



ASX Announcement
2 April 2024

OPTISCAN APPOINTS US CLINICAL & REGULATORY HEADS

- Optiscan establishes US Regional Office in Rochester Minnesota
- Ken Lock appointed as US-based Head of Clinical Affairs
- Nicole Williams appointed as US-based Head of Regulatory Affairs

Optiscan Imaging Limited (ASX: OIL) ('the Company' or 'Optiscan') is pleased to announce the establishment of its US Regional Office in Rochester Minnesota, and the appointment of two US-based Heads of Clinical and Regulatory Affairs respectively.

Ken Lock has been appointed as Head of Clinical Affairs and comes to Optiscan with vast experience running global clinical trials to support commercialization of Class II and Class III medical devices in the US. He has extensive experience with the FDA, including clinical strategy development, protocol negotiation, trial submissions and outcome reporting. In addition, he has experience selecting clinical trials sites, study execution, safety reporting and CRO management. Post-trial completion, he has worked with numerous physicians to publish the results of clinical trials. Ken worked as a Sr. Director of Clinical Affairs for both large and small companies including, AGA Medical, St. Jude Medical, Boston Scientific, and Vice President of Clinical Affairs for Stereotaxis and Occlutech.

Nicole Williams has been appointed as Head of Regulatory Affairs and comes to Optiscan with significant experience in medical devices, sterilization, and medical device reproprocessors at leading companies including STERIS, Richard Wolf Medical Instruments, and more recently Steriluent where she worked as Director of Clinical & Regulatory Affairs. Over a 20-year period, she has led teams in multiple ISO 13485 certifications, prepared multiple 510k submissions leading to regulatory approvals, and maintained global registrations. She has deep experience and knowledge of surgical endoscopes and sterilization; and has worked across multiple medical device types, with experience in development, regulatory, quality, sales, software, and technical training at Medical Optics and Alphasource Group.

Both Ken and Nicole take on their new roles on 2 April 2024 and will operate between Minneapolis/St Paul and Optiscan's new Regional Office in Rochester, Minnesota, and will be supported by the wider Optiscan team in Australia.

Optiscan CEO and Managing Director, Dr Camile Farah, said, "We are delighted to welcome both Ken and Nicole to Optiscan at a pivotal moment in the Company's evolution as we grow our US operation and cement our presence in the Minnesota medtech landscape. Both Ken and Nicole bring a wealth of relevant and critical experience and expertise to support the Company's expansion in the US as we roll out our portfolio of new clinical devices. Both will play key roles leading our clinical and regulatory portfolios as the Company establishes

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clinical studies in the US and progresses its regulatory submissions to satisfy the FDA before clinical deployment.”

Dr Farah adds, “The Company has taken up premises at the Minnesota BioBusiness Center that serves as an incubator for private research and development companies to promote biotechnology development and research in the Rochester area. We are confident that our presence at the Minnesota BioBusiness Center and the appointment of new Heads of Clinical and Regulatory Affairs will buttress our US strategy, as we work toward securing US regulatory approval. The complexity of the FDA regulatory pathway and that of our device/drug combination product necessitates that the Company has local experts to support both the clinical and regulatory effort required to secure appropriate approvals for our precision surgery and digital pathology solutions. This process will be ongoing as we rollout various hardware and software clinical solutions and continue to innovate.”

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

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For investor queries, please contact:

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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* digital 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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