ASX Announcement
9 October 2020

United States Food and Drug Administration (FDA) Regulatory Approval Update

Highlights

- **Optiscan has received written feedback received from the United States Food and Drug Administration (FDA) indicating Optiscan's 510(k) pathway remains on track for the use of its InVivage™ device in Oral Cancer Screening and/or Surgery.**
- **Optiscan will commence third party validation and verification testing of the InVivage™ device in the current quarter to support its intended 510(k) submission.**
- **510(k) submission planned for the first half of 2021.**

Optiscan Imaging Limited (ASX: OIL) ('the Company' or 'Optiscan') is pleased to announce that it has received written feedback from the Center for Devices and Radiological Health (CDRH) of the FDA in response to specific questions raised by the Company following its meeting with the FDA in January 2020 and subsequent written submissions made in late June 2020.

Following this feedback, Optiscan will continue to prepare its submission for 510(k) clearance to market the InVivage™ device for legal sale in the United States in Oral Cancer Screening and/or Surgery. In particular, Optiscan is pleased with the affirmative responses from the FDA regarding the proposed Product Code, Primary Predicate Device and use of the CONVIVO® device as a Reference Device.

The next step is the clinical study regarding the effectiveness (dosing and time to imaging) of the use of a topically applied imaging agent for use in conjunction with the InVivage™ device will be conducted with the Melbourne Dental School and will take place simultaneously with the third party validation and verification testing which is required to be completed for the 510(k) submission. This testing will commence in the current quarter.

The completion of all these components form the path to 510(k) submission planned for the first half of 2021.

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

For investor queries, please contact:
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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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