ASX Announcement: 22 July 2026 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX: OIL)

Optiscan Signs New Research Agreement for Breast Study

Optiscan has signed a Research Agreement to commence a US breast cancer imaging study designed to potentially generate clinical evidence for planned FDA 510(k) submissions and potentially validate the commercial pathway for its imaging platforms.

HIGHLIGHTS

- Research Agreement with Mayo Clinic enables commencement of Optiscan's US breast cancer imaging study.
- Study will evaluate InVue™ for *in vivo* surgical imaging and InForm™ for *ex vivo* digital pathology imaging in 35 US patients undergoing breast conserving surgery.
- Study seeks to validate an integrated surgical-pathology workflow for US market entry and broader clinical expansion.

Figure 1: Optiscan's InVue™ and InForm™ devices

Optiscan Imaging Limited (ASX:OIL) ('**Optiscan**' or the '**Company**') to commence a US clinical study assessing the safety, performance and workflow utility of its InVue™ precision surgery imaging device and InForm™ digital pathology imaging device in patients undergoing breast conserving surgery.

The study's site initiation has been completed and recruitment is open for 35 patients. It will evaluate intraoperative breast cancer margin assessment after lumpectomy using Optiscan's InVue™ and InForm™ devices.

The study could generate clinical evidence for planned US FDA 510(k) submissions for both devices in H2 CY2026 and support AI and machine learning development for breast cancer tissue assessment.

ADVANCING REAL-TIME SURGICAL IMAGING

The US study will be led by Mayo Clinic Principal Investigator Jeffrey Johnson M.D., Surgical Oncologist and Co-Principal Investigator Judy Boughey M.D., Surgical Oncologist.

During surgery, InVue™ will capture *in vivo* microscopic images of the surgical cavity following tumour resection. Intravenous fluorescein sodium AK-FLUOR 10%, supplied by Long Grove Pharmaceuticals (see ASX announcement dated 23 June 2025), will be used as a contrast agent to assess tissue differentiation and real-time imaging dynamics.

Resected tissue will then be assessed *ex vivo* using InForm™, with topical Acridine Orange applied to support digital pathology imaging and workflow evaluation. Together, the data will form part of the clinical evidence package for planned U.S. FDA submissions.

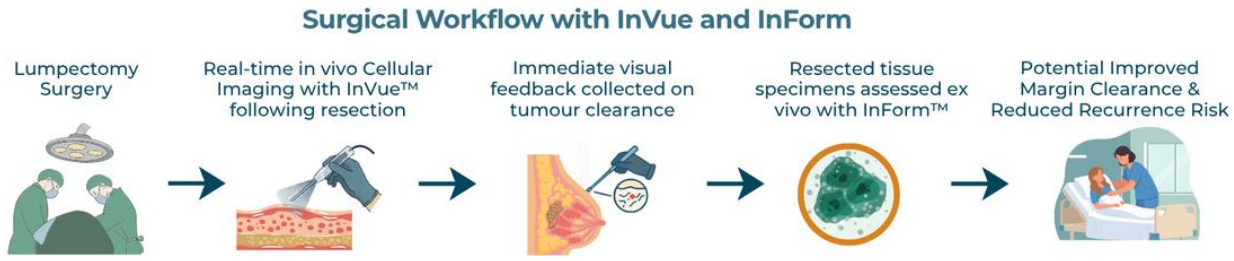

Figure 2: Planned surgical workflow using InVue™ and InForm™ devices in US clinical study

ADDRESSING A GLOBAL OPPORTUNITY

Breast cancer is the most commonly diagnosed cancer among women worldwide and remains a major global health challenge, with millions of new cases reported each year. Breast-conserving surgery, or lumpectomy, is a widely used treatment approach that seeks to remove the tumour while preserving as much healthy tissue as possible. However, ensuring clear surgical margins - where no cancer cells remain at the edge of the excised tissue - continues to be one of the most significant challenges in achieving optimal surgical outcomes.

The ability to visualise tissue in vivo and in real time has the potential to improve surgical precision, support more complete tumour removal, and reduce the need for repeat surgeries, ultimately enhancing patient outcomes and healthcare efficiency. Optiscan believes the study will further validate InVue™'s

capability to bring advanced microscopic imaging directly into the operating theatre and establish a new standard for precision-guided breast cancer surgery.

Figure 3: Breast cancer statistics from the World Health Organization

STRATEGIC SIGNIFICANCE

By combining Mayo Clinic's surgical, pathology and patient-care expertise with Optiscan's imaging platforms, the collaboration is intended to accelerate validation, regulatory progress and commercial readiness.

The integrated use of InVue™ and InForm™ within a single surgical-pathology workflow supports Optiscan's strategy to build a connected digital ecosystem for cancer surgery and tissue pathology assessment, with potential application beyond breast cancer.

REGULATORY SIGNIFICANCE

Data from the study could support planned US FDA 510(k) premarket submissions for InVue™ and InForm™ by generating evidence on device performance, workflow integration and imaging outcomes in a real-world surgical setting. This represents a key regulatory step toward US market clearance for both platforms.

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

COMMERCIAL SIGNIFICANCE

Breast cancer provides a high-value initial indication to demonstrate Optiscan's potential to improve intraoperative decision-making and surgical outcomes. The study is designed to potentially generate evidence needed for regulatory clearance while supporting clinician adoption and commercial positioning in the US market.

Evaluating both devices in one workflow reinforces Optiscan's end-to-end platform strategy across surgery and pathology, creating a broader pathway for expansion into additional procedures, clinical settings and commercial applications.

CEO COMMENT

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

"The Research Agreement enables Optiscan to commence a US clinical study designed to support our planned 510(k) premarket submissions and potentially validate the role of InVue™ and InForm™ in breast cancer surgery. Patient recruitment in the US is a major milestone in generating high-quality clinical evidence and refining our technologies for demanding surgical and pathology workflows."

"By evaluating both devices within one clinical workflow, we are building evidence for a potentially integrated surgical-pathology solution that could support faster intraoperative decisions and extend point-of-care tissue assessment into digital pathology. Breast cancer surgery is an important first commercial application given the scale of the market and the clinical need for better intraoperative margin assessment. The study outcomes could support our regulatory submissions and lay the foundation for broader commercial adoption of Optiscan's imaging platforms."

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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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