



**OptiScan Imaging Limited
(OIL)**

Angus Holt – Executive Chairman

September 2012

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An Australian Technology and Product Development company

“at the forefront of live micro imaging, the next frontier of medical imaging”



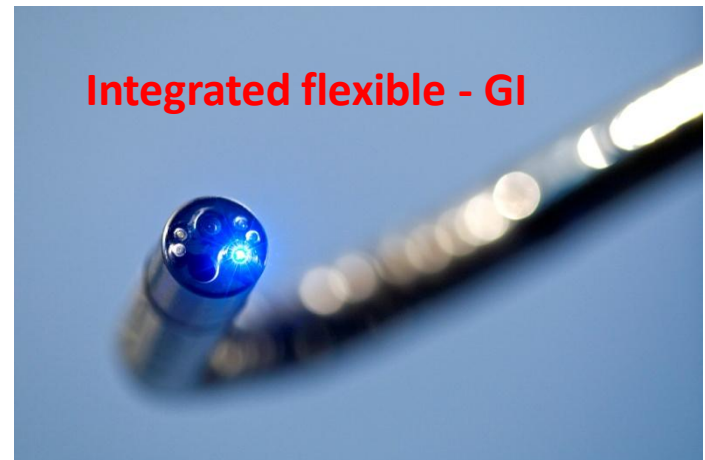
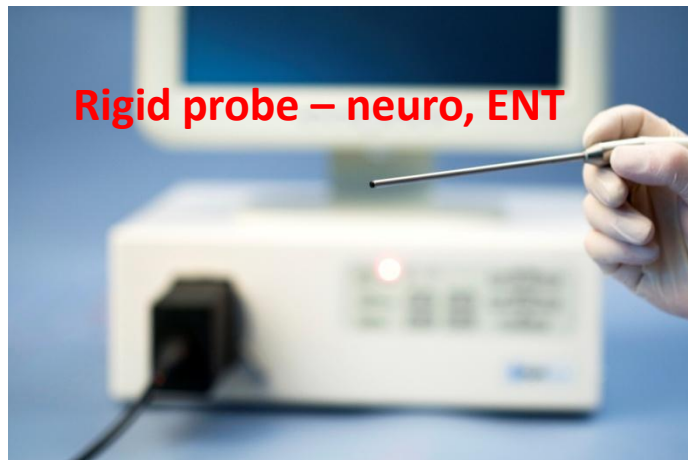
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Appendix – Competition and Major Players

THE TECHNOLOGY

- ✓ The world's first and highest resolution miniaturized microscope for interactive, in vivo imaging of surface and subsurface cell layers
- ✓ A unique combination of computer (h/w, s/w), laser, optical fiber, scanning and lens technology



In-House Manufacturing

- ISO13485 accredited organisation
- Proprietary know-how embedded in the process
- Generic components are out-sourced
- Clean room facilities
- Significant scope for large scale manufacturing and service



Robust Intellectual Property Portfolio

- ~50 patent families
- Long-life patents
- Granted in all major jurisdictions
- No royalties
- No infringements/disputes – FTO
- Long pipeline of technological/IP development

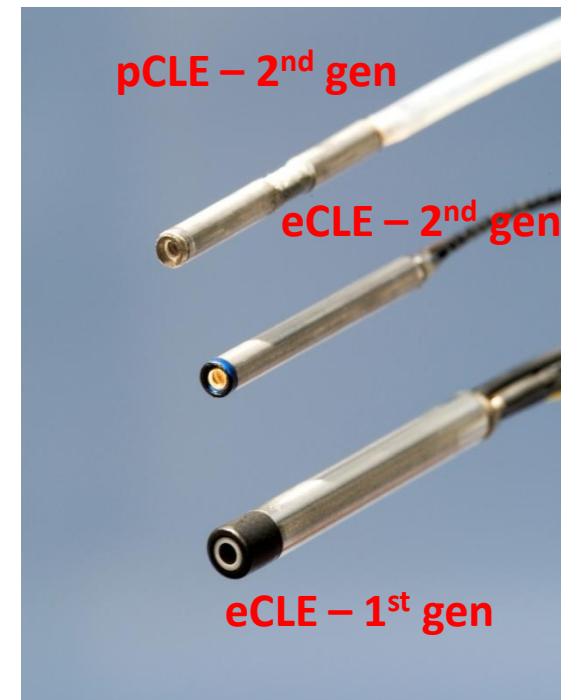
New (2nd) Generation Technology

OptiScan has developed a second generation endomicroscopy system, the scanner being more streamlined, efficient and 70% smaller in volume than that (1st generation) present in Pentax's ISC 1000 endomicroscope

The 2nd Generation Technology offers:

- The potential to integrate with all major endoscope brands in HD (eCLE)
- High definition viewing at near video rates
- A more robust scanner
- A smaller footprint (1 box)
- The potential to operate as a stand-alone probe based system (pCLE)

Scanner



PURPOSE/USE

- ✓ The ability to visualise cells (largely cancerous and pre-cancerous lesions) in real time and in HD leads to more efficient and fewer procedures with better patient outcomes and consequent healthcare system benefits:
 - ✓ See & treat approach made possible
 - ✓ Fewer biopsies and more disease found (targeted biopsy)
 - ✓ Less invasive
 - ✓ Earlier detection
 - ✓ Margin identification leading to more accurate tumour resection (esp. neuro)
 - ✓ Immediate diagnosis leading to less time on the table (neuro)

EFFICACY/TRIALS



Investigator/Partner Sponsored Clinical Trials

- **Gastroenterology Trials: Over 100 published studies containing original clinical trial data**
 - Trials in U.S., Germany, France, Italy, China, Singapore, Australia
 - Multi-center European trials led by Johannes Gutenberg University
 - Multi-center U.S. and International trials led by Johns Hopkins University
 - Multi-center Asian trial (not yet open) – Shandong University (China), Prince of Wales Hospital (HK), University of New South Wales (Aus), National University Hospital, NUS (Singapore)
- **Neurosurgery:** Trials at Barrow Neurological Institute in Phoenix in conjunction with Carl Zeiss

OptiScan Sponsored Clinical Trials

- **Gastroenterology Trials:** “First time in human” studies at two centers.
- **Cervical Trials:** 3 published papers, including the *British Journal of Obstetrics and Gynaecology*
- **Endometriosis Trials:** (incomplete, paused due to resourcing constraints)
- **Pancreatic Cancer Resection Trial:** Published in *Annals of Surgery*
- **Liver Disease Trial:** Two published papers in *Hepatology* and *Endoscopy*
- **Robotic Prostatectomy Trial:** Possible co-application with robot-assisted surgery
- **Thoracic Malignancies Trial:** Used to investigate lesions on the extremity of the lungs and surrounding membranes (pleura) (ongoing)
- **Ophthalmology Trial:** Published in *Journal of Anatomy*



the women's
the royal women's hospital
victoria



TheAlfred



THE HOSPITAL
AT WESTLAKE MEDICAL CENTER*

Milestone International Multi Center Trial – paper presented May 2012 in San Diego, CA

- **International multi center to** compare High Resolution Endoscopy (HRE) to Endomicroscopy (eCLE = Optiscan's technology)

- **Trials took place at:**
 - Johns Hopkins, Baltimore, MD
 - Mount Sinai School of Medicine, NY, NY
 - Massachusetts General Hospital, Boston, MA
 - University of Pennsylvania, Philadelphia, PA
 - University of Mainz, Mainz, Germany

- **Conclusion compared to gold standard:** (Based on 178/200 patients):
 - Diagnostic yield 5.2x (4x per patient) greater using eCLE
 - 100% sensitivity was achieved (no missed disease).
 - eCLE changed the HRE diagnosis to a correct diagnosis in 15 (53.6%) and correctly changed the treatment plan in 9 (34.6%).

MARKETS

Near Term

- ✓ Gastroenterology
 - ✓ In market for 6 years (2006 via Pentax ISC-1000)
 - ✓ >20,000 procedures
 - ✓ Clear patient, clinician and system benefits
 - ✓ US insurance reimbursement set for implementation in January 2013
 - ✓ Addressable market >\$1bn
- ✓ Neuro (Carl Zeiss partner) incl. spine:
 - ✓ Trials complete save for small scale process validation
 - ✓ Target FDA & CE clearance mid 2013, immediately followed by commercial launch
 - ✓ Price inelastic market
 - ✓ Carl Zeiss is the leading neuro visualisation company in the world

MARKETS

Medium, Longer term & Blue Sky

- ✓ Carl Zeiss licensed:
 - ✓ ENT (near term)
 - ✓ Ophthalmology
 - ✓ Breast
- ✓ Women's health – endometriosis, cervical cancer
- ✓ Prostate
- ✓ Liver
- ✓ Pancreas
- ✓ Lung and pleura
- ✓ Skin
- ✓ Telepathology

THE COMPANY AND OPPORTUNITY



A company resurrected from the GFC and poised to break into multiple major medical markets in the near term.

Highlights

- Pioneers and world leaders in endomicroscopy
- OptiScan is one of only two technologies that allow for *in vivo* imaging at the cellular level & multiple cell layers in both humans and animals
- OptiScan's technology has been incorporated into medical product (flexible GI endoscopy) since 2006
- Optiscan has the validation of world leading partners such as Carl Zeiss Meditec in neurosurgery and Pentax Lifecare in flexible endoscopy
- ~50 patent families
- Strong research and development capability (core asset)
- >90m invested to date
- Huge and multiple markets and growth potential

Major Milestones/Events

- ✓ 1994 Optiscan founded by Peter Delaney and Martin Harris
- ✓ **1997** **Optiscan raises \$3m under its IPO and lists on the ASX**
- ✓ 2001 FDA clearance and release of Stratum (skin scanner)
World's First human confocal endomicroscopy by OptiScan – “endomicroscopy” is born
- ✓ **2002** **\$20m agreement with Pentax to develop world's first flexible endomicroscope**
- ✓ 2004 ISO 13485 quality accreditation achieved
Pentax ISC-1000 receives FDA clearance and CE mark
- ✓ **2006** **Market release of Pentax ISC-1000**
- ✓ **2007** Market release of research system, the Optiscan FIVE-1
Zeiss collaboration signed
- ✓ 2010 Optiscan achieves U.S. FDA 510k approval for the CEIS (Optiscan equivalent of Pentax product – generation 1)
- ✓ **2012** Two second generation HD flexible endomicroscopes built under custom order to two Australian institutions – in use today
Sale of first neurosurgery systems to Carl Zeiss (not yet FDA cleared)

Capital Structure and Financial

Capital & Corporate Structure

- ~159m ordinary shares on issue, no material options/warrants
- Optiscan Pty Ltd operating company (100% subsidiary of OIL)
- ~3,500 shareholders

Financial

- 2013FY – cash inflows virtually certain as at September 2012, inclusive of \$1m capital raising are >\$3m
- Underlying monthly costs ~200k
- Core infrastructure stable and ready for enhancement
- Total of 17 (14.6 FTE) staff with aggregate 100+ years with Optiscan
- Income from research sales (FIVE-1 product), partner development payments and related product sales, custom orders