

# ASX Announcement 23 June 2025 (Melbourne, Australia) Optiscan Imaging Ltd (ASX: OIL)

# Optiscan Signs Agreement with Long Grove Pharmaceuticals

The agreement will see Long Grove's fluorescein drug (AK-FLOUR®) used in combination with Optiscan's imaging technology in clinical studies and trials, potentially identifying new applications for the drug and expediting regulatory submissions.

# **Highlights**

- Optiscan has signed an exclusive Collaboration Agreement with US-based drug company, Long Grove Pharmaceuticals.
- The Agreement will see both companies work together to develop new intended uses for Long Grove's intravenous fluorescein sodium contrast agent (AK-FLOUR®).
- AK-FLOUR® is required for Optiscan's fluorescence-based endomicroscopic imaging systems.
- The Long Grove drug will be used exclusively in US clinical studies and trials with Optiscan's InVue® device in a range of clinical applications commencing with breast surgery.
- Data from the collaboration studies will be used to support Optiscan's US FDA regulatory submissions for its InVue® surgical device.
- Optiscan will provide support to Long Grove in relation to US FDA supplementary New Drug Application submissions for AK-FLUOR®.

**Optiscan Imaging Limited (ASX: OIL)** ('**Optiscan**' or the '**Company**') is pleased to announce it has entered into an exclusive Collaboration Agreement with US-based drug company, Long Grove Pharmaceuticals, LLC ('**Long Grove'**). The agreement will see both companies work together to develop new intended applications for Long Grove's intravenous drug, fluorescein sodium (AK-FLOUR®). This drug is a contrast agent specifically used with Optiscan's current generation of fluorescence-based endomicroscopic imaging devices for surgical applications.

# Long Grove is a quality pharma group with ultra-high industry standards

Long Grove Pharmaceuticals is a US-based private company. It is a leading provider of high-quality, costeffective pharmaceuticals, and is dedicated to advancing global healthcare by delivering reliable solutions to patients worldwide. With state-of-the-art manufacturing facilities and a strong adherence to rigorous quality assurance processes, Long Grove has a reputation for meeting the highest industry standards. Long Grove places a high priority on patient safety and therapeutic efficacy, making it a trusted partner for healthcare providers and a reliable source for effective treatment options. Long Grove is the legal manufacturer of the fluorescein sodium contrast agent (AK-FLOUR®) required for use with Optiscan's fluorescence-based endomicroscopic imaging systems such as its InVue® surgical imaging device.

## The collaboration leverages the relative strengths of Optiscan and Long Grove

The collaboration combines Optiscan's cutting edge digital endomicroscopic hardware and software solutions with Long Grove's extensive experience in developing high-quality, specialised pharmaceuticals. It is a potential win-win for both parties, as it simultaneously supports:

- Optiscan's clinical studies and regulatory approvals for its InVue® surgical device, and
- Long Grove's quest to identify new applications for its AK-FLOUR® fluorescein sodium drug.

The agreement could also conceivably open up new clinical and commercial opportunities for both companies.

#### The collaboration will encompass clinical studies, trials, and regulatory submissions

The collaboration will run for a five-year period, unless terminated earlier at the agreement of both companies. It will see Long Grove supply AK-FLUOR® (10% Fluorescein Sodium Injections) which will be used in combination with Optiscan's fluorescence-based endomicroscopic imaging devices for surgical applications to undertake clinical studies and trials in the U.S. commencing with breast surgery and expanding to include other imaging applications. The Optiscan-Long Grove device-drug combination will subsequently be utilised in other imaging modalities including gastrointestinal endoscopy, gastrointestinal surgery, robotic surgery, and laparoscopic surgery.

The data from the initial studies will be used to support Optiscan's U.S. FDA regulatory submissions for its InVue® device. Future studies will provide data for regulatory submissions for gastrointestinal, laparoscopic and robotic-assisted surgical procedures.

Long Grove will also provide support to Optiscan in relation to the Company's U.S. FDA regulatory submissions, by providing access to AK-FLUOR®'s existing pharmacokinetic and chemistry, manufacturing and controls (CMC) data. CMC data could expedite Optiscan's efforts to obtain the necessary regulatory approvals for its surgical devices to be used in the lucrative U.S. market. In turn, Optiscan will provide support to Long Grove in relation to U.S. FDA supplementary New Drug Application (NDA) submissions for AK-FLUOR®, should new applications for this drug in combination with Optiscan's devices be identified.

**Optiscan CEO and Managing Director, Dr Camile Farah, said:** "This collaboration agreement with Long Grove Pharmaceuticals is a clear-cut win-win for both companies' development strategies. For Optiscan, it gives us a supply of Long Grove's AK-FLUOR®, which will be used in combination with our fluorescence-based endomicroscopic imaging devices to undertake studies and clinical trials. The data flowing from these studies will be an invaluable resource for our regulatory submissions. Having Long Grove's assistance as we work through U.S. FDA regulatory approval processes for Optiscan's devices is a significant bonus as we pursue a toehold in the large and lucrative U.S. market. For Long Grove, the collaboration should hopefully identify new uses for its AK-FLUOR®

drug. Optiscan will assist Long Grove complete U.S. FDA supplementary New Drug Application submissions for any such new applications."

**Dr Farah added**: "This collaboration agreement represents another significant step in Optiscan's ongoing efforts to integrate its ground-breaking technology into clinical practice. It provides further evidence that more and more healthcare sector-related groups are wanting to partner with Optiscan's technology, as they search for ways to enhance and/or expand usage of their own product offerings. We will continue to seek out opportunities to combine Optiscan's unique IP and inhouse expertise with such groups. Such partnerships will undoubtedly help accelerate the adoption by clinicians of real-time endomicroscopic imaging, which in turn paves the way for improved outcomes for patients undergoing a range of surgical procedures."

**Long Grove Pharmaceutical's President, Mr Peter J. Karas, said**: "We are excited to partner with Optiscan. By combining our dedication to delivering high-quality pharmaceutical products with Optiscan's advanced imaging technology, we are poised to drive innovation and enhance patient outcomes throughout the healthcare industry. Together, we look forward to making a meaningful impact."

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

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# About Optiscan

Optiscan Imaging Ltd (ASX: OIL) is a commercial stage medical technology company creating a suite of digital pathology and precision surgery hardware and software solutions that enable live optical biopsy for life sciences, diagnostic and surgical applications. Optiscan pioneered the development and manufacturing of miniaturised digital endomicroscopes with spatial resolution more than 1000x that of medical CT and MRI.

Using a revolutionary "tissue contact" method, Optiscan's patented technology produces super high-resolution digital pathology images for cancer diagnosis and surgical treatment, to unlock real-time insights during surgery, diagnostics, and pre-clinical research. By enabling live, non-destructive, 3D, in-vivo digital imaging at the single-cell level, Optiscan's technology supports earlier disease detection, precision treatment, and improved patient outcomes across a wide selection of clinical applications and settings.

The global addressable market for Optiscan's medical imaging technology extends beyond traditional surgery and pathology, to also encompass the fast-growing digital health market including robotic surgery. With an expanding product suite and increased demand for digital health solutions, Optiscan is uniquely positioned to bridge the gap

between surgery and pathology and deliver better outcomes for healthcare professionals and their patients.

To learn more about Optiscan, visit <u>www.optiscan.com</u> or follow us on <u>LinkedIn</u>, <u>X</u> or <u>Instagram</u>.

#### About Long Grove Pharmaceuticals®

Long Grove Pharmaceuticals was established in 2019 by Water Street Healthcare Partners, a strategic investor focused exclusively on the health care industry. The company is part of Capstone Development Services, which has been developing products in partnership with the world's premier pharmaceutical and medical device organisations since 2013. Combining decades of collective leadership experience with a portfolio of specialised, complex generic drug formulations, Long Grove Pharmaceuticals is poised to innovate across the generic injectable and topical markets.

For more information about Long Grove, visit www.longgrovepharma.com

## 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.