



ASX Announcement
2 March 2023

OPTISCAN INTENDS TO PURSUE DE NOVO PATHWAY FOR INVIVAGE

Optiscan Imaging Limited (ASX: OIL) is pleased to announce it has received feedback from the US Food and Drug Administration (FDA) in relation to its Pre-Market Notification (510(k)) application for the InVivage® product intended for oral tissue imaging.

Optiscan's CEO and Managing Director, Dr Camile Farah said, "The FDA have provided feedback to the Company that due to the first-in-class nature of the InVivage® and the novelty of its intended use, it could not evaluate substantial equivalence of our device/drug combination product due to the absence of a predicate, and as such they have deemed that the De Novo Classification Request pathway is more suitable for our purposes."

Dr Farah also said, "While this advice differs from that previously provided to the Company by the FDA in Q-Submission, we are encouraged by the review process and feedback offered in our recent meetings with the FDA which have been extremely positive and productive. The review period has been time well spent as it strengthens our next submission. In addition to discussions around novelty, first-in-class, and available pathways for clearance, the FDA recommended additional studies to expedite a future De Novo submission."

Regulatory clearance of the Company's combination product mandates that both the fluorescent contrast agent drug and the device used to visualise microscopic structures are cleared for use in the intended clinical setting. The additional data requested by the FDA for inclusion in the Company's De Novo submission relates mostly to the novelty of the contrast agent and its intended application to oral tissues.

Optiscan's Chairman, Mr Robert Cooke said, "The Company's intended De Novo submission will be directly overseen by our CEO. We are fortunate to have Dr Farah lead a future submission from its inception. His training as both a physician and pathologist, coupled with his expertise as a medical researcher will undoubtedly strengthen the Company's submission and ensure its success. The positive working relationship established between Dr Farah and the FDA review panel will facilitate progress of the InVivage® submission."

Optiscan intends to carry out additional studies to satisfy the recommendations made by the FDA in the shortest time possible, while remaining in close contact with the review team to accelerate progress. In addition to the De Novo submission for the InVivage® product, the Company is expanding its product portfolio with planning underway for new devices and novel applications that will benefit from the FDA feedback.

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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 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.

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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