Optiscan Imaging Ltd (ASX:OIL)

Unlocking the Potential in Human Applications

Diagnostic and
Intraoperative Clinical Devices

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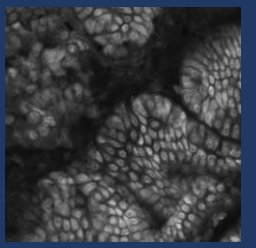
OptiScan

Confocal Endomicroscopic Imaging Technology

For medical, translational and pre-clinical markets



Global leader in handheld confocal laser microscopy

Launched second generation system with smaller probe diameter, faster scanning and higher resolution

Developing oral, cervical, oesophageal and breast cancer clinical applications

CONVIVO® developed for neurosurgical clinical application, in collaboration with Carl Zeiss Meditec, with US and European approvals in place

Where we are today

Current work → **Future vision**

Pre-clinical & Translational Research

- Product re-branded FIVE2 (ViewnVivo)
- Multiple trial demonstrations & funding being sought by research institutions for potential purchase in Australia, North America, EU & China

Brain Cancer

- Collaboration with Carl Zeiss Meditec
- FDA510(k) and CE Mark obtained
- CZM advises commercialisation progressing

New Cancer Applications

- Breast
- Oral
- Cervical
- Oesophageal

Focus of this presentation

Highlights : Progress on our vision

"Developer of In-Human Diagnostic and Intraoperative Clinical Devices in Cancer"

1

Working with Memorial Sloan Kettering Cancer Centre (MSKCC)[1] and Summit Biomedical Imaging (SBI)

Development of screening, early diagnosis and surgical tools targeting cancer cells for oral, oesophageal and cervical cancers

2

Progressed to Stage 2 of Breast Cancer Research Trial at Hollywood Private Hospital

Imaging of fresh tissue samples with PARPi-FL and matching histopathology

3

Seeking FDA 510(k) Clearance and Other Regulatory Approvals for FIVE2 Clinical Device (FIVE2C)

Minimal immediate need for further research and development. Product modifications for clinical device well underway

1. Memorial Sloan Kettering Cancer Center is the world's oldest and largest private cancer center, situated in New York, USA (MSKCC website, 2019)

Combination of PARPi-FL agent & Optiscan FIVE2C

PARPi-FL
A molecular based optical imaging agent targeting PARP1 which is an enzyme that is highly overexpressed in several human cancers

Optiscan's FIVE2C
Unique capability for in vivo microscopic imaging, providing instantaneous in vivo examination of the tissue targeting cancer cells highlighted by PARPi-FL

Optiscan's FIVE2C in combination with PARPi-FL enabling high precision & low cost:

- Cancer screening
- Cancer diagnosis (where to biopsy)
- Surgical margin detection (confirm complete removal of the cancer)

We are working with the world-leading Memorial Sloan Kettering Cancer Center in New York in oral, oesophageal and cervical cancer and dysplasia (pre-cancer)

Improving global practice with FIVE2C

1. For many cancers, early detection requires regular reviews and biopsies
2. Current global practice (intraoperative frozen section biopsies) is both costly and time consuming
3. Current practice can also have sub-optimal results, with sampling error due to limited samples, processing artifacts and significant surgical time delays

FIVE2C can **address this world-wide problem** by delivering a microscopic approach (which can augment the traditional macroscopic approach) in diagnosing cancer and confirming complete removal

Cancer is **identified** under UV light (traditional macroscopic approach) and then **confirmed for selective biopsy** using the **FIVE2C**

After the cancer is removed, the surgical bed can be **examined with the FIVE2C** to identify any **residual cancer**

FIVE2 application with MSKCC

August 2018	Nov 2018	Feb 2019	Feb 2019	Apr 2019	Apr 2019	Apr 2019
Proof of concept usage for Oral Cancer	FIVE2 provided to MSKCC for ex vivo imaging	Collaboration agreement with SBI signed	MSKCC working with FIVE2 in oral, cervical and oesophageal applications (ex vivo)	MSKCC began investigational device exemption process for FIVE2C use in an Oral human Cancer trial	MSKCC initial ex-vivo analysis supports further use and study of FIVE2C in Cervical & Oesophageal applications	Visit by MSKCC surgeon & research investigator to Melbourne and Perth to further the collaboration, including presentations at Melbourne (Peter MacCallum Cancer Centre) and Perth (Hollywood Private Hospital)

Scale of Oral, Oesophageal and Cervical Cancer

Oral Cavity, Lip & Pharyngeal Cancer

53,000
Estimated new cases in the USA each year[1]

48,100
Estimated new cases in China each year[2]

Oesophageal Cancer

17,650
Estimated new cases in the USA each year[1]

477,900
Estimated new cases in China each year[2]

Gynaecological Cancer

13,170
Estimated new cases in the USA each year[1]

214,000
Estimated new cases in China each year[2]

1. American Cancer Society Estimated 2019 Statistics
2. Cancer Statistics 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.

Breast cancer is 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 cancer[2]

556 centers

There are 556 Breast Centers in the USA accredited by the US Commission on Cancer[3]

145 hospitals

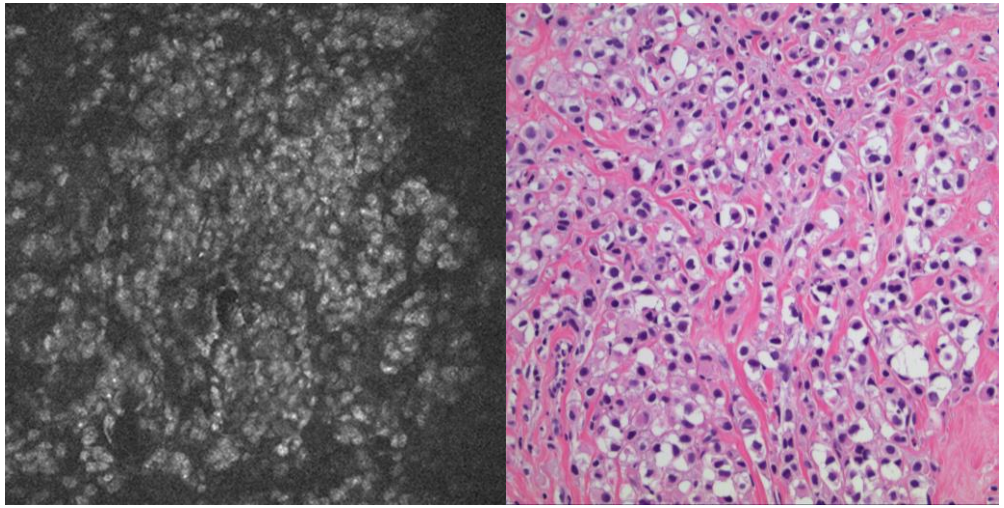
There are 145 hospitals in Australia performing breast cancer surgeries[4]

Title: GLOBOCAN 2018 estimates; uses Bray et al 2018 paper in CA: A Cancer Journal for Clinicians, page 402

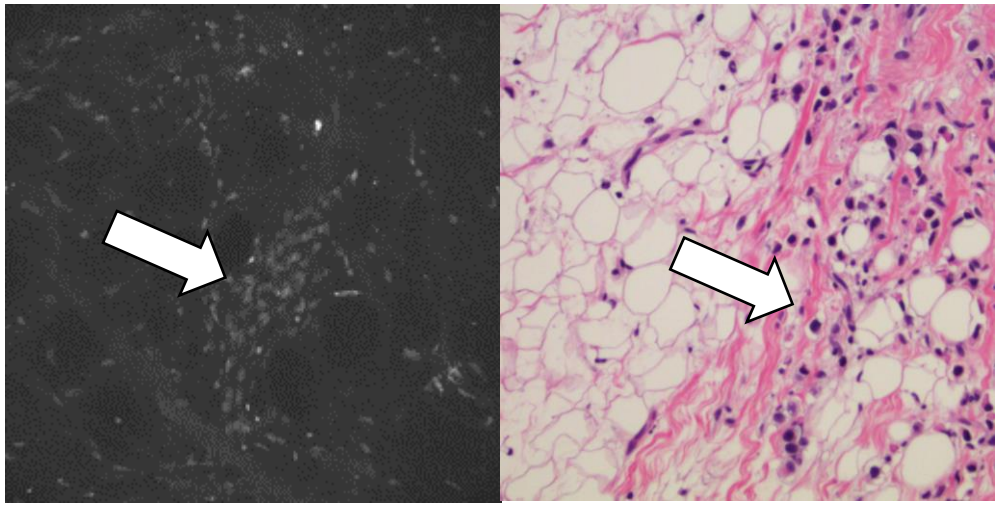
1. GLOBOCAN 2018 estimates; uses Bray et al 2018 paper in CA: A Cancer Journal for Clinicians, page 398
2. American Cancer Society Estimated 2019 statistics
3. The CoC was established by the American College of Surgeons (ACoS) in 1922 and its purposes include the establishment of standards to ensure quality, multidisciplinary, and comprehensive cancer care delivery in health care settings. https://www.facs.org/search/cancer-programs
4. https://www.myhospitals.gov.au/compare-hospitals/cancer-surgery-waiting-times/breast-cancer

Stage 2 of the Breast Cancer Surgical Margin Assessment Trial *conducted at Hollywood Private Hospital*

Underway with multiple specimens from 5 mastectomy patients with PARPi-FL matching histopathology



Matching CLE and H&E – Cancer cells throughout



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

Progress to date on Breast Cancer Trial

Examination of ex vivo excised breast tissue specimens by CLE and Histopathology

Examination of ex vivo fresh breast tissue specimens in conjunction with PARPi-FL imaging agent in pathology lab

Examination of ex vivo fresh breast tissue specimens in the operating theatre during operating procedure

Examination of breast tissue in vivo during operating procedure

Trial: Breast Cancer Surgical Margin Assessment Trial conducted at Hollywood Private Hospital and Western Diagnostic Pathology. In conjunction with Dr Peter Willsher (Breast Surgeon) and Dr Jespal Gill (Pathologist)

Optiscan is Seeking:

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

For use of the FIVE2C in breast, oral, and cervical applications

- An internal assessment of the required technical and regulatory tasks for FDA 510(k) clearance has been undertaken
- Discussions are currently taking place with a number of regulatory advisory firms regarding their potential engagement to assist Optiscan in applying for 510(k) clearance

Modifications underway to meet strategic & regulatory needs

Product changes are underway to enable the use of a modified FIVE2 (ViewnVivo) system (FIVE2C), in the:

- Proposed MSKCC Oral and Cervical Cancer trials
- Breast Cancer Surgical Margin Trial

The design and manufacturing of the first re-sterilisable sheaths for Oral, Breast & Cervical trials is expected to be complete by June 30, 2019

- There are different length sheaths for cancer types

External validation of the sterilisability of the sheath for the Oral Cancer Trial is expected by 30 June 2019

Other changes in product specifications required to meet medical grade certification have previously been undertaken by Optiscan

The required medical grade PC, Monitor and Trolley for use in operating theatres has been identified

Design of one of Optiscan's sterilisable sheaths completed with third party validation testing commencing

Key takeaways

1

Working with MSKCC and SBI on novel tools for cancer screening, diagnosis and surgical margins

2

Developing relationships, planning and approvals for Breast, Oral, Oesophageal and Cervical Cancer Clinical Trials

3

Completing product modifications to meet expected strategic and regulatory requirements

4

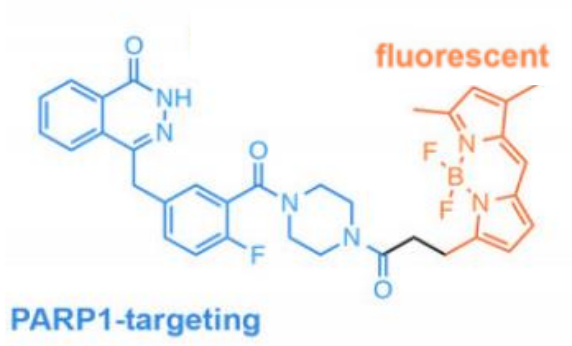
Seeking global certifications in the USA (510(k)), in Europe (CE Mark) and in Australia (TGA)

Appendix

Further technical detail

PARPi-FL – Optical molecular cancer imaging agent

- A molecular based imaging agent
- Has unique pharmacokinetics properties for topical & intravenous use
- Targets PARP1, an enzyme that is highly overexpressed in several human cancers such as oral cancer, cervical cancer, breast cancer and brain glioblastoma



Objectives are to:

- Play a key role for image-guided surgery as an intra-operative imaging agent only targeting cancer
- Enable a new point-of-care technology for cancer screening, diagnosis, and surgical margin detection with high precision and low costs

Combination with the FIVE2 (ViewnVivo)

- The FIVE2 Clinical Device is intended to be used to obtain microscopic precision and instantaneous in-vivo histological examination of the tissue imaging specifically for the cancer cells to guide screening, biopsy selection or need for further cancer resection. The 488 nm laser of the FIVE2 (ViewnVivo) is the optimal wavelength for PARPi-FL excitation