



ASX Announcement
22 August 2022

OPTISCAN IMAGING SUBMITS FDA 510(k) APPLICATION for InVivage® DEVICE

Optiscan Imaging Limited (ASX: OIL) is pleased to announce submission of its FDA (United States Food and Drug Administration) Pre-Market Notification (510(k)) application for the InVivage® device intended for oral tissue imaging.

InVivage® is a next generation, non-invasive, instantaneous form of oral imaging, targeting the severe health consequences of late-stage diagnosis of oral cancers and precancerous lesions. The technology platform enables real-time, non-destructive, 3D, *in-vivo* imaging at the sub-cellular level which aims to provide physicians, surgeons and pathologists with high resolution microscopic images intraoperatively that can be used to assist with diagnosis and treatment of various oral pathologies.

Optiscan's CEO and Managing Director, Prof. Camile Farah said, "I'm delighted to announce the submission of our 510(k) application for InVivage®, a truly landmark achievement for the company. This is a key step towards strengthening the commercialisation of the InVivage® device and bringing our revolutionary imaging and real-time pathology technology to the world. This submission strengthens the path for commercialisation of InVivage®, which is aligned with our new strategic direction, as we continue to move forward in our go-to-market plans as well as actively look to diversify our product offering."

Optiscan's Regulatory Affairs Manager, Mr Peter Pavlicek said, "This submission is a significant milestone for the company, and a testament to the efforts of our team members who have worked tirelessly to bring this to fruition."

Optiscan's Chairman, Mr Robert Cooke said, "The Board is delighted by this 510(k) submission to the FDA, and looks forward to its clearance in due course. The company will pursue appropriate regulatory approval processes for other markets and will provide further updates on this at a later point in time."

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

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For investor queries, please contact:

Prof Camile Farah
CEO & Managing Director – Optiscan Imaging Ltd
E: cfarah@optiscan.com

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 sub-cellular 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.

Phone (61 3) 9538 3333
Website www.OptiScan.com
16 Miles St, Mulgrave VIC 3170

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.

Disclaimer

All statements other than statements of historical fact included on this announcement including, without limitation, statements regarding future plans and objectives of OptiScan or any of the other parties referred to herein, are forward-looking statements. Forward-looking statements can be identified by words such as 'anticipate', 'believe', 'could', 'estimate', 'expect', 'future', 'intend', 'may', 'opportunity', 'plan', 'potential', 'project', 'seek', 'will' and other similar words that involve risks and uncertainties. These statements are based on an assessment of present economic and operating conditions, and on assumptions regarding future events and actions that are expected to take place. Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of the Company, its directors and management of OptiScan that could cause actual results to differ from the results expressed or anticipated in these statements.

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