OptiScan Imaging Limited
ABN 81 077 771 987

ASX Announcement
31 January 2020

Corporate Update

Highlights:

- **Optiscan met in late January 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 InVivage® system in human Oral Cancer Surgery and/or Oral Cancer Screening applications.**

- **Optiscan is building a number of InVivage® systems to support various testing of the InVivage® system required as part of a 510(k) submission.**

- **Optiscan remains on its pathway to make a 510(k) submission for the InVivage® system in Oral Cancer.**

- **Carl Zeiss Meditec (CZM) orders for products and services increase from $550k to $700k.**

Meeting with the US Food and Drug Administration (FDA)

Optiscan Imaging Limited (ASX: OIL) ('the Company' or 'Optiscan') is pleased to advise that it met in Washington D.C. with the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) in late January and obtained feedback on the proposed content and format to support its 510(k) submission in Oral Cancer Surgery and/or Oral Cancer Screening in humans. Following the meeting with the FDA, Optiscan will send the FDA supplementary information in relation to the proposed content to further support a 510(k) submission.

Optiscan is currently building a number of InVivage® systems to support validation and verification activities, including electrical and laser safety testing, required prior to the formal 510(k) submission. These tests are similar to those previously performed and met by the CONVIVO®, developed in collaboration with Carl Zeiss Meditec, albeit that Optiscan's InVivage® system focuses on the Oral Cancer rather than the Neurosurgical application in humans.

Carl Zeiss Meditec Collaboration

Optiscan has received additional orders from Carl Zeiss Meditec increasing its orders of products and services for delivery since July 2019 from $550k to $700k.

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Optiscan's Executive Chairman Darren Lurie, said:

"Optiscan had a highly productive and positive meeting with the FDA and received valuable insight in relation to fulfilling the requirements for making our 510(k) submission for the Optiscan InVivage® system in human Oral Cancer. This interaction with the FDA has provided clear guidance helping us de-risk our route toward a successful 510(k) application.

At the same time, we are very pleased to receive additional orders from Carl Zeiss Meditec, as they progress their commercial worldwide rollout plans for the CONVIVO® in neurosurgery."

For and on behalf of the Board:

Darren Lurie
Executive Chairman – Optiscan Imaging
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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

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