



ASX Announcement

4 November 2019

Optiscan initiates FDA feedback for Oral Cancer 510(k) submission

Highlight:

- **Optiscan requests meeting with the US Food and Drug Administration (FDA) to discuss a 510(k) submission to enable the legal sale in the United States of the Optiscan system in oral cancer screening and /or surgery.**

Optiscan Imaging Limited (ASX: OIL, Optiscan) is pleased to advise that it has submitted a meeting request to the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) seeking feedback on its proposed content to support a 510(k) submission. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to an already legally marketed device.

The request for a meeting submitted by Optiscan comprises a 40-page summary of the Optiscan system and its intended application to create in-vivo confocal laser scanning images of the internal microstructure of tissue within the oral cavity (including the oropharynx).

There is a significant opportunity for Optiscan to improve health care outcomes for the more than 50,000 patients diagnosed in the United States with oral or oropharyngeal cancer this year. "Historically, the death rate associated with this cancer is particularly high not because it is hard to discover or diagnose, but due to the cancer being routinely discovered late in its development. Today, (2019) that statement is still true, as there is no comprehensive program in the US to opportunistically screen for the disease, and without that late-stage discovery is more common.¹"

Optiscan's Executive Chairman Darren Lurie, said:

"This is an exciting step forward for the Company as we progress the application of Optiscan technology in oral cancer screening and/or surgery and complements the previously announced current and proposed trials in oral cancer screening with Memorial Sloan Kettering Cancer Centre (MSKCC) in New York and the Melbourne Dental School in collaboration with Royal Melbourne Hospital, Peter MacCallum Cancer Centre, MSKCC and Australian Centre for Oral Oncology Research & Education."

¹ <https://oralcancerfoundation.org/facts/>

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About Optiscan

Optiscan is an Australian company that has developed and patented miniaturised confocal microscopes, and is a global leader in the development and application of microscopic imaging and related technologies for medical and research markets.

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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