



ASX Announcement

25 November 2019

Optiscan Market Update

Highlights

- **US Food and Drug Administration (FDA) grants Optiscan Imaging Limited (ASX:OIL) (Optiscan) a meeting to discuss its 510(k) submission to enable the legal sale in the United States of the Optiscan system in oral cancer screening and /or tumour margin detection. The meeting is to take place in late January 2020.**
- **Carl Zeiss Meditec (CZM) orders for products and services of \$550k for delivery during the current half year and in late February/early March.**
- **Chinese University Tender success directly attributable to new Chinese multi-distributor model.**

Request for Meeting with the FDA

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has agreed to meet with Optiscan following the completion of the FDA's conduct of an administrative acceptance review of Optiscan's submission for the meeting. The meeting is to seek feedback on the proposed content to support a 510(k) submission 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).

A lead reviewer has been assigned to the submission and the FDA has agreed to meet with Optiscan in late January 2020.

Carl Zeiss Meditec Orders

Optiscan has received orders for products and services from Carl Zeiss Meditec (CZM) for \$550k for delivery during the current half year and in late February/early March.

CZM is actively marketing the CONVIVO® developed in collaboration with Optiscan, with the CONVIVO® forming 1 of the 3 elements of "the all-new concept of ZEISS Tumor Workflow" in combination with the CZM KINEVO® 900 and INTRABEAM® 600. These marketing activities included the demonstration of the CONVIVO® at the highly regarded European Association of Neurosurgical Societies (EANS) Conference in September 2019.

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Sale of FIVE2 (ViewnVivo) system in China

The new Optiscan multi-distributor model in China has had a positive early impact, with success for the FIVE2(ViewnVivo) system in a tender with a leading Chinese university. The University is based in Eastern China and Optiscan is in discussions with the distributor in relation to an exclusive arrangement for this region.

Optiscan's Executive Chairman Darren Lurie, said:

"It is pleasing to see the positive developments across all areas of the business, including progress with regulatory aspects of our own clinical system, our orders from CZM and the early impact of our new China distributor model. These initiatives have been some time in the making and it is rewarding to see them starting to come to fruition".

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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.

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