ASX Announcement: 31 March 2026 (Melbourne, Australia)
Optiscan Imaging Ltd (ASX: OIL)

Optiscan Submits InSpecta® FDA Dossier

HIGHLIGHTS

- Optiscan has submitted a regulatory dossier to the U.S. FDA for InSpecta®, marking a key step towards entry into the United States veterinary market.
- This marks a major inflection point for InSpecta®, signalling the device's readiness and the transition into the next phase of its commercial development.
- The submission moves InSpecta® into formal regulatory review, supporting the expansion of clinical reference sites and strengthening engagement with veterinary customers and partners.
- It also establishes a regulatory standard and process that can be applied to future devices across the Optiscan portfolio.

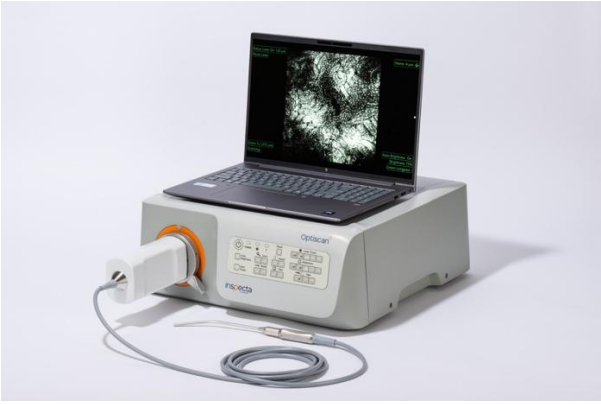

Figure 1: InSpecta® device

Figure 2: InSpecta® device and probe in use

Optiscan Imaging Limited (ASX:OIL) ('**Optiscan**' or the '**Company**') is pleased to announce the submission of a regulatory dossier to the United States Food and Drug Administration **('FDA')** for its InSpecta® veterinary device, a major step forward in the device's development plan.

ADVANCING TOWARDS US MARKET ENTRY

Optiscan has reached a critical milestone in its development journey, with the submission of a FDA Centre for Veterinary Medicine regulatory dossier for InSpecta®, the Company's novel microscopic imaging device designed specifically for the veterinary medicine market.

FDA submission is a key step in bringing any medical device into the U.S. market. It marks the point where a device moves from internal development and testing, into formal regulatory review, with clearance enabling commercial marketing, sale and use in the United States.

For Optiscan, this represents more than a single regulatory submission. It reflects the level of maturity reached across the Company's technology, documentation and internal processes, and signals readiness to progress toward clinical use and commercialisation.

InSpecta® was unveiled in June 2025 as Optiscan's first device designed specifically for the veterinary medicine market, expanding the Company's technology into a large and rapidly growing sector. The veterinary market represents a significant commercial opportunity for the Company, with the U.S. market alone valued at approximately US$11.92 billion in 2022 and projected to grow at a compound annual rate of 8.7% through 2030[1].

With an estimated 76 million dogs and 60 million cats in U.S. households, demand for advanced veterinary care continues to increase, particularly for complex conditions such as cancer. InSpecta® is designed to address this need by providing real-time, non-invasive imaging across a broad range of animal applications, positioning Optiscan to participate in a substantial and expanding market.

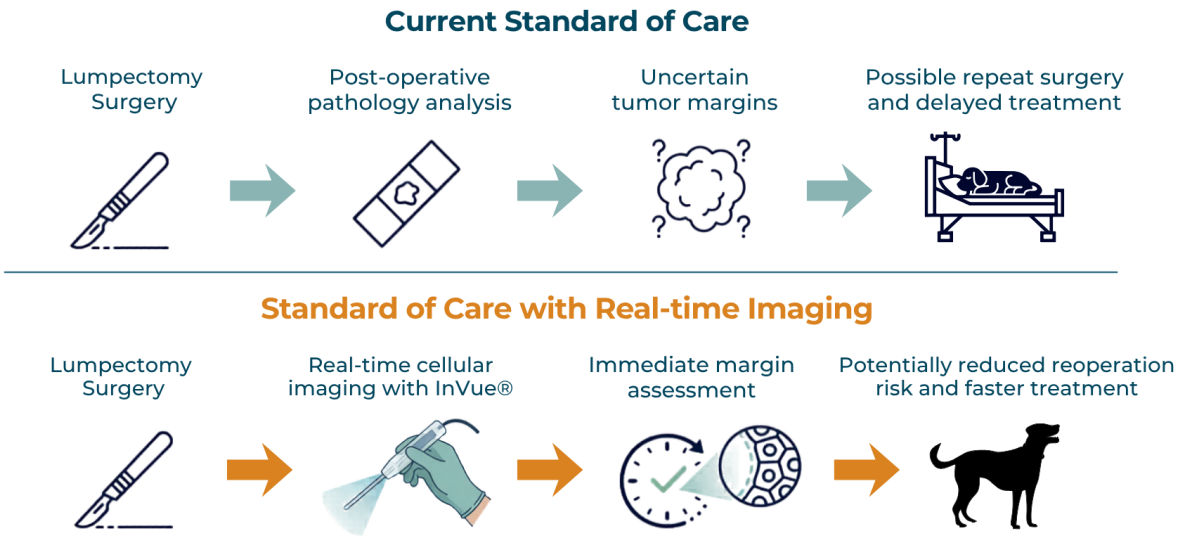

Figure 3: Current veterinary pathology standard workflow compared to real-time imaging

A REGULATORY-READY DEVICE AND A CAPABILITY THAT SCALES

With the regulatory dossier submission complete, InSpecta® now enters the FDA review process which includes potential engagement with the regulator and potential requests for additional information.

The submission brings together the full body of work completed on InSpecta® to date. This includes how the device is designed and performs, how it is used within veterinary workflows, and the data generated through testing and validation. It also includes the detailed technical and regulatory documentation required for FDA reviews.

At the same time, the submission allows Optiscan to progress several important activities in parallel. The Company is now in a stronger position to expand its network of clinical and veterinary reference sites, which are critical for demonstrating how the device performs in practice. Optiscan initially expects this network to comprise a mix of large veterinary referral hospitals, specialty oncology centres, and corporate clinics that account for up to 9,000 of the 34,000 veterinary clinics in the United States. The submission also supports broader engagement with veterinary clinics, hospitals and academic institutions, as well as more advanced discussions with potential commercial and distribution partners. Being able to reference an FDA submission provides a clear signal that the device is progressing toward market entry, which is important in building confidence with customers and partners.

Importantly, this submission provides a foundation for future regulatory activity, supporting a more efficient and repeatable pathway for other Optiscan devices.

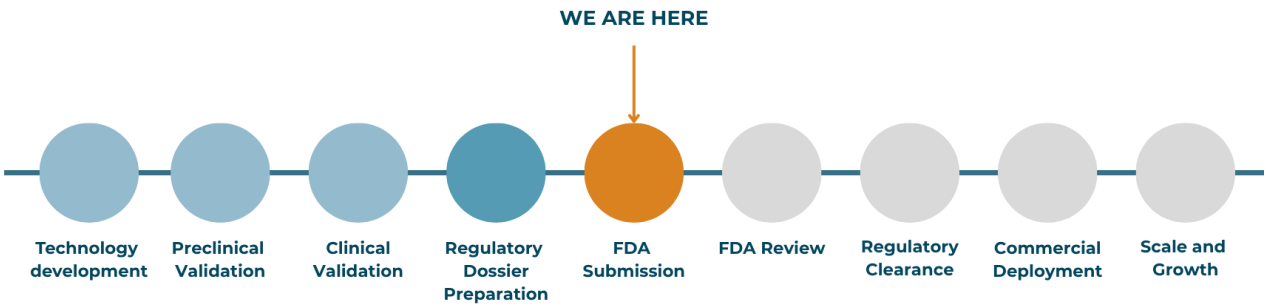

Figure 4: FDA milestone progress

STRATEGIC SIGNIFICANCE

This submission marks an important step in Optiscan's development journey. It demonstrates the Company's ability to move a device through the full pathway from concept and development, into regulatory review which is a critical capability for any company seeking to build a portfolio of medical devices and scale its business operations.

For InSpecta®, the submission represents a transition from a developed product to one that is progressing toward real-world use. For Optiscan as a whole, it reinforces the Company's strategy to build a suite of imaging devices across both clinical and veterinary applications, supported by a common technology platform.

REGULATORY SIGNIFICANCE

Preparing and submitting an FDA dossier requires a high level of detail, consistency and coordination. This submission demonstrates that Optiscan has reached a regulatory-grade standard across its documentation and internal processes. It also shows that the Company can align its engineering, clinical and regulatory activities to meet FDA requirements.

This experience is important as it is expected to reduce the time, complexity and risk associated with future submissions, supporting a more efficient regulatory pathway for other devices in the pipeline.

COMMERCIAL SIGNIFICANCE

The submission is a key step along the commercial pathway for InSpecta® as it allows Optiscan to begin more active positioning of the device within the lucrative United States veterinary market. It also supports the expansion of clinical reference sites, which play an important role in driving awareness, adoption and validation in real-world settings.

In parallel, the Company can progress discussions with potential customers, partners and distributors with greater confidence, supported by a clear regulatory pathway.

Over time, this is expected to support the establishment of an installed base and ongoing use of the device across veterinary practices. More broadly, the ability to progress devices into the regulatory phase strengthens Optiscan's commercial profile and supports future growth across its product portfolio.

CEO COMMENT

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

"Creating and lodging an FDA dossier is not a simple process. In our case, this detailed document unambiguously demonstrates Optiscan's ability to translate its complex imaging technology into a format suitable for regulatory review, a critical step in the journey toward clinical adoption. Importantly, the frameworks and capabilities developed through this process are expected to support and accelerate future submissions across our portfolio, which we are currently making excellent progress on.

"The U.S. veterinary market represents a significant opportunity for Optiscan on two counts. As well as the commercial opportunity offered by this market segment, it will also showcase the real work impact our technology can have in the treatment of animals. By introducing real-time, non-invasive imaging across the full spectrum of veterinary services, InSpecta® has the potential to fill a critical gap and help transform the way millions of companion animals are treated."

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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.

[1] https://www.grandviewresearch.com/industry-analysis/us-veterinarians-market