



Annual General Meeting  
Notting Hill, VIC, Australia  
19 November 2013



## **Review & Update**

**Angus Holt – Executive Chairman**

Annual General Meeting  
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## Chairman's Address to Annual General Meeting 2013

Welcome and thank you for your attendance and interest in Optiscan.

Following my address I will hand over to Peter Delaney, Director Technology, for a review of activity and developments in clinical, technology and with product, after which I will undertake the formal business of the meeting including the resolutions as put to shareholders in the notice of meeting. After closure of the formal business of the AGM we will have an open forum for questions and our team will also further demonstrate the capabilities of our second generation endomicroscopy system.

As per our Directors' Report, I see it as useful to briefly recap on the recent history of Optiscan, specifically from mid 2009 when I joined the Board. Since then, Optiscan has operated on an historically low resource base while pursuing the development of its second generation platform in conjunction with its continually growing role in the collaboration with Zeiss in rigid endomicroscopy.

This resource constrained environment, one of both exogenous and endogenous origins, leads to extended development timelines and thus defers revenue generating milestones. While not the optimum development framework, it is a framework that has allowed the Company to endure the past 4-5 years where its second generation platform is best in class, near product in neurosurgery and is also the most validated technology in the ever growing gastrointestinal market for endomicroscopy or as it is increasingly being referred to, optical biopsy.

As I commented earlier, we have been operating within a necessarily sub-optimal framework for some time now with the management of available working capital and personnel resources a highly dynamic process.

Following a small capital raising in the first half of in September 2012 and the receipt of milestones and orders from Zeiss, we devoted additional resources to the final development tasks associated with our neurosurgery system. Despite a 27% increase in spending on R&D to more than \$1.5m, Optiscan's single largest expense, progress on the final development stage has been frustratingly slow and has consequently adversely affected our product release timetable and thus our short term revenue profile. I am however pleased with the point we have now reached with this final component which is now only subject to small manufacturing advancement and sterility and packaging related testing. The result is an elegant, high quality disposable sterility solution for our rigid neurosurgery endomicroscopy systems. Once this final testing is complete, a further small human trial will be conducted after which regulatory submission will be made.

While initially not a large market (annual addressable market in the order of US\$50m), this market is at the sharp end of endomicroscopy applications, is highly price inelastic and free from competition. Further the cutting edge nature of this market should see this flagship



system create substantial flow on benefits for other endomicroscopy applications, of which there are many.

In contrast to the neurosurgery market, the gastrointestinal market for endomicroscopy is large, and Optiscan's technology has seen extensive application since the clinical launch of its pioneering technology in 2006 (Pentax ISC-1000). The main flexible endoscopy applications are presently targeting of biopsies or see and treat workflows in Barrett's Esophagus (US reimbursement active), Ulcerative Colitis, margin assessment in CRC and gastric cancer. These applications alone represent annual addressable markets in excess of US\$1bn. There are numerous additional (although less mature) gastrointestinal applications, including in inflammation, microscopic colitis, epithelial healing, bacterial colonization and drug and other therapeutic responses.

This flexible endomicroscopy platform (ISC-1000) has generated level 1 evidence in an international multicentre study led by Johns Hopkins out of Baltimore, the results of which have recently been published, creating further drive for our systems to be incorporated into medical practice guidelines. Peter will elaborate on the findings and significance of this publication in his presentation.

In conjunction with advances in market development in gastrointestinal endomicroscopy, Optiscan has progressed its probe based developments over the past year resulting in a significantly smaller ultra hi-spec prototype probe (Peter will elaborate). The broadening of our capabilities in probe (pCLE) and the continued supremacy of the endoscope based system (eCLE) creates a single platform from which both eCLE and pCLE may be utilised. This is a compelling package for release of this technology into the large and highly validated gastrointestinal endomicroscopy market, where our path to market is under positive development. At this point we are unable to publicly elaborate further on our proposed modality of flexible endoscope market entry.

In summary, we are moving to capitalise on the status of our product and existing markets through flexible endoscopy market penetration and completion of the final steps to product release in neurosurgery. Success in these key areas will open up multiple opportunities and markets and consequently provide a means to operating Optiscan in a far less constrained manner going forward.

I will now hand over to Peter Delaney to present on technology, product and clinical status and developments.

# Peter Delaney Director of Technology

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Unlocking the world of **Live Micro Imaging (LMI) technology**

# Technology and Market Update

- Key Markets
  - Neurosurgery (Zeiss)
  - GI (Gastrointestinal) endoscopy
- Key Technical Developments
  - Scanners and Probes
  - Platform

# Carl Zeiss Meditec Ag Product Development



- Rigid endoscope system for neurosurgery
- Details Remain confidential
- Final regulatory approval trials yet to be undertaken
- Slower than hoped, but progressing strongly
- System performance for Zeiss product leverages second generation platform

# GI Endomicroscopy

- Largest market opportunity for Optiscan
- Multiple clinical indications for use
- 3 Category 1 CPT codes in place
- Preliminary reimbursement in place
- Optiscan offers compelling technical leadership
- Highest level clinical result support Optiscan's technology



# CPT codes & reimbursement

- American Medical Association (AMA) allocated 3 CPT codes in late 2012



- These were formally granted in January 2013
- Ambulatory reimbursement codes were announced by Medicare in August 2013
- These offer interim payment to doctors performing upper gastrointestinal endoscopy with endomicroscopy
- Clinicians continue to lobby for dedicated reimbursement at a higher level.



"WE PAY YOU, WE PAY YOU NOT. WE  
PAY YOU, WE PAY YOU NOT."

# Level 1 Clinical Evidence – Barrett’s Esophagus

ARTICLE IN PRESS

ORIGINAL ARTICLE

## In vivo endomicroscopy improves detection of Barrett’s esophagus–related neoplasia: a multicenter international randomized controlled trial (with video)

Marcia Irene Canto, MD, MHS,<sup>1</sup> Sharmila Anandasabapathy, MD,<sup>2</sup> William Brugge, MD,<sup>3</sup> Gary W. Falk, MD,<sup>4</sup> Kerry B. Dunbar, MD, PhD,<sup>5</sup> Zhe Zhang, PhD,<sup>6</sup> Kevin Woods, MD, MPH,<sup>7</sup> Jose Antonio Almario, BS, MHS,<sup>1</sup> Ursula Schell, BS,<sup>8</sup> John Goldblum, MD,<sup>9</sup> Anirban Maitra, MD,<sup>10</sup> Elizabeth Montgomery, MD,<sup>10</sup> Ralf Kiesslich, MD, PhD,<sup>8</sup> for the Confocal Endomicroscopy for Barrett’s Esophagus or Confocal Endomicroscopy for Barrett’s Esophagus (CEBE) Trial Group

Baltimore, Maryland, USA

**Background:** Confocal laser endomicroscopy (CLE) enables in vivo microscopic imaging of the GI tract mucosa. However, there are limited data on endoscope-based CLE (eCLE) for imaging Barrett’s esophagus (BE).

**Objective:** To compare high-definition white-light endoscopy (HDWLE) alone with random biopsy (RB) and HDWLE + eCLE and targeted biopsy (TB) for diagnosis of BE neoplasia.

**Design:** Multicenter, randomized, controlled trial.

**Setting:** Academic medical centers.

**Patients:** Adult patients with BE undergoing routine surveillance or referred for early neoplasia.

**Intervention:** Patients were randomized to HDWLE + RB (group 1) or HDWLE + eCLE + TB (group 2). Real-time diagnoses and management plans were recorded after HDWLE in both groups and after eCLE in group 2. Blinded expert pathology diagnosis was the reference standard.

**Main Outcome Measurements:** Diagnostic yield, performance characteristics, clinical impact.

**Results:** A total of 192 patients with BE were studied. HDWLE + eCLE + TB led to a lower number of mucosal biopsies and higher diagnostic yield for neoplasia (34% vs 7%;  $P < .0001$ ), compared with HDWLE + RB but with comparable accuracy. HDWLE + eCLE + TB tripled the diagnostic yield for neoplasia (22% vs 6%;  $P = .002$ ) and would have obviated the need for any biopsy in 65% of patients. The addition of eCLE to HDWLE increased the sensitivity for neoplasia detection to 96% from 40% ( $P < .0001$ ) without significant reduction in specificity. In vivo CLE changed the treatment plan in 36% of patients.

**Limitations:** Tertiary-care referral centers and expert endoscopists limit generalizability.

**Conclusion:** Real-time eCLE and TB after HDWLE can improve the diagnostic yield and accuracy for neoplasia and significantly impact in vivo decision making by altering the diagnosis and guiding therapy. (Clinical trial registration number: NCT01124214.) (Gastrointest Endosc 2013; ■:1-11.)

- Preliminary oral report given at DDW 2011
- Even better results in final analysis
- Now peer reviewed and published
- Now eligible for inclusion in review of practice guidelines
- Very strong trial design
- Stellar results
- High impact on intra-procedural decision making
- Results rested on key advantages of Optiscan’s technology
- Not applicable to competitor’s product

# Optiscan Full Screen True HD Image



Competitor's "HD"  
Image

Optiscan's true HD scan is unmatched by any competing product.

Shown here, a competing probe that is configured close to Optiscan resolution is limited to a tiny field of view. Working with the probe is like sampling a real-time Optiscan image through a keyhole. In this case, there are several different cellular anomalies within a single scan at our large field of view that would likely be missed with our competitor's product.

# Scanner and Probe Development



Scanner for probe prototype 2 and beyond

Probe Prototype 1

Generic – Zeiss, rigid, flexible, other

Second Generation

First Generation

- 5mm diameter x 43mm length
- Original Pentax product in GI
  - Established of GI endomicroscopy
  - Generated level 1 evidence
  - Unmatched by competition
- Original Zeiss neurosurgery prototypes
  - 2 clinical studies completed
  - Basis for product specification

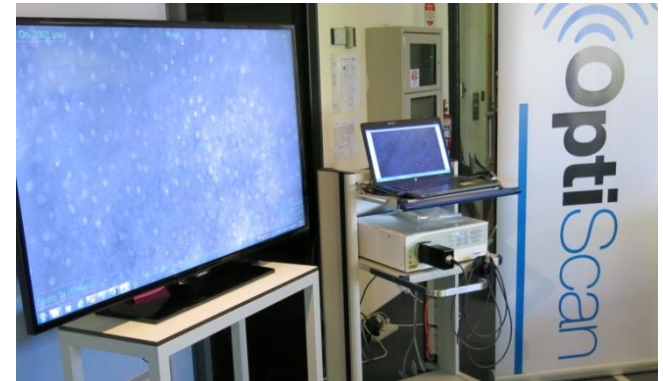
|                  | Gen-1 | Gen-2 eCLE | Gen-2 Probe-1 | Gen-2 Probe-2 | Gen-2 Probe-3* |
|------------------|-------|------------|---------------|---------------|----------------|
| Diameter         | 5mm   | 3.5mm      | 3.5mm         | 3.5mm         | 2.4mm          |
| Rigid Length     | 43mm  | 34mm       | 20mm          | 19mm          | 16mm           |
| Volume reduction | -     | 70%        | 70%           | 83%           | 93%            |

\* Proposed

*All probes in development up to probe-2 are without any compromise in image quality*

# System Demonstration

- Optiscan's Second generation platform was demonstrated live during the AGM.

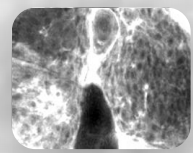


- For those not present, key features demonstrated were:
  - Full 1920x1080p live scanning on large format HD Screen
  - Small scanner
  - Fast, interactive rate scanning
  - Live cellular imaging of presenter's own cheek cells in mouth
  - Interactive depth control
  - Advanced automated image optimisation and collection features

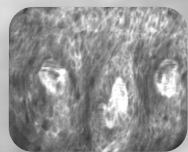
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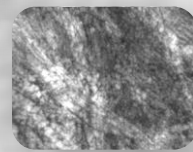
Brain



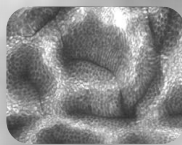
Esophagus



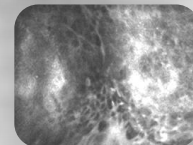
Tendons



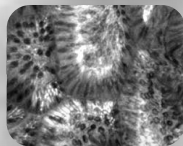
Stomach



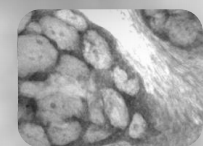
Airways



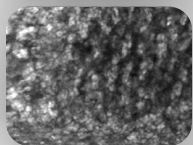
Small bowel



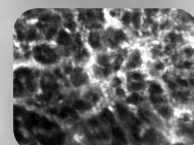
Pleura



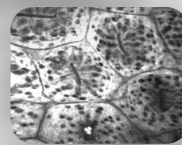
Liver



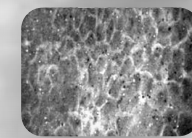
Pancreas



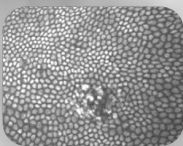
Colon



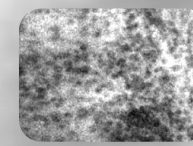
Bladder



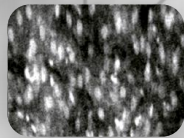
Ovaries



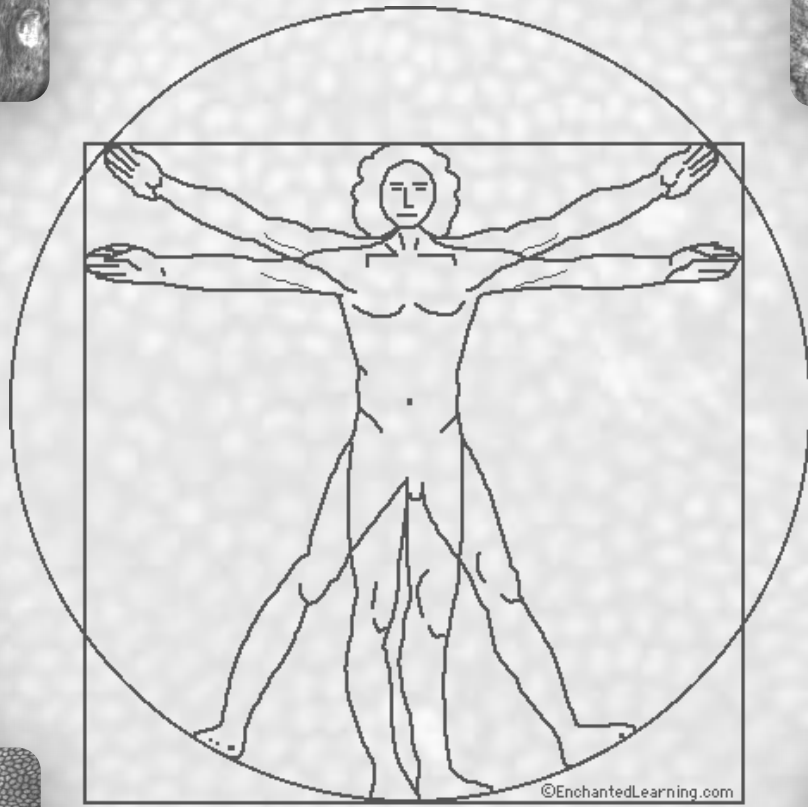
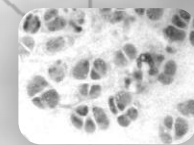
Prostate



Uterine Cervix



Cartilage



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## **Formalities and Notice of Meeting**

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- To consider the accounts for the year ended 30 June 2013, together with the reports of the directors and auditors.
- The company has received proxy votes totalling 34,195,510 shares, representing 21.0% of the issued capital.
- I declare that the proxies as tabled before the meeting comply with the requirements under the constitution of the Company.
- In relation to proxy votes, I advise that undirected proxies will be cast in favour of the resolutions



## Resolution 1:

That the Remuneration Report included in the Annual Report for the year ended 30 June 2013 be adopted.

Of the total proxies received

99.2% representing 33,916,011 shares were in favour of the resolution or appointed the Chairman to vote on their behalf;

102,220 votes representing 0.3% were against the resolution; and

177,279 votes representing 0.5% abstained.

### ☐ Resolution 2:

☐ That Bruce Andrew, a director retiring by rotation in accordance with the Company's constitution, being eligible and having signified his candidature for the office, be re-elected a director of the Company.

☐ Of the total proxies received

☐ 99.5% representing 34,032,108 shares were in favour of the resolution or appointed the Chairman to vote on their behalf;

☐ 42,202 votes representing 0.1% were against the resolution; and

☐ 121,200 votes representing 0.3% abstained.

## ☐ Resolution 3:

☐ That, in accordance with Australian Stock Exchange Listing Rule 7.4, shareholders ratify the issue of 4,082,185 fully paid ordinary shares on the dates and at the prices set out in the explanatory memorandum accompanying the Notice of Meeting

☐ Of the total proxies received

☐ 99.6% representing 34,077,416 shares were in favour of the resolution or appointed the Chairman to vote on their behalf;

☐ 77,684 votes representing 0.2% were against the resolution; and

☐ 40,410 votes representing 0.1% abstained.