

ASX Announcement: 5 October 2026 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX: OIL)

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

The advancement of Optiscan's InVue™ precision surgery device to the U.S. FDA review stage demonstrates the maturity of the Company's technology platform and validates the depth of technical, clinical and regulatory capability built across its development program.

HIGHLIGHTS

- Optiscan has lodged a U.S. FDA 510(k) application for its InVue™ precision surgery device.
- This submission comes soon after the recently announced U.S. FDA 510(k) application for Optiscan's InForm™ device.
- The InVue™ submission represents the culmination of years of technical, clinical and regulatory development, and a major milestone in the program's progression toward market.
- The submission demonstrates the maturity of InVue™ and moves Optiscan closer to potential entry into the substantial and expanding United States surgical market.
- Optiscan continues to advance commercial readiness for InVue™ through clinical reference sites, customer engagement, manufacturing scale-up and discussions with commercial partners.



Figure 1: Optiscan's InVue™ precision surgery device

Optiscan Imaging Limited (ASX:OIL) ('Optiscan' or the 'Company') is pleased to announce the successful submission of a 510(k) application with the United States Food and Drug Administration ('FDA') for the Optiscan InVue™ precision surgery device. This follows hot on the heels of the 510(k) submission for Optiscan's InForm™ digital pathology device (see ASX announcement dated 1 October 2026), and marks another important advancement toward FDA clearance of its flagship real-time surgical imaging platform and entry into the United States ('U.S.') market.

The submission represents the culmination of extensive technical, performance and clinical development and moves InVue™ into formal independent regulatory review. FDA clearance is a critical gateway to commercialisation in the U.S, and if achieved, would position Optiscan to progress InVue™ from an advanced clinical-stage technology toward commercial market entry.

ADDRESSING A SIGNIFICANT U.S. SURGICAL OPPORTUNITY

Optiscan unveiled InVue™ in June 2024 as a next generation microscopic medical imaging device specifically designed for precision surgery. The U.S. represents a substantial surgical oncology opportunity, with approximately 60% of cancer patients undergoing surgery to treat or stage their disease (that is, measure how far their disease had spread)¹ – equivalent to around 1.27 million patients annually based on 2026 cancer incidence². Cancer surgery is also the largest segment of the U.S. cancer treatment facilities market, representing an estimated US\$4.8 billion in annual revenue, while the broader intraoperative imaging market is forecast to reach US\$1.55 billion by 2030³.

InVue™ has been developed to bring microscopic, cellular-level imaging directly into the operating environment, enabling surgeons to visualise tissue in real time while the patient remains in theatre. By providing information at the point at which surgical decisions are being made, InVue™ has the potential to support more informed assessment of tissue and surgical margins across a range of procedures and clinical specialties, with significant clear-cut utility in surgical oncology in the first instance.

Surgical oncology represents a particularly compelling initial target healthcare market segment for InVue™, given the scale and diversity of cancer surgery across disciplines including breast, head and neck, colorectal, genitourinary, skin and other solid tumour procedures. Across these settings, surgeons face the same fundamental challenge, namely to determine during the procedure whether suspicious or residual tumour remains. The ability to provide immediate microscopic information at the surgical site

¹ https://www.facs.org/for-medical-professionals/news-publications/news-and-articles/bulletin/2026/january-2026-volume-111-issue-1/coc-operative-standards-drive-improvements-in-cancer-surgery/?utm_source=chatgpt.com

² https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2026/2026-cancer-facts-and-figures.pdf?utm_source=chatgpt.com

³ https://www.grandviewresearch.com/horizon/outlook/cancer-treatment-facilities-market/united-states?utm_source=chatgpt.com

has the potential to address this unmet need across multiple clinical pathways, giving InVue™ a broad platform opportunity rather than limiting its application to a single cancer type or surgical specialty.

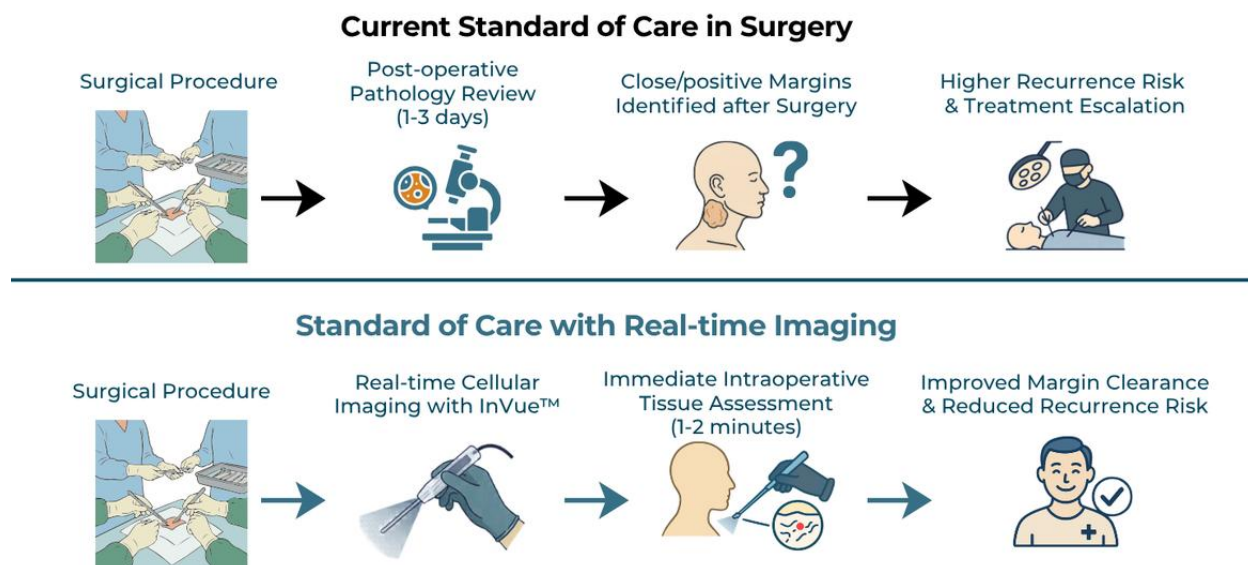


Figure 2: Current standard of care in surgery compared to real-time imaging with Optiscan's InVue™

PROGRESSING ALONG THE FDA 510(K) PATHWAY

Advancing InVue™ to a US FDA 510(k) submission stage reflects the completion of an extensive program spanning engineering, clinical validation, external testing, and regulatory preparation. The submission brings together detailed evidence on device performance, safety, verification and validation, risk management and clinical use, with each element contributing to the overall case presented to the FDA.

For InVue™, reaching this stage is particularly significant given the complexity of developing a technology intended for use within a sterile surgical environment, where performance must be demonstrated in the context of real-time clinical decision-making. Clinical studies have played an important role in generating evidence to support the submission and will continue beyond it, providing additional data across surgical workflows and helping strengthen the foundation for future clinical adoption and commercialisation.



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

THE NEXT PHASE OF PROGRESS

Having been submitted for assessment, InVue™ will now move into formal FDA review, where the U.S. regulatory authority will assess the technical, performance and clinical evidence supporting Optiscan's application. The FDA may request clarification or additional information during this process before determining whether the device meets the requirements to be cleared.

At the same time, Optiscan will continue advancing its clinical and commercial programs, including further evidence generation, engagement with surgeons and clinical partners, and preparation for potential U.S. market entry. This parallel approach enables regulatory review and commercial readiness to progress together rather than sequentially.

REGULATORY SIGNIFICANCE

The 510(k) submission represents an important regulatory inflection point for InVue™, bringing together the technical, performance and clinical evidence generated through the development program into a formal FDA application.

The clinical studies completed to date have contributed directly to building this evidence base, while ongoing studies will continue to generate additional data beyond submission. Progression to FDA review would move InVue™ into the next stage of its regulatory pathway and, if clearance is achieved, provide the basis for commercial roll-out in the U.S. for its cleared indications.

STRATEGIC SIGNIFICANCE

InVue™ represents an important demonstration of Optiscan's ability to translate its imaging platform into a technology designed for use directly within the surgical workflow. The FDA submission reflects well on both the maturity of the device itself, and the Company's growing capability to execute complex clinical, regulatory and product development programs.

The ongoing clinical program also provides an opportunity to validate InVue™ across different surgical settings and indications, generating evidence that can support future adoption while strengthening Optiscan's relationships with leading surgeons, hospitals and clinical institutions.

COMMERCIAL SIGNIFICANCE

The commercial opportunity for InVue™ is driven by the scale of the U.S. surgical market and the increasing role of imaging and precision technologies in the operating room. Surgeons are increasingly being provided with tools that deliver more information during procedures, creating a growing market for technologies capable of supporting real-time clinical decision-making.

InVue™ is differentiated by its ability to provide microscopic, cellular-level imaging directly at the surgical site without relying on the conventional process of removing tissue and sending it away for

laboratory preparation before review. The platform is tissue agnostic and has wide application across many tissue types. This creates the potential for InVue™ to establish a new imaging capability within the surgical workflow and provides Optiscan with exposure to a substantial and expanding addressable market.

CEO COMMENT

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

“Lodgement of InVue™’s 510(k) submission with the FDA represents yet another key deliverable in the broader development strategy for our medical technology platform. It means we are now much closer to making a technology designed to give surgeons microscopic insight in real-time commercially available in the world’s most important healthcare markets. The InVue™ submission, along with the earlier FDA submission for the InForm™ digital pathology device, are both powerful validations of how far our platform has progressed. It is a real credit to our team’s ability to advance Optiscan’s clinical program and hone the Company’s inhouse-developed regulatory capability skillsets.”

“InVue™ potentially offers multiple advantages to surgeons working in operating theatres. It could change what they can see, when they can see it, and, flowing from the first two advantages, provide them with a better course of action during surgery. From breast and head and neck cancer to other solid tumour procedures, the opportunity is to bring cellular-level information directly into the operating theatre where life-changing decisions need to be made. That is a compelling clinical proposition, and a significant commercial opportunity as we build toward U.S. market entry.”

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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](#).

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