



ASX Announcement

14 March 2019

## **OptiScan March 2019 Presentation (Amended)**

Optiscan Imaging Limited (ASX: OIL) provides the attached amended presentation to the previous version lodged on 14 March 2019. It is noted that the only amendment to the previous version is to slide 16 of the presentation.

### **About Optiscan**

Optiscan is an Australian company that has developed and patented miniaturised confocal microscopes, and is a global leader in the development and application of microscopic imaging and related technologies for medical and research markets.

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14 March 2019

## OptiScan March 2019 Presentation

Dear Shareholders,

Optiscan Imaging Limited (ASX: OIL) is pleased to provide this presentation on the development of additional human applications for the use of Optiscan's confocal laser endomicroscope technology. The presentation highlights the exciting progress made in recent months on the additional human applications which were referred to in the 2018 AGM Presentation and the Directors Report as part of the 31 December 2018 Interim Report.

This progress has taken place during a period when the Company has remained committed to its collaboration with Carl Zeiss Meditec and increased its focus on Australian Pre-Clinical and Translational markets. The board remains committed to its management of cash flows which has resulted in a reduction of the Company's cash based expenses by in excess of \$600k in the first 6 months of the 2019 financial year as compared to the prior corresponding period.

We look forward to providing further updates on our progress in the coming months.

On behalf of the Board:

A handwritten signature in black ink, appearing to read "D Lurie", is positioned above the name of the Executive Chairman.

Darren Lurie  
Executive Chairman

### About Optiscan

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# Optiscan Imaging Ltd (ASX:OIL)

Diagnostic and Intraoperative Clinical Devices

“Unlocking the Potential in Human  
Applications”



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# Disclaimer

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# Optiscan Imaging Ltd

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## Developer and Manufacturer of Clinical and Translational EndoMicroscopes

### New Human Clinical Application Developments

- Product development and modifications to the FIVE2 (ViewnVivo) being undertaken to enable oral, cervical, breast and other human clinical applications. Prototype re-processable sheaths have been developed and will undergo third party validation testing.
- Memorial Sloan Kettering Cancer Centre, a world leading cancer hospital and research institution, using Optiscan technology to assist Optiscan to develop novel tools for early detection, screening and intraoperative margin assessment in humans including oral, oesophageal and cervical dysplasias and carcinoma in situ.
- Collaboration agreement signed with Summit Biomedical Imaging LLC (SBI) regarding commercialization of a drug/device combination of SBI's PARPi-FL imaging agent and Optiscan's FIVE2 (ViewnVivo) confocal endomicroscope.
- Nearing completion of Stage 1 of Breast Cancer Surgical Margin Assessment Trial. Following receipt of ethics approval, Stage 2 has commenced with imaging of first 2 fresh mastectomy tissue specimens with PARPi-FL imaging agent.
- Commencement of regulatory approval planning including in relation to seeking FDA 510(k) clearance for modified FIVE2 (ViewnVivo).
- Leverage current and previous regulatory approvals in humans for devices with embedded Optiscan technology including ZEISS CONVIVO™ (neurosurgery) and Pentax ISC-1000 (gastroenterology endoscopy).
- Initial exploration of use of FIVE2 (ViewnVivo) in the Pathology Lab where standard "frozen section" is still the standard of care in pathological intraoperative assessment (eg. sentinel node for breast cancer, head and neck resection margins, parathyroid confirmation, thyroid cancer, omental nodules, ovary, lung resection - malignant vs benign).

# Clinical and Pre-Clinical Applications

	CLINICAL APPLICATION STATUS					PRE-CLINICAL APPLICATIONS
APPLICATION	BREAST	CERVICAL	ORAL	OESAPHAGEAL	NEURO	PRE-CLINICAL
Device	Optiscan Rigid Endomicroscope	Optiscan Rigid Endomicroscope	Optiscan Rigid Endomicroscope	Flexible Endomicroscope*		FIVE2 (ViewnVivo)
Institution	Hollywood Private Hospital (HPH) (Dr Peter Willsher and Dr Jespal Gill)	Memorial Sloan Kettering Cancer Centre (MSKCC)	MSKCC	MSKCC		
Status	<p>Stage 1 nearly completed (ex vivo analysis of 42 specimens)</p> <p>First 2 specimens imaged as part of stage 2</p> <p>HPH Research Ethics Committee approval for examination of fresh breast tissue specimens in conjunction with PARPi-FL imaging agent</p>	<p>Use of Optiscan technology by MSKCC in conjunction with PARPi-FL imaging agent</p>	<p>Use of Optiscan technology by MSKCC in conjunction with PARPi-FL imaging agent</p>	<p>Use of Optiscan technology by MSKCC in conjunction with PARPi-FL imaging agent</p>	CZM Collaboration	<p>Multiple demonstrations currently taking place at or are planned for in Australian, North American, European and Chinese institutions</p>

\* Integration of Optiscan scanner into third party flexible endoscope required to facilitate this application. Prototype available for initial research.

# ASX Announcements

## **Memorial Sloan Kettering Cancer Centre (MSKCC) Announcement 26 February 2019**

ASX Announcement

26 February 2019

### **OptiScan technology used in research at major cancer center**

Optiscan is pleased to announce that Memorial Sloan Kettering Cancer Center (MSK) in New York City is using Optiscan technology in research efforts at the institution. MSK's use of this technology will help Optiscan continue to develop novel tools for early detection, screening and intraoperative margin assessment including oral, oesophageal and cervical dysplasias and carcinoma in situ.

## **Summit Biomedical Imaging LLC (SBI) Announcement 26 February 2019**

ASX Announcement

26 February 2019

### **Collaboration Agreement with Summit Biomedical Imaging LLC (SBI)**

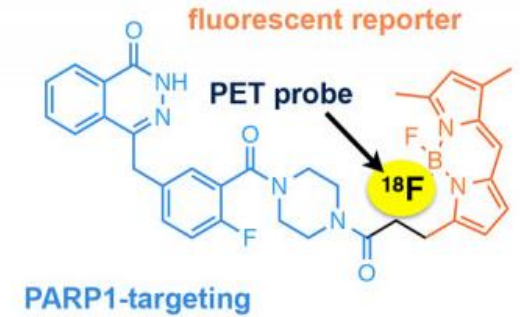
Optiscan is pleased to announce that it has entered into a collaboration agreement with SBI for the purposes of discussions regarding commercialization of a drug/device combination for various clinical applications involving SBI's PARPi-FL imaging agent and Optiscan's FIVE2 (Viewnvivo) confocal endomicroscope. These applications include using PARPi-FL in the breast cancer tumour margin assessment trial currently being conducted by Optiscan.



# PARPi-FL – Optical and Diagnostic Imaging Agent

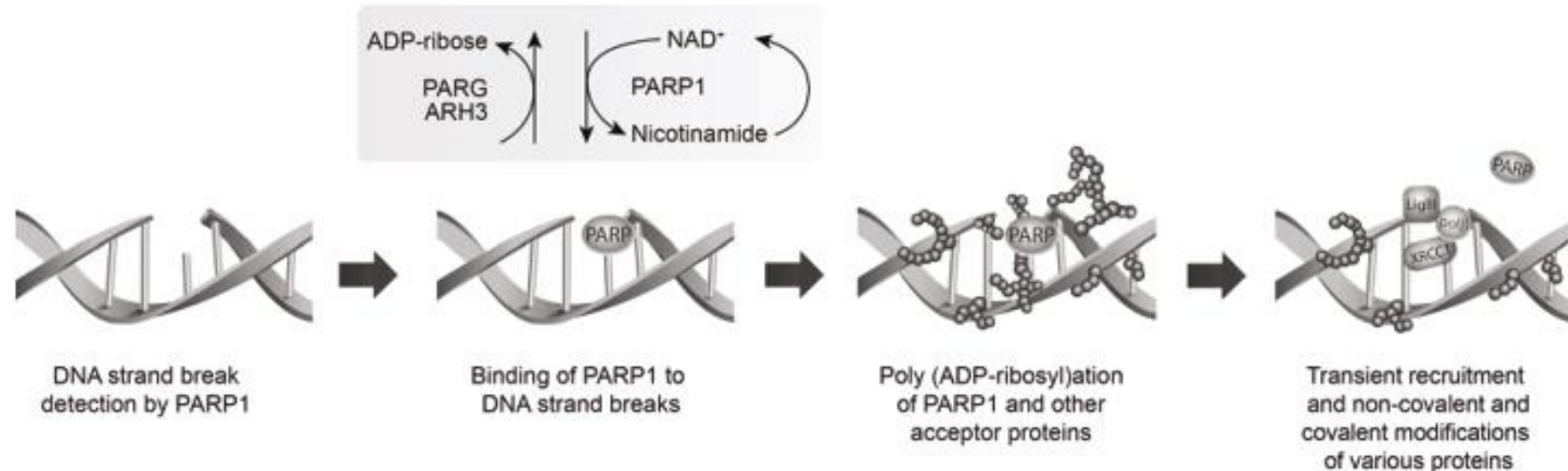
## PARPi-FL

- A molecular based imaging agent
- Possesses unique pharmacokinetics properties for topical as well as intravenous injection
- Targeting PARP1, an enzyme that is highly overexpressed in several human cancers such as oral squamous cell carcinoma, cervical cancer, breast cancer and glioblastoma.
- Objectives are to:
  - to play a key role for image-guided surgery as an intraoperative imaging agent targeting cancer tissue only;
  - enable a new point-of-care technology for cancer screening, diagnosis, and margin detection with high precision and low costs.
- **Combination with the FIVE2 (ViewnVivo)**
  - The FIVE2 (ViewnVivo) is intended to be used for intraoperative, PARPi-FL-based in vivo imaging without excision of tissue. The 488 nm laser of the FIVE2 (ViewnVivo) is the optimal wavelength for PARPi-FL detection.



# What is PARP1 and PARP1 Inhibitors?

Poly(ADP-ribose) polymerase PARP1, is an enzyme in the cell nucleus which is activated by DNA damage acting as a 'molecular nick sensor' to signal DNA single-strand breaks (SSBs) and assist in their repair. It is significantly over expressed (high quantities) in cancer cells<sup>1</sup>. This has led to the development of anticancer drugs (PARP1 inhibitors) which block the action. Olaparib is one of these drugs which form the basis of the optical molecular probe PARPi-FL.<sup>2</sup>



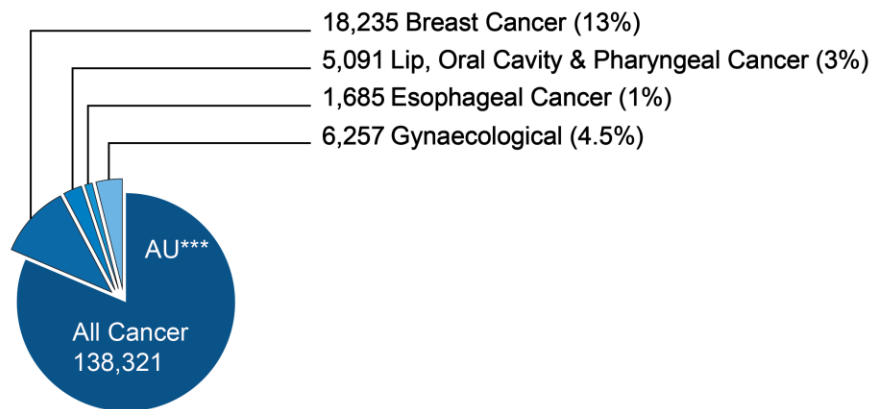
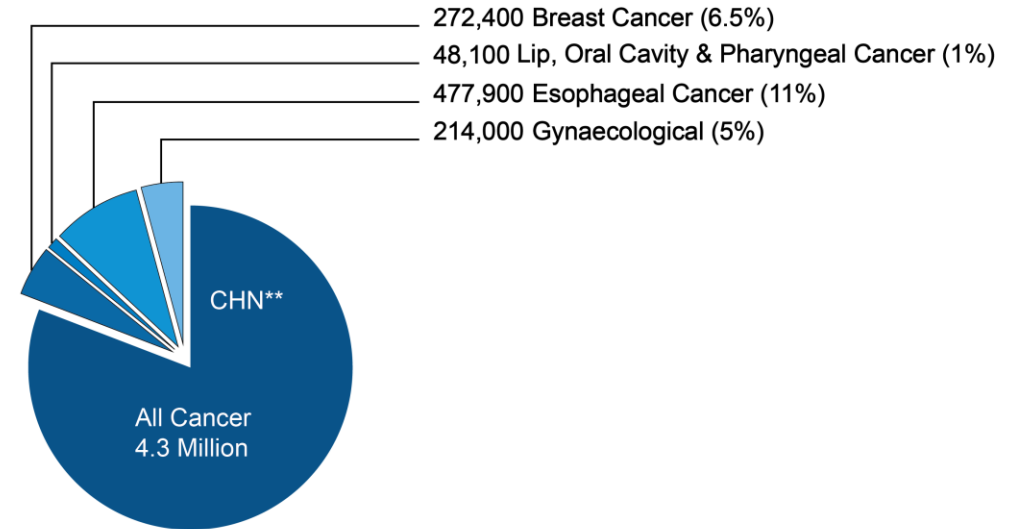
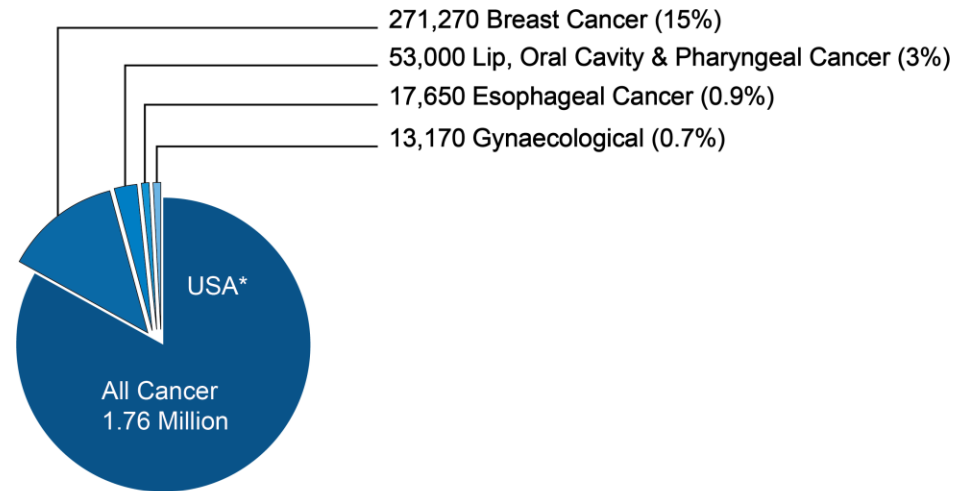
**Figure 1. Mechanism of PARP1-mediated DNA repair.** ARH3, ADP-ribosyl acceptor hydrolase 3; LigIII, DNA ligase III; PARG, poly(ADP-ribose) glycohydrolase; PARP, poly(ADP-ribose) polymerase; polβ, DNA polymerase; XRCC1, X-ray repair cross-complementing 1.

<sup>1</sup> Plummer R: Poly(ADP-ribose) polymerase inhibition: a new direction for *BRCA* and triple-negative breast cancer? *Breast Cancer Research* 2011, 13:218. <https://doi.org/10.1186/bcr2877>

<sup>2</sup> Reiner T, Lacy J, Keliher EJ, et al. Imaging therapeutic PARP inhibition in vivo through biorthogonally developed companion imaging agents. *Neoplasia*. 2012;14(3):169–177. <https://doi.org/10.1593/neo.12414>

# Breast, Cervical, Oral and Oesophageal Cancer

Estimated incidence of cancer types below with far higher number of potential diagnostic assessments



\* American Cancer Society Estimated 2019 Statistics.  
 \*\* Cancer Statistics in China, 2015, published in CA: A Cancer Journal for Clinicians, researchers led by Wanqing Chen, PhD, MD, of the National Cancer Center in Beijing. Estimated 2015 Statistics.  
 \*\*\* Cancer Australia (Australian Government) Estimated 2018 Statistics.

# Opportunities for Improved Patient Outcomes with Optiscan Confocal Laser Endomicroscopy (CLE)

## BREAST CANCER

- 13% and 15% of all cancers in Australia and the United States respectively.
- “Best estimates suggest that 60–80% of women with early-stage breast cancer in Australia undergo breast-conserving surgery, and that this proportion is increasing.”<sup>1</sup>
- “Almost 3000 women who have surgery for early breast cancer this year will likely face the trauma of repeat surgery within three months, according to big data used in a new Australian study...Health scientists from the University of NSW used big data to study breast-conserving surgery across the state over 10 years to 2013. They found it was unsuccessful in 30 per cent of cases.”<sup>2</sup>
- Determination of sufficient tumour margin at the time of surgery with Optiscan CLE could alleviate the multiple negative consequences of a “positive surgical margin” including patient emotional trauma, post-operative infections, poor cosmesis, prolonged hospital stay, delayed adjuvant therapies and higher costs.
- Financial savings for the health system and patients are huge. With a cost of at least \$5,000 for each repeat surgery, savings in Australia could be in excess of \$15m per annum.<sup>3</sup>

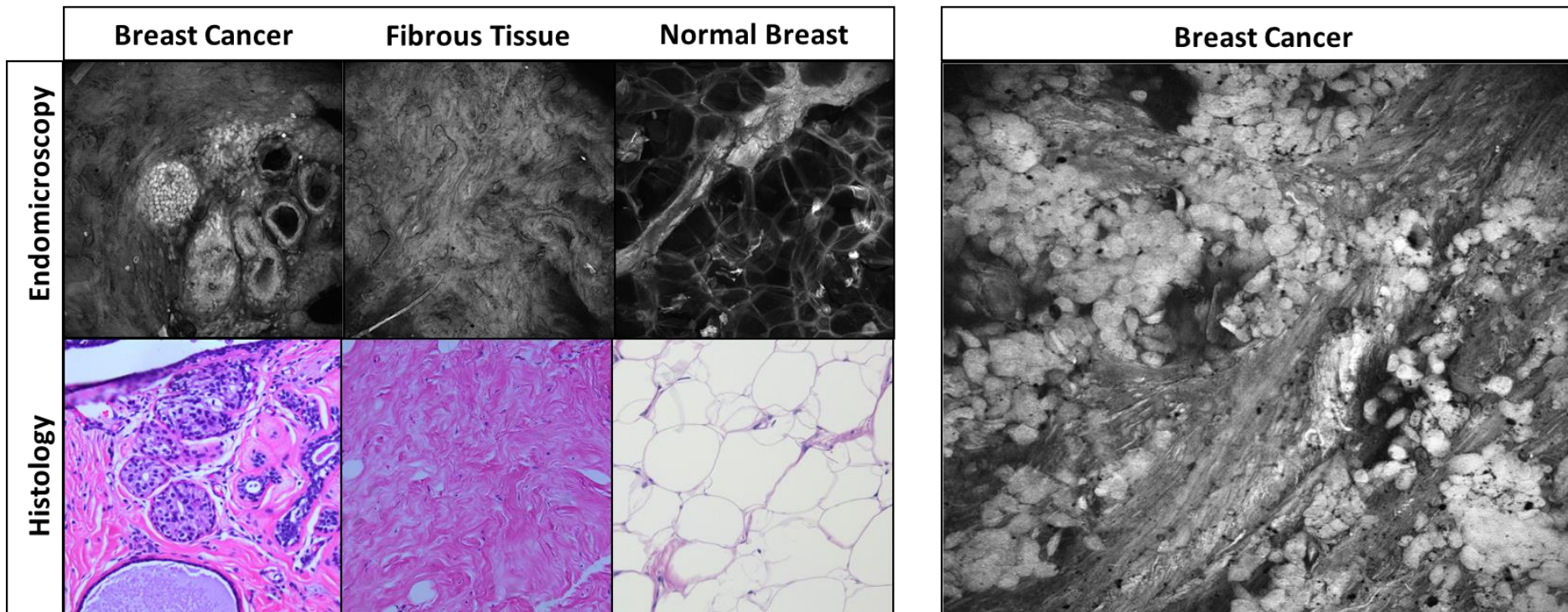
<sup>1</sup> <https://insightplus.mja.com.au/2018/22/reoperation-rates-after-breast-conserving-surgery/>

<sup>2</sup> <https://www.afr.com/lifestyle/health/mens-health/almost-3000-australian-women-face-trauma-of-repeat-surgery-for-breast-cancer-20180612-h119ye>

<sup>3</sup> Cost based on MBS item numbers for surgery, pathology, & hospital costs and savings based on 30% reoperation rate.

# Assessment of Breast Cancer Surgical Margin

- 271,270 estimated new cases of invasive breast cancer diagnosed in the United States in 2019 and 18,235 new cases diagnosed in Australia in 2018.
- Nearing completion of Stage 1 of breast cancer surgical margin assessment trial. Imaging analysis of 42 ex vivo breast tissue specimens and comparison of CLE imaging and Histopathology.
- Ethics approval extended to include fresh tissue imaging from mastectomy procedures and application of PARPi-FL stain.
- Stage 2 has commenced. 2 fresh mastectomy specimens have been imaged with PARPi-FL.



# Opportunities for Improved Patient Outcomes with Optiscan Confocal Laser Endomicroscopy (CLE)

## ORAL CANCER

- Comprise 85% of head and neck cancers (excluding brain cancers). Worldwide, there are over 450,000 new cases each year. <sup>1</sup>
- 53,000 Americans will be diagnosed with oral or oropharyngeal cancer in 2019, causing over 9,750 deaths. Approx \$3.2 billion is spent in the USA each year on the treatment of head and neck cancers.<sup>1</sup>
- 5 year survival rate of only 57% with death rate much higher than many other better known cancers. <sup>1</sup>
- Oral cancer is routinely discovered late in its development accounting for the high mortality.<sup>1</sup>
- Similar to breast cancer, tissue biopsy and histopathology is currently the “gold standard” for oral cancer diagnosis.

“Accordingly, the gold standard in diagnosis of oral cancer is still incisional biopsy and histopathological assessment, although this procedure itself is burdened by errors in both sampling and interpretation and lacks sensitivity to determine lesion progression. PARP1–targeted optical imaging could fill this gap because it has the potential to provide highly accurate detection of cancerous lesions combined with spatial resolution.” <sup>2</sup>

<sup>1</sup> <https://oralcancerfoundation.org/facts/>

<sup>2</sup> Kossatz, S., Weber, W., & Reiner, T. (2017). Detection and Delineation of Oral Cancer With a PARP1-Targeted Optical Imaging Agent. Molecular Imaging. <https://doi.org/10.1177/1536012117723786>

# Opportunities for Improved Patient Outcomes with Optiscan Confocal Laser Endomicroscopy (CLE)

## CERVICAL CANCER

- Cervical cancer is the fourth most common cancer among women globally. In Australia, there were 930 new cases in 2018 and 258 deaths and in the USA for 2019 it is estimated to be 13,170 new cases and 4250 deaths.
- While effective screening programs have led to major declines in the numbers of cervical cancer deaths in the last 50 years and the HPV vaccine protects against nine HPV types which cause around 90% of cervical cancers in women, cervical cancer will continue to be diagnosed. Twelve years after the first HPV vaccine registration, less than half of WHO Member States have introduced HPV vaccine into the routine national immunization schedule.<sup>1</sup> Even in the USA, the uptake of HPV vaccine is limited with only 1/3 of adolescent females having been fully vaccinated in 2012.<sup>2</sup>
- Currently Punch Biopsies, Cone Biopsies and Endocervical curettage procedures are all used to remove tissue from the cervix.

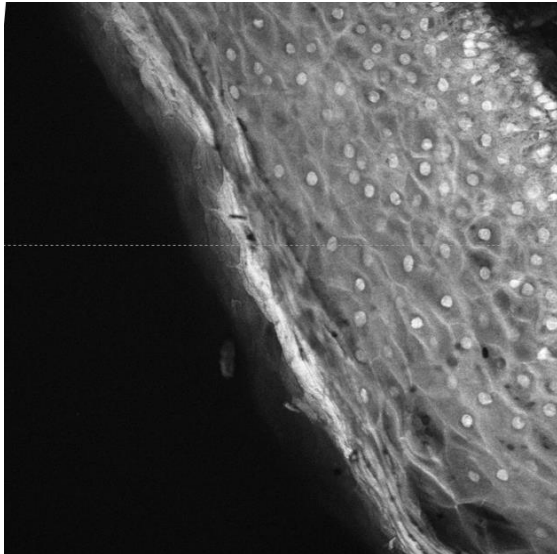
<sup>1</sup> [https://www.who.int/immunization/programmes\\_systems/procurement/v3p/platform/module2/WHO HPV market study public summary.pdf](https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module2/WHO_HP_V_market_study_public_summary.pdf)

<sup>2</sup> <https://deainfo.nci.nih.gov/advisory/pcp/annualreports/hpv/ExecutiveSummary.htm>

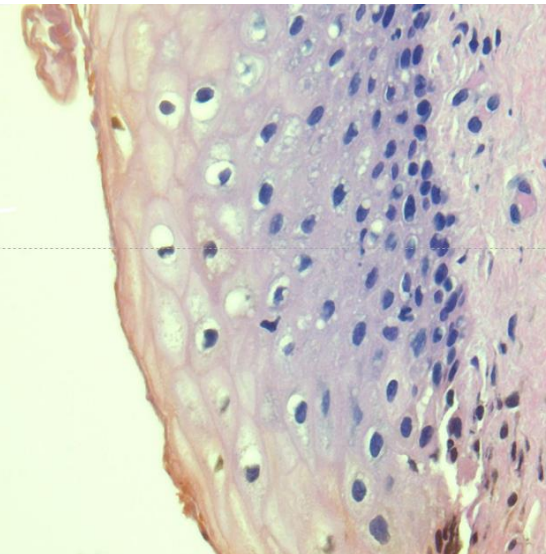
# Cervix – CLE and Histopathology Correlation

“The majority of the decline in invasive cervical cancer rates in developed countries is due to a reduction in squamous cell carcinoma. In contrast, the incidence of adenocarcinomas has not declined, largely attributed to difficulties in detecting these types of cancer through cervical screening using the Pap test. In Australia, the incidence of adenocarcinoma has been increasing since the early to mid-2000s and this cancer now comprises over one in four of all cervical cancers diagnosed.”<sup>1</sup>

**Normal Ectocervix**



**CLE**

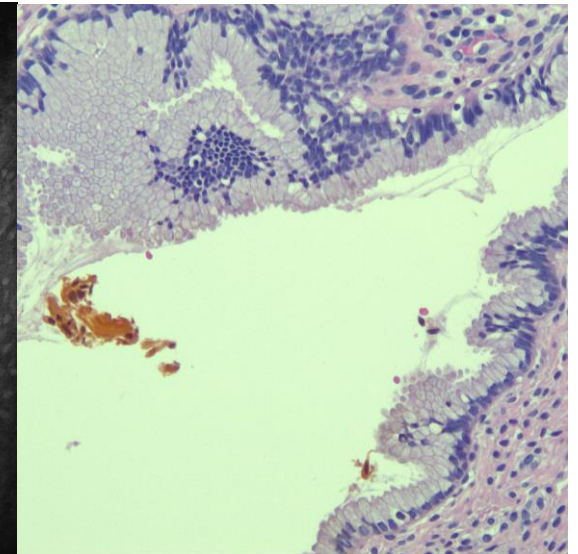


**Histopathology**

**Normal Endocervix**



**CLE**



**Histopathology**

<sup>1</sup> [https://wiki.cancer.org.au/policy/Cervical\\_cancer/Impact](https://wiki.cancer.org.au/policy/Cervical_cancer/Impact)



# Sterilizable Probe Sheath



Design of Optiscan's sterilizable sheath completed. Third party validation testing to be undertaken in the near term.




# Translational and Pre-Clinical Research

- Increased profile in Australian translational and pre-clinical research markets.
- Multi-faceted re-branding of FIVE2 (ViewnVivo) including new website in late 2018.
- Conducted workshop at Light Microscopy Association conference in Brisbane, March 2019 and will be at Biophotonics Conference at Swinburne University, Melbourne in September 2019.
- Collaboration with CSIRO to identify new applications including organoid and 3D cellular structures.
- FIVE2 (ViewnVivo) located at Monash Micro Imaging to assist development of research applications.
- Multiple demonstrations currently taking place at or are planned for in additional Australian, North American, European and Chinese institutions.

## Handheld Confocal Endomicroscopy

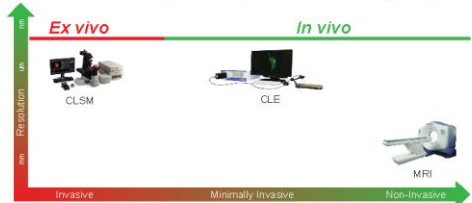
High-Resolution | In Vivo Imaging |  
Portable Fluorescence Confocal | Now at Monash

### FIVE2 Endomicroscope



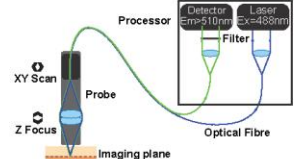
Portable, flexible handheld or arm mounted probes.

### Filling A Gap In Live Imaging



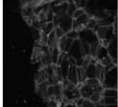


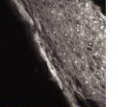
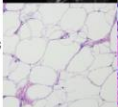
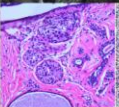
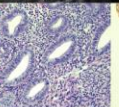
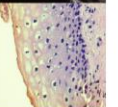
Confocal laser endomicroscopy (CLE) provides cellular resolution in vivo.

### CLE Technology



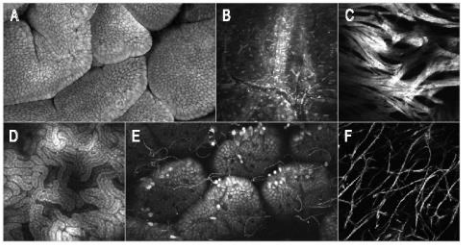
Miniaturised fibre optic scanning mechanism provides sub micron lateral resolution and 3D optical sectioning.


### Rapid Virtual Histology

	Normal Breast	Breast Cancer	Healthy Endometrium	Healthy Cervix
CLE				
Histology				

### In Vivo Imaging

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






### Contact

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# Summary and Future Outlook

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- A strategic transformation of Optiscan has taken place **over the last 10 months**.
- Optiscan CLE is being enabled for intraoperative and diagnostic use in the operating theatre, medical and dental clinic and pathology laboratory.
- Human applications of CLE have grown from only neurosurgery to now include breast, oral, oesophageal and cervical cancer.
- Optiscan is working with Memorial Sloan Kettering Cancer Centre to develop novel tools for early detection, screening and intraoperative margin assessment in oral, oesophageal and cervical applications.
- A clinical version of the FIVE2 (ViewnVivo) has been developed with a sterilisable probe sheath.
- A collaboration agreement has been signed for discussions regarding a drug/device combination of a cancer specific optical imaging agent (PARPi-FL) and Optiscan CLE.
- Stage 2 of the Optiscan Breast Cancer Surgical Margin trial has commenced including using PARPi-FL.
- Strong pathway to finally fully commercialise the long promised Optiscan CLE technology.