

ASX Announcement
3 February 2025 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX:OIL)

Optiscan Initiates GI Study in Germany with First Prototype

Optiscan completes first gastrointestinal (GI) flexible prototype to collect images from the GI tract and activates GI study at University Medical Center Mainz, Germany

Highlights

- Optiscan initiates pre-clinical GI study with University Medical Center Mainz, Germany
- To support the study, Optiscan has completed its first prototype to collect images from the GI tract
- The study will assess Optiscan's Gen2 real-time imaging capability on GI tract tissue
- Data from the study will be used to determine the utility of in vivo imaging in GI-related diagnosis and treatment and to build AI algorithms.

Optiscan Imaging Limited (ASX:OIL) ('**Optiscan**' or the '**Company**') is pleased to announce both the completion of the first prototype to collect images from the gastrointestinal (GI) tract, as well as the commencement of an important pre-clinical GI study with University Medical Centre of the Johannes Gutenberg University Mainz, Germany.

Optiscan CEO & Managing Director Dr Camile Farah visited Germany in January 2025 to activate the study, which aims to capture images of the GI tract. These collected images will be used to assess the real-time imaging capability of Optiscan's Gen2 technology in diagnosing and treating GI diseases, including cancer, and progress planning for the upcoming clinical phase to follow over coming months. This staged approach to collecting pre-clinical and then clinical data with the Gen2 prototype will assist Optiscan engineers in the development of the Company's Gen3 flexible endomicroscope, which will be used in future clinical trials. In addition, this current study will allow collection of imaging datasets of various disease processes to assist with initiation of AI algorithm development by the Company's CRC-P partner, Monash University.

GI diseases pose a major global health challenge, with colon cancer ranking as the second leading cause of cancer-related deaths worldwide. In 2020, more than 1.9 million new cases of colorectal cancer and more than 930,000 deaths due to colorectal cancer were estimated to have occurred worldwide¹. The diagnostic challenge lies in the reliance on invasive procedures and delayed results, as traditional methods struggle to provide the real-time precision needed for effective decision-making and timely interventions.

Through this study, Optiscan will explore the ability to deliver high-resolution, real-time visualization of cellular structures of the GI tract using its more advanced Gen2 technology, in a planned sequential staged development plan as it develops its next generation stand-alone flexible endomicroscope. This innovation could enable earlier detection and more accurate diagnoses, addressing the global healthcare burden associated with GI diseases while reshaping diagnostic and therapeutic approaches.

By providing real-time, high-resolution imaging at the cellular level, Optiscan's technology has the ability to enable clinicians to visualize and assess GI tissues with unprecedented clarity during screening procedures. This capability can help facilitate immediate identification of abnormalities, such as pre-cancerous lesions or early-stage cancers, reducing the need for multiple biopsies and enabling more precise interventions. Its ability to deliver live imaging minimises delays associated with traditional histopathology, streamlining decision-making and enhancing patient outcomes and improved procedural efficiency.

Optiscan CEO and Managing Director, Dr Camile Farah, said: "We are thrilled to be undertaking this study with the prestigious University Medical Center of Mainz. It will be under the leadership of renowned world-leading gastroenterologist Professor Ralph Kiesslich, and represents a major step forward in helping to better understand and manage one of the world's biggest health issues. GI diseases represent a significant global health challenge, affecting millions of lives each year. Early detection and precise intervention are critical, yet traditional diagnostic tools often fall short in providing timely and accurate insights."

"Our partnership with Professor Kiesslich and his team represents a pivotal step forward in extending the capabilities of Optiscan's real-time, high-resolution imaging technology, as the Company plans to re-enter the GI endoscopy market with its own private label device. Professor Kiesslich was instrumental in the design, deployment and clinical uptake of Optiscan's Gen1 flexible endomicroscope in partnership with Pentax in the early 2000s, and will also play a key role in advancing Optiscan's Gen3 device over the coming year."

The Company is working towards receiving ethical clearance for the clinical phase of its planned studies, and will update the market once achieved.

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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/colorectal-cancer>