ASX Announcement
30 June 2025 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX: OIL)

Optiscan Initiates Breast Cancer Study in Melbourne

Optiscan has initiated its innovative clinical study at the Royal Melbourne Hospital and will commence recruitment to assess surgical margins in patients receiving treatment for breast cancer using the Company's InVue® and InForm™ devices.

Highlights

- Optiscan has initiated its first in-human breast cancer study in Melbourne.
- Enrolment for recruitment into the study will commence at the Royal Melbourne Hospital.
- The study will utilise the capability of Optiscan's InVue® precision surgery imaging device for *in vivo* imaging and its InForm™ digital pathology imaging device for *ex vivo* imaging.
- A total of 50 patients undergoing breast-conserving procedures will be recruited.
- Data from the study will be used for US FDA regulatory submissions for both devices.

Optiscan Imaging Limited (ASX: OIL) ('**Optiscan**' or the '**Company**') is pleased to announce the initiation of its ground-breaking first in-human breast cancer clinical study at the Royal Melbourne Hospital (**'RMH'**).

The 50-patient study has completed site initiation and will now welcome patients for recruitment for *in vivo* clinical assessment of breast cancer margins following lumpectomy procedure. The study will utilise Optiscan's innovative InVue® precision surgery and InForm™ digital pathology imaging devices. Data from the study will be used in U.S. FDA regulatory submissions for both devices.

The study is being led by Professor Bruce Mann, Director of Breast Cancer Services at the Royal Melbourne and Royal Women's Hospitals, alongside Breast and Endocrine Surgeon Dr. Laura Chin-Lenn and Anatomical Pathologist Dr. Anand Murugasu.

Research on new breast cancer treatment commences utilising Optiscan's platform

This milestone was achieved following ethical clearance for the study being granted in mid calendar 2024 (see ASX announcement dated 15 July 2024). Recruitment at RMH will get underway on a new treatment regime for breast cancer which has the potential to better those currently available.

The study will specifically research the clinical workflow and real-time imaging capabilities of Optiscan's InVue® precision surgery microscopic imaging platform (see ASX announcement dated 4 June 2024) and Optiscan's InForm™ digital pathology imaging device, which was revealed earlier in calendar 2025 (see ASX announcement dated 19 February 2025). This research will see InVue® used during surgery to capture *in vivo* live imaging data from the surgical cavity after tumour removal, providing immediate feedback on tumour

clearance. Intravenous fluorescein sodium will be employed as a contrast agent to assess its uptake and imaging dynamics in distinguishing between normal and cancerous breast tissues. Resected tissue will be further examined with InForm™ *ex vivo* outside the body with topical dyes which will provide additional data on imaging and pathology workflows to complement in vivo imaging and build further data for U.S. FDA submission for Optiscan's pathology device. In addition to utility in regulatory submissions, all imaging data will be used in continue building of artificial intelligence/machine learning (AI/ML) algorithms currently in development.

The real-time imaging capabilities of InVue® are transformative

This study will highlight the transformative role of the real-time imaging capabilities of InVue® in breast cancer surgery. By bridging the gap between diagnostic imaging and surgical decision-making, Optiscan is targeting significantly reduced reliance on post-operative pathology, which would enable surgeons to achieve greater accuracy in determining tumour margins during the initial surgical procedure. Real-time, *in vivo* imaging at the cellular level can promote precise tumour removal, potentially minimising follow-up surgeries, and improving overall patient care. Optiscan is confident that the study will show InVue®'s ability to bring advanced microscopic imaging directly into the operating theatre, in the process setting a new benchmark for precision and efficiency in breast cancer treatment.

Breast cancer is the most common cancer among women globally[1] and remains a significant health challenge, with millions of new cases diagnosed annually. Among the treatment options, breast-conserving surgery - commonly known as a lumpectomy - aims to remove the tumour while preserving as much healthy breast tissue as possible. However, achieving clear surgical margins - where no cancerous cells are left at the edges of the removed tissue - poses a significant surgical challenge.

The RMH clinical study will also incorporate Optiscan's InForm™ device

In addition to the deployment of InVue® in the operating theatre for live patient imaging, the study will also incorporate Optiscan's recently revealed InForm™ for imaging samples removed from the body either chairside or in the pathology laboratory. This will allow collection of matched *ex vivo* data. Not only will the InForm™ device provide additional *ex vivo* data to the *in vivo* data obtained from the InVue®, the use of both devices in a seamless surgical oncology-pathology workflow will provide further evidence for a holistic transition to a digital workflow for common surgical procedures, and build more evidence around the potential utility of the InForm™ as a replacement for the frozen section technique.

Optiscan CEO and Managing Director, Dr Camile Farah, said: *"We are confident that the study which will recruit 50 patients undergoing breast-conserving procedures will demonstrate the capabilities of our InVue® and InForm™ imaging devices. We believe our innovative real-time microscopic imaging platform represents a genuine breakthrough in surgical cancer management by bringing live cellular imaging to the bedside. In the process, InVue® will provide surgeons with digital tools to make confident, informed decisions about tumour clearance before patients leave the operating theatre. The significance of any proven capability to evaluate tumour margins*

with cellular-level precision during surgery coming out of the study cannot be over-estimated. It has the potential to revolutionise breast cancer treatment, as real-time imaging opens the way for complete tumour removal to occur, while at the same time preserving healthy tissue. By providing surgeons with direct, live imaging of cellular structures, we're setting a new standard for precision and patient-centred care in oncology."

"An exciting aspect of the Royal Melbourne Hospital breast cancer clinical study is that it will also incorporate our purpose-built digital pathology device, InForm™. This device provides pathologists with a unique ability to assess freshly excised tissue with exceptional speed and accuracy at super high resolution and magnification, to give surgeons additional reassurance on the clearance of their resections. While our InVue® and InForm™ devices are designed to operate independently of each other, we have purposefully included both in this study to maximise the collection of data, minimise the need to recruit more patients, and accelerate our regulatory submissions. The matched ex vivo and in vivo data will also allow a more efficient analysis and reporting of results for regulatory submissions. We look forward to updating the market on outcomes of this study."

Professor Bruce Mann, Director of Breast Cancer Services at the Royal Melbourne and Royal Women's Hospitals, said: *"Inadequate margins often lead to additional surgeries, increasing physical and emotional strain on patients, delaying subsequent treatments, and raising healthcare costs. This highlights the critical need for innovative solutions that enable surgeons to assess tumour margins accurately and in real-time during the initial surgical procedure, improving outcomes for patients and reducing the burden on healthcare systems."*

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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.

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1. *https://www.who.int/news-room/fact-sheets/detail/breast-cancer*