

ASX Announcement: 1 October 2026 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX: OIL)

Optiscan Lodges U.S. FDA 510(k) Submission for InForm™

Optiscan's advancement to US FDA review for its InForm™ digital pathology device follows the completion of substantial technical, clinical and regulatory work, and marks an important step toward the device's commercialisation in the United States.

HIGHLIGHTS

- Optiscan has lodged a 510(k) submission with the U.S. FDA for InForm™, the Company's digital pathology device.
- The submission is a key step in the regulatory approval process for InForm™, and a necessary prerequisite to the device's commercial development.
- The submission represents a major milestone in Optiscan's plans to digitalise pathology imaging.
- Lodgement of the U.S. FDA 510(k) submission follows the completion of substantial technical, clinical and regulatory work.
- As InForm™ progresses through its formal regulatory review, Optiscan will continue to build its clinical reference network and deepen engagement with pathology customers, institutions and potential commercial partners.



Figure 1: Optiscan's InForm™ digital pathology device

Optiscan Imaging Limited (ASX:OIL) ('**Optiscan**' or the '**Company**') is pleased to announce the Company's lodgement of a 510(k) submission with the United States Food and Drug Administration ('**FDA**') for the Optiscan InForm™ pathology device. This submission is a major deliverable in InForm™'s development strategy, being a necessary prerequisite for regulatory clearance of the device by the FDA, and its subsequent commercialisation in the United States ('**U.S.**') market.

Lodgement of a 510(k) submission to the FDA represents an important step in the development journey for a yet-to-be-approved medical device. It effectively moves the device beyond its internal development, testing and validation phase into a formal regulatory assessment process. Successful completion of this pathway is an important precursor to commercial marketing, sale and use of InForm™ within the U.S. market.

TARGETING A GROWING DIGITAL PATHOLOGY MARKET

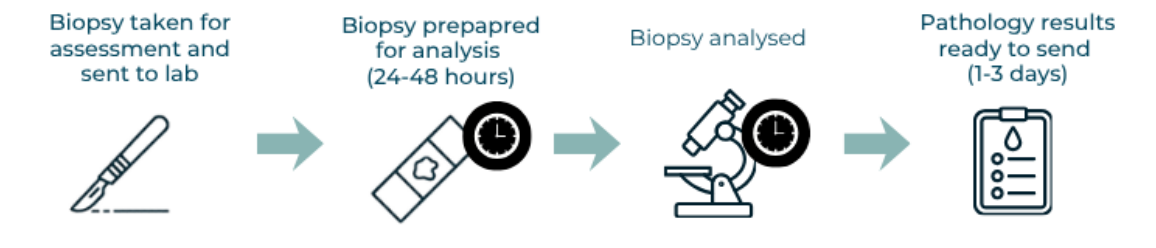
InForm™ was unveiled in February 2025 as Optiscan's next generation microscopic medical imaging device specifically designed for pathology workflows. With the U.S. anatomic pathology market valued at approximately US\$10.6 billion in 2025 and forecast to reach US\$15.35 billion by 2030, pathology represents a substantial and growing healthcare market spanning the diagnosis and assessment of a broad range of diseases and conditions¹.

Pathology remains largely analogue, with conventional workflows still dependent on tissue processing, and the preparation of glass slides that are reviewed under a physical microscope. Digital pathology is now beginning to transform current day pathology workflows, with it revolutionising how microscopic information is captured in the first place.

Optiscan's InForm™ device enables real-time, slide-free digital microscopic imaging to be reviewed directly from freshly excised tissue at the point of contact or from tissue fixed in preservatives commonly used in pathology labs. This positions Optiscan as an early mover in an emerging segment of digital pathology, with the opportunity to establish a new workflow rather than compete solely within the existing slide-scanning market. This first-mover position is likely to be accompanied by a longer adoption curve, as clinical validation, workflow integration and user acceptance will be required before technological differentiation translates into meaningful commercial adoption. Nonetheless, Optiscan retains a significant competitive advantage as a first mover given the super-high resolution, speed and cost effectiveness of its imaging platform.

¹ <https://www.grandviewresearch.com/industry-analysis/us-anatomic-pathology-market-report>

Current Standard of Care in Pathology



Standard of Care with Optiscan Real-time Imaging



Figure 2: Current standard of care in pathology compared to real-time imaging with Optiscan's InForm™

SIGNIFICANCE OF THE FDA 510(K) PATHWAY

Lodging the 510(k) submission for InForm™ has been a complex undertaking. Preparing InForm™ for submission required the completion and integration of a substantial body of technical, clinical and regulatory work since the device was unveiled in February 2025. This work brought together extensive external technical testing, clinical evidence gathering and regulatory documentation to demonstrate safety and performance of InForm™ and establish its equivalence to existing FDA-cleared devices. Reaching submission therefore represents the culmination of a complex development program rather than simply the completion of a regulatory filing. For InForm™, this work has required the technology to be evaluated within relevant pathology workflows, with clinical studies generating data that contributed directly to the submission.

Importantly, these studies will continue beyond submission, further expanding the clinical evidence base and supporting the device's broader development and commercialisation.



Figure 3: FDA milestone progress for Optiscan's InForm™

MOVING TOWARDS U.S. MARKET ENTRY

Optiscan's InForm™ will enter the FDA's formal 510(k) review process now the submission has been lodged. This process will include an initial acceptance assessment followed by substantive review of the device's technical, performance and supporting evidence.

While this regulatory review is progressed, Optiscan will continue its clinical studies and broader commercial readiness activities, further building the clinical evidence base, strengthening engagement with key pathology stakeholders and preparing for potential market entry. A successful 510(k) determination should provide FDA clearance for InForm™ to be commercially distributed in the U.S. for its cleared indications, representing a major transition from clinical and regulatory development toward commercialisation.

REGULATORY SIGNIFICANCE

A 510(k) submission represents the culmination of a substantial body of technical, clinical and regulatory work undertaken to demonstrate the safety, performance and substantial equivalence profile of InForm™ to an appropriate legally marketed predicate. The clinical studies conducted to date have contributed important data to this evidence package and will continue beyond submission to further strengthen the device's clinical evidence base.

Following submission, InForm™ will enter the FDA's formal review process, during which the agency will assess the supporting evidence and may seek clarification or additional information before making a determination. Successful clearance would represent a major regulatory milestone, enabling commercial distribution of InForm™ in the U.S for its cleared indications and materially advancing Optiscan's commercialisation strategy. The Company anticipates working directly with the FDA on provision of additional data if requested and answering questions that may arise from the agency's review of the 510(k) submission.

STRATEGIC SIGNIFICANCE

Progression of InForm™'s regulatory approval process to delivery of its US FDA 510(k) submission is an important marker of Optiscan's increasing organisational maturity. The work required to support the submission has strengthened inhouse capabilities across regulatory affairs, clinical development, quality systems, engineering, manufacturing and operational execution. It has also enhanced the internal knowledge, processes and experience required to support Optiscan's commercial-scale medical device development plan.

These capabilities are also being tapped as Optiscan progresses the development strategies for other products in its portfolio. The systems, regulatory frameworks and cross-functional expertise established through the InForm™ program provide a stronger platform for future submissions across Optiscan's portfolio, with the potential to improve execution, reduce duplication and accelerate subsequent

regulatory pathways. In parallel, continued investment in people, manufacturing readiness and scalable systems is positioning Optiscan to support a broader pipeline as products progress from development to regulatory review and ultimately to commercialisation.

COMMERCIAL SIGNIFICANCE

The U.S. represents a substantial commercial opportunity for InForm™, given its large pathology market remains predominantly analogue and is only now beginning to transition toward digital workflows. While most existing digital pathology solutions focus on scanning prepared glass slides, the InForm™ device delivers real-time, slide-free, digital microscopic imaging directly from fresh or fixed tissue at the point of contact, creating the potential to establish a new point of use within the pathology workflow. Advancing toward FDA clearance is therefore a key step forward in Optiscan's plans for penetration of the large U.S. health care sector, with a clearly defined go-to-market strategy designed to drive commercial adoption. Optiscan's initial focus is expected to centre on building clinical reference sites, engaging pathology stakeholders, demonstrating workflow and economic value, and establishing early use cases that can support broader adoption. These activities will help advise wider commercial rollout, including customer targeting, sales models, training and support requirements, and potential partnerships. As with any new clinical workflow, adoption is expected to build progressively as awareness, evidence and user confidence increases.

CEO COMMENT

Optiscan CEO and Managing Director, Dr Camile Farah, said:

"Lodgement of InForm™'s 510(k) submission with the FDA represents a key deliverable in our pathology device's development strategy. InForm™ represents one of the most exciting opportunities within our portfolio. The device is not just digitising an existing pathology process. It has real potential to change where and when microscopic information becomes available for clinical use. Submitting our FDA submission brings us closer to introducing a fundamentally different workflow into the U.S., one of the world's largest pathology markets. While InForm™'s regulatory approval process is progressed, Optiscan and its collaborators will continue to generate valuable clinical evidence that will be critical in demonstrating where InForm™'s value - and also that for our other devices - can be realised."

"Achievement of this submission milestone would not have been possible without the inhouse skillsets Optiscan now possesses. The quality of our people, systems, regulatory capabilities, clinical experience and manufacturing readiness have been enhanced over time, and are now at the standard required to move our complex medical technology platform towards market. These capabilities, which have so effectively progressed InForm™'s development strategy, will now be drawn on as Optiscan advances future regulatory submissions, and builds its existing stable of commercial partnerships, both of which

are central to the Company effectively executing its broader growth strategy with speed and confidence.”

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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 www.optiscan.com or follow us on [LinkedIn](#), [X](#) or [Instagram](#).

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.