focuses on commercialization of its principal product—MelaFind®—a non-invasive point-of-care software driven image analysis instrument to aid in the detection of melanoma. MelaFind® consists of a hand-held component that emits light of multiple wavelengths to capture digital data from clinically atypical pigmented skin lesions. The image is then analyzed utilizing proprietary algorithms to provide physicians with information to assist in the management of the patient's disease, including information useful in the decision of whether to biopsy the lesion. The FDA has approved a MelaFind® PMA for use in the U.S. MELA Sciences has also been granted CE Mark approval for sale of MelaFind® in the EU. The company was formerly known as Electro-Optical Sciences, Inc. and changed its name MELA Sciences, Inc. in April 2010. MELA Sciences was founded in 1989 and is based in Irvington, New York.

NinePoint Medical, Inc.

NinePoint Medical is a medical device company developing real-time imaging devices by utilizing advanced optical technologies, aimed at supporting clinical decision, and aiding biopsy placement and treatment planning. Utilizing an advanced form of Fourier-domain optical coherence tomography (FD-OCT), the company's proprietary NvisionVLE™ Imaging System enables physicians to endoscopically view real-time, high resolution, cross-sectional volumetric images of organs and tissues up to 3mm deep, with an initial focus on esophageal tissue. Developed at the Wellman Center for Photomedicine at Massachusetts General Hospital, this OCT technology was licensed by NinePoint Medical in 2010. Headquartered in Cambridge, Massachusetts, NinePoint Medical is backed by Third Rock Ventures, Prospect Venture Partners, and Corning Incorporated (GLW-NYSE).

Olympus Corporation (OCPNY-OTC)

Olympus manufactures and sells precision machineries and instruments worldwide. It operates in four segments: medical business, scientific solutions business, imaging business, and others business. The medical business segment provides endoscopy systems, including videoscopes, light sources, and peripheral equipment such as image recording and endoscopic devices for various diagnostic and treatment procedures. The scientific solutions business segment's product portfolio includes an array of high-end microscopes, fluorescence imaging devices, bio-imaging systems, and X-ray diffraction analyzers. Olympus Corporation was founded in 1919 and is headquartered in Tokyo, Japan.

OncoScope, Inc.

OncoScope is a medical imaging company that develops an optical biopsy platform to help physicians accurately and instantly identify dysplastic or precancerous tissue for biopsy. The device is based on Angle-resolved Low Coherence Interferometry (a/LCI) imaging technology, which uses the properties of scattered light to measure the average size of cell structures, including cell nuclei. OncoScope, which received an exclusive worldwide license rights from Duke University to a/LCI optical imaging technology in 2007, has created an optical screening platform that uses scattered light to identify cells with enlarged nuclei, the primary early marker for cancer. While esophageal cancer is the primary focus for Oncoscope's technology, the company believes that its technology platform has the potential to guide biopsies in the colon, cervix, stomach, lung, bladder, and oral cavity cancer segments. The company is based in Durham, North Carolina.

PENTAX Medical, a division of HOYA Corporation (HOCPY-OTC)

HOYA engages in the manufacturing and sale of precision devices and instruments based on advanced optics technologies, with an emphasis in the fields of life care and information technology. Through the operations of Pentax Medical, it offers endo-imaging solutions based on optical technologies. These offerings include a partnership with Hitachi that combines the company's ultrasound endoscopes with Hitachi's Real-time Tissue Elastography (HI-RTE) medical imaging technology, providing enhanced diagnostic capabilities. In addition, PENTAX Medical's i-SCAN™ image processing technology provides digital image enhanced endoscopy (IEE), resulting in real-time virtual chromoendoscopy in support of early detection of disease lesions. The combination of i-SCAN and PENTAX Medical's HD endoscopes has shown to increase adenoma detection rates. HOYA was founded in 1941 and is headquartered in Tokyo, Japan.

University of Texas at Austin's Cockrell School of Engineering

Researchers from the University of Texas at Austin's Cockrell School of Engineering have developed a probe that combines in one device three methods of using light to measure the properties of skin tissue and detect cancer. The device could reduce unnecessary biopsies and provide rapid non-invasive examination of melanomas. The device combines three common spectroscopic techniques–Raman spectroscopy, diffuse reflectance spectroscopy, and LIF spectroscopy–into a single probe to create a more complete picture of a skin lesion. As normal skin becomes cancerous, cell nuclei enlarge, the top layers of skin can thicken, and the skin cells can increase their consumption of oxygen and become disorganized. The changes alter the way light interacts with the tissue. The use of three different spectroscopic techniques by the device is hoped to facilitate the detection of all of these changes in one step. The researchers have begun testing the 3-in-1 device in pilot clinical trials and are partnering with funding agencies and start-up companies for future commercialization.

Verisante Technology, Inc. (VRS-TSX.V)

Verisante is a medical device company focused on the development and commercialization of innovative systems for the early detection of cancer. The Company's offerings—the Verisante Aura™ for skin cancer detection and the Verisante Core™ series for lung, colon, and cervical cancer detection—utilize a proprietary cancer detection platform developed by the BC Cancer Agency and the University of British Columbia and tested and refined on approximately 1,000 lesions at the Skin Care Centre at Vancouver General Hospital. Verisante Aura™, a spectroscopy system to aid in the detection of various skin cancers, including basal cell carcinoma, squamous cell carcinoma, melanoma, pre-cancerous lesions, and actinic keratosis, was awarded the 2014 North American Technology Innovation of the Year Award for In Vivo Cancer Detection by Frost & Sullivan, *Popular Science* Magazine's "Best of What's New Award" for 2011, awarded a 2013 Prism Award for Innovation in Photonics, and an Edison Award for Excellence in Innovation in 2013. In addition, Core™ was named one of the top 10 cancer breakthroughs of 2011 by the Canadian Cancer Society. The company was formerly known as T-Ray Science Inc. and changed its name to Verisante Technology, Inc. in January 2011. Verisante was founded in 2006 and is headquartered in Vancouver, Canada.

Historical Financial Results

Figures 22, 23, and 24 (pages 35-37) provide a summary of SpectraScience's key historical financial statements: its Statements of Operations, Balance Sheets, and Statements of Cash Flows, as presented in the Company's Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on May 14, 2015.

Figure 22

SpectraScience, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenue	$ —	$ —
Cost of revenue	(6,000)	(6,000)
Gross profit	6,000	6,000
Operating expenses:		
Research and development	174,680	258,180
General and administrative	381,454	519,831
Sales and marketing	39,862	89,560
	595,996	867,571
Loss from operations	(589,996)	(861,571)
Other income (expense)		
Interest expense	(144,502)	(98,971)
Change in fair value of derivative and warrant liabilities	(677,584)	(2,082,640)
Amortization of derivative and warrant liabilities discount	(290,109)	(150,733)
Amortization of deferred debt issuance costs and original issue discount	(87,814)	(47,124)
Gain on extinguishment of debt	82,728	—
Other income (expense), net	(2,413)	(9,118)
	(1,119,694)	(2,388,586)
Net loss	$ (1,709,690)	$ (3,250,157)
Basic and diluted loss per share	$ (0.01)	$ (0.02)
Weighted average common shares outstanding:		
Basic and diluted	194,355,277	167,208,694

Source: SpectraScience, Inc.

Figure 23

SpectraScience, Inc. and Subsidiaries

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2015 (Unaudited)	December 31, 2014 (Audited)
ASSETS		
Current assets:		
Cash	$ 69,955	$ 223,529
Inventory	283,883	283,624
Deferred debt issuance costs	78,609	107,636
Prepaid expenses and other current assets	228,876	244,173
Total current assets	661,323	858,962
Fixed assets, net	2,828	3,665
Patents, net	1,307,288	1,347,894
	$ 1,971,439	$ 2,210,521
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 850,267	$ 836,136
Note payable	115,000	100,000
Convertible debt, net of discounts of $387,508 as of March 31, 2015 and $576,502 as of December 31, 2014	4,447,674	3,920,100
Derivative liability	1,690,188	1,061,839
Accrued expenses	709,563	673,012
Total current liabilities	7,812,692	6,591,087
COMMITMENTS AND CONTINGENCIES		
Stockholders' deficit		
Series A Convertible Preferred Stock, $.01 par value; 0 shares authorized, issued and outstanding as of March 31, 2015 and December 31, 2014	—	—
Series B Convertible Preferred Stock, $.01 par value; 2,585,000 shares authorized, issued and outstanding as of March 31, 2015 and December 31, 2014; liquidation value of $517,000 plus accumulated and unpaid dividends of $106,931 as of March 31, 2015 and December 31, 2014	25,850	25,850
Series C Convertible Preferred Stock, $.01 par value; 1,000,000 shares authorized; 500,000 shares issued and outstanding as of March 31, 2015 and December 31, 2014; liquidation value of $100,000 as of March 31, 2015 and December 31, 2014	5,000	5,000
Common stock, $.01 par value; 746,915,000 shares authorized; 196,834,654 and 194,355,277 shares issued and outstanding as of March 31, 2015 and December 31, 2014	1,968,347	1,943,553
Additional paid in capital	39,733,324	39,509,115
Accumulated deficit	(47,573,774)	(45,864,084)
Total stockholders' deficit	(5,841,253)	(4,380,566)
	$ 1,971,439	$ 2,210,521

Source: SpectraScience, Inc.

Figure 24

SpectraScience, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Operating activities:		
Net loss	$ (1,709,690)	$ (3,250,157)
Adjustments to reconcile net loss to cash used in operating activities:		
Amortization and depreciation	41,443	54,562
Non-cash issuance of stock options and warrants	59,768	266,017
Amortization of derivative and warrant liabilities discount	290,109	150,733
Amortization of deferred debt issuance costs and original issue discount	87,814	47,124
Change in fair value of derivative and warrant liabilities	677,584	2,082,640
Gain on extinguishment of debt	(82,728)	—
Fair market value of common stock issued for services	—	15,500
Changes in assets and liabilities:		
Accounts receivable	—	60,000
Inventory	(259)	(43,659)
Prepaid expense and other assets	15,297	15,798
Accounts payable	14,131	(169,492)
Accrued expenses	66,957	165,432
Net cash used in operating activities	(539,574)	(605,502)
Investing activities:		
Purchases of fixed assets	—	(6,275)
Net cash used in investing activities	—	(6,275)
Financing activities:		
Proceeds from issuance of convertible notes payable	410,000	511,376
Payments against note payable to affiliate	—	(15,000)
Proceeds from exercise of stock options	—	18,624
Debt issuance costs	(24,000)	(43,500)
Net cash provided by financing activities	386,000	471,500
Net increase (decrease) in cash	(153,574)	(140,277)
Cash, beginning of year	223,529	236,597
Cash, end of period	$ 69,955	$ 96,320
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ —	$ —
Income taxes	$ —	$ —
Non Cash Investing and Financing Activities:		
Conversion of convertible notes and accrued interest to common stock	$ 114,604	$ —
Conversion of accrued interest to note payable	$ 15,000	$ —

Source: SpectraScience, Inc.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by SpectraScience, Inc. ("SpectraScience" or "the Company") with the assistance of Crystal Research Associates, LLC ("CRA") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in SpectraScience's statements on Forms 10-K, 10-Q, and 8-K, as well as other forms filed from time to time.

The content of this report with respect to SpectraScience has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings. SpectraScience is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by SpectraScience or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA has been compensated by the Company in cash of forty thousand U.S. dollars and three hundred thousand warrants for its services in creating this report and updates. For more complete information about the risks involved in an investment in the Company, please see SpectraScience's Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 20, 2015, and available at https://www.sec.gov/Archives/edgar/data/727672/000161577415000532/s100865_10k.htm.

Investors should carefully consider the risks and information about SpectraScience's business, as described below. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in SpectraScience's Form 10-K are not the only risks that the Company faces. Additional risks and uncertainties not presently known to SpectraScience or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, SpectraScience's business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company's shares could decline.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. Additional information about SpectraScience and its public filings, as well as copies of this report, can be obtained in either a paper or electronic format by calling (858) 847-0200.

RISKS RELATED TO SPECTRASCIENCE'S BUSINESS

SpectraScience has a limited operating history with significant losses and expects losses to continue for the foreseeable future.

SpectraScience has yet to establish any history of profitable operations. The Company has incurred annual operating losses of approximately $2,706,000 and $2,732,000, respectively, during the past two years of operations. As a result, at December 31, 2014, SpectraScience had an accumulated deficit of approximately $45,864,000. The Company has incurred net losses from continuing operations of approximately $4,488,000 and $2,750,000 for the years ending December 31, 2014 and 2013, respectively. Its revenues have not been sufficient to sustain operations and SpectraScience expects that they will be insufficient to sustain operations for the foreseeable future. The Company's failure to generate meaningful revenues and ultimately profits from the WavSTAT System and applications of its technology could and will likely require that it raise additional capital which may not be available or available on acceptable terms. This could ultimately reduce or suspend SpectraScience's operations and ultimately cause the Company to go out of business. Profitability will require the successful commercialization of the Company's imaging systems and no assurances can be given when this will occur or if SpectraScience will ever be profitable.

SpectraScience will require additional financing to sustain operations, and without it, may not be able to continue operations.

At December 31, 2014, SpectraScience had a working capital deficit of approximately $5,732,000. The Company had an operating cash flow deficit of approximately $2,442,000 for the year ended December 31, 2014, and an operating cash flow deficit of approximately $1,613,000 in 2013. SpectraScience may not have sufficient financial resources to fund operations and will likely require additional funds to continue operations.

The Company may face intense competition from companies that have greater financial, personnel, and research and development resources.

Competitive forces may impact SpectraScience's projected growth and ability to generate revenues and profits, which would have a negative impact on business and the price of its common stock. Competitors may be developing products that compete with the WavSTAT Systems. Commercial opportunities would then be reduced or eliminated should competitors develop and market products for any of the diseases that SpectraScience targets that are more effective or are less expensive than the products or product candidates the Company is developing.

Even if SpectraScience is successful in developing an effective WavSTAT System, and obtains FDA and other regulatory approvals necessary for commercialization, its products may not compete effectively with other successful products. Researchers are continually learning more about diseases, which may lead to new technologies and tools for analysis.

SpectraScience's competitors include fully integrated medical device companies, universities, and public and private research institutions. Many of the organizations competing with it may have substantially greater capital resources, larger research and development staffs and facilities, greater experience in product development and in obtaining regulatory approvals, and greater marketing capabilities.

The market for medical devices is intensely competitive. Many of SpectraScience's potential competitors have longer operating histories, greater name recognition, more employees, and significantly greater financial, technical, marketing, public relations, and distribution resources than the Company. This intense competitive environment may require the Company to make changes in its products, pricing, licensing, services, or marketing to develop, maintain, and extend its current technology. Price concessions or the emergence of other pricing or distribution strategies of competitors may diminish revenues, adversely impact margins, or lead to a reduction in market share, any of which may harm business.

The WavSTAT System technology may become obsolete.

The WavSTAT System products may be made unmarketable by new scientific or technological developments where new treatment modalities are introduced that are more efficacious or more economical. Any one of SpectraScience's competitors could develop a more effective product which would render the Company's technology obsolete.

SpectraScience's inability to attract and retain qualified personnel could impede its ability to generate revenues and profits and to otherwise implement its business plan and growth strategies, which would have a negative impact on business and could adversely affect the price of the Company's common stock.

SpectraScience currently has a staff of nine employees and consultants, consisting of, among others, its chief executive officer, chief financial officer, director of sales and marketing, and chief engineer director, as well as administrative employees. The Company will be required over the longer-term to hire highly skilled managerial, scientific, and administrative personnel to fully implement its business plan and growth strategies. SpectraScience cannot assure investors that it will be able to engage the services of such qualified personnel at competitive prices or at all, particularly given the risks of employment attributable to the Company's limited financial resources and lack of an established track record.

Planned growth will place strains on SpectraScience's management team and other company resources to both implement more sophisticated managerial, operational, and financial systems, procedures, and controls and to train and manage the personnel necessary to perform those functions. An inability to manage growth could impede the Company's ability to generate revenues and profits and to otherwise implement its business plan and growth strategies, which would have a negative impact on business and the market value of the Company.

SpectraScience will need to significantly expand operations to implement its longer-term business plan and growth strategies. The Company will also be required to manage multiple relationships with various strategic partners, technology licensors, customers, manufacturers, and suppliers, consultants, and other third parties. This expansion and these expanded relationships will require it to significantly improve or replace existing managerial, operational, and financial systems, procedures, and controls; to improve the coordination between various corporate functions; and to manage, train, motivate, and maintain a growing employee base. The time and costs to effectuate these steps may place a significant strain on management personnel, systems, and resources, particularly given the limited amount of financial resources and skilled employees that may be available at the time. SpectraScience cannot assure anyone that it will institute, in a timely manner or at all, the improvements to managerial, operational, and financial systems, procedures, and controls necessary to support anticipated increased levels of operations and to coordinate various corporate functions, or that it will be able to properly manage, train, motivate, and retain the anticipated increased number of employees.

SpectraScience may have difficulty in developing and retaining an effective sales force or in obtaining effective distribution partners and may not be able to achieve sufficient revenues to affect its business plan.

The market for skilled sales and marketing personnel is highly competitive and specialized. If SpectraScience is unable to hire and retain skilled and knowledgeable salespeople, it may negatively impact the Company's ability to introduce its products or generate revenue sufficient to affect its future business plans. In addition, SpectraScience's inability to develop business relationships with key technical distributors may also negatively impact its ability to successfully market products.

SpectraScience may have difficulty in attracting and retaining management and outside independent members to its Board of Directors, as a result of their concerns relating to their increased personal exposure to lawsuits and shareholder claims by virtue of holding these positions in a publicly held company.

The directors and management of publicly traded corporations are increasingly concerned with the extent of their personal exposure to lawsuits and shareholder claims, as well as governmental and creditor claims which may be made against them, particularly in view of recent changes in securities laws imposing additional duties, obligations, and liabilities on management and directors. Due to these perceived risks, directors and management are also becoming increasingly concerned with the availability of directors' and officers' liability insurance to pay on a timely basis the costs incurred in defending such claims. SpectraScience currently carries directors' and officers' liability insurance, but such insurance is expensive and can be difficult to obtain. If the Company is unable to obtain directors' and officers' liability insurance at affordable rates or at all in the future, it may become increasingly more difficult to attract and retain qualified outside directors to serve on the Board of Directors. The fees of directors are also rising in response to their increased duties, obligations, and liabilities as well as increased exposure to such risks. As a company with a limited operating history and limited resources, SpectraScience will have a more difficult time attracting and retaining management and outside independent directors than a more established company due to these enhanced duties, obligations, and liabilities.

If SpectraScience fails to comply with extensive regulations enforced by domestic and foreign regulatory authorities, the commercialization of its products could be prevented or delayed.

The WavSTAT Systems are subject to extensive government regulations related to development, testing, manufacturing, and commercialization in the U.S. and other countries. The determination of when and whether a product is ready for large-scale purchase and potential use will be made by the government through consultation with a number of governmental agencies, including the FDA, the National Institutes of Health, and the Centers for Disease Control and Prevention (CDC). Some of SpectraScience's product candidates are in the clinical stages of development and have not received required regulatory approval from the FDA for applications the Company

hopes to commercially market. The process of obtaining and complying with the FDA and other governmental regulatory approvals and regulations is costly, time consuming, uncertain, and subject to unanticipated delays. Despite the time and expense incurred, regulatory approval is never guaranteed. SpectraScience is also subject to the following risks and obligations, among others:

- The FDA may refuse to approve an application if it believes that applicable regulatory criteria are not satisfied;
- The FDA may require additional testing for safety and effectiveness;
- The FDA may interpret data from preclinical testing and clinical trials in different ways than SpectraScience;
- If regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
- The FDA may change approval policies and/or adopt new regulations.

Failure to comply with these or other regulatory requirements of the FDA may subject SpectraScience to administrative or judicially imposed sanctions, including warning letters; civil penalties; criminal penalties; injunctions; product seizure or detention; product recalls; and total or partial suspension of production.

Delays in successfully completing SpectraScience's clinical and European evaluation trials could jeopardize the Company's ability to obtain regulatory approval or market the WavSTAT System candidates on a timely basis.

SpectraScience's business prospects will depend on its ability to complete clinical trials, obtain satisfactory results, obtain required regulatory approvals, and successfully commercialize its WavSTAT System product candidates. Completion of clinical trials, announcement of results of the trials, and the Company's ability to obtain regulatory approvals could be delayed for a variety of reasons, including unsatisfactory results of any clinical trial; the failure of principal third-party investigators to perform clinical trials on anticipated schedules; and different interpretations of preclinical and clinical data, which could initially lead to inconclusive results.

SpectraScience's development costs will increase if it has material delays in any clinical trial or if it needs to perform more or larger clinical trials than planned.

If clinical or evaluation trial delays are significant, or if any of the WavSTAT System product candidates do not prove to be safe or effective or do not receive required regulatory approvals, SpectraScience's financial results and the commercial prospects for its product candidates will be harmed. Furthermore, the Company's inability to complete clinical trials in a timely manner could jeopardize its ability to obtain regulatory approval.

The independent clinical investigators that SpectraScience relies upon to conduct clinical trials may not be diligent, careful, or timely, and may make mistakes, in the conduct of clinical trials.

SpectraScience depends on independent clinical investigators to conduct clinical trials. The investigators are not employees, and SpectraScience cannot control the amount or timing of resources that they devote to its product development programs. If independent investigators fail to devote sufficient time and resources to the Company's product development programs, or if their performance is substandard, it may delay FDA approval of SpectraScience's products. These independent investigators may also have relationships with other commercial entities, some of which may compete with the Company. If these independent investigators assist competitors at SpectraScience's expense, it could harm the Company's competitive position.

SpectraScience's product development efforts may not yield marketable products due to results of studies or trials, failure to achieve regulatory approvals or market acceptance, proprietary rights of others, or manufacturing issues.

The Company's success depends on its ability to successfully develop and obtain regulatory approval to market new products. SpectraScience expects that a significant portion of the research that it will conduct will involve new and unproven technologies. Development of a product requires substantial technical, financial, and human resources even if the product is not successfully completed. Potential products may appear to be promising at various stages of development yet fail to reach the market for a number of reasons, including a lack of adequate quality or sufficient prevention benefit, or unacceptable safety during preclinical studies or clinical trials; failure to receive necessary regulatory approvals; existence of proprietary rights of third parties; and/or and inability to develop manufacturing methods that are efficient, cost effective, and capable of meeting stringent regulatory standards.

SpectraScience's inability to protect its intellectual property rights could negatively impact projected growth and ability to generate revenues and profits, which would have a negative impact on business and the value of an investment.

SpectraScience relies on a combination of patent, patent pending, copyright, trademark and trade secret laws, proprietary rights agreements, and non-disclosure agreements to protect its intellectual properties. These measures may not prove to be effective in protecting intellectual properties. In the case of patents, SpectraScience's existing patents may be invalidated, any patents that it currently or prospectively applies may not be granted, or any of these patents may not ultimately provide significant commercial benefits. Further, competing companies may circumvent any patents that SpectraScience may hold by developing products which closely emulate but do not infringe its patents. While SpectraScience currently has and intends to seek patent protection for its products in selected foreign countries, those patents may not receive the same degree of protection as they would in the U.S. SpectraScience may not be able to successfully defend its patents and proprietary rights in any action it may file for patent infringement. Similarly, SpectraScience may be required to defend litigation involving the patents or proprietary rights of others, or may be able to obtain licenses for these rights. Legal and accounting costs relating to prosecuting or defending patent infringement litigation may be substantial.

The WavSTAT System is protected by 34 issued patents in the U.S. and approximately 25 foreign patents, which SpectraScience owns, and one additional patent for which it owns the exclusive license. SpectraScience also relies on proprietary designs, technologies, processes, and know-how not eligible for patent protection. Competitors may independently develop the same or superior designs, technologies, processes, and know-how.

While SpectraScience has and will continue to enter into proprietary rights agreements with employees and third parties giving it proprietary rights to certain technology developed by those employees or parties while engaged by the Company, courts of competent jurisdiction may not enforce those agreements.

The patents SpectraScience owns comprise a large portion of its assets, which could limit its financial viability.

SpectraScience's patents comprise approximately 60% of the Company's assets as of December 31, 2014. If existing patents are invalidated or if they fail to provide significant commercial benefits, it will severely hurt the Company's financial condition, as a significant percentage of its assets would lose value. Further, since patents are amortized over the course of their term until they expire, SpectraScience's assets composed of patents will continually be written down to zero.

Legislative actions and potential new accounting pronouncements are likely to impact SpectraScience's future financial position and results of operations.

Compliance with publicly traded company regulations adversely impacts resources. As a publicly traded company, SpectraScience is subject to rules and regulations that increase its legal and financial compliance costs, make some activities more time consuming and costly, and divert management's attention away from the operation of business. SpectraScience is obligated to file with the SEC annual and quarterly information and other reports that are specified in the Securities Exchange Act of 1934, or the Exchange Act, and is also subject to other reporting and corporate governance requirements, including requirements of the Sarbanes-Oxley Act of 2002, and the rules and regulations promulgated thereunder, which impose significant compliance and reporting obligations upon SpectraScience. The Company may not be successful in complying with these obligations, and compliance with these obligations could be time consuming and expensive. Failure to comply with the additional reporting and corporate governance requirements could lead to fines imposed on SpectraScience, deregistration under the Exchange Act, and in the most egregious cases, criminal sanctions could be imposed.

SpectraScience's products may be subject to recall or product liability claims.

The WavSTAT System products may be used in connection with medical procedures in which it is important that those products function with precision and accuracy. If SpectraScience's products do not function as designed, or are designed improperly, the Company may be forced by regulatory agencies to withdraw such products from the market. In addition, if medical personnel or their patients suffer injury as a result of any failure of SpectraScience's products to function as designed, or due to an inappropriate design, the Company may be subject to lawsuits seeking significant compensatory and punitive damages. Any product recall or lawsuit seeking significant monetary damages may have a material effect on SpectraScience's business and financial condition.

Glossary

510(k) Clearance—Section 510(k) of the Food, Drug, and Cosmetic Act requires device manufacturers to notify the FDA at least 90 days in advance of an intent to market a medical device. The FDA may then issue a 510(k) marketing clearance, allowing the commercialization of the device, upon making a determination that the device to be introduced into commercial distribution is safe and effective.

Adenoma—A benign tumor formed from glandular structures in epithelial tissue.

CE Mark—The regulatory approval system for all medical devices to be sold in the European Union (EU). It is used to indicate that a product conforms to the relevant EU health, safety, and environmental quality standards.

Colonoscopy—An exam used to detect changes or abnormalities in the large intestine (colon) and rectum. During a colonoscopy, a long, flexible tube (a colonoscope) is inserted into the rectum.

Crohn's Disease—A chronic inflammatory bowel disease that causes scarring and thickening of the intestinal walls and frequently leads to obstruction.

CT Colonography—Another name for a virtual colonoscopy. The term CT colonography provides a more accurate description of the technique that employs computerized tomography (CT) but not a colonoscope. This scan may also be useful in detecting cancers outside the colon, such as renal, lung, and lymph node cancers.

Current Procedural Terminology (CPT)—A code set used to report medical procedures and services to entities such as physicians, health insurance companies, and accreditation organizations.

Dysplasia—The enlargement of an organ or tissue by the proliferation of cells of an abnormal type, as a developmental disorder or an early stage in the development of cancer.

EN 13485:2003—ISO 13485 is an International Organization for Standardization (ISO) standard, published in 2003, which represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.

Endoscope—An instrument that can be introduced into the body to give a view of its internal parts.

Fluorescence—The visible or invisible radiation emitted by certain substances as a result of incident radiation of a shorter wavelength such as X-rays or ultraviolet light. Essentially, it is the property of absorbing light of short wavelength and emitting light of longer wavelength.

Good Manufacturing Practices (GMP)—The practices required in order to confirm to guidelines recommended by the FDA and other agencies worldwide that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical and device products. These guidelines provide minimum requirements that a manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public.

Interstitial Cells of Cajal—A cell network composed of cells having processes described by the 19th century Spanish neuroanatomist S. Ramon y Cajal. These cells found in the gastrointestinal tract are probable progenitor cells of gastrointestinal stromal tumors (GIST).

In Situ—Situated in the original, natural, or existing place or position. Especially of a cancerous growth or tumor, not seen to be spreading from a localized position.

In Vivo—Occurring or carried out in the living organism.

In Vitro—Made to occur outside the living organism in an artificial environment, such as a culture medium.

ISO 9001—This standard establishes criteria for a quality management system. It can be used by any organization, large or small, regardless of its field of activity. The quality management principles of ISO 9001 include a strong customer focus, the motivation and implication of top management, the process approach, and continual improvement.

Managed Care Organizations—An organization that combines the functions of health insurance, delivery of care, and administration, and that accepts a set per member per month (capitation) payment for these services from benefit providers such as Medicaid. Managed care is a healthcare delivery system organized to manage cost, utilization, and quality.

Negative Predictive Value (NPV)—The probability that patients with a negative screening test truly do not have the disease.

Perforation—An abnormal opening in a hollow organ or viscus, as one made by rupture or injury.

Polyp—A projecting growth from a mucous surface, as of the nose, being either a tumor or a hypertrophy of the mucous membrane.

Positive Predictive Value—The probability that patients with a positive screening test truly have the disease.

Premarket Approval (PMA)—The FDA process of scientific and regulatory review to evaluate the safety and effectiveness of certain medical devices.

Sensitivity—The proportion of individuals in a population that will be correctly identified when administered a test designed to detect a particular disease, calculated as the number of true positive results divided by the number of true positive and false negative results.

Sigmoidoscopy—An examination of the sigmoid colon by means of a flexible tube inserted through the anus.

Specificity—The statistical probability that an individual who does not have the particular disease being tested for will be correctly identified as negative, expressed as the proportion of true negative results to the total of true negative and false positive results.

Spectroscopy—The study of the interaction between matter and electromagnetic radiation.

Ulcerative Colitis—Chronic ulceration in the large intestine, characterized by painful abdominal cramps and profuse diarrhea containing pus, blood, and mucus.

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Facts Without Fiction

EXECUTIVE INFORMATIONAL OVERVIEW®

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880 Third Avenue, 6th Floor, New York, NY 10022 Office: (212) 851-6685