



ASX Announcement
14 March 2023

OPTISCAN PLATFORM HIGHLY ACCURATE FOR ORAL CANCER DIAGNOSIS

Optiscan Imaging Limited (ASX: OIL) is pleased to announce interim results of its oral imaging study conducted by Professor Farah and his team at the Australian Centre for Oral Oncology Research & Education.

Data analysed as part of the Company's recently acquired Intellectual Property (IP) shows that the Optiscan technology is extremely accurate for the diagnosis of oral cancer (squamous cell carcinoma) and precancer (epithelial dysplasia).

The study, which was conducted by Optiscan's CEO/MD prior to him joining the Company, assessed 47 patients presenting with 63 distinct oral mucosal lesions which were subjected to Optiscan's real-time in vivo confocal laser endomicroscope (CLE). CLE images were captured live during clinical examination with acriflavine and assessed on-the-fly for the presence of cytological and architectural features of dysplasia/carcinoma as determined by World Health Organisation diagnostic criteria.

Diagnostic accuracy was extremely high at 88.9% for the presence of dysplasia/carcinoma, while other performance metrics were sensitivity (Sn) 86.8%, specificity (Sp) 92%, positive predictive value (PPV) 94.3% and negative predictive value (NPV) 82.1%. 100% of cancer cases were diagnosed correctly using Optiscan's CLE device.

The Company's CEO/MD said, "One of the study's strengths was the inclusion of 3 blinded anatomical pathologists from Perth and Harvard University who reported the traditional histopathological findings of each biopsied lesion independently, and then provided a consensus definitive diagnosis to which the optical biopsy from Optiscan's device was compared to. This is an extremely high hurdle to clear for diagnostic accuracy."

Optiscan's Chairman, Mr Robert Cooke said, "The results from this interim study show that Optiscan's fluorescence-based CLE device is a highly accurate, easy-to-use, rapid and slide-free point-of-care optical imaging technology for diagnosing oral cancer and precancer."

Dr Farah adds, "The use of optical biopsy with Optiscan's CLE platform permits the discrimination between dysplastic and non-dysplastic pathology, and demonstrates near-perfect agreement with traditional consensus histopathology without the need for physical tissue biopsy."

The Company is in the process of analysing the remaining data from this study, as it seeks to maximise the utility of its recently acquired IP. The IP contains a rich mix of datapoints relevant to the detailed understanding of how its platform technology and various contrast agents can be used to maximise product development and

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clinical adoption. The data is currently being used to develop machine learning algorithms for use in computer-assisted diagnosis and telepathology applications in the Company's partnership with Canadian-based ProLucid Technologies.

Additionally, the results of this interim analysis, and data contained within the Company's oral imaging datasets, will support the Company's US Food and Drug Administration (FDA) De Novo Classification application for its InVivage® product intended for oral tissue imaging.

"The results of this study are timely as they provide supplementary evidence that validates the clinical utility of our CLE technology for diagnostic oral tissue imaging, and will fast-track our ability to provide the FDA with responses to some additional queries recently requested, further accelerating our De Novo submission for Invivage®." Dr Farah concluded.

The Company will report the findings of its full analysis of this arm 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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