Nathan Graves
Investment Analyst
nathan@prenzlergroup.com.au

Joel Fishlock
Director – Equity Capital Markets
joel@prenzlergroup.com.au

Optiscan Builds Toward Dual FDA Submissions

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Company Snapshot

Company	Optiscan Imaging Limited (ASX: OIL)
Lead assets	InVue (hand-held surgical imaging probe) and InForm (bench-top pathology imaging device)
Lead indication	Real-time inspection of surgical margins
Shares on issue	1,044.2m
Share Price (8 Sep 2026)	$0.15
Market Capitalisation	$156.6m
Cash (30 Jun 2026)	$14.4m

When a surgeon cuts out a tumour, the most important question is whether they got all of it. Today that question is answered by a pathology lab, where the removed tissue is fixed, sliced, stained and read under a microscope. That takes hours to days. So, the surgeon closes the wound without knowing, and if the pathologist later finds cancer at the edge of the removed tissue (an "involved margin"), the patient comes back for a second operation. Approximately 25% of women who have a lumpectomy (breast conserving surgery or partial mastectomy) need to have a follow up surgery.

Optiscan's core technology is confocal laser endomicroscopy. In plain terms, it is a laser microscope shrunk into a pen-sized probe. Touch the probe to living tissue, with a fluorescent dye to get a cell-level image on screen instantly, without cutting a sample out or preparing a slide.

The company has packaged this into three devices:

- **InVue**, a hand-held probe for the surgeon, used inside the surgical cavity straight after the tumour is removed to look for leftover cancer.
- **InForm**, a bench-top device for pathologists that images fresh or fixed tissue instantly
- **InSpecta**, a version for veterinary clinics, launched commercially in the US.

Also in development is a cloud telepathology platform, which lets a pathologist view the live images from anywhere, an AI program with Monash University for detection and analysis, and a robotic surgery integration co-developed with Mayo Clinic.

Clinical Evidence

The strongest published numbers so far come from an oral cancer study run on an earlier-generation device, in which 47 patients with 63 lesions were imaged and the results were judged against blinded pathologists. That study reported 88.9% accuracy, 86.8% sensitivity (the share of true cancers and pre-cancers the device picked up) and 92% specificity (the share of benign lesions it correctly cleared).

The evidence for the current devices is more qualitative. An earlier breast study on removed tissue covering 50 patients and 59 tumours reported images comparable to conventional histopathology, and in the live Royal Melbourne Hospital breast study the first 18 analysed cases showed nine clear, four narrowly clear and five involved margins. What has not yet been published is a sensitivity or specificity figure for InVue or InForm measured against final pathology, and that is the number the FDA, and later surgeons, will want to see.

Ongoing Trials

On 1 September 2026 Optiscan announced it has started a 35-patient head and neck cancer study at Mayo Clinic in Rochester, Minnesota, under a new research agreement. InVue images the surgical cavity during surgery, and InForm images the removed tissue afterwards, so the study produces both in-body and out-of-body data for the FDA package.

It is the second of two planned Mayo studies. A 35-patient US breast cancer study opened for recruitment in July.

The Australian studies that feed the same evidence package are further along.

Study	Site and partner	Devices	Status
Breast cancer margins, 50 patients (AUS)	Royal Melbourne Hospital, with a second site at Frances Perry House	InVue and InForm	34 of 50 imaged at 30 June 2026
Head and neck cancer, 50 patients (AUS)	St John of God Murdoch Hospital, Perth, with Australian Clinical Labs	InVue and InForm	10 patients through Stage 1; Stage 2 live imaging started mid-July 2026
Anatomical pathology image bank (AUS)	Australian Clinical Labs, Western Australia	InForm	60 datasets across 16 tissue types at 30 June 2026, expected to reach the hundreds
Breast cancer, 35 patients (US)	Mayo Clinic Rochester	InVue and InForm	Recruiting from July 2026
Head and neck cancer, 35 patients (US)	Mayo Clinic Rochester	InVue and InForm	Recruiting from September 2026
Gastrointestinal imaging, up to 50 patients (EU)	University Medical Center Mainz, Germany	Flexible endomicroscope prototype	Ethics approved in the June quarter; site initiation under way

On the commercial side, InSpecta (the company's veterinary imaging device) was launched at the American Veterinary Medical Association convention in Anaheim on 10 July 2026, making it the company's first clinical device on sale in the US.

Next Steps

- **FDA 510(k) submissions for InVue and InForm.** Company guidance is the second half of calendar 2026.
- **Royal Melbourne breast study completion.** 34 of 50 patients at 30 June, with a second site speeding up enrolment.
- **Perth head and neck Stage 2.** Live imaging with InVue started in mid-July.
- **Mayo enrolment.** Two 35-patient studies are now open. The pace of enrolment at a single US centre will tell us how quickly the US evidence base can be built.
- **Mainz gastrointestinal study** and the CRC-P flexible endomicroscope program.

Upcoming Catalysts

Catalyst	Expected timing	Significance
U.S. FDA 510(k) submissions for InVue and InForm	H2 CY2026	Moves the human platforms into formal regulatory review and is the clearest near-term de-risking milestone.
Mayo Clinic breast and head & neck study recruitment / evidence updates	H2 CY2026 / ongoing	Adds U.S. patient data and tests the workflow in two oncology settings.
Australian breast and head & neck study progress	H2 CY2026 / ongoing	Expands evidence and the clinical dataset supporting the submissions.
FDA decisions on InVue and InForm	CY2027 [analyst estimate]	The gate to US human sales.
InSpecta U.S. commercial traction	FY27 / ongoing	First proof point for converting the imaging platform from regulatory preparation into customer adoption and revenue.

Indicative timing only. Events may be delayed, modified or may not occur.

Competitive Landscape

Optiscan is not the first company to address the "did we get it all" question in the operating theatre. Two US products for breast lumpectomy margins have been approved in the last two and a half years. Lumicell's LumiSystem, which pairs an injected fluorescent agent with a handheld scanner that lights up leftover cancer in the cavity, was approved by the FDA in April 2024 and received a permanent CMS billing code for the drug from January 2025. Perimeter Medical Imaging AI's "Claire" system, which uses a light-based scan of the removed tissue with an AI overlay, received FDA premarket approval in March 2026.

Perimeter booked US$385k of revenue in the March 2026 quarter and US$503k in the June quarter. Lumicell is private so does not disclose its revenues.

Dilon's MarginProbe has been on the market for more than a decade. Dilon is also private, so revenues are unavailable. Mauna Kea Technologies, inventor of Cellvizio and the pioneer of clinical confocal endomicroscopy and the nearest technology comparator to Optiscan, reported first-half 2026 total sales of EUR 3.2 million.

Prenzler Group Pty Ltd ABN 77 621 100 730 | Authorised Rep of AFSL 456663

Suite 1 Level 12/25 Bligh St, Sydney NSW 2000, Australia

www.prenzlergroup.com.au

ASX-listed Medtech Peers

The table below sets out ASX listed regulatory-stage medtech companies inside, or near an FDA submission/review.

Company (Ticker)	Product	Clinical Stage	Market Capitalisation (AUD, m)
EchoIQ (ASX: EIQ)	EchoSolv AS: identify severe aortic stenosis EchoSolv HF: detect heart failure	FDA cleared; HF application Received NSE determination; not cleared	948.1
Artrya (ASX: AYA)	Salix Coronary Anatomy: artery anatomy Salix Coronary Plaque: plaque analysis Salix Coronary Flow: blood flow assessment	FDA-cleared; FDA-cleared; 510(k) application is being finalised	638.7
EMVision (ASX: EMV)	emu Brain Scanner: portable bedside brain imaging with AI for suspected stroke	Pivotal validation trial underway, De Novo submission to follow	171.0
Optiscan Imaging (ASX: OIL)	InVue / InForm: surgical-margin assessment and digital pathology	U.S. clinical studies active, dual 510(k)s targeted H2 CY26	156.6
BlinkLab (ASX: BB1)	DX1: Smartphone diagnostic aid for autism	Pivotal validation underway, 510(k) targeted by end-CY26	120.3

Market Cap Source: Iress as of 8 Sep 2026

Optiscan is no longer simply demonstrating that it can build high-resolution imaging devices. FY26 produced the first FDA regulatory dossier, the first U.S. commercial launch of an Optiscan clinical device and a multi-site evidence program for the human platforms. The central investment question is now whether that evidence can be converted into timely 510(k) submissions and, after review, U.S. clearances and adoption.

The Mayo Clinic head and neck study adds a second U.S. oncology setting alongside the breast program and tests the same InVue/InForm workflow across different tissues and surgeries. Filing both 510(k)s in H2 CY2026 would materially advance the regulatory story and shift the next stage of risk toward FDA review and commercial execution. A delay would indicate that evidence, quality or documentation requirements remain a gating item. InSpecta provides a parallel, earlier commercial proof point while the human devices progress toward the U.S. market.

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