



# Optiscan Imaging Ltd (ASX:OIL)

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

# Notice

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# Corporate Snapshot

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## 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.

## Total Securities on Issue

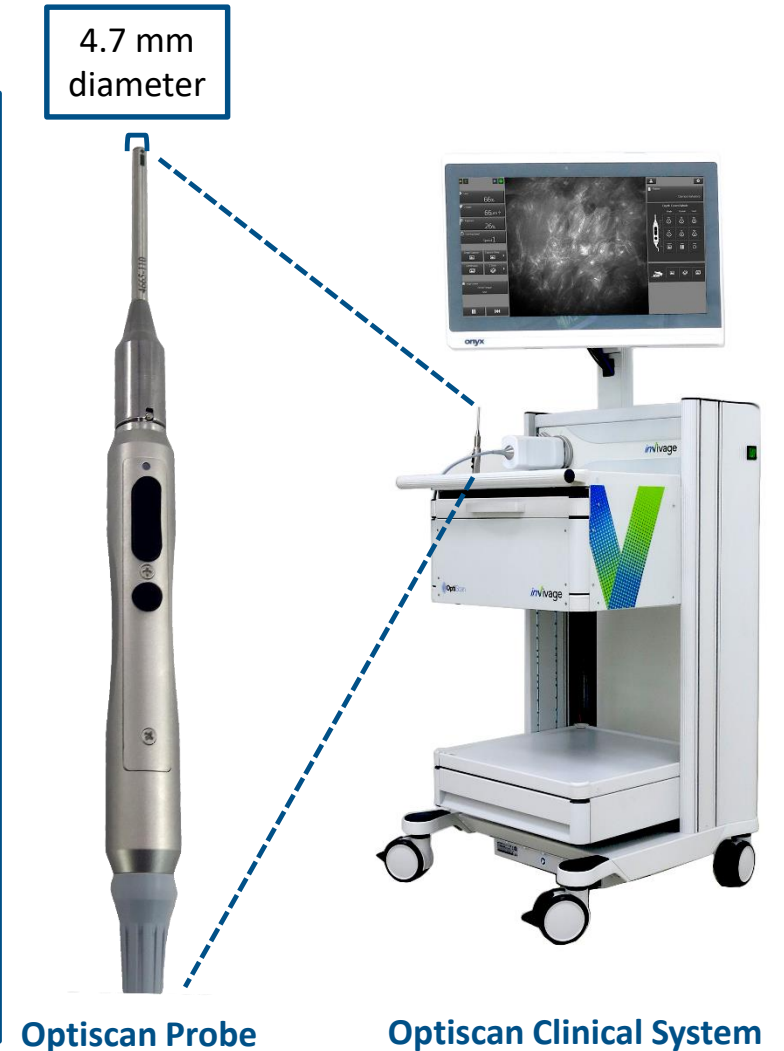
- 477,778,800 Ordinary Shares
- 25,600,000 unlisted options

**Market Capitalisation: ~\$13million @2.7c**

# OPTISCAN Introduction - Technology

## Optiscan Technology

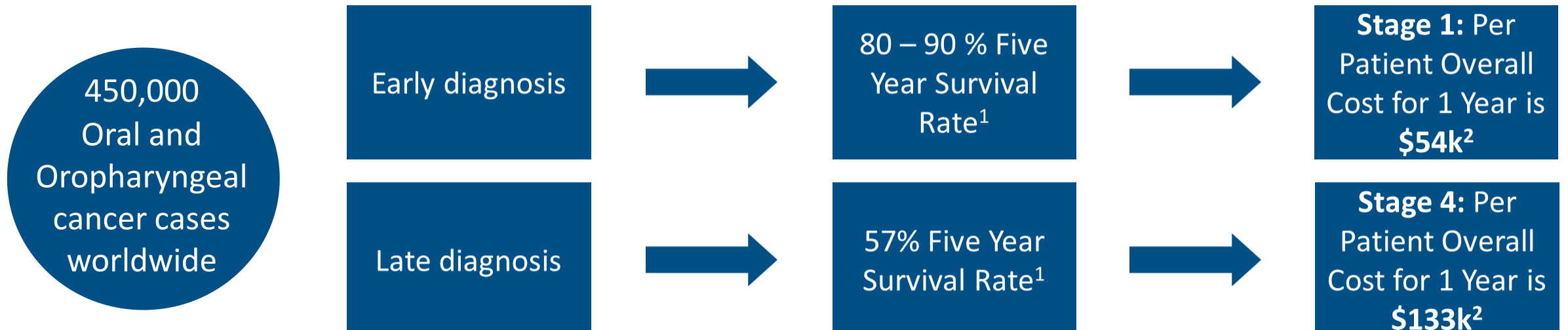
- Successful Development of hand-held Confocal Microscope for Medical and Research Imaging
- World-leading and Patent Protected Technology
- Real-time “Virtual Biopsy”, visualisation of human living tissue
- Capture all Cancer Cells in Surgery and reduce cutting of surrounding Tissue (“Tumour Margin”)
- Reduce Number of and More Targeted Biopsies
- 4mm Diameter Probe (4.7mm inc Sheath)
- Incorporated in Optiscan “InVivage” and Carl Zeiss Meditec “Convivo” devices



# Optiscan's Future: Enabling "Real Time Virtual Biopsy"

## InVivage<sup>®</sup> Optiscan's Clinical Device

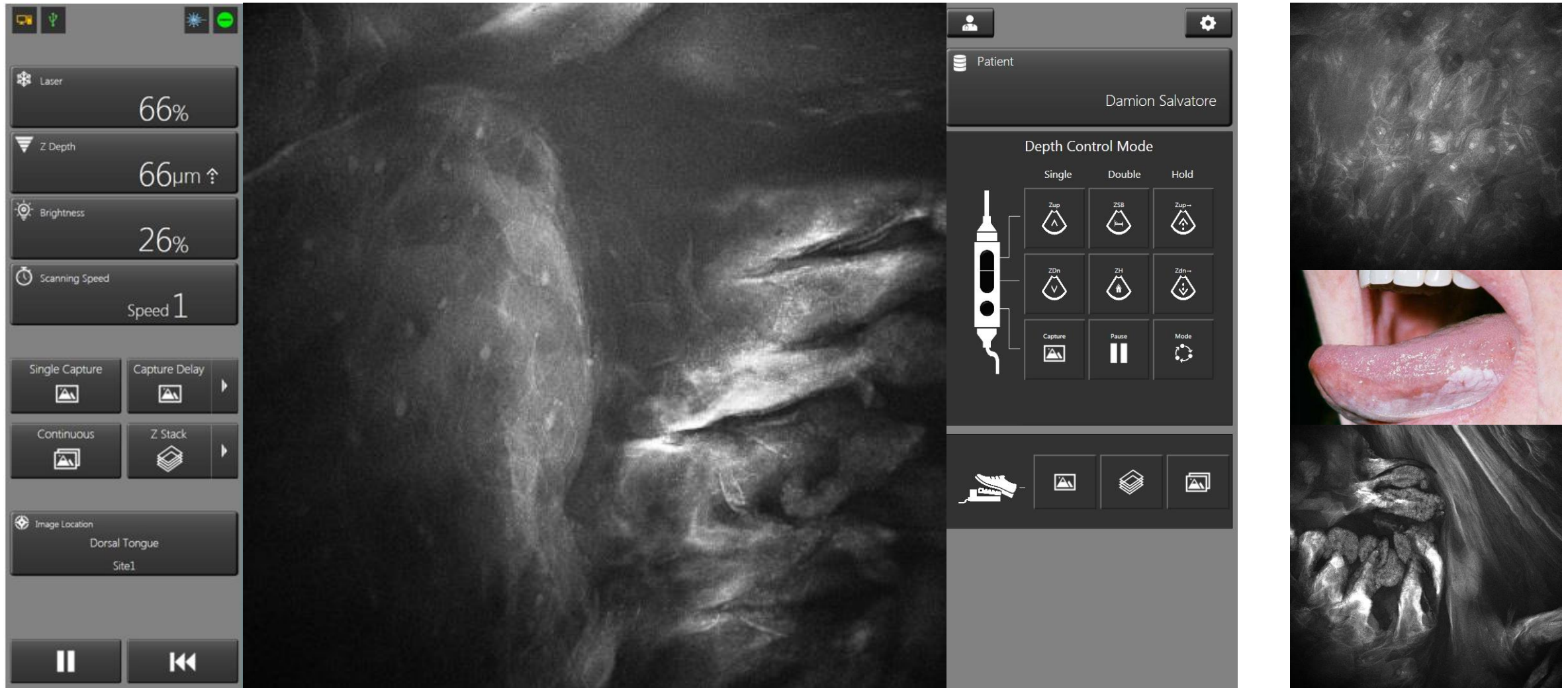
- Screening, Early Cancer Diagnosis and Targeted Biopsies
- Tumour margin detection in Cancer Surgery
- Initial Target Application: Oral Cancer



1. Oral Cancer Foundation. <https://oralcancerfoundation.org/>

2. Pollaers, K., et al., The economic burden of oral squamous cell carcinoma in Australia. Journal of Oral Pathology & Medicine, 2019. 48(7): p. 588-594. doi: 10.1111/jop.12907. Epub 2019 Jun 27.

# New InVivage® User Interface Designed for Doctors



Squamous epithelial cells and taste bud papillae in tongue (0.5mm x 0.5mm view)

# OPTISCAN – FY2020 Progress

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## 3 Oral Cancer Studies and Trials:

- Memorial Sloan Kettering Cancer Centre in New York (“MSK”) (on-going)
- Melbourne Dental School in collaboration with Peter MacCallum Cancer Centre, Royal Melbourne Hospital, MSK and Australian Centre for Oral Oncology Research and Education (awaiting final ethics approval)
- Australian Centre for Oral Oncology Research and Education (on-going)

## Met with US FDA and obtained feedback for proposed 510(k) submission to market in the US

- Preparing documentation and plans for required testing for US regulatory approval



# OPTISCAN – Steps for US Approval to Market Device

## United States Food and Drug Administration (FDA) 510(K) Submission

Pre-Submission meeting with FDA in the USA - Jan 2020

Completed

Supplemental Q-Sub (Request for Feedback) document being prepared for FDA based on meeting feedback

Commenced

Building of additional InVivage Systems for clinical trials and regulatory testing

Commenced

Arranging and scheduling required Activities for 510(k) Submission:

Dosing study for use of topical fluorescein

Usability Studies

Electrical Safety and EMC Certification Testing

Biocompatibility and Reprocessing Testing of Sheath

Environment and Packaging Integrity Testing

# Breast Cancer - Most Common Cancer in Women

**2.1**  
**Million**

2.1 million new cases of breast cancer predicted in 2018 (globally)<sup>1</sup>

**15%**  
**of cases**

15% of all new cancer cases in the United States are breast cancer<sup>2</sup>

**556**  
**centers**

There are 556 Breast Centers in the USA accredited by the US Commission on Cancer<sup>3</sup>

**145**  
**hospitals**

There are 145 hospitals in Australia performing breast cancer surgeries<sup>4</sup>

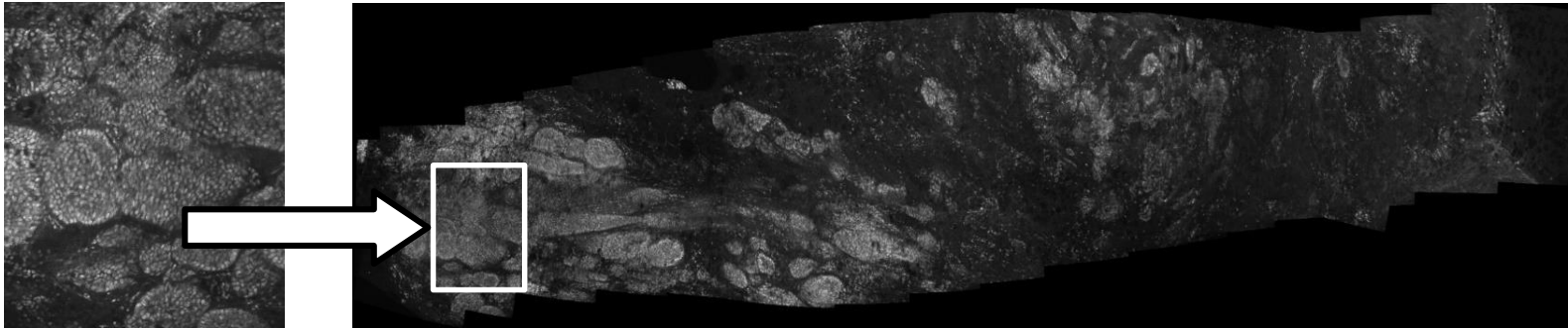
The number of breast cancer cases and defined cancer centres represent a large target market. 20-30% of lumpectomy patients currently require repeat surgery with current practice (histopathology analysis) often taking up to 3-4 days post initial surgery

# Optiscan - Breast Cancer Surgery

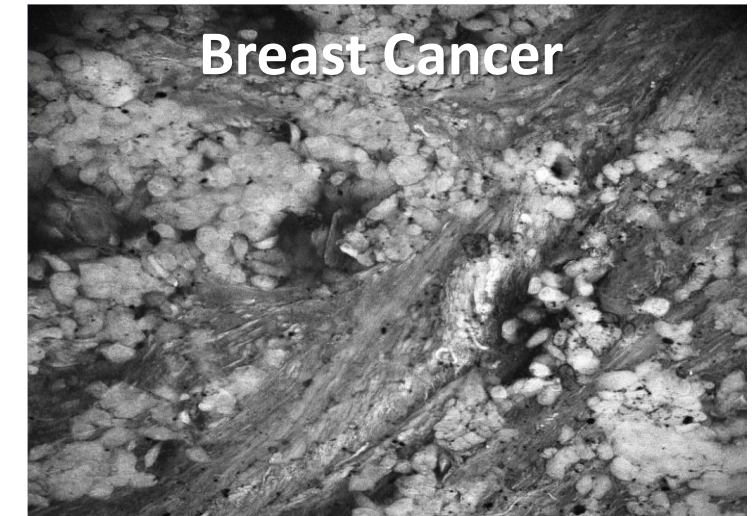
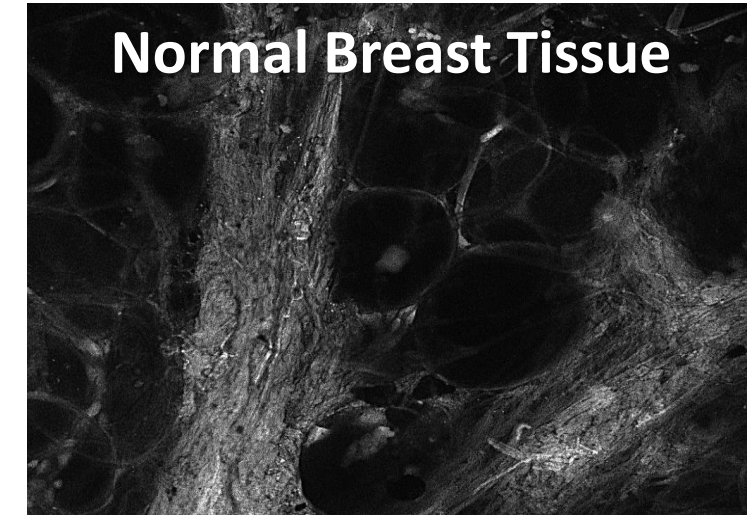
## Intraoperative Assessment of Breast Cancer Surgical Margin

- **Goal:** Assist breast surgeons and pathologists to provide real-time cellular assessment of surgical margin.
- **Benefits:** Reduce risk of residual tumour, need for repeat surgery, patient emotional distress, costs for patients, hospitals, insurers and the taxpayer by reducing the number of repeat surgeries

**MDPP Workshop in Feb 2020 with 6 Breast Surgeons and a Pathologist from 5 Leading Melbourne Hospitals. Strong interest to arrange Stage 3 of Breast Cancer Trial in Melbourne.**



**Creation of panoramas: developing a more macro view of the specimen assisting in the CLE and H&E correlation**

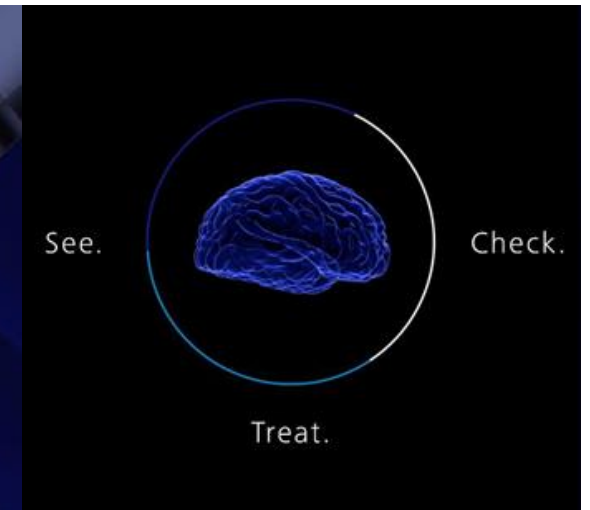
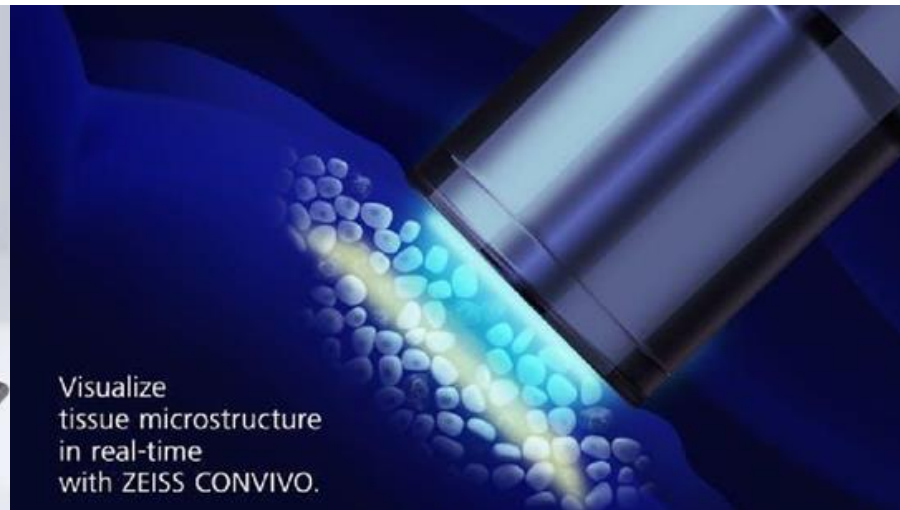


# ZEISS CONVIVO® – CARL ZEISS MEDITEC (CZM) COLLABORATION

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

## ZEISS CONVIVO®

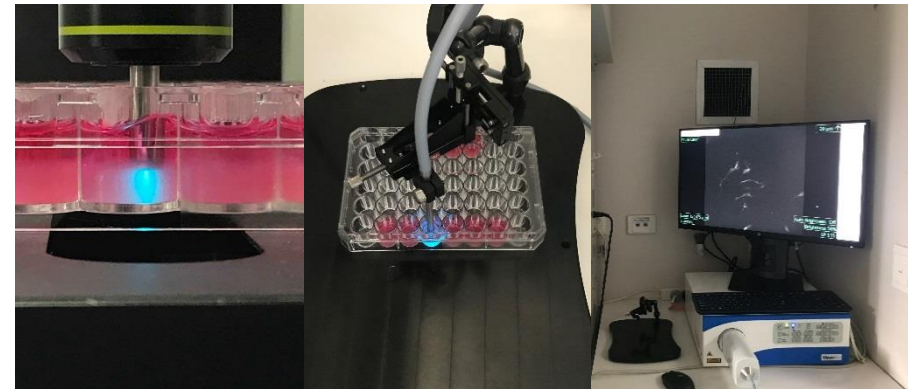
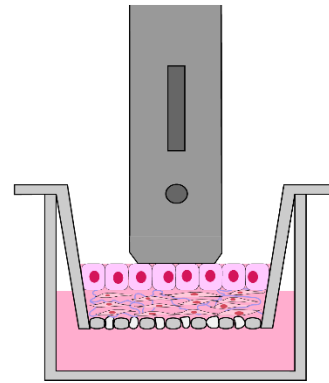
- Target Application: Tumour margin detection in Brain Cancer surgery
- Current 2nd half FY20 orders of at least \$450k with ongoing discussions re further revenue opportunities
- Zeiss is an international leader in optics and optoelectronics with a ~€9.0billion market capitalisation



# OPTISCAN Research Device: Development of New Applications

Working in collaboration with CSIRO and Monash and Michigan Universities for new applications in 3D Tissue Culture and Anterior Cruciate Ligament (ACL) imaging respectively

- 3D tissue culture imaging application developed in collaboration with CSIRO



- Autofluorescence imaging in ACL microdamage research in collaboration with Monash and Michigan Universities. Image on the left is a normal ACL while image on the right shows ACL microdamage (collagen disorder)



# Distributor Strategy for Research Markets in China and North America

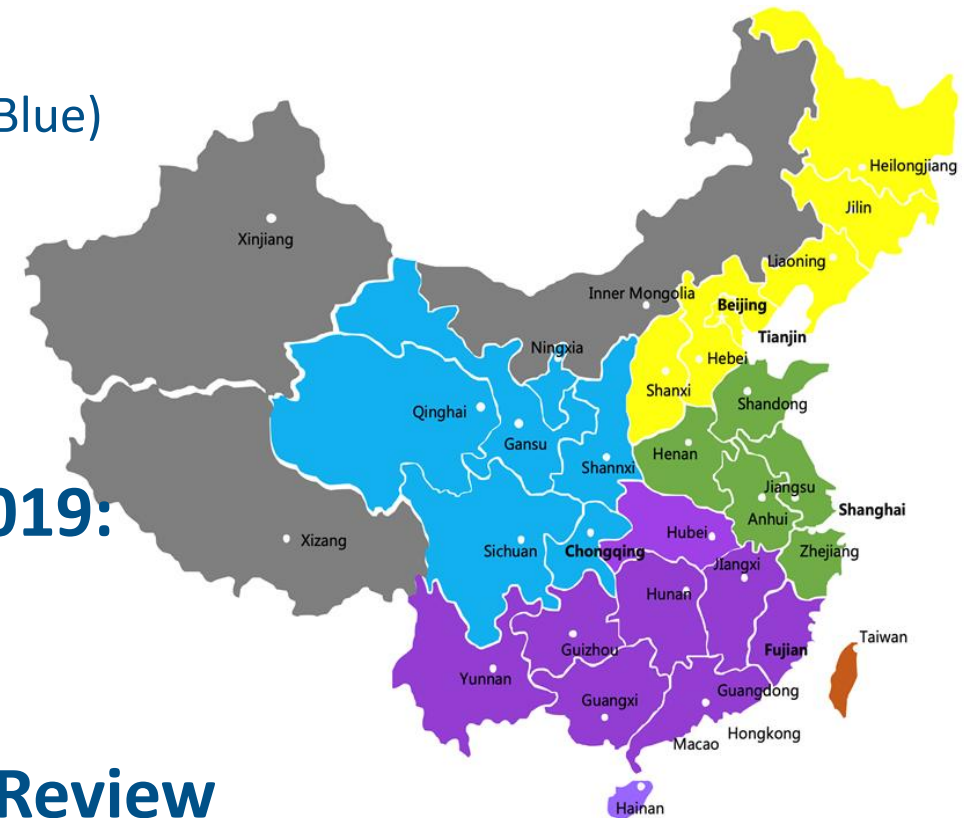
- **New multi-distributor model in China with appointment of exclusive distributor in Southern and Western China.**

- **South and West China:** Guangzhou Yunxing (Purple and Blue)
- **East China:** Biotimes Technology Limited (Green)
- **North China:** To be Advised

- **Sale of FIVE2 (ViewnVivo) System in late 2019:**

- Chinese University Tender success directly attributable to new Chinese multi-distributor model.

- **North America Distributor Strategy Under Review**



- Optiscan Device developed for “Real-time Virtual Biopsy” for Human Cancer Screening and Surgery
  - Button control features for single-handed operation unique to InVivage
- Jan 2020: 510(k) Pre-Submission Meeting with FDA for Oral Cancer
- Preparing documentation and arranging testing required for FDA 510(k) submission
- Medical Device Partnering Program Workshop in Feb 2020 with 6 Breast Surgeons and a Pathologist from 5 Leading Melbourne Hospitals. Strong interest to arrange Stage 3 of Breast Cancer Trial in Melbourne.
- Commercialisation of Carl Zeiss CONVIVO progressing in United States and Europe
  - \$450k of orders for Carl Zeiss CONVIVO received for second half of FY2020 and on-going discussions re further Revenue opportunities in this half and beyond.