



**ASX Announcement**  
**19 September 2023**

## **OPTISCAN CORRELATES WITH HISTOLOGY IN BREAST STUDY**

**Optiscan Imaging Limited (ASX: OIL)** is pleased to provide an interim readout on its Breast Cancer Intraoperative Assessment Study.

The Study, currently being undertaken at the Royal Melbourne, Frances Perry and Epworth Hospitals, involves a collaboration between Optiscan, breast surgeon Professor Bruce Mann, and pathologist Dr Anand Murugasu. Supported by the Medical Device Partnering Program (MDPP), the primary objective is to determine if real-time intraoperative imaging of excised breast tissue using Optiscan technology can detect involved surgical margins.

The imaging stage of the Study encompassed 50 patients and 59 distinct tumours. Ex vivo interoperative imaging was performed for all fresh tumours, while 12 patients with 15 distinct tumours also underwent imaging subsequent to tissue fixation and processing in the pathology laboratory. Initial data examining the correlation between Optiscan confocal laser endomicroscopic (CLE) imaging and that of conventional histopathology has revealed excellent correlation between Optiscan's real-time CLE technology and traditional histological analysis.

Interim readout on fixed and processed breast tumour and margin samples shows that the Optiscan platform can provide images comparable to conventional histopathology for determination of presence of cancer and for determination of tumour involvement in surgical margins. This was possible in all 15 resected tumours which underwent fixation, with final diagnoses including invasive lobular carcinoma and invasive carcinoma NST. Additionally, the Optiscan CLE probe could identify and differentiate healthy marginal tissue from cancer-involved margins in each case that was identified on gross sectioning and on final definitive histopathology. Assessment of fresh tissue produced excellent imaging quality and fixation did not negatively affect quality of imaging compared to that of fresh tissue. Importantly, imaging could be achieved bedside or in the pathology lab.

Optiscan CEO and Managing Director, Dr Camile Farah, commented, "The strong correlation and concordance of Optiscan technology to histopathology provides another strong indication for the utility of our unique digital CLE technology in breast surgery, as an adjunct in supporting clinical decision making in the operating theatre in the context of breast cancer margin analysis. Additionally, it paves the way for an ex vivo approach to assess fresh or fixed tissue with standalone in vitro diagnostic platforms which we are developing."

Dr Farah adds, "Breast conserving surgery is a complex challenge for health systems, with over 175,000 lumpectomies performed in the US alone and evidence revealing a re-excision rate of up to 35%. The utility of our slide-free, biopsy-free real-time imaging technology presents an exciting opportunity in this modality. We

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look forward to completing the analysis of the Study with Prof. Mann in collaboration with the broader research team, pursuing appropriate publications, and advancing efforts to develop a new surgical device for this highly addressable market in parallel to a standalone in vitro pathology device.”

By combining surgical precision, minimally invasive techniques, personalized treatment strategies, and real-time monitoring, Optiscan’s technology has the potential to reduce recurrence rates in lumpectomy patients to make a lasting positive impact on their lives. It is estimated that CLE imaging has the potential to reduce operating time by 25% saving hospitals millions of dollars in operating costs, and reduce total recurrence costs in the breast cancer space by USD\$6.4 billion.

Following the promising outcomes of the ex vivo imaging study, the Company is now preparing for an intraoperative in vivo imaging study to assess the utility of the CLE probe in the hands of surgeons in real-time. This information will be critical for the development of a clinical user case, and future US Food and Drug Administration submissions for oncological breast surgery.

The Company will report further findings and analysis of the Study in the next quarter.

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

**For investor queries, please contact:**

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**About Optiscan**

Optiscan Imaging Ltd (ASX:OIL) is a global leader in the development, manufacturing, and commercialisation of confocal endomicroscopic imaging technologies for medical, translational and pre-clinical applications. Our technology enables real-time, non-destructive, 3D, *in-vivo* imaging at the single-cell level.

We are driven by developing technology and its use to give healthcare providers and researchers the highest quality real-time microscopic imaging tools to enable the early detection and management of disease, improve patient outcomes, and reduce the high cost of curative medicine and associated procedures.

Our patent-protected proprietary technology, using specially miniaturised componentry, has created a pen-sized digital microscope, which can be used on any tissue it contacts to produce high resolution digital pathology images for cancer diagnosis and surgical margin detection in real-time. The aim of our technology development is for earlier diagnosis and subsequent treatment of cancerous tumours with expected associated improved patient outcomes.

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## **Disclaimer**

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