

Welcome, to the 2<sup>nd</sup> edition of the Optiscan newsletter – Seeing the Light.

It has been a busy quarter and we are pleased to report on the progress we have made in R&D, the new patents that we have been granted and receipt of an innovation award from Frost and Sullivan.

I would also recommend to you the report written by Peter Delaney. Peter's paper explains recent technology advances and the synergies between high definition endoscopy and our own endomicroscopy product. It is clear that the introduction of HD endoscopy provides an even greater rationale for the use of endomicroscopy in gastroenterology.

Vicki Tutungi  
CEO

### R&D Progress

Last quarter we reported on the progress of our second generation smaller scanner. We are now pleased to report on development of our second generation processor which is currently in debugging phase. The prototype has a significantly smaller footprint than its predecessor which was made up of two units. The new processor also provides greater functionality to endoscopists. For instance, endoscopes can be plugged into the system and unplugged from the system without having to reboot it. The new design also has lower manufacturing costs and is easier to service. Debugging along with final software development will require some further work, thereafter, several prototypes will be deployed in clinical trials.



New 2<sup>nd</sup> Generation Processor



1<sup>st</sup> Generation System

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# HD Endoscopy Creates a Dilemma and an Opportunity

by Peter Delaney

Originally, endoscopy was used for finding obvious disease. Since that time there has been a steady trend towards detecting more subtle disease as technology has improved. The most recent improvement in endoscopes are the high definition scopes.

High definition (HD) endoscopy enables “seeing more detail” by offering a higher resolution macroscopic view of the tissue through use of higher resolution CCDs. The better the macroscopic image, the more you can see. This is presently offered by Olympus, Fujinon and Hoya-Pentax. Studies have consistently found that HD endoscopy improves the sensitivity of detecting suspicious lesions. Moreover, studies comparing HD to standard definition scopes consistently show HD to find more lesions than standard definition.

A HD scope is an undeniably attractive tool for an endoscopist being described by endoscopists as “like having cataracts removed from your eyes”. However, these improvements have created a looming dilemma for the endoscopist – the latest generation of scopes and processors allow the endoscopist to *detect* more lesions, but fall short of allowing them to determine which ones are the most relevant. Now the endoscopist has to contend with finding much more during endoscopy. There is a requirement to spend more time looking and to take more biopsies. This additional procedure, may find only marginal additional clinically relevant disease. Macro image improvements increase sensitivity, but their high false-positive rate worsens efficiency. The Optiscan endomicroscope directly addresses this deficiency.

Diagnosis of gastrointestinal disorders usually rests on biopsy. Biopsy is time consuming (about a minute per biopsy), painful for the patient and offers poor sampling statistics. Two millimetres away from a life threatening lesion can yield normal pathology results. HD endoscopy is known NOT to significantly improve the rate of diagnosis due to a high false positive rate. Even though they find more disease, they also find more suspicious tissue that is actually normal.

The gold standard of diagnosis is the histopathology of biopsy. That is, looking at the cellular level detail of biopsied tissue. To date, endomicroscopy is the only technology to offer this in vivo. An endoscopist can use the HD scope to find the points of interest and then can use the endomicroscope to determine which of those points should be biopsied. Studies have already proven this phenomenon, with investigators taking fewer biopsies but actually finding more disease overall. (Kiesslich R, Goetz M, Lammersdorf K, Schneider C, Burg J, Stolte M, Vieth M, Nafe B, Galle PR, Neurath MF. Chromoscopy-guided endomicroscopy increases the diagnostic yield of intraepithelial neoplasia in ulcerative colitis. *Gastroenterology* 2007; 132: 874–882)

So rather than compete with HD endoscopy, the introduction of HD endoscopy creates an increased need for endomicroscopy. Optiscan plans to leverage this need through the release of its second generation technology. The Optiscan second generation smaller scanner has been designed specifically so that it can fit into the more cramped environment of a HD scope. This will mean for the very first time, a scope could be offered with both HD capability and endomicroscopy.

# Optiscan wins Frost and Sullivan Award

F R O S T & S U L L I V A N

May 11, 2009

Vicki Tutungi  
CEO  
Optiscan Pty. Ltd., Australia

Dear Vicki,

**RE: CONGRATULATIONS – 2009 ASIA PACIFIC FROST AND SULLIVAN PRODUCT INNOVATION AWARD IN THE FIELD OF CONFOCAL MICROSCOPY**

On behalf of Frost & Sullivan, we are pleased to announce that **Optiscan** has been awarded the **2009 Asia Pacific Frost and Sullivan Product Innovation award in the field of Confocal Microscopy**

To choose a recipient of this Award, the analyst team tracks all new product launches, research and development (R&D) spending, products in development, and new product features and modifications. This is accomplished through interviews with the market participants and extensive secondary and technology research. All new product launches and new products in development in each company are compared and evaluated based on degree of innovation and customer satisfaction. Companies are then ranked by number of new product launches and new products in development.

The Award is conferred for its development of the **Fluorescent In-Vivo Endomicroscope** which could prove to be a valuable tool for diagnosis of gastrointestinal disorders. Optiscan has developed a **Fluorescent In-Vivo Endomicroscope** known as **FIVE1**. The endomicroscope, based on a patented technology has led to the miniaturization of the confocal microscope so as to capture real time images in the body. The caliber of the company's employees along with a fast paced innovation culture has helped the company to develop new products that has made it possible to stand out against competition.

Wishing you every success. We look forward to working closely with you in the future.

Thank you.

Sincerely,



Cindy Gan  
Director  
Asia Pacific Best Practices and Events  
Frost & Sullivan

We recognise the value of keeping competitors out of our space and continue to strengthen our patent position . We are pleased to report that in May 2009, the US Patent “Tuning Fork Type Scanning with Counterweight” was granted and in July 2009, the Japanese patent number 4311979, with the title “Endoscope” was granted in the joint names of Optiscan and Hoya .

Patent News

## Recent Endomicroscopy Papers

**Bojarski C, Gunther U, Rieger K, Heller F, Loddenkemper C, Grunbaum M, Uharek L, Zeitz M, Hoffman JC.** In vivo diagnosis of acute intestinal graft-versus-host disease by confocal endomicroscopy. *Endoscopy* 2009; 41(5):433-438.

**Cotruta B, Gheorghe C, Bancila I.** Magnifying endoscopy with narrow-band imaging or confocal laser endomicroscopy for in vivo rapid diagnostic of Barrett's Esophagus. *J Gastrointest Liver Dis* 2009; 18(2): 258-259.

**Gheorghe C, Iacob R, Dumbrava M, Becheanu G, Ionescu M.** Confocal laser endomicroscopy and ultrasound endoscopy during the same endoscopic session for diagnosis and staging of gastric neoplastic lesions. *Chirurgia (Bucur)* 2009; 104(1): 17-24.

**Leung KK, Maru D, Abraham S, Hofstetter WL, Mehran R, Anandasabapathy S.** Optical EMR: confocal endomicroscopy-targeted EMR of focal high-grade dysplasia in Barrett's Esophagus. *Gastrointest Endosc* 2009; 69(1): 170-171.

**Liu H, Li YQ, Yu T, Zhao YA, Zhang JP, Zuo XL, Li CQ, Zhang JN, Guo YT, Zhang TG.** Confocal laser endomicroscopy for superficial esophageal squamous cell carcinoma. *Endoscopy* 2009; 41(2): 99-106.

**Nguyen NQ, Biankin AV, Leong RW, Chang DK, Cosman PH, Delaney P, Kench JG, Merrett ND.** Real time intraoperative confocal laser microscopy-guided surgery. *Ann Surg* 2009; 249(5): 735-737.

**Trovato C, Sonzogni A, Ravizza D, Pruneri G, Rossi M, de Roberto G, Tamayo D, Vanazzi A, Fiori G, Crosta C.** Confocal laser endomicroscopy diagnosis of gastric adenocarcinoma in a patient treated for gastric diffuse large-B-cell lymphoma. *Dig Liver Dis* 2009; 41(6): 447-449.

**Sanduleanu S, Driessen A, Hameeteman W, van Gemert W, de Bruine A, Masclee A.** Inflammatory cloacogenic polyp: diagnostic features by confocal endomicroscopy. *Gastrointest Endosc* 2009; 69(3): 595-598.

**Venkatesh K, Cohen M, Akobeng T, Ashok D, Abou-Taleb A, Evans C, Howarth K, Taylor C, Thomson M.** Diagnosis and management of the first reported case of esophageal, gastric and small-bowel heterotopias in the colon, using confocal laser endomicroscopy. *Endoscopy* 2009; 41 (Suppl 2): E58.

**Venkatesh K, Cohen M, Evans C, Delaney P, Thomas S, Taylor C, Abou-Taleb A, Kiesslich R & Thomson M.** Feasibility of confocal endomicroscopy in the diagnosis of paediatric gastrointestinal disorders. *World J Gastroenterol* 2009; 15(18): 2214-2219.

**Watson AJ, Duckworth CA, Guan Y, Montrose MH.** Mechanisms of epithelial cell shedding in the Mammalian intestine and maintenance of barrier function. *Ann N Y Acad Sci* 2009; 1165: 135-142.