



# 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

## 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

- 470,178,800 Ordinary Shares
- 2,600,000 Performance Rights
- 25,600,000 unlisted options

**June Capital Raising: \$1.7million @4.0 c**  
**Market Capitalisation: ~\$19million @4.1c**

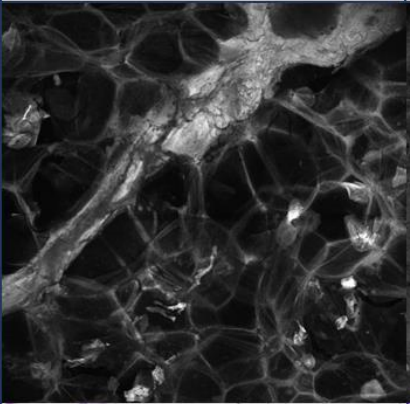
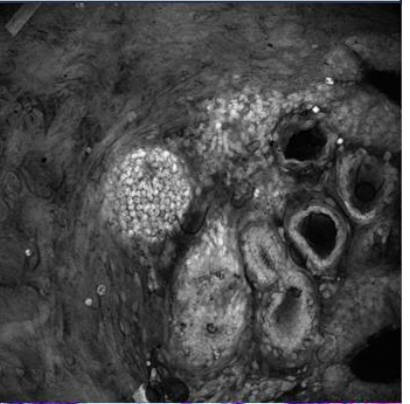
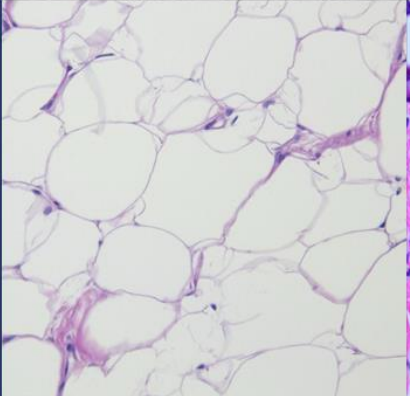
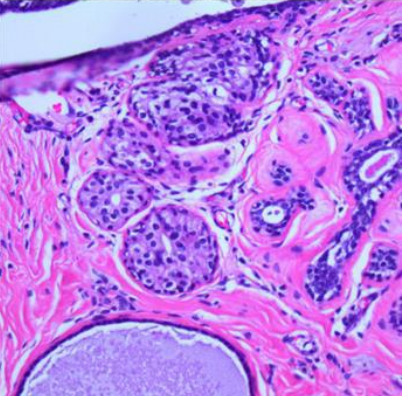


# Optiscan's Future: Enabling "Real Time Virtual Biopsy"

Optiscan technology changing pathology and surgical cancer practice

Screening, early cancer diagnosis and targeted biopsies

Tumour margin detection in cancer surgery

	Normal	Cancer
Virtual Biopsy		
Histopathology		



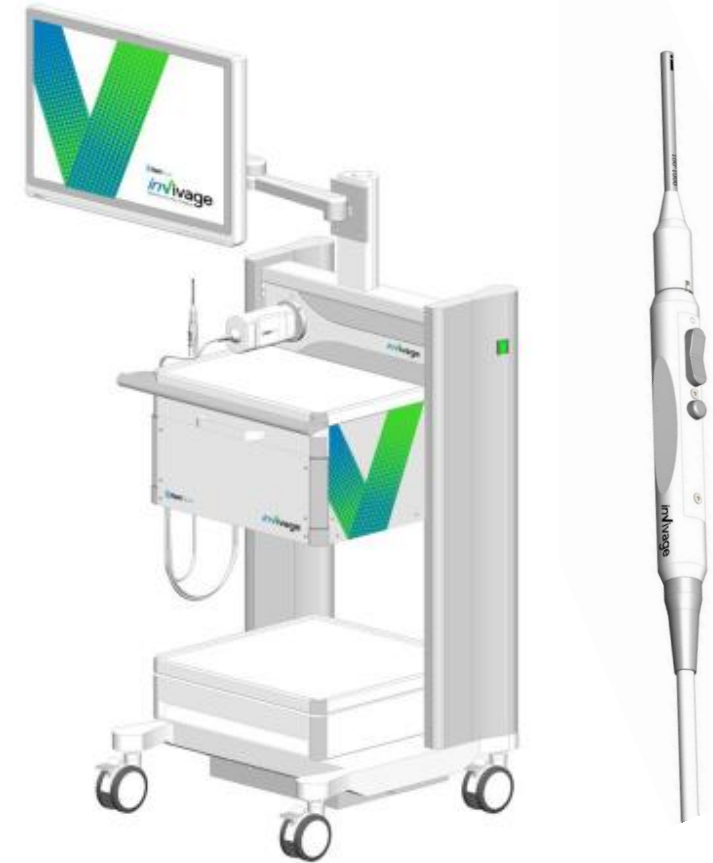
# InVivage<sup>®</sup> Optiscan's Clinical System

# Optiscan FIVE2 Laboratory and InVivage® Clinical Systems

## FIVE2 (ViewnVivo) Laboratory System



## InVivage® Clinical System





# Optiscan InVivage® Clinical System



## InVivage® Key Features

- Single Hand Operation with control features operated from probe
- Medical Grade Screen on Trolley Arm enabling preferred positioning by clinician
- Graphic User Interface (GUI) software
- DICOM compliant software to enable integration with Hospital Picture Archiving and Communication System (PACS)
- Sterilisable Sheath



# Cancer Cases Worldwide – Addressable Market

18.1M total  
cancer cases  
p.a.

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

450,000  
Oral and  
Oropharyng  
eal 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**

**InVivage®  
Application**

**Flexible  
Endoscope  
Applications**

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

# Oral Cancer Global Incidences

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450,000 Cases of  
cancer of the Lip,  
Oral Cavity and  
Oropharynx  
worldwide<sup>1</sup>

90,000  
Cases in  
Europe<sup>2</sup>

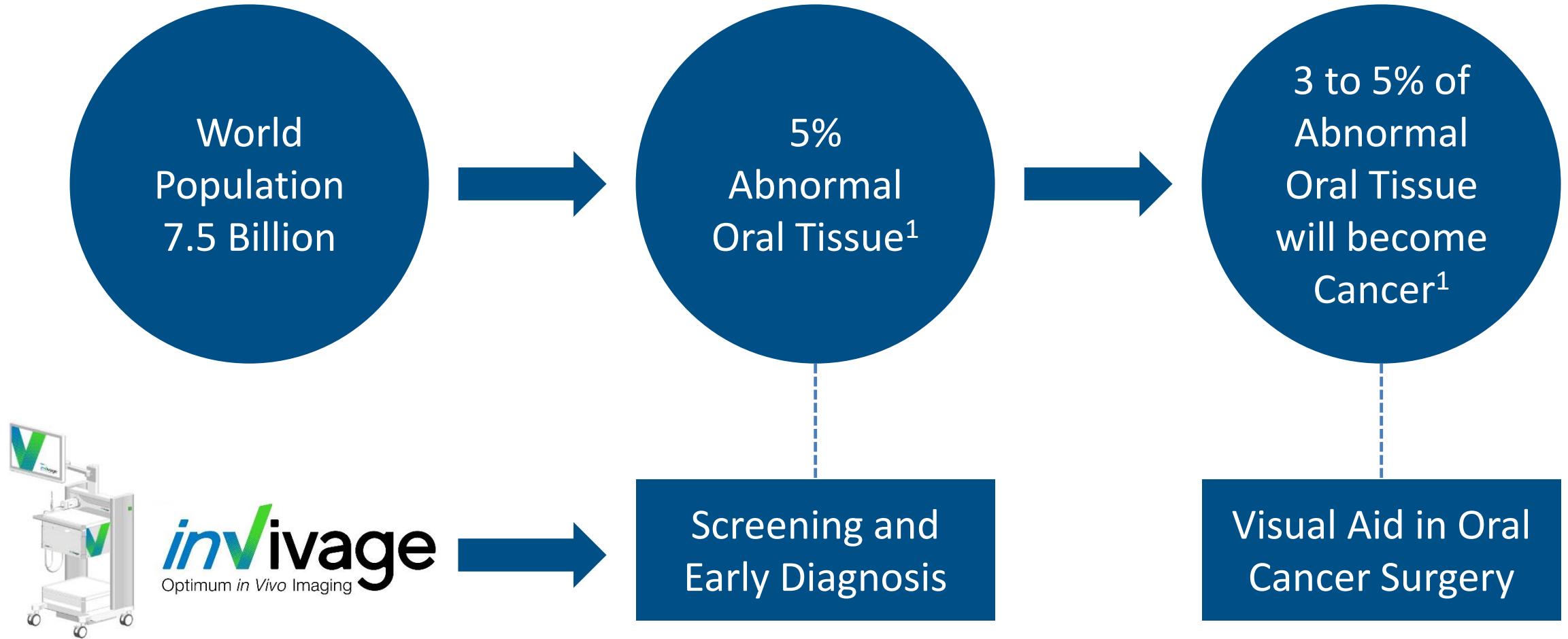
53,000  
Cases in  
USA<sup>3</sup>

48,000  
Cases in  
China<sup>4</sup>

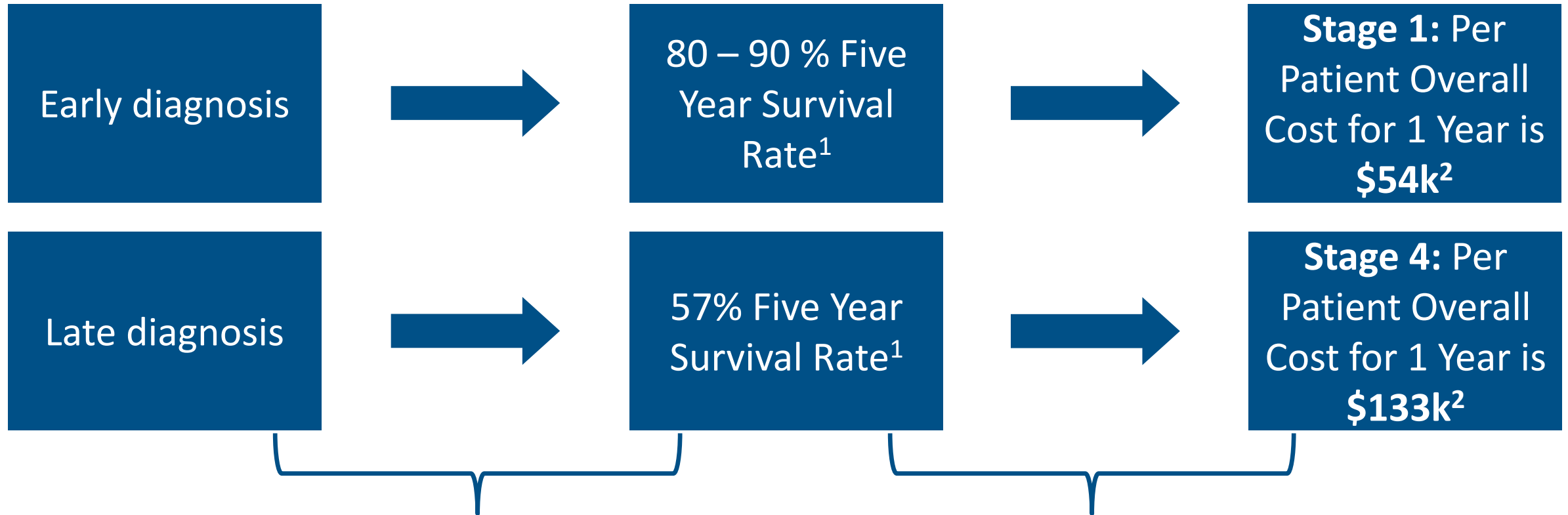
5,000  
Cases  
in Au<sup>5</sup>

1. Global cancer statistics 2018: GLOBOCAN. <https://doi.org/10.3322/caac.21492>
2. American Cancer Society Estimated 2019 Statistics.
3. Global Cancer Observatory- Europe. <https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf>
4. Cancer Statistics in China, 2015, Cancer statistics in China, 2015. <https://doi.org/10.3322/caac.21338>
5. Cancer Australia (Australian Government) Estimated 2018 Statistics

# Oral Cancer – Screening and Surgical Requirement



# Early Diagnosis: Survival Rates and Economic Cost



“need to investigate novel techniques and technologies to detect oral squamous cell carcinoma early and reduce recurrence and mortality rates.”<sup>1</sup>

“...clear economic support for oral cancer screening initiatives to detect earlier stage cancers”<sup>1</sup>

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.

# Oral Cancer Screening: Clinical Trials and Studies

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## Clinical Trials & Studies

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Memorial Sloan Kettering Cancer Centre in New York (MSKCC)

Commenced

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Australian Centre for Oral Oncology Research & Education (ACOORE) in Perth

Commenced - 10 patients imaged in the past month

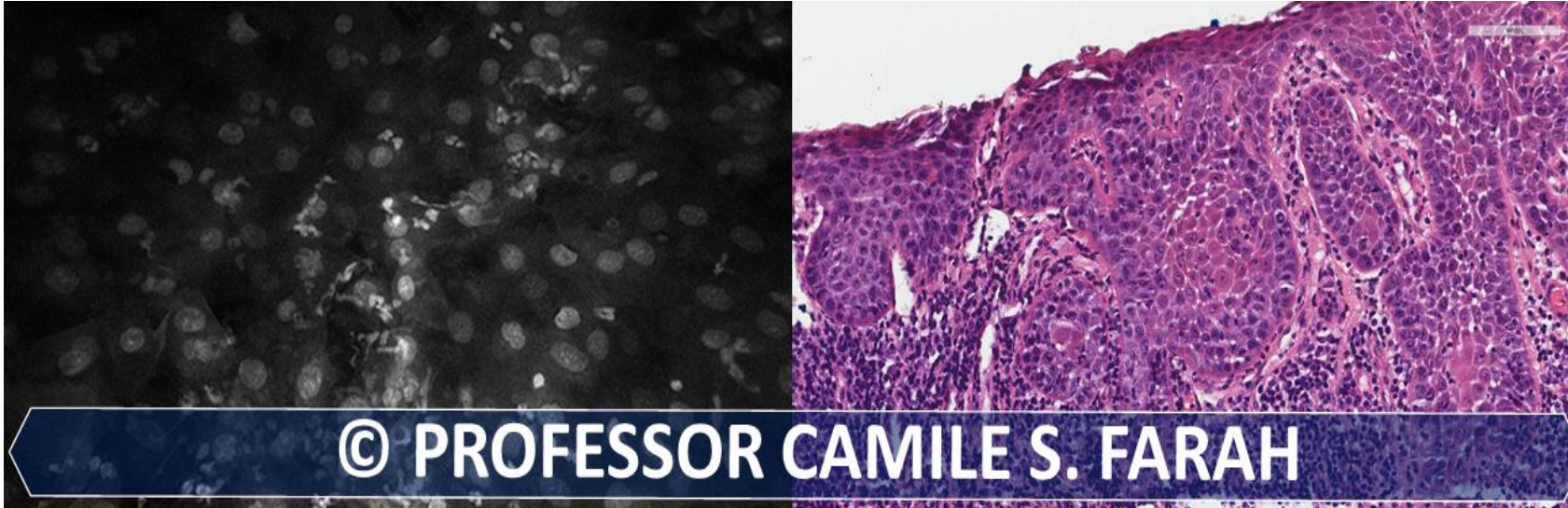
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Melbourne Dental School (University of Melbourne) in collaboration with Royal Melbourne Hospital, Peter MacCallum Cancer Centre, MSKCC and ACOORE

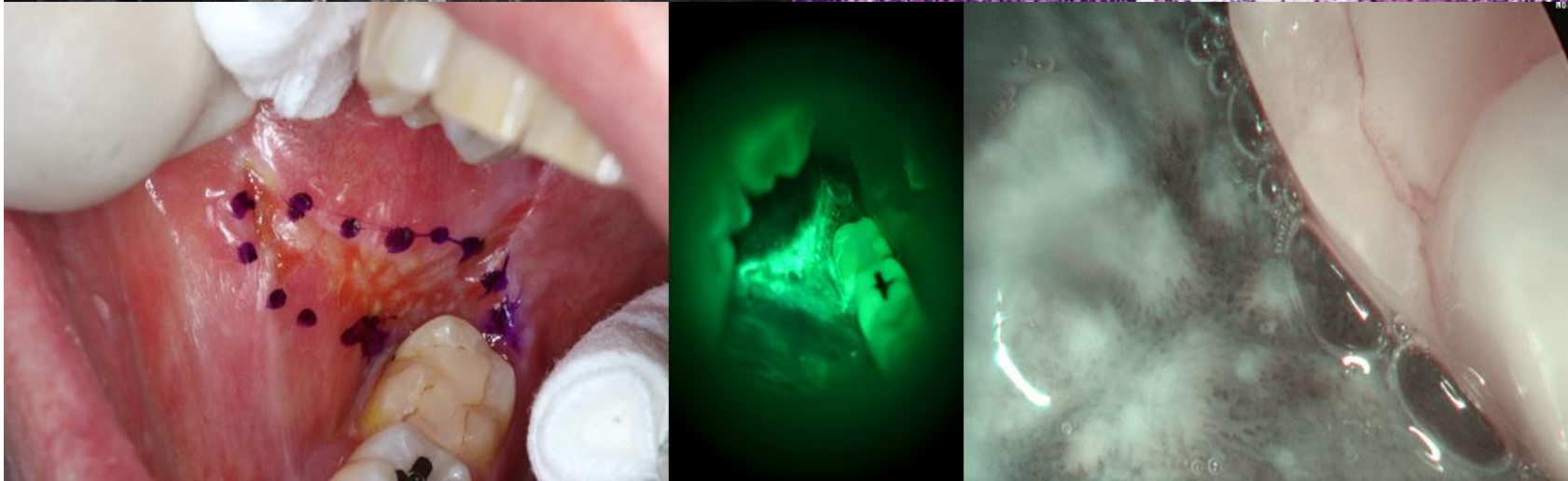
Ethics approval requested to commence trial

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# Australian Centre for Oral Oncology Research & Education Clinical Study



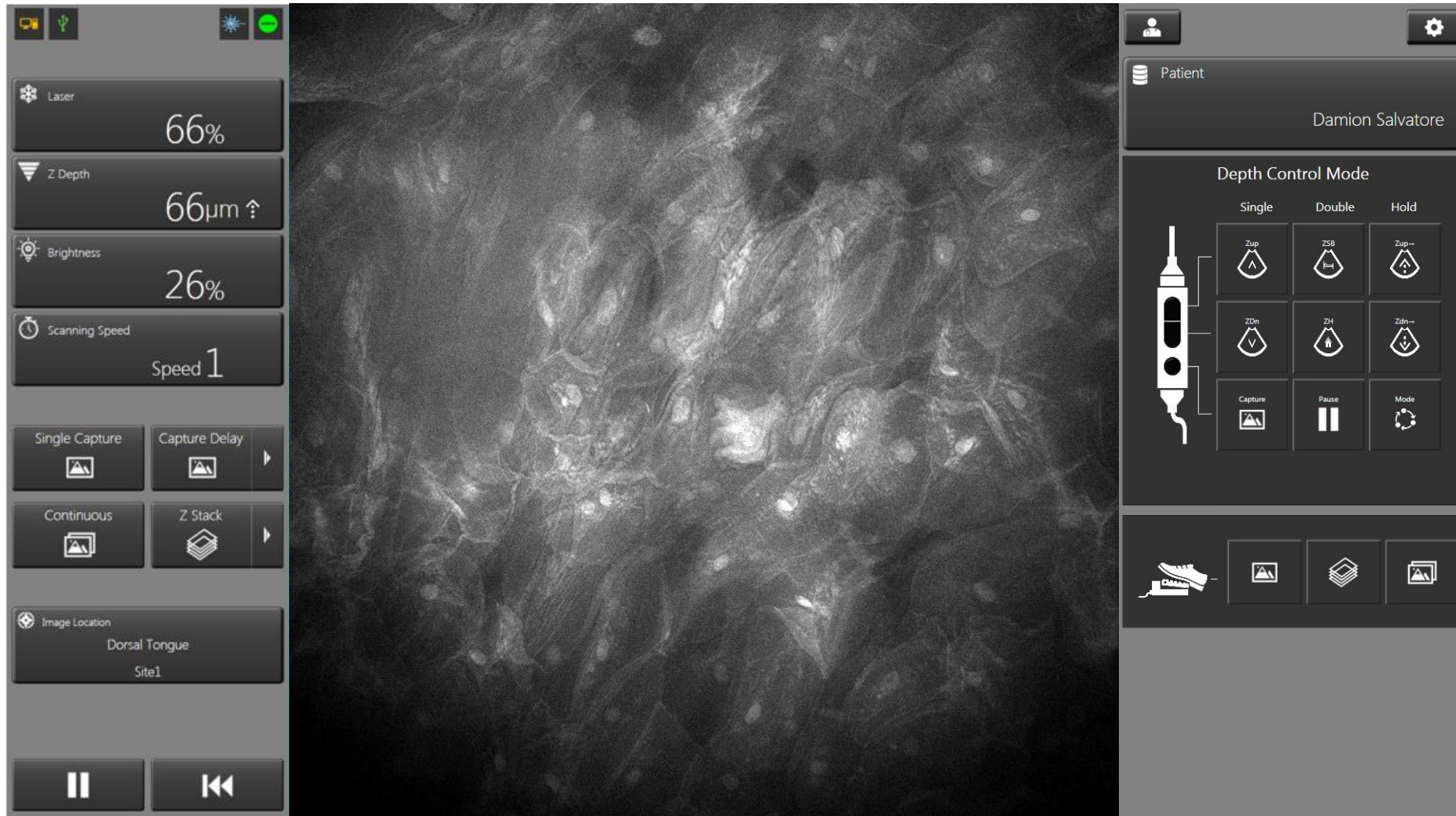
Comparison  
between Optiscan  
imaging and  
histopathology



Other imaging  
modalities for  
detection of oral  
cancer

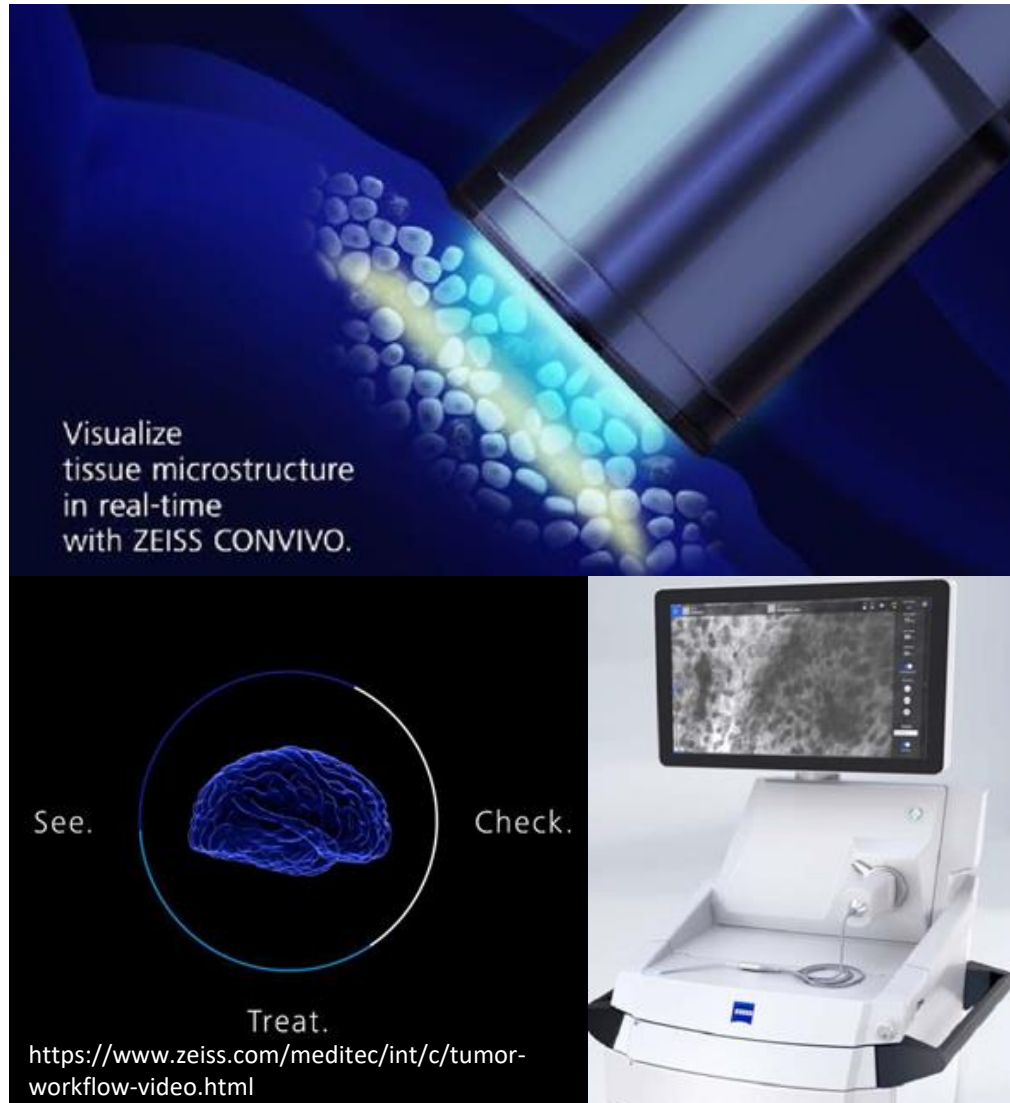


# New InVivage® User Interface Designed for Doctors





# Brain Cancer – Carl Zeiss Meditec AG Collaboration Update



Date	Progress
April 2018	European (CE Mark) approval obtained
October 2018	United States (FDA 510(k)) approval obtained
May 2019	CONVIVO “Digital Biopsy Tool” (Check) an integral part of the 3 step Zeiss Tumour Workflow in Neurosurgery
November 2019	\$550k of orders for products and services for delivery during the current half year and in late Feb/early March 2020.

**Zeiss is an international leader in the field of optics and optoelectronics with a market capitalisation of ~€9.7billion**

# Breast Cancer - The Most Common Cancer in Women

**2.1**

Million new  
cancer cases  
(globally)<sup>1</sup>

**15%**

New Cancer  
cases in  
United States<sup>2</sup>

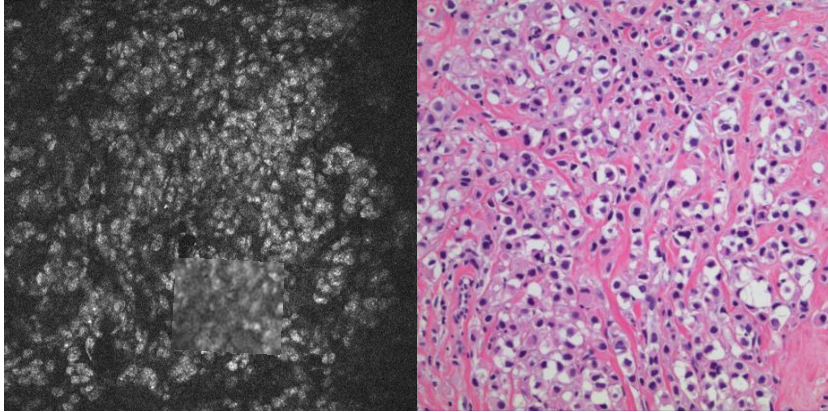
**556**

US Accredited  
Breast  
Cancer  
Centres<sup>3</sup>

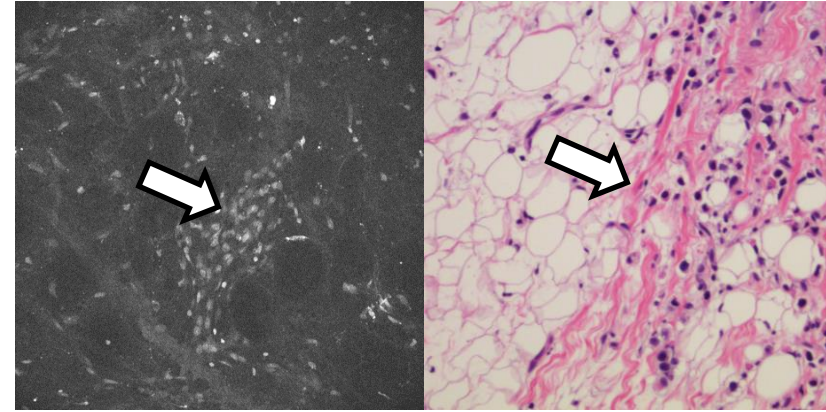
- 4 Stage Breast Cancer Trial at Hollywood Private Hospital (Western Australia's largest private hospital)
- Nearing completion of Stage 2: 3 pathologists assisting comparison of Optiscan images (CLE) and H&E histopathology.
- 30 surgical patients (ex vivo) with multiple specimens per patient (>120 total) across Stage 1 and Stage 2.
- Greater imaging and comparison of CLE and H&E supporting development of imaging protocols and CLE Breast Atlas.
- Discussions with hospitals on-going to establish Stage 3 multi-centre study in the operating theatre with ex vivo imaging of the excised breast lump.
- Optiscan InVivage Clinical system is proposed for Stage 4.

1. GLOBOCAN 2018 estimates; uses Bray et al 2018 paper in CA: A Cancer Journal for Clinicians, page 398
2. American Cancer Society Estimated 2019 statistics
3. <https://www.facs.org/search/cancer-programs>

# Breast Cancer Trial – CLE & Histopathology Correlation

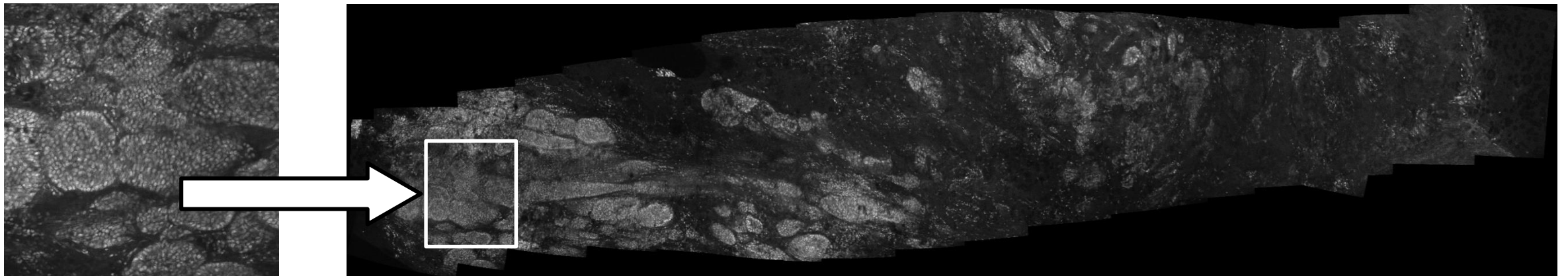


Matching CLE and H&E Cancer cells throughout



Matching CLE and H&E Cluster of cancer cells (Arrows)

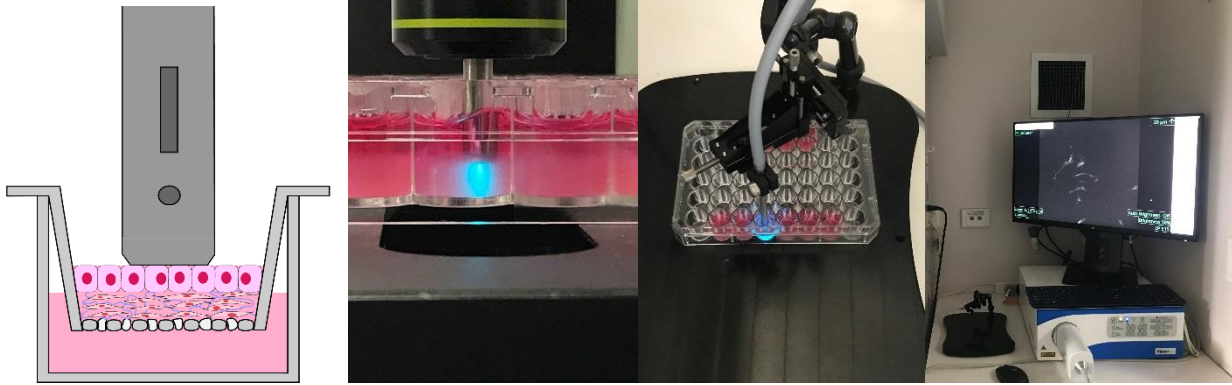
Creation of panoramas: developing a more macro view of the specimen assisting in the CLE and H&E correlation





# Development of new applications in research market

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).

# Rapid Impact of New Distributor Strategy for Chinese Market

- **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:** Under Negotiation (Green)

**North China:** To be Advised

- **Sale of FIVE2 (ViewnVivo) System in Nov 2019:**  
Chinese University Tender success directly attributable to new Chinese multi-distributor model.



# Pre-clinical Marketing Collateral

**Handheld Confocal Endomicroscopy**  
High-Resolution | In Vivo Imaging | Portable Fluorescence Confocal | Now at Monash

**FIVE2 Endomicroscope**

Portable, flexible handheld or arm mounted probes.

**CLE Technology**

Confocal laser endomicroscopy (CLE) provides cellular resolution in vivo.

**Rapid Virtual Histology**


World's first | First CLE | First in Endomicroscopy | Health Care

Minutised fibre optic scanning mechanism provides sub-micron lateral resolution and 3D optical sectioning.

**In Vivo Imaging**

Prediclinical applications include real time virtual biopsy, thrombosis detection, microbiome imaging, calcium imaging, tissue culture imaging, blood vessel imaging, etc. Clinical applications include confocal endomicroscopy and tumor margin detection. Images on the right are dog stomach imaged with a confocal gastroscope (A), Thrombosis detection in petal brain (B), heart muscles expressing VFP (C), kidney (D), nicotinic in mouse gut (E) and maximum brightness projection of a 3D tissue culture specimen (F).

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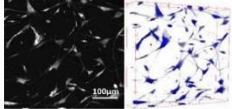


**Real-time imaging of in vitro 3D tissue culture**

Tissue cultures are used in research for modelling normal tissue in vitro. Scaffolds are used to grow cultures in 3D to mimic the in vivo tissue environment. 3D environments enable specific exposure to signaling molecules and supplementary cues that are needed at specific growth phases so cells can differentiate into desired cell types. As a result, 3D tissue culture can resemble the cellular arrangement and tissue morphology of an in vivo environment.

Tissue cultures are usually grown in culture wells or transwell inserts. High-resolution imaging of tissue cultures is challenging since conventional microscope objective lenses cannot access inside the wells and have limited working distance. Another approach is to image the tissue culture from underneath using an inverted microscope. However, this does not work well when using transwell inserts, as they require long working distances and contain devices that block light from entering the sample from below. As a consequence, high-resolution imaging of tissue culture is currently performed by removing it from the well and fixing it prior to imaging.

This application note provides details on how endomicroscopy can be used for confocal imaging of live tissue cultures over time in incubators and biosafety cabinets.

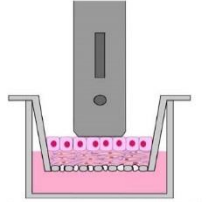


Maximum brightness projection (left) and 3D modeling (right) of human dermal fibroblasts, imaged directly from tissue culture wells using the FIVE2 endomicroscope.

**Live Imaging of Tissue Culture Samples**


- 1. Tissue culture**  
Grow cell culture in an appropriate media in a transwell insert or cell culture well plate.
- 2. Selection of appropriate imaging agents**  
Depending on specific characteristics of interest, various stains can be used. Fluorochromes like rhodamine, fluorescein, acridine, and DAPI can be used for viewing the overall morphology of the culture. Antibody targeted stains and transgenic cells producing bright incoherent fluorescent proteins can also be imaged.
- 3. Prepare sample for imaging inside the biosafety cabinet**  
In order to maintain sterility of live samples, live tissues may need to be imaged inside a biosafety cabinet or incubator. In this case, place a vibration isolated probe holding platform inside the cabinet and install the stereofixation probe. Place the sample well plate on the probe holding platform. Use the platform's x, y, and z controls to align the probe to the imaging sample. The 4 mm diameter probe will easily reach the sample surface from the top.
- 4. Live imaging**  
Once the probe is positioned correctly, the z-position of the focal plane can be adjusted with the image software application using the inbuilt z controls within the probe. Use imaging parameters as needed to capture image. As the cells remain unfixed, this process can be used to capture tissue growth over time by imaging at regular intervals.

**Method example: 3D Tissue culture**  
Human fibroblasts were grown in rat tail collagen type I for 7 days in a cell culture well [1, 2].




A schematic representation of Optiscan's FIVE2 (ViewnVivo) endomicroscope scanner being used inside a tissue culture well.


Optiscan's small diameter confocal endomicroscopes can access the inside of culture wells to provide high-resolution 3D imaging of tissue cultures. In addition, Optiscan's endomicroscope system can be easily combined with a biosafety cabinet or an incubator allowing live imaging of laboratory grown tissue samples. The addition of endomicroscopy techniques in tissue culture has the potential to provide new information on cellular proliferation, death, rearrangement, and morphology by enabling imaging of culture in platforms (e.g. scaffolds, perfusion systems and/or fluidic devices).




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**1 FIVE2 Start Up Sequence**



**2 FIVE2 Screen Controls**



**3 FIVE2 Z Controls**



**4 Types of Image Capture with The FIVE2 System**

Pre-clinical application poster

3D tissue culture application developed with CSIRO

FIVE2 (ViewnVivo) tutorial videos for prospective and existing users

# Participation in Industry and Investor Conferences

Industry Conferences	Investor Conferences
2019: Light Microscopy Australia Conference at Translational Research Institute, Brisbane	2019: Gold Coast Investment Showcase
2019: 17 <sup>th</sup> World Federation for Ultrasound in Medicine and Biology Congress (WFUMB), Melbourne	2019: Australia Biotech Invest & Partnering
2019: BioPhotonics Career Workshop, Swinburne University of Technology, Melbourne	2019: Proactive Investors Corporate Video Presentation
2019: China Neuroscience Society Conference, Suzhou China	



<b>Month/Year</b>	<b>Milestones</b>
<b>February 2019</b>	Memorial Sloan Kettering Cancer Centre (MSKCC) using Optiscan technology to develop tools for early detection, screening and intraoperative margin assessment.
<b>February 2019</b>	Collaboration agreement with Summit Biomedical Engineering re potential drug/device combination of PARPi-FL and Optiscan FIVE2 (ViewnVivo) system.
<b>March 2019</b>	Commencement of Stage 2 of Breast Cancer Clinical Trial at Hollywood Private Hospital
<b>June 2019</b>	\$1.7m Capital Raising
<b>August 2019</b>	Optiscan system approved for use in MSKCC Oral Cancer Human Clinical Trial
<b>August 2019</b>	Optiscan re-sterilisable sheath receives independent 3 <sup>rd</sup> party validation
<b>September 2019</b>	Melbourne Dental School (in collaboration with MSKCC, Peter MacCallum Cancer Centre, Royal Melbourne Hospital and Australian Centre for Oral Oncology Research & Education) to seek ethics approval for human clinical trial to diagnose cancerous change in oral mucosa
<b>October 2019</b>	Launch Multi-Distributor China Model and appointment of South and West China Distributor
<b>November 2019</b>	US Food and Drug Administration (FDA) grants Optiscan a meeting to discuss proposed content of a 510(k) submission
<b>November 2019</b>	Receipt of orders from Carl Zeiss Meditec (CZM) for \$550k for delivery during the current half year and in late February/early March.
<b>November 2019</b>	Sale of FIVE2 (ViewnVivo) System to leading Chinese University in East China

# Summary



- Optiscan InVivage® Clinical System developed to enable “Real-time Virtual Biopsy” for Human Cancer Screening and Surgical Margin Detection
- Key features of the Optiscan InVivage® Clinical System include new single hand probe controls.
- Pre-Submission hearing with the FDA re 510(k) clearance for InVivage® for Oral Cancer Screening and /or Surgery to take place in the 2nd half of January 2020.
- Current use of Optiscan systems in 3 clinical trials and studies (current and awaiting Ethics approval) for Oral Cancer Screening.
- Discussions with hospitals on-going to establish Stage 3 multicentre Breast Cancer study in the operating theatre with ex vivo imaging of the excised breast lump.
- Collaboration with Carl Zeiss Meditech AG for Brain Cancer Surgical Device progressing with marketing at major neurosurgical conferences and \$550k of orders for products and services for delivery during the current half year and in late Feb/early March 2020.
- Launch of Multi-Distributor China Model and appointment of South and West China Distributor. Sale to University in East China within 2 months of commencement of new model.