ASX Announcement: 1 September 2026 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX: OIL)

Optiscan Initiates Head and Neck Cancer Study in the US

The study will evaluate the performance of Optiscan's InVue™ and InForm™ platforms in assessing surgical margins in head and neck cancer patients undergoing treatment, with its findings to be used in the Company's U.S. FDA regulatory submissions.

HIGHLIGHTS

- Optiscan has initiated a new U.S.-based head and neck cancer imaging study after signing another Research Agreement with Mayo Clinic.
- The study will assess the performance of Optiscan's InVue™ and InForm™ imaging platforms in head and neck tumour resections.
- Patient recruitment has been initiated at Mayo Clinic Rochester, marking further progress in the clinical evaluation of Optiscan's technology in a wider range of clinical settings.
- Data from the study will be used for the Company's U.S. FDA regulatory submissions for both devices scheduled to occur later in calendar 2026.

Figure 1: The InVue™ device with hand-held surgical probe to be used in the study.

Optiscan Imaging Limited (ASX:OIL) ('**Optiscan**' or the '**Company**') is pleased to announce it has initiated a new U.S.-based imaging study for head and neck cancer patients as part of its ongoing clinical collaboration with Mayo Clinic in Rochester. This clinical study will evaluate the effectiveness of Optiscan's technology tested across a new cancer type and surgical setting, and represents a key step in the Company's efforts to expand the addressable markets for its platforms.

Patient recruitment for the 35-patient study is now underway. The study will assess the performance of the Optiscan's InVue™ and InForm™ devices in evaluating head and neck cancer surgical margins during tumour resection surgical procedures. By utilising Optiscan's InVue™ precision surgery imaging platform for in vivo imaging and its InForm™ digital pathology imaging platform for ex vivo imaging in a U.S. patient population, the study will generate data that can support Optiscan's planned U.S. FDA submissions.

EXPLORING NEXT GENERATION IMAGING

The study will be led by Mayo Clinic Principal Investigator Kyle Ettinger, M.D., Oral & Maxillofacial Surgeon and co-Principal Investigator Kevin Arce, M.D., Oral & Maxillofacial Surgeon. The clinical study will explore the use of InVue™ and InForm™ within the surgical and pathology workflow, focusing on their ability to provide high-resolution imaging in real-time, during and after head and neck cancer surgical resection.

Optiscan's InVue™ device will be used during head and neck tumour resections to capture real-time, in vivo microscopic images within the surgical cavity following tumour removal. The use of intravenous fluorescein sodium AK-FLUOR 10% contrast agent, supplied by Long Grove Pharmaceuticals LLC (see ASX announcement dated 23 June 2025), will enable researchers to evaluate tissue visualisation characteristics and its potential to distinguish cancerous tissue from surrounding healthy structures.

Following excision, tissue specimens will be analysed ex vivo using InForm™, with topical dye Acridine Orange applied to facilitate digital pathology imaging. This component of the study will assess the integration of InForm™ within pathology workflows while generating complementary imaging data alongside the intraoperative findings obtained with InVue™.

The resulting data will complement the in vivo imaging findings and contribute to the clinical evidence package supporting Optiscan's U.S. FDA submissions for both devices.

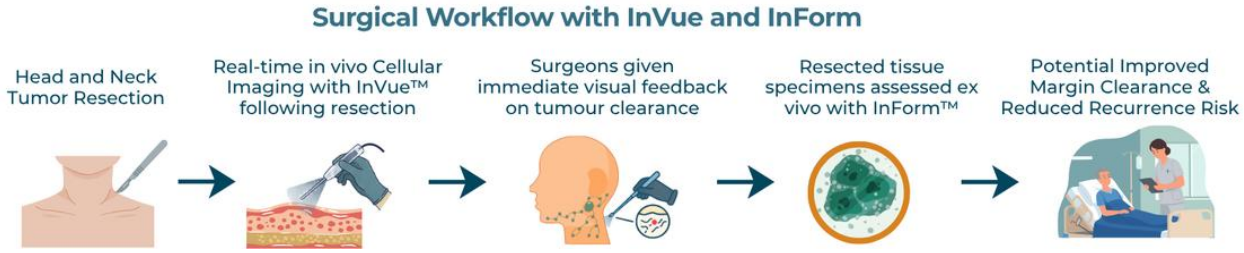

Figure 2: Planned surgical workflow with InVue™ and InForm™ in head and neck tumour resection

HEAD AND NECK CANCER REQUIRES COMPLEX SURGICAL INTERVENTION

Head and neck cancer represents a significant and growing global healthcare burden, with approximately 890,000 new cases diagnosed and 450,000 deaths recorded each year worldwide, making it the seventh most common cancer globally. The disease encompasses a range of tumour types affecting the oral cavity, pharynx and larynx, and often requires complex surgical intervention as part of treatment. Despite advances in care, clinical outcomes remain heavily dependent on the surgeon's ability to completely remove cancerous tissue while preserving critical anatomical structures responsible for speech, swallowing and breathing.[1]

The abovementioned substantial disease burden is compounded by high rates of recurrence, with up to 50% of patients experiencing disease recurrence following treatment. This ongoing clinical challenge has driven demand for technologies that can provide surgeons with improved real-time visualisation of tumour margins and residual disease during surgery, with the goal of improving surgical precision, reducing recurrence rates and ultimately enhancing patient outcomes.[2]

Figure 3: Global head and neck cancer statistics

STRATEGIC SIGNIFICANCE

The head and neck cancer study now initiated represents an important milestone in the continued development of Optiscan's imaging platform, extending its evaluation into a new and clinically challenging surgical application. This provides an opportunity to demonstrate the versatility of InVue™ and InForm™ across multiple oncology indications and further validate the platform's broader clinical utility.

REGULATORY SIGNIFICANCE

The study is expected to generate clinical data from a U.S. patient population that will support Optiscan's U.S. FDA submissions for both InVue™ and InForm™. Data collected during the study will contribute to the near complete body of evidence demonstrating device performance in multiple tissue and cancer types, and workflow integration and clinical utility in a real-world surgical setting. Importantly, the study will generate both in vivo and ex vivo imaging data, providing a comprehensive dataset to support regulatory submissions and clinical pathways.

Figure 4: Optiscan's U.S. FDA milestone progress for InVue™ and InForm™

COMMERCIAL SIGNIFICANCE

Head and neck cancer surgery represents a significant clinical market and provides another compelling application for Optiscan's imaging technologies. Successful completion of the study -could further strengthen the clinical evidence supporting the adoption of InVue™ and InForm™ by healthcare providers seeking improved imaging capabilities during surgery and pathology assessment.

By potentially demonstrating the complementary value of both devices within a single workflow, the Company is building a foundation for future opportunities across medical devices, digital pathology, software and AI-enabled clinical applications, with potential expansion into additional cancer types and surgical procedures.

CEO COMMENT

Optiscan CEO and Managing Director, Dr Camile Farah, said:

"The just initiated U.S.-based head and neck study is another great opportunity for our technology to be evaluated in an increased number of surgical settings where achieving complete tumour removal is critical. Despite advances in the treatment of head and neck cancers, their recurrence remains a major challenge for the many patients suffering these diseases. Through this study, we're seeking to better understand how real-time imaging can support surgical decision-making and help address an important unmet clinical need."

"We look forward to the study delivering valuable insights into how our technology performs in different surgical environments. As a package, these findings could help us in our efforts to identify future clinical and commercial opportunities for Optiscan's innovative platforms. Head and neck cancer represents a significant area of unmet need, and we believe technologies that help surgeons visualise tissue in real time could have the potential to make a meaningful difference for both clinicians and patients."

"One of the unique points of differentiation for our technology is its breadth of applications and the value add it delivers across multiple clinical settings. If the study demonstrates the potential role of real-

time imaging during head and neck cancer surgery, it could further demonstrate the tangible impact InVue™ and InForm™ may have in the treatment of a wide range of cancer types in a host of surgical settings."

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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.

To learn more about Mayo Clinic, visit www.mayoclinic.org

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1. Bray F, Laversanne M, Sung H, et al. Global Cancer Statistics 2022: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2024;74(3):229–263.
2. Kao HF, et al. Advances in Recurrent Head and Neck Cancer: Epidemiology, Treatment, and Surveillance. Front Oncol. 2022;12:955712.