

ASX Announcement
15 July 2024 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX:OIL)

Optiscan Receives Ethical Clearance for Breast Cancer Study

With this ethical clearance delivered, Optiscan can demonstrate the capability of its recently revealed InVue™ precision surgery imaging platform.

Highlights

- Optiscan has received ethical clearance to undertake *in vivo* in-human imaging for breast cancer
- The study will assess Optiscan's recently unveiled InVue™ precision surgery imaging platform in breast cancer
- Data demonstrates the high concordance between Optiscan's imaging platform and the gold standard histopathology
- Image analysis reveals similar morphological, architectural and cellular features observed by pathologists

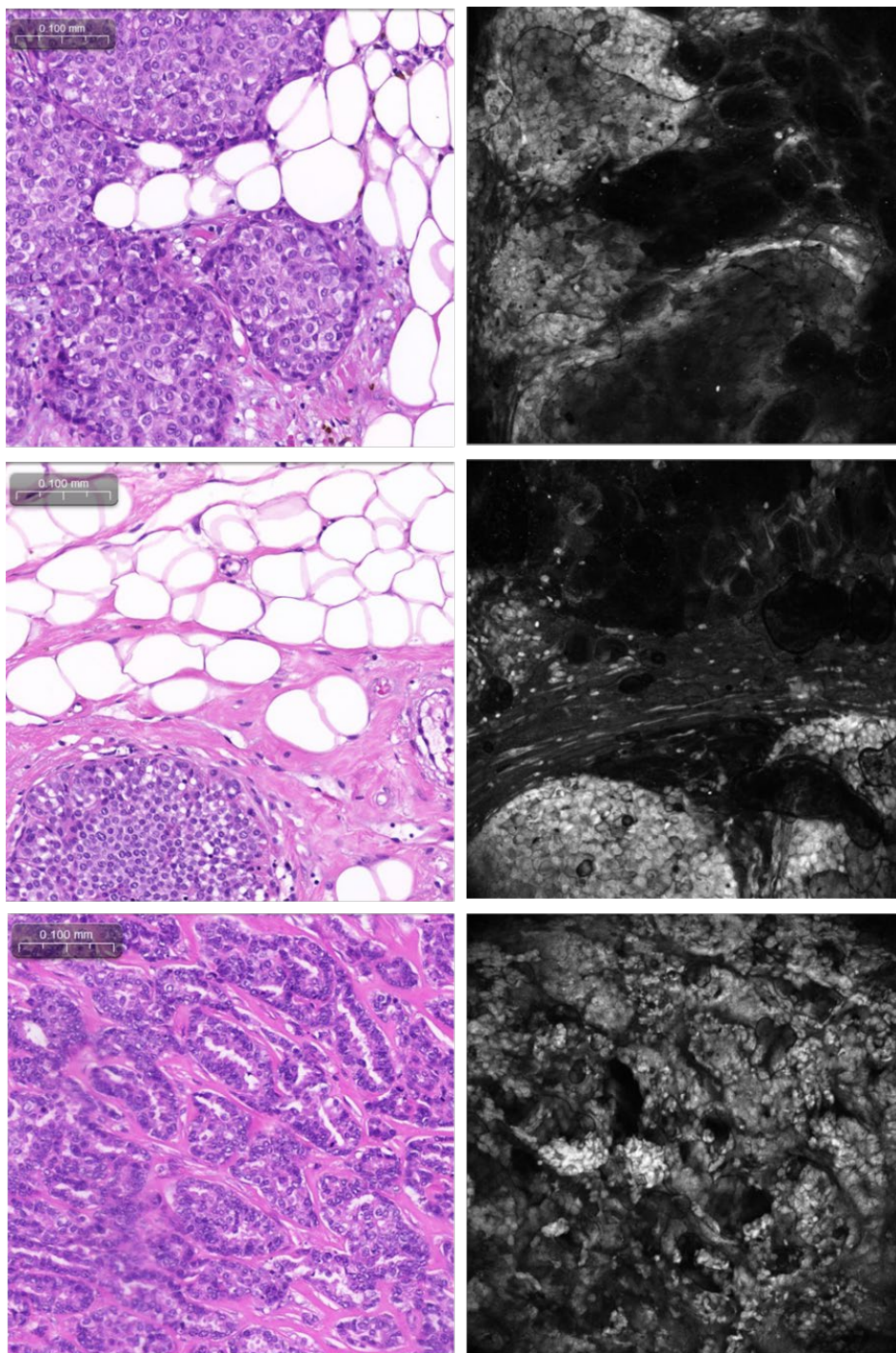
Optiscan Imaging Limited (ASX:OIL) ('Optiscan' or 'The Company') is pleased to announce that it has received ethical clearance from the Royal Melbourne Hospital Human Research Ethics Committee to undertake an *in vivo* clinical study for assessment of cancer margins in patients presenting for surgical treatment of breast cancer.

The study will assess the clinical workflow and real-time imaging capability of Optiscan's recently unveiled InVue™ precision surgery imaging platform. The device will be used during surgery to collect *in vivo* imaging data of the surgical cavity intraoperatively after tumour removal to determine clearance of the tumour in real-time. The study will utilise intravenous fluorescein sodium as the contrast agent, and will assess the uptake of the contrast dye and the dynamics of imaging normal and cancerous breast tissues.

The study will recruit 50 patients undergoing breast conserving cancer surgery "lumpectomy" procedures at the Royal Melbourne Hospital, Frances Perry House and Epworth Hospital. Overseeing the study will be Professor Bruce Mann, Director of Breast Service, Royal Melbourne and Royal Women's Hospital in conjunction with Dr Laura Chin-Lenn and Dr Anand Murugasu.

Optiscan CEO and Managing Director, Dr Camile Farah, said: "The non-interventional study design will allow the research team the opportunity to gather imaging data without the procedure interfering with standard of care. Once this stage is completed, we anticipate progressing to further recruitment with an interventional protocol. In this phase, collected images will guide surgeons in decision-making, determining tumour clearance or the need for additional tissue related to microscopic spread, before patient discharge."

The study proposal is based partly on new data from recent analyses of breast cancer lumps imaged *ex vivo* outside the body using topical acriflavine dye showing complete concordance between Optiscan's confocal imaging (the images displayed on the right-hand side of the panel below) and gold standard histopathology as determined on physical glass slides (the images displayed of the left-hand side of the panel).



Dr Farah adds:

“Evaluation of invasive breast cancers from the *ex vivo* patient cohort reveals the same morphological, architectural and cellular features observed by pathologists for post-surgery reporting. In the upcoming phase of our clinical work, the use of fluorescein angiography is expected to enhance these observations, providing even crisper cellular details due to blood perfusion of the imaged tissues.”

“This study represents a significant step in demonstrating the value InVue™ can deliver in managing and treating breast cancer. By delivering real-time, detailed cellular imaging directly in the operating theatre, we can empower surgeons with immediate, actionable insights to significantly improve the management and treatment of breast cancer.”

The Company is preparing study logistics and will update the market on progress in due course.

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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 8999 3699

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 endoscopes 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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