



Optiscan Imaging Ltd (ASX:OIL)

Enabling “Real-time Virtual Biopsy” for
Human Cancer Screening and Surgical
Margin Detection

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Corporate Snapshot

Board

Darren Lurie – Executive Chairman

B.LLB (Hons) and B.COM (Hons)

Former Group CFO and Head of Corporate Development for EduCo International (an investee company of Baring Private Equity Asia). Darren is a former chair and non-executive director of ASX listed Farm Pride Foods Ltd (ASX:FRM).

Dr Philip Currie – Non Executive Director

MBBS (Hons), FRACP, MBA

Dr Currie is a leading cardiologist with more than 35 years experience in medical research, clinical cardiology and business. He completed his cardiology fellowship at the prestigious Mayo Clinic, staff cardiologist at both Mayo Clinic and Cleveland Clinic and was the Director of Echocardiography at Michigan Heart and Vascular Institute.

Graeme Mutton – Non Executive Director

CPA

Graeme is a long-standing shareholder in Optiscan and has a deep understanding of Optiscan's technology and applications. He is a former manager of an accounting practice and successful business owner and operator.

Major Shareholders

- Peters Investments Pty Ltd: 10.0%
- Ibsen Pty Ltd: 9.9%

Total Securities on Issue

- 432,678,800 Ordinary Shares
- 2,600,000 Performance Rights
- 25,600,000 unlisted options

Market Capitalisation: \$20million @4.7c



From Laboratory Benchtop to Operating Theatre



Desktop Confocal Microscope



Optiscan's confocal device

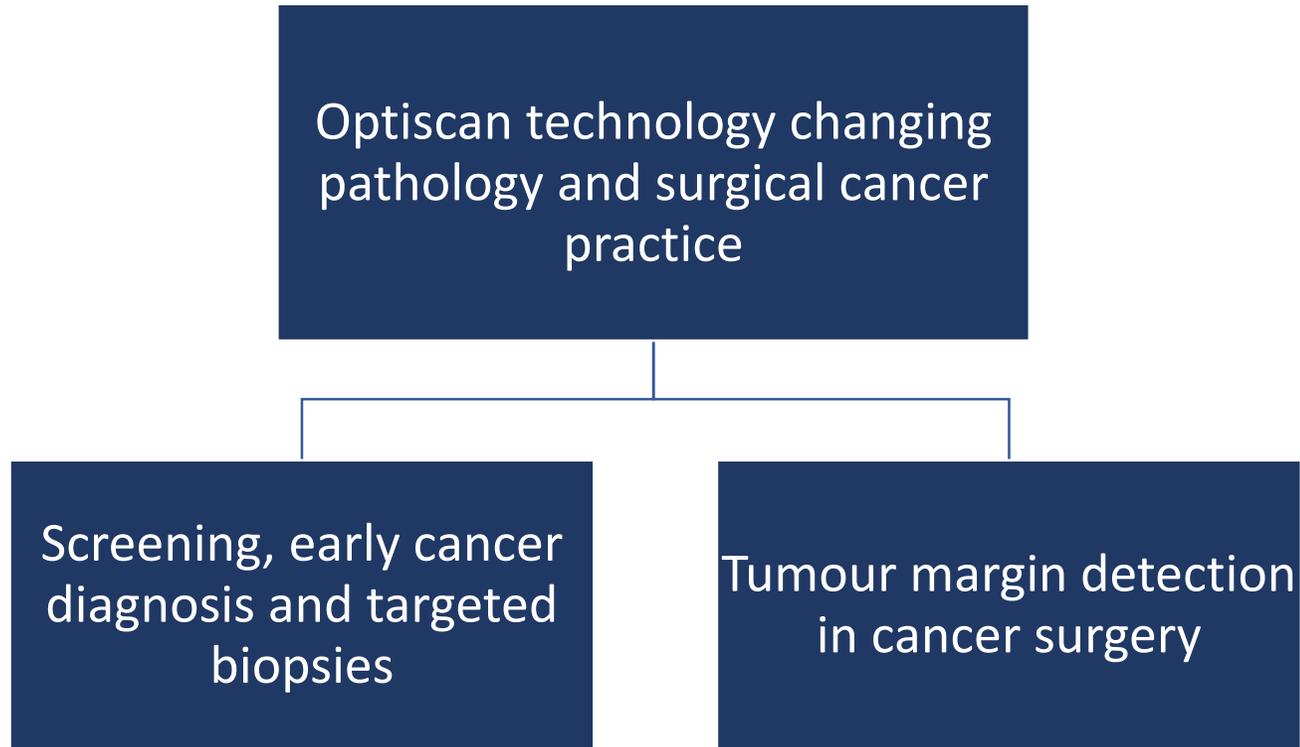


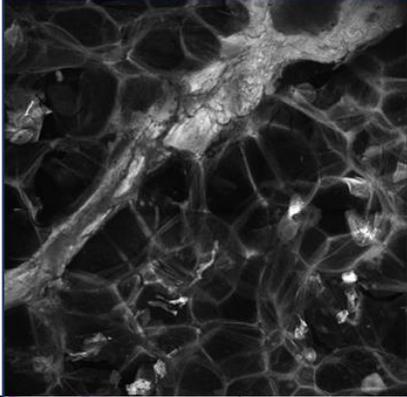
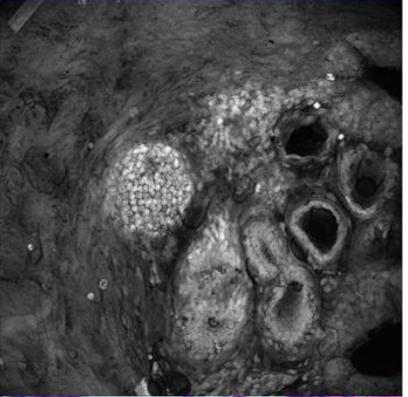
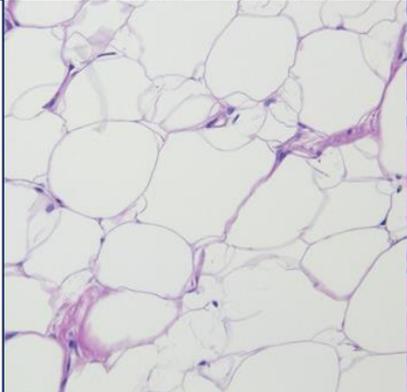
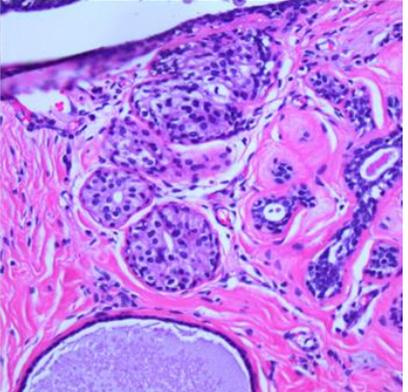
Successfully miniaturised high resolution benchtop confocal microscope into hand-held probe with 4.0mm diameter providing unique microscopic imaging for clinicians. Underpinned by multi-patented technology.

Commercial Focus

- Optiscan entering new commercial phase
- Sales of Carl Zeiss Meditec CONVIVO are expected in the first few months of FY20
- Optiscan is implementing plans to seek regulatory approvals for the sale of its own in human clinical device in multiple cancer applications
- FIVE2 (ViewnVivo) sales are anticipated in coming months in the United States, China and Australia with funding submissions to purchase the FIVE2 made by multiple institutions
- “Rental with Option to Buy” offered to institutions as alternative to straight purchase of the FIVE2
- Cost reduction focus has already saved in excess of \$1.0m per annum

Optiscan Technology Enables “Real Time Virtual Biopsy”



	Normal	Cancer
Virtual Biopsy		
Histopathology		

Images available instantaneously compared to waiting 3-4 days for the return of pathology results

Cancer Cases Worldwide – Addressable Market

18.1M total
cancer cases
p.a.

297,000
Brain and
CNS
cancer
cases p.a.

350,000
Lip and
Oral
cancer
cases p.a.

570,000
Cervix &
Uterus
cancer
cases p.a.

2.1M Breast
cancer cases
p.a.

3.4M Upper and
Lower GI cancer
cases p.a.

**Carl Zeiss
Meditec
Collaboration**

**Application with Optiscan's
Existing Probe Design
(Seeking Regulatory Approval)**

**Flexible Endoscope
Applications
(Seeking Partner)**

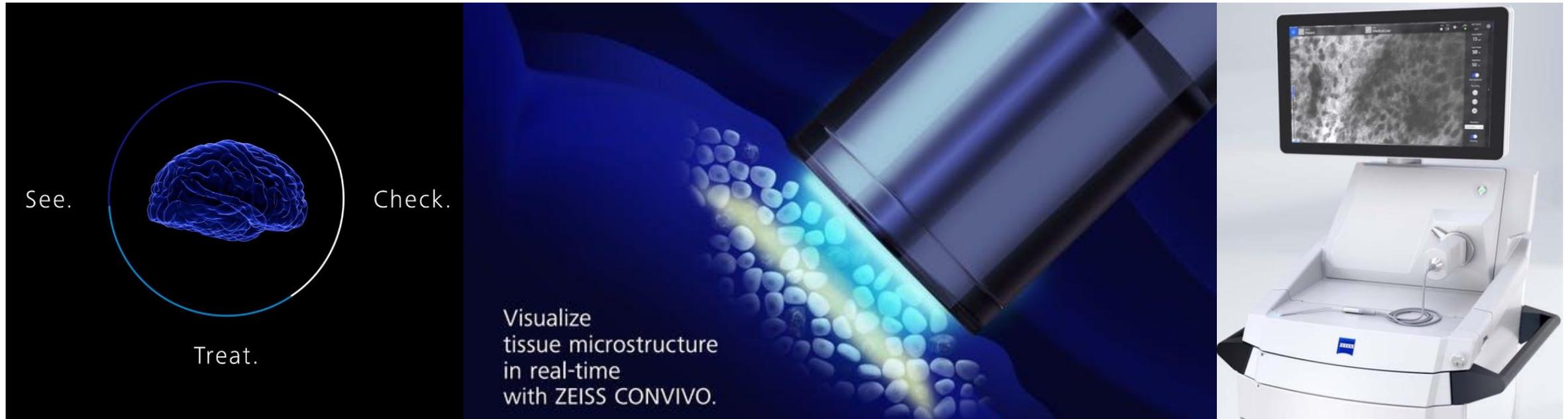
Sales opportunities for Optiscan devices exist for both cancer screening and in-surgery use.
In most applications, the number of screening procedures is many times the number of surgeries.

Current Cancer Applications

CANCER APPLICATIONS	PROGRESS
Brain Cancer	<ul style="list-style-type: none"> • Carl Zeiss Meditec Collaboration – FDA and CE Mark already obtained • Expected sales in first few months of FY20
Oral and Cervical Cancer	<ul style="list-style-type: none"> • Optiscan seeking FDA and other regulatory approvals for own device* • Expect Carl Zeiss CONVIVO is regulatory precedent as built upon the same technology • Working with Memorial Sloan Kettering – world leading cancer centre (MSK)
Breast Cancer	<ul style="list-style-type: none"> • Optiscan seeking FDA and other regulatory approvals for own device* • Expect Carl Zeiss CONVIVO is regulatory precedent as built upon the same technology • Trial at Hollywood Private Hospital (Western Australia’s largest private hospital) with leading breast cancer surgeon and pathologist
Oesophageal Cancer	<ul style="list-style-type: none"> • Working with MSK • Previous successful collaboration with Pentax Medical incorporating Optiscan technology in flexible endoscope • Actively seeking collaboration with flexible endoscope manufacturer

*Process and timing in seeking approvals to be determined in conjunction with selected regulatory advisory firm

Brain Cancer – Collaboration with Carl Zeiss Meditec AG



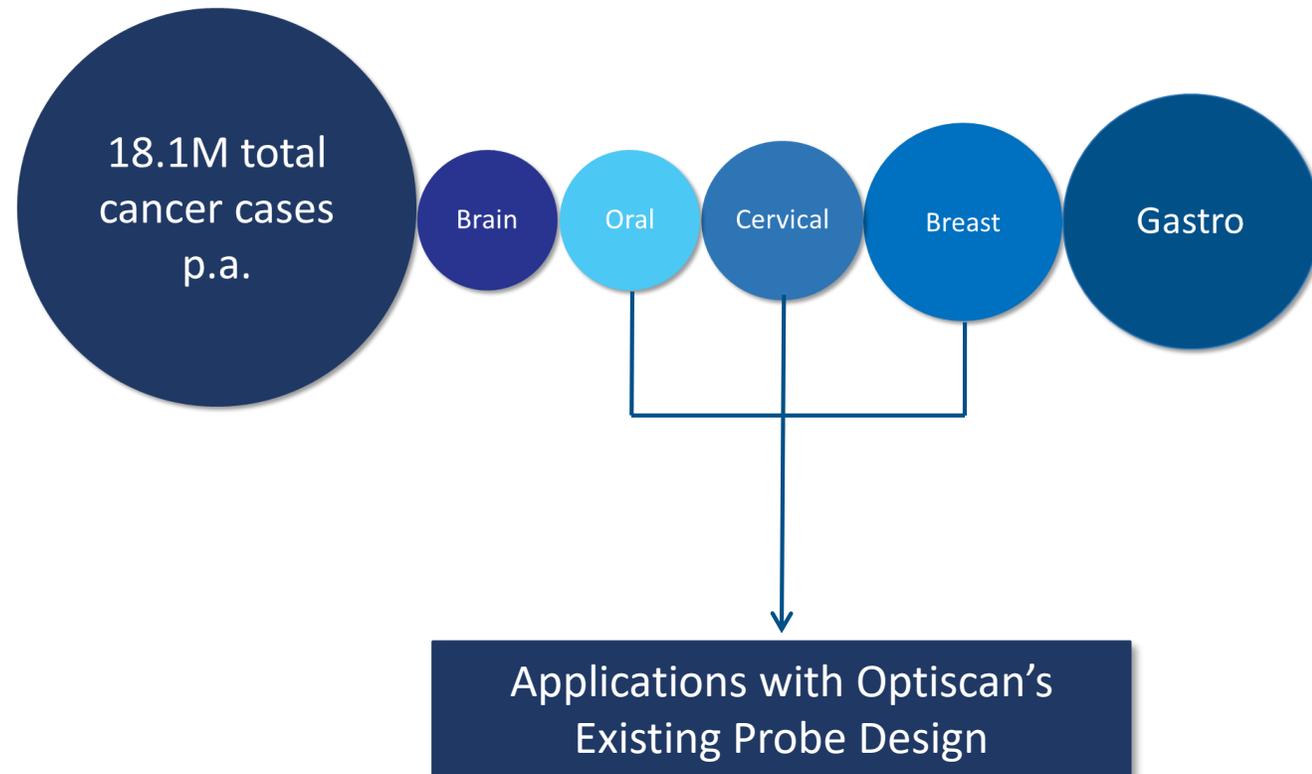
- United States (FDA 510(k)) and European (CE Mark) approvals obtained
- CONVIVO “Digital Biopsy Tool” (Check) an integral part of the 3 step Zeiss Tumour Workflow in Neurosurgery
- Sales expected in first few months of FY20
- <https://www.zeiss.com/meditec/int/c/tumor-workflow-video.html>

Zeiss is an international leader in the field of optics and optoelectronics
with a market capitalisation of ~€7.5billion

Optiscan is Seeking:

- ❑ 510(k) clearance (USA)
- ❑ CE Mark (Europe)
- ❑ TGA approval (Australia)

For use of the Optiscan clinical device in human breast, oral and cervical applications*



FDA and other regulatory approvals will significantly broaden the clinical applications for the sale of Optiscan technology into many organ systems

*Process and timing in seeking approvals to be determined in conjunction with selected regulatory advisory firm

Breast Cancer - The Most Common Cancer in Women

2.1
Million

2.1 million new cases of breast cancer predicted in 2018 (globally)¹

15%
of cases

15% of all new cancer cases in the United States are breast cancer²

556
centers

There are 556 Breast Centers in the USA accredited by the US Commission on Cancer³

145
hospitals

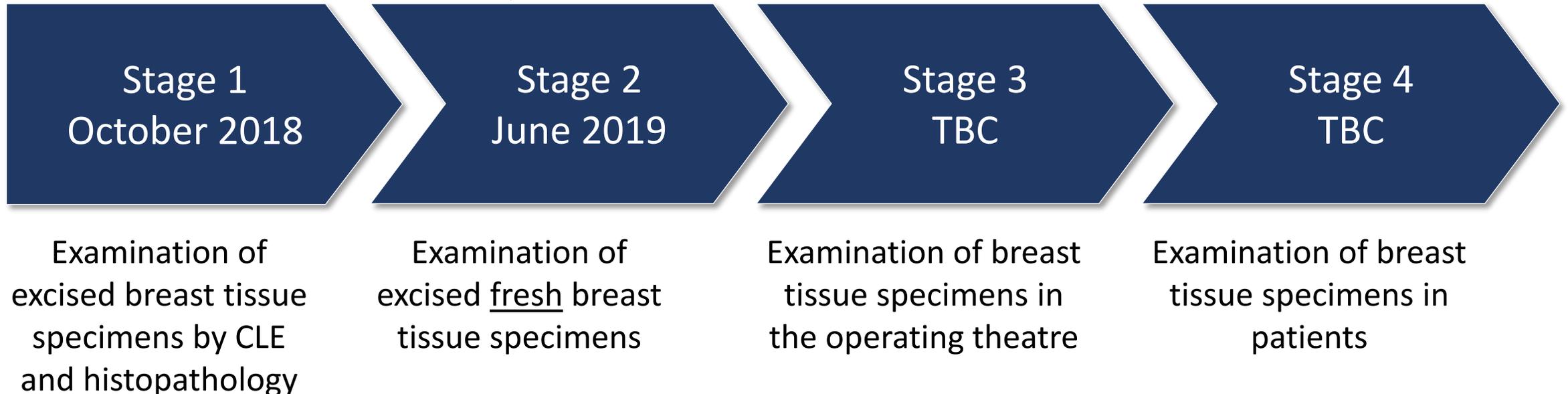
There are 145 hospitals in Australia performing breast cancer surgeries⁴

The number of breast cancer cases and defined cancer centres represent a large target market. 20-30% of lumpectomy patients currently require repeat surgery with current practice (histopathology analysis) often taking up to 3-4 days post initial surgery.

Breast Cancer Clinical Trial

Trial at Hollywood Private Hospital in Perth with Principal Investigators

- Dr Peter Willsher, Breast Surgeon of the Breast Cancer Research Centre –WA
- Dr Jespal Gill, Anatomical Pathologist and Head of Histopathology of Western Diagnostic Pathology
- Dr Philip Currie – Cardiologist, Cardiac Imaging Specialist and Optiscan Director

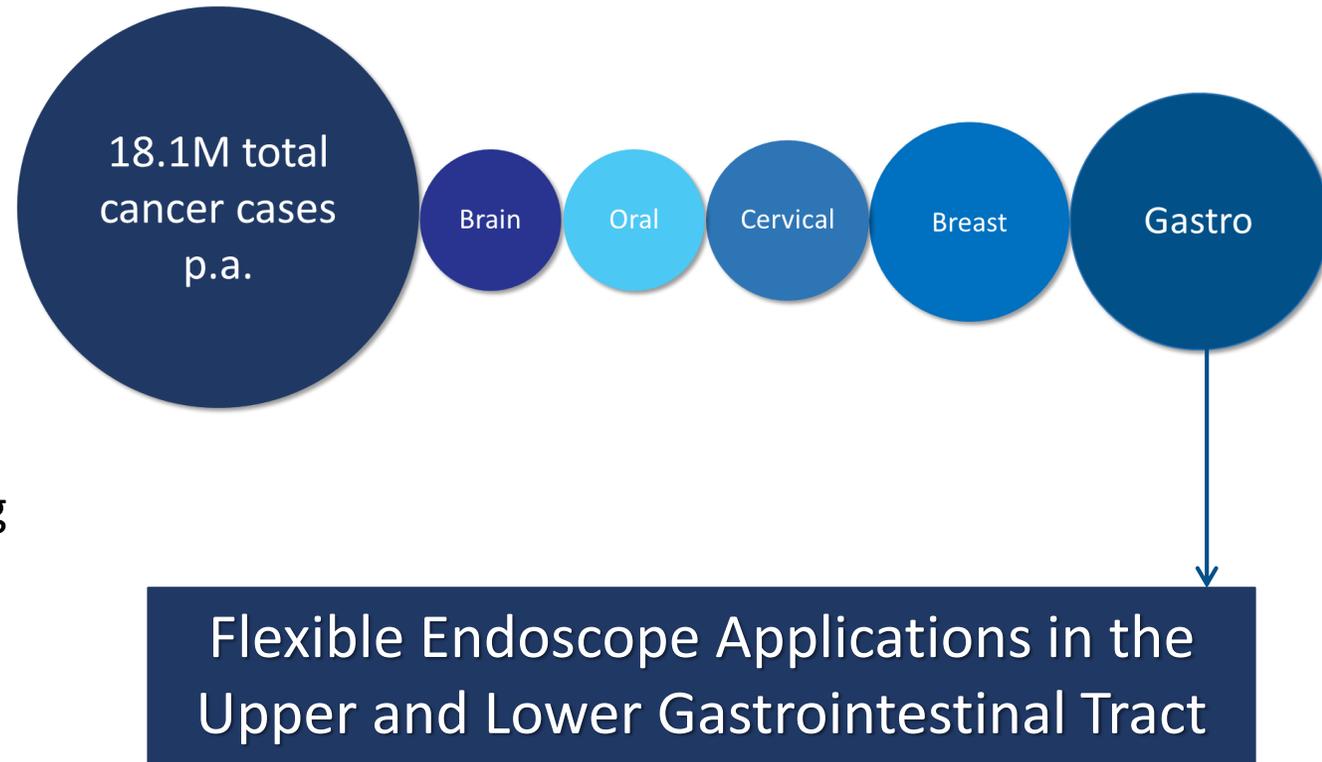


Oral, Cervical and Oesophageal Cancer Applications: Working with Memorial Sloan Kettering Cancer Centre (MSK)

- MSK is the world's oldest and largest private cancer center, situated in New York, USA.
- MSK's use of Optiscan's device provides critical endorsement of its unique imaging capabilities.
- Optiscan is working with MSK for the development of screening, early diagnosis and surgical tools targeting cancer cells in oral, cervical and oesophageal applications.
- MSK is currently seeking approval for use of an Optiscan system in an oral cancer trial. Further approvals are intended to be sought for the cervical and oesophageal cancer trials.
- Presentations by MSK surgeon & research investigator in April 2019 in Melbourne (Peter MacCallum Cancer Centre) and Perth (Hollywood Private Hospital).

Gastrointestinal Applications

- 3.4 Million Gastrointestinal cancer cases world wide
- MSK collaboration for oesophageal (upper GI) application
- Previous successful collaboration with Pentax Medical with over 100 devices sold
- Collaboration ceased following takeover of Pentax Medical
- Pentax systems developed with Optiscan still being used by leading gastroenterologists
- US reimbursement codes already in existence
- Optiscan is actively seeking a new partner in the flexible endoscope market for collaboration in gastrointestinal applications



Optiscan Technology in Pre-clinical Market

Progress in the Preclinical market

- Product re-branded FIVE2 (ViewnVivo)
- Identified opportunities to change existing research techniques for enhanced outcomes
- Multiple trial demonstrations & funding being sought by research institutions for potential purchase in Australia, North America, EU & China
- Working with CSIRO and Monash University for new applications in Cell Cultures and Anterior Cruciate Ligament (ACL) imaging respectively



Research Applications with FIVE2 (ViewnVivo)

- Cancer research
- Tissue regeneration
- Cell tracking
- Photodynamic therapy
- Infection & treatment
- Pharmacology
- Pathology
- Microvascular research
- Animal models
- Molecular Imaging

Key Milestones for the Coming Financial Year

● July 2019

● December 2019

June 2020 ●

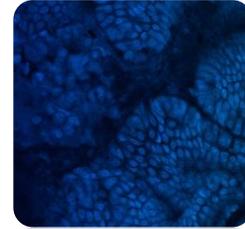
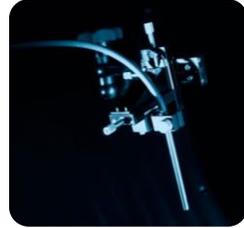
1st Half

- 1 Lodge submissions for FDA and other regulatory approvals for one or more cancer applications
- 2 Enter production phase for supply of devices to Carl Zeiss Meditec
- 3 MSK commence in vivo oral cancer trial
- 4 Complete Stage 2 and commence Stage 3 of breast cancer trial

Full Year

- 5 MSK commence cervical and oesophageal cancer trials
- 6 Establish collaboration with flexible endoscope manufacturer for gastrointestinal applications
- 7 Extend breast cancer trial to second medical centre
- 8 Sale of 5+ research and pre-clinical FIVE2 systems

Investment Highlights



- Optiscan is entering into new commercial phase
- Optiscan device enabling “Real-time Virtual Biopsy” for Human Cancer Screening and Surgical Margin Detection
- Collaboration with Carl Zeiss Meditech AG for Brain Cancer Surgical Device (US FDA and EU certifications already approved for use) and expected sales in first few months of FY20
- Working with world-leading Memorial Sloan Kettering Cancer Centre in Oral, Cervical and Oesophageal Cancer applications with Oral Cancer trial awaiting internal Ethics Approval to commence
- Seeking US FDA and other regulatory approvals for Optiscan device for Human Oral, Cervical and Breast Cancer applications