

ASX Announcement

21 August 2019

Optiscan System Approved for Prestigious Cancer Centre Trial

Highlights

- **Optiscan cutting-edge real time virtual biopsy technology approved for use in Memorial Sloan Kettering Cancer Centre oral cancer human clinical trial**
- **Optiscan re-sterilisable sheath receives independent third-party validation**
- **Nearing completion of Stage 2 of Breast Cancer Clinical Trial at Western Australia's largest private hospital, Hollywood Private Hospital**
- **On-going clinical and pre-clinical marketing initiatives and activities**

Optiscan Limited (ASX: OIL, Optiscan) is pleased to advise that it has met one of its key milestones for the first half of FY20 as set out in its June Investor Presentation with the approval by the Institutional Review Board of Memorial Sloan Kettering Cancer Centre (MSKCC) for the use of the Optiscan system and confocal laser endomicroscope technology in the MSKCC oral cancer human clinical trial. The system is being sent to MSKCC and imaging is expecting to commence in the near term.

MSKCC is the world's oldest and largest private cancer center, situated in New York, USA. The centre's use of Optiscan's technology provides a critical endorsement of the system's unique imaging capabilities and is testament to the quality of the Company's breakthrough technology.

Optiscan currently works with MSKCC on the development of screening, early diagnosis and surgical tools targeting cancer cells in oral, cervical and oesophageal applications. Following MSKCC's approval of Optiscan's technology for its oral cancer trial, it is anticipated that further approvals are intended to be sought for the conduct of cervical and oesophageal cancer trials, which would include the use of Optiscan's technology.

A pre-requisite for the use of the Optiscan system at MSKCC has been the receipt of independent third-party validation of the re-sterilisability of the Optiscan sheath which has now been received. This testing has confirmed the re-sterilisability of the sheath for up to 10 cycles in an autoclave machine.

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Optiscan has been in discussions with leading Australian health institutions about the use of its technology to assist research. There is potential for the Optiscan system to be used in further clinical cancer trials and a leading Australian health care institution is currently preparing an ethics submission for use of the Optiscan system in a second human oral cancer clinical trial.

Breast Cancer Developments

Optiscan (led by Dr Philip Currie) in conjunction with Dr Peter Willsher and Dr Jespal Gill is nearing completion of the imaging required to complete Stage 2 of its Breast Cancer trial at Hollywood Private Hospital (Western Australia's largest private hospital) and discussions have commenced regarding the possibility of conducting Stage 3 of the trial as a multicentre trial, including Melbourne based hospitals.

Optiscan has been invited to present details of this breast cancer research at the 17th World Federation for Ultrasound in Medicine and Biology Congress (WFUMB) in Melbourne in early September. The WFUMB will be attended by over 2,000 delegates and a global committee led by renowned Prof George Condous as Convenor are assembling the largest ultrasound focused program held in Australia in over five years.

Regulatory Update

Optiscan is engaging with its selected US based regulatory advisers who are assisting Optiscan to prepare a FDA 510(k) submission.

Pre-clinical and translational initiatives and marketing activities

Optiscan continues to engage in multiple pre-clinical and translational initiatives and marketing activities. These include working with Monash University and the University of Michigan investigating a new hypothesis into the causes of anterior cruciate ligament injury during normal athletic activity.

Work is also continuing with the CSIRO in relation to the use of the Optiscan system to enable real-time imaging of in vitro 3D tissue culture.

Optiscan has continued to deepen its engagement with the research community, recently hosting a tour of its facilities by members of the Australian Institute of Physics and agreeing to sponsor (and provide a presentation) at the Biophotonics Careers Workshop, to be held at Swinburne University in November. Optiscan is also a sponsor of the Light Microscopy Association in vivo imaging competition for 2019.

Optiscan's Executive Chairman Darren Lurie, said:

"Optiscan is entering a new commercial phase and we remain focused on bringing our breakthrough technology to new applications in the clinical market with our own device. Our technology which enables real-time virtual biopsies for cancer screening and the assessment of tumour margin in many types of cancer surgeries is set to be a game changer in a number of clinical applications. Following a recent capital raising we are now well placed to move forward and obtain regulatory approvals for our clinical device. It is an exciting period for us as we take key steps forward on our plan for FY20 and beyond."

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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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