ASX Announcement: 4 June 2026 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX: OIL)

Halfway Mark Reached in Optiscan Breast Cancer Study

The study being undertaken by Optiscan Imaging and The Royal Melbourne Hospital assessing surgical margins in breast cancer patients has reached its halfway recruitment milestone.

HIGHLIGHTS

- Optiscan Imaging has reached the halfway milestone in its first in-human breast cancer study at The Royal Melbourne Hospital.
- Twenty-five of the target 50 patients have been imaged, and the study has been expanded to a second clinical site to accelerate recruitment.
- The study is assessing InVue® for *in vivo* imaging and InForm® for *ex vivo* imaging.
- Study data will support U.S. FDA submissions for both devices expected to be completed in the second half of calendar year 2026.

Optiscan Imaging Limited (ASX:OIL) ('**Optiscan**' or the '**Company**') is pleased to announce attainment of the halfway mark milestone in its first in-human breast cancer imaging study, with 25 of the target 50 patients imaged at The Royal Melbourne Hospital (**RMH**).

The study is assessing surgical margins in breast cancer patients undergoing lumpectomy procedures using the following two Optiscan devices:

- The InVue® precision surgery imaging device for *in vivo* imaging, and
- The InForm® digital pathology imaging device for *ex vivo* imaging.

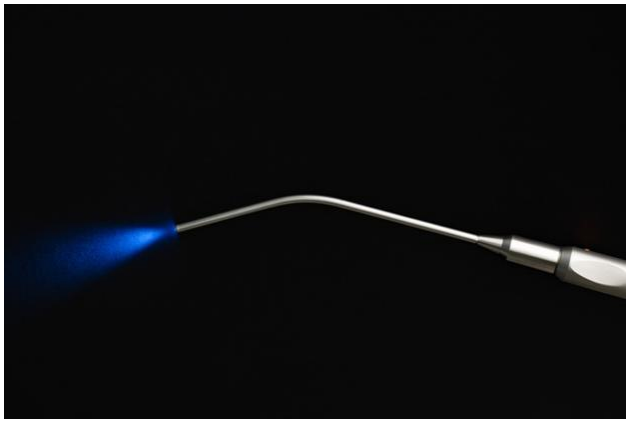

Figure 1: The Optiscan miniaturised surgical probe currently being used in RMH breast cancer imaging study

ADVANCING REAL-TIME TISSUE ASSESSMENT IN BREAST SURGERY

The Optiscan/RMH study began in June 2025 (see ASX Announcement dated 30 June 2025). In the intervening period, 25 of the target 50 patients have been imaged. Recruitment has been supported by two clinical research assistants, and accelerated by expansion to a second site at Frances Perry House. The study is evaluating how the real-time imaging capabilities of InVue® and InForm® can be integrated into the surgical workflow.

InVue® is used intraoperatively in the resection cavity to generate live *in vivo* images immediately after tumour removal.

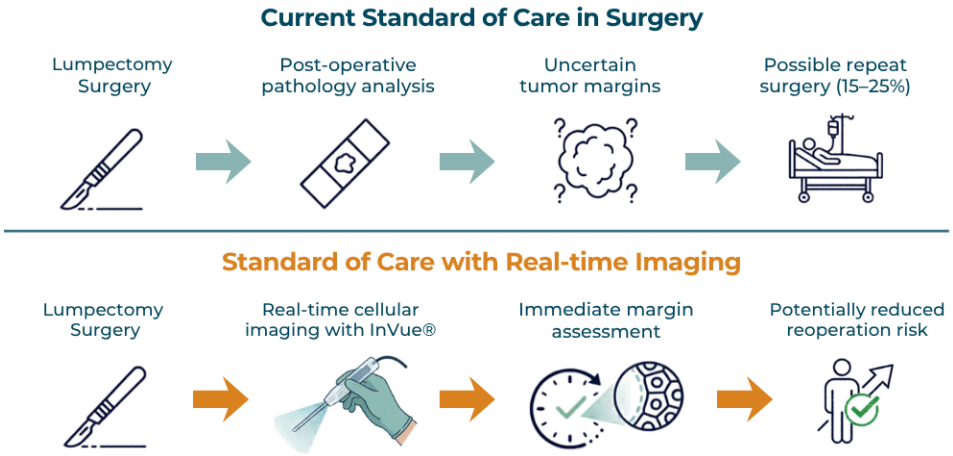

Figure 2: Current standard surgical workflow compared to real-time imaging with InVue®

Excised tissue is then analysed using InForm®, providing additional insight alongside intraoperative findings.

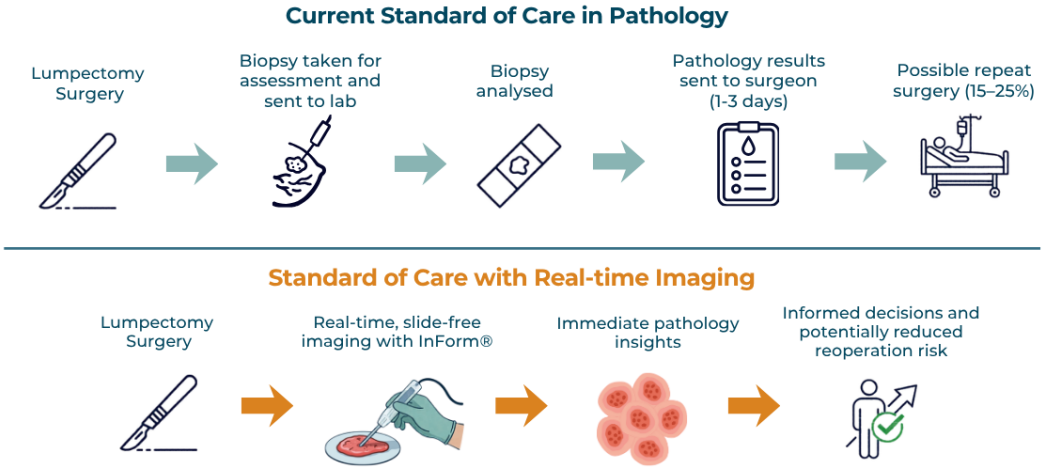

Figure 3: Current standard pathology workflow compared to real-time imaging with InForm®

The combined data will support U.S. FDA submissions for both devices and ongoing development of the Company's artificial intelligence and machine learning models.

CLINICAL READOUTS

Clinical readouts of analysed cases to date (n=18) demonstrate nine with clear margins, four with narrowly clear margins, and five with involved margins. Concordance between Optiscan imaging and definitive histopathology on hematoxylin and eosin-stained slides shows like-for-like cellular and architectural features of both healthy normal tissues and invasive cancer. There have been no reported adverse events related to intravenous sodium fluorescein contrast agent injections. Both devices have demonstrated ease of operation, acquiring interpretable images in a matter of seconds to minutes depending on workflow, dye and comparator.

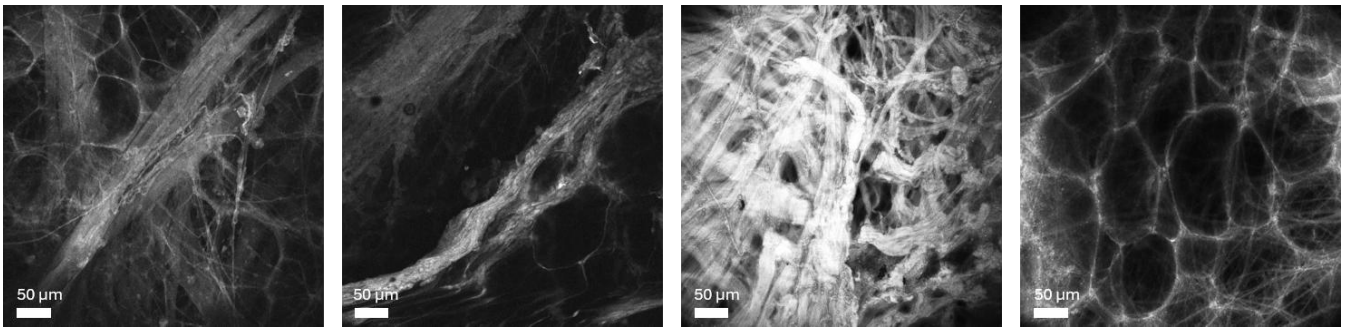

Figure 4: InVue® intra-operative imaging utilising sodium fluorescein contrast agent demonstrating healthy fibro-fatty connective tissue after tumour removal.

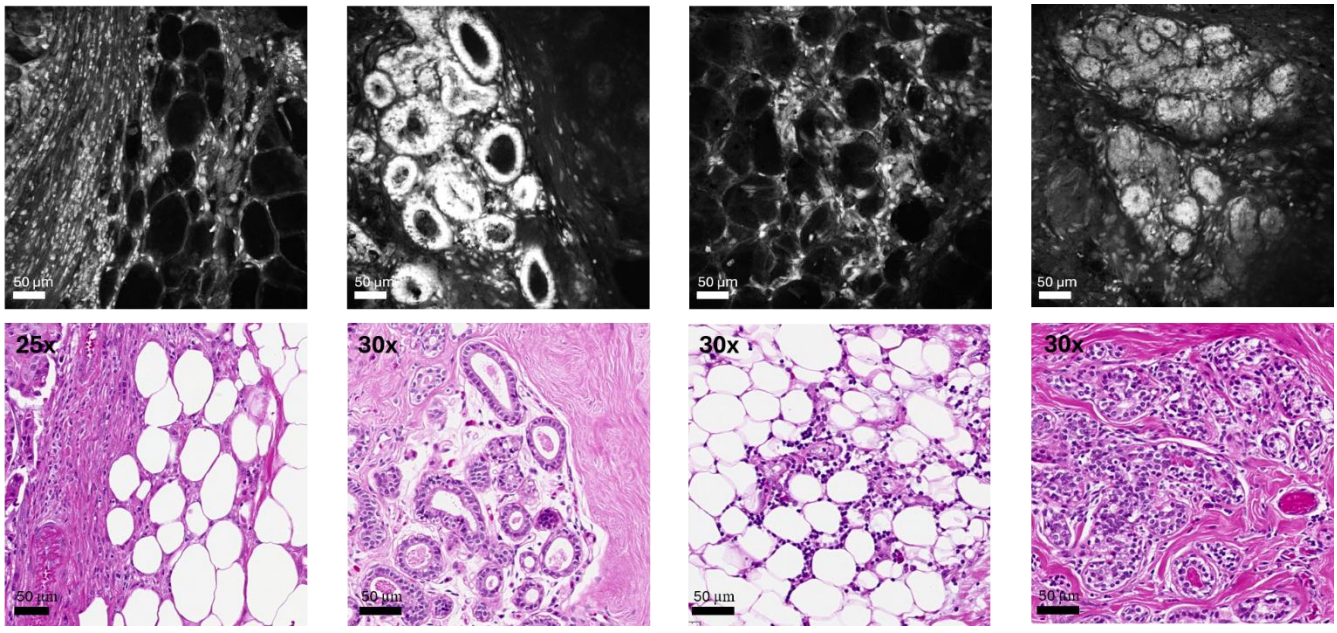

Figure 5: InForm® post-operative imaging utilising acridine orange contrast agent (top row) demonstrating cellular and architectural features ranging from healthy fibro-fatty tissues (left) to invasive carcinoma (right) consistent with standard hematoxylin and eosin staining (bottom row).

REGULATORY SIGNIFICANCE

Reaching this recruitment milestone advances Optiscan's U.S. regulatory submissions for InVue® and InForm® and supports the pathway to clinical use and commercialisation for both devices. The study keeps the Company on track for delivery of planned U.S. FDA submissions for both devices in the second half of calendar year 2026.

Figure 6: FDA milestone progress for InVue® and InForm®

STRATEGIC & COMMERCIAL SIGNIFICANCE

The recruitment milestone for the RMH study is an important step in Optiscan's strategy to commercialise its private label devices, demonstrating InVue® and InForm® in a live clinical setting and supporting progress toward its planned U.S. market entry. The study is demonstrating potential real-world value, validating workflow fit and helping position InVue® and InForm® for broader commercial adoption.

Breast cancer is historically one of the most resource-intensive malignancies to manage in the U.S.[1] With approximately 275,000 new invasive breast cancer diagnoses occurring annually in the U.S.[2], the sheer volume of surgeries commands massive clinical expenditures. The global breast-conserving surgery market size was estimated at USD $2.45 billion in 2024 and is projected to reach USD $4.58 billion by 2033, growing at a CAGR of 7.26% from 2025 to 2033.[3]

CEO COMMENT

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

"We are proud of the progress made in the RMH breast cancer study since its commencement in mid-calendar year 2025. Target patient recruitment for the study has already hit the halfway mark, helped by patient onboarding now occurring at two clinical sites. And in another positive, results to date coming out of the study have been very encouraging. Our entire team is excited to see Optiscan's InVue® and InForm® devices operating in a live clinical setting and clearly demonstrating the potential they have to improve breast cancer surgery. The study is definitely shaping up as an important step in our efforts to bring real-time imaging into the operating theatre, and in the process enhancing surgical decision-making and patient outcomes.

"The study also has another benefit for Optiscan over and above its demonstration of the clinical importance of the Company's medical technology. It will additionally make a valuable contribution to our efforts to deliver regulatory approvals, a core requirement in Optiscan's plans to commercialise its product offering. The insights generated by this RMH study will definitely continue to inform our commercial strategy and support broader market adoption of our devices."

RMH COLLABORATOR COMMENT

Lead Investigator on the RMH Study, Professor Bruce Mann, said:

"Despite the prevalence of breast cancer surgery globally, surgeons still have limited access to immediate, detailed information during procedures. This study is assessing how Optiscan's imaging technologies can support more informed decisions at the point of care.

"We are pleased with the progress of this study, particularly its exploration of real-time tissue assessment during surgery. These technologies may give surgeons more immediate insight during procedures and open up new possibilities to potentially reduce the need for re-operative surgeries."

– ends –

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

For further information, please contact:

Shareholder & General Enquiries
Optiscan Imaging Ltd
Dr Camile Farah
T: +61 3 9538 3333
E: ceo@optiscan.com

Media & Investor Enquiries
The Capital Network
Julia Maguire
T: +61 2 7257 7338
E: julia@thecapitalnetwork.com.au

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.

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. J Natl Cancer Inst. 2011;103(2):117-28.
2. Cancer. 2022;128(24):4251-4284.
3. https://www.grandviewresearch.com/industry-analysis/breast-conserving-surgery-market-report