

ASX Announcement
3 December 2025 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX: OIL)

Optiscan Initiates Head & Neck Cancer Imaging Study

Optiscan has partnered with Australian Clinical Labs to launch the first-in-human head and neck cancer imaging study in Australia utilising the Company's InVue® and InForm™ devices, which will be undertaken at St John of God Murdoch Hospital in Perth

Highlights

- Optiscan is sponsoring a ground-breaking clinical study for head and neck cancer imaging at St John of God Murdoch Hospital in Perth after the receipt of ethical clearance.
- The study led by prominent Perth head and neck cancer surgeon Dr Chady Sader will be the first formal study to collect intra-operative surgical imaging data using Optiscan's InVue® and InForm™ devices to evaluate real-time imaging in head and neck cancer surgery.
- Data generated from the study will support US FDA regulatory submissions and advance Optiscan's oral cancer AI imaging algorithm.
- Optiscan will collaborate with Australian Clinical Labs in all pathology specimen analysis work undertaken in the study.

Optiscan Imaging Limited (ASX: OIL) ('Optiscan' or the 'Company') is pleased to announce the initiation of a ground-breaking imaging study in head and neck cancer surgery at St John of God Murdoch Hospital, Perth. The study, which will be undertaken in collaboration with Australian Clinical Labs, will utilise Optiscan's InVue® precision surgery and InForm™ digital pathology devices.

A Broader Evaluation of the Imaging Capabilities of InVue® and InForm™

The study which has received ethical clearance from St John of God Health Care Research Ethics Committee, will recruit 50 patients undergoing head and neck cancer surgery as standard of care at St John of God Murdoch Hospital in Perth. Prominent Perth head and neck cancer surgeon, Dr Chady Sader, is the principal investigator on the study, and will oversee its execution. The Optiscan-sponsored study will evaluate the clinical performance and real-time imaging capabilities of the Company's devices in patients undergoing surgery for oral, oropharyngeal and associated squamous cell carcinomas of the head and neck region. The study will also assess the uptake of the contrast agent fluorescein sodium, and the dynamics of imaging normal and cancerous tissues. Pathology specimens will be processed at Optiscan's pathology partner, Australian Clinical Labs, utilising Optiscan's InForm™ digital pathology device examining both fresh and fixed tissues. This represents a second study flowing from the recent collaboration agreement signed by both Optiscan and Australian Clinical Labs in November 2025 (see ASX announcement dated 10 November 2025).

Head and neck cancers, which encompass cancers of the mouth and oropharynx - including the lips, tongue, cheeks, floor of the mouth, hard palate, sinuses, and throat - are very complex in nature. Oral cancer, the most challenging of these cancers requiring surgery, is a significant global health concern, with an estimated 389,846 new cases reported in 2022¹, making it one of the most common cancers globally. It accounts for a notable portion of cancer-related deaths, with more than 177,000 deaths each year². The survival rate for oral cancer is heavily influenced by the stage at diagnosis and completeness of surgical removal with clear margins.

Coupled with Optiscan's developing oral cancer AI algorithms, which will benefit from data gathered in this study, Optiscan's InVue® and InForm™ devices are expected to enhance the future treatment of these cancers, by providing surgeons with detailed microscopic insights of cellular and tissue level structures that enable them to assess and monitor the presence and clearance of cancer across these diverse and challenging anatomies.

Optiscan's InVue®, one of the devices to be used in the study, is designed to deliver high-resolution sub-cellular imaging of any soft tissue during surgery. The device, which is tissue and cancer agnostic, allows surgeons to observe detailed, real-time images of tissue structures at microscopic level, enabling more precise real-time diagnosis and treatment. With its confocal imaging platform technology, InVue® is ideal for exploring tissue layers as deep as 400 µm with intravenous administration of US FDA approved contrast agent fluorescein sodium.

Intravenous fluorescein sodium will be used in combination with Optiscan's imaging technology in the study, aligning with the future planned use of Long Grove Pharmaceuticals' drug (AK-FLUOR®) in US-based studies to be initiated in the near future. This after Optiscan signed a collaboration agreement with US-based drug company, Long Grove Pharmaceuticals earlier in calendar 2025, under which the Company will use Long Grove's fluorescein drug (AK-FLUOR®) in combination with Optiscan's imaging technology in clinical studies and trials in the US (see ASX announcement dated 23 June 2025).

Optiscan CEO and Managing Director, Dr Camile Farah, said: "We are thrilled to set in motion this study, in partnership with St John of God Murdoch Hospital in Perth. I want to personally thank respected head and neck cancer surgeon, Dr Chady Sader, for leading this study and the Hospital for their willingness to support him in undertaking it. It is the first formal study utilising our InVue® precision surgery and InForm™ digital pathology devices to collect intra-operative data to evaluate real-time imaging in head and neck cancer surgery. Importantly, the non-interventional design of this study means this vital imaging data will be gathered without disrupting standard of care protocols."

Dr Farah added: "The significance of the study cannot be under-stated, both from the perspective of potential enhancements to treatments for patients suffering head and neck cancers, and from the perspective of Optiscan's plans to develop and commercialise its medical technology platform. From a patient care angle, the study is expected to demonstrate that Optiscan's technology bridges the gap between traditional histopathology and immediate clinical decision-making, opening the way for surgeons to better assess tissue, determine completeness of resection and clearance of surgical margins, and refine surgical approaches in

real time. This represents a paradigm shift in head and neck oncology, offering both patients and clinicians a safer, more efficient pathway to future diagnosis and treatment.

The study is also highly significant for Optiscan's stated development strategy – both from the viewpoint of the Company's ongoing efforts to validate its technology in new tissues sites and pathologies, and key partnership and collaboration agreements now in place. The study will leverage two recently signed agreements, and demonstrate the inherent value of these collaborations. Pathology specimens from the study will be processed at Optiscan's pathology partner, Australian Clinical Labs, utilising our InForm™ digital pathology device to examine fresh and fixed tissues, as part of our recently announced collaboration in anatomical pathology. Thanks to a another agreement put in place earlier this year with US-based Long Grove Pharmaceuticals, the manufacturer of the US FDA approved fluorescein sodium drug (AK-FLUOR®), we will be in a strong position to leverage the data collected in this study with others planned in the US for FDA regulatory submissions.”

Dr Chady Sader, the study's Principal Investigator said: “I'm excited to be leading this study looking at improving methods for the accurate assessment of head and neck cancers. I've been encouraged by the early investigations utilising this technology. This clinical study represents an important step toward advancing surgical tools and expanding our understanding of how cancer can be detected and treated more effectively. I'm optimistic that the findings will contribute to better outcomes for patients in the future.”

The Company will update the market on progress with patient recruitment and interim results as the study proceeds.

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This announcement has been authorised for release by the Board of Optiscan.

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About Optiscan

Optiscan Imaging Ltd (ASX: OIL) is a commercial stage medical technology company creating a suite of digital pathology and precision surgery hardware and software solutions that enable live optical biopsy for life sciences, diagnostic and surgical applications. Optiscan pioneered the development and manufacturing of miniaturised digital endomicroscopes with spatial resolution more than 1000x that of medical CT and MRI.

Using a revolutionary "tissue contact" method, Optiscan's patented technology produces super high-resolution digital pathology images for cancer diagnosis and surgical treatment, to unlock real-time insights during surgery, diagnostics, and pre-clinical research. By enabling live, non-destructive, 3D, in-vivo digital imaging at the single-cell level, Optiscan's

technology supports earlier disease detection, precision treatment, and improved patient outcomes across a wide selection of clinical applications and settings.

The global addressable market for Optiscan's medical imaging technology extends beyond traditional surgery and pathology, to also encompass the fast-growing digital health market including robotic surgery. With an expanding product suite and increased demand for digital health solutions, Optiscan is uniquely positioned to bridge the gap between surgery and pathology and deliver better outcomes for healthcare professionals and their patients.

To learn more about Optiscan, visit www.optiscan.com or follow us on [LinkedIn](#), [X](#) or [Instagram](#).

About St John of God Murdoch Hospital

St John of God Murdoch Hospital is part of St John of God Health Care, one of the largest Catholic providers of health care services in Australia. Established in 1994 to provide comprehensive, quality health services for patients in Perth's southern suburbs, St John of God Murdoch Hospital has 525 beds including a 20-bed hospice, a 24-hour emergency department, 20-chair cancer centre, and a wide range of clinical and diagnostic services including medical, surgical, paediatric, maternity, and critical and coronary care.

For more information about St John of God Murdoch Hospital please visit www.sjog.org.au/murdoch

About St John of God Health Care

St John of God Health Care (SJGHC) is one of the largest Catholic providers of health care services in Australia. Established in Western Australia in 1895, it is a not-for-profit private health care group and a ministry of the Catholic Church. It employs 16,000 caregivers (staff) across Australia and New Zealand and operates 25 facilities comprising more than 3200 beds in Australia and New Zealand, as well as home nursing, disability services and social outreach programs.

Disclaimer

All statements other than statements of historical fact included on this announcement including, without limitation, statements regarding future plans and objectives of Optiscan or any of the other parties referred to herein, are forward-looking statements. Forward-looking statements can be identified by words such as "anticipate", "believe", "could", "estimate", "expect", "future", "intend", "may", "opportunity", "plan", "potential", "project", "seek", "will" and other similar words that involve risks and uncertainties. These statements are based on an assessment of present economic and operating conditions, and on assumptions regarding future events and actions that are expected to take place. Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of the Company, its directors and management of Optiscan that could cause actual results to differ from the results expressed or anticipated in these statements.

1. <https://www.wcrf.org/preventing-cancer/cancer-statistics/mouth-and-oral-cancer-statistics/>
2. <https://pubmed.ncbi.nlm.nih.gov/35732291/>