Optiscan

Immediate Informed Decisions

A validated imaging platform

taking its own products to market

Optiscan Imaging Limited

ASX: OIL

INVESTOR PRESENTATION

BELL POTTER HEALTHCARE CONFERENCE

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Investment highlights

From technology supplier to product company: two human FDA submissions filed, and manufacturing in place.

01 **Proven technology, now sold under Optiscan's own name**

The core sits inside two cleared partner-branded devices (Pentax, Carl Zeiss) and 150+ papers. In July 2026 Optiscan launched InSpecta™, its first own-brand clinical product, in the US veterinary market.

02 **Two human devices before FDA, based on Optiscan's own predicates**

InForm™ and InVue™ 510(k)s filed October 2026, seeking a general, tissue-agnostic indication. Clearances anticipated from October 2027, subject to review.

03 **A costly problem, and a buyer with a reason to adopt our technology**

Margins are judged by eye and confirmed 2–7 days later; 25–30% of breast-conserving patients return to theatre. InVue™ gives a cellular answer in seconds.

04 **Recurring revenue that scales with use, and with evolving tech over time**

Consoles placed into up to five US reference sites, then the first 10–20 accounts. Every procedure can use a single-use sheath; maintenance is contracted; Telepathology and AI products (medium-long term) create a SaaS-type model.

WHERE THE COMPANY STANDS TODAY

150+
peer-reviewed publications

3
approved devices using Optiscan's technology.

2
human FDA 510(k) submissions under review

3
device configurations, one imaging core

Catalysts start in 1H 2027 with reference-site appointments, well ahead of clearance.

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Proven by global majors, now going to market alone

Optiscan spent its formative years proving the technology inside Pentax and Carl Zeiss products.
It now manufactures, has regulatory experience and has its own product in market.

1994 — Founded in Melbourne
Miniaturised confocal imaging research

1997 — ASX listing
ASX: OIL

2002 — Pentax agreement
Core built into a GI endoscopy product Pentax ISC-1000

2007 — Carl Zeiss agreement
Core built into a neurosurgical product CONVIVO

2021 — New leadership
Dr Camile Farah appointed CEO

Jul 2026 — InSpecta™ launched
First own-brand clinical product (US vet)

Oct 2026 — Two human 510(k)s
InForm™ and InVue™ filed with FDA

THEN

Built by Optiscan, sold by partners

Pentax · GI endoscopy · FDA, CE, TGA cleared

Carl Zeiss · Neurosurgery · FDA, CE, TGA cleared



HELD BY OPTISCAN

- Technology and IP
- Clinical validation
- Manufacturing
- Regulatory files

NOW

Built and sold by Optiscan

InSpecta™
Vet · launched

InForm™
Pathology · filed

InVue™
Surgery · filed



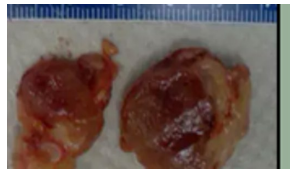
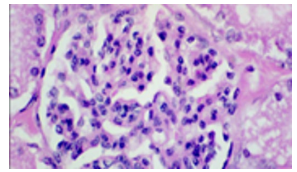
The long build is an asset. A$106m invested in the platform to date. The core is already inside cleared devices, Optiscan makes it, and InSpecta™ shows it can take its own product to market.

Company history as advised by the Company. OEM arrangements with Pentax and Carl Zeiss are historical and legacy OEM revenue is in structural decline.

The answer arrives after the decision

WHERE CONVENTIONAL PATHOLOGY LEAVES A GAP

The surgeon needs to know whether the margin is clear while the patient is still open. The conventional answer leaves the theatre and takes days, after the surgery is complete.

Resection	Fixation	Processing	Embedding	Sectioning	De-waxing	Staining	Pathologist read
							

▲ the surgical decision is made here

the answer arrives here ▲

TYPICALLY, 2–7 DAYS · treatment waits on the laboratory

Decisions made without a cellular view

Margin calls are made by eye and feel, then confirmed days later.

Re-excision and repeat procedures

Reported re-excision rates of 25-30% in breast-conserving surgery and 20-25% positive margins in head & neck cancer surgery.

Theatre time and cost

Intra-operative sampling adds time under anaesthesia. US operating room time is costed at ~$50 per minute. 23% total time savings/procedure.

With Optiscan: seconds, not days

A cellular image on screen inside the procedure, while the patient is still on the table. The decision can still be changed.

Describes conventional histopathology workflow and typical turnaround. Turnaround, re-excision rates and theatre costs vary by institution, specimen and jurisdiction. Illustrative; no clinical claim is made or implied.

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How Optiscan works, and why it is hard to copy

HOW IT WORKS

01 A probe contacts the tissue

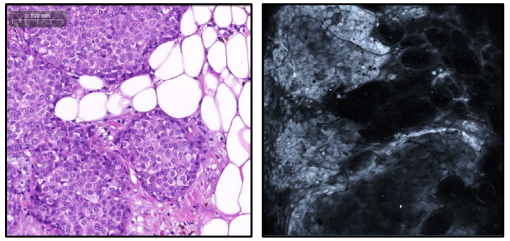
A miniaturised confocal probe images tissue where it is, in the body or freshly excised. The scanner sits at the tip, so resolution holds at the point of contact.

02 A scanning laser captures the image

Point-by-point optical sectioning gives near-histology detail at sub-cellular resolution, on screen in seconds.

03 The image is digital at capture

No slide, no scanner, no separate digitisation step. Reporting, archiving and algorithms sit directly on top.



Conventional H&E slide vs Optiscan image


Pen-sized probe


Console

WHY IT IS HARD TO COPY

Distal-end architecture

Scanning at the probe tip preserves image quality.
Proprietary, single-fibre built to ensure highest image quality and resolution.

Three decades of engineering

No direct competitor has replicated the distal probe design.

Validated to an OEM standard

Pentax and Carl Zeiss placed the core into their own cleared products.

One core, several products

The same engine is packaged for theatre, laboratory and clinic.

The barrier to entry is an engineering position built over three decades, validated by two OEM partners, with manufacturing know-how, now carried into Optiscan's own products.

Images of production ready units. H&E and Optiscan images are of same breast cancer tissue.

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Patient, hospital and surgeon all come out ahead

What a hospital value analysis committee will test. Only reviewed figures are shown; per-site outcomes follow once reference-site data is observed.

$45-55
per minute of US operating room time

10–45 min
added under anaesthesia by frozen section

25–30%
of breast-conserving surgeries need re-excision

$5,000–7,000
cost of one repeat procedure

WHO	TODAY	WITH INVUE™	WHAT THEY GET
Patient	Margin confirmed 2–7 days later. 25–30% of breast-conserving patients go back to theatre.	A cellular image in seconds, while still on the table.	Fewer second operations, anaesthetics and recoveries. Better outcomes. Less time waiting for an answer.
Hospital	Frozen section adds 10–45 min/section at $45-55 a minute. 20–30 tissue cassettes per case @ $20 a cassette.	Read inside the procedure. Modelled at 2–3 cassettes for definitive pathology. Console placed, sheath from the operating budget.	Shorter procedure time (23%), theatre capacity increased, lower lab cost, and no capital request to start.
Surgeon	Margin call made by eye and feel, or waiting in theatre on frozen section.	A cellular view in the surgeon's hand at the moment of decision.	More confidence in the margin call and fewer returns to theatre. Estimated reduction of 66%.
Payer	Pays for the repeat procedure.	Fewer repeat procedures.	$5,000–7,000 avoided for each procedure not repeated. Additional costs of adjuvant radio-chemo-therapy saved.

The case study to come. Each reference site is set up to measure theatre time saved, repeat procedures and cost per case. A named site case follows once the data is observed and signed off.

Cost and volume figures are third-party estimates and Company modelling; basis, geography and year vary by source. Benefits depend on regulatory clearance and clinical evidence. No clinical or economic outcome claim is made.

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Why we are confident on FDA clearances

Both devices were filed as 510(k)s in October 2026, seeking a general, tissue-agnostic imaging indication. Clearances are anticipated from October 2027, subject to FDA review.

InVue™

SURGERY · FILED 5 OCT 2026

Predicate	Mauna Kea Technologies Cellvizio® (K212322) cleared on the Pentax® Medical system (K042740 & K042741) built on Optiscan's core; i.v. fluorescein sodium contrast agent; reference Zeiss Convivo® (K181116)
What is different	InVue™ scans at the probe tip in seconds without image stitching; Cellvizio relays the image through a fibre bundle, stitches images before final view; lower image resolution and FOV; addressed through performance testing.
Performance	Surgeon determined image quality and clinical benefit across three tissue types. Sensitivity and specificity data not required or requested. Assessment made on imaging performance.
FDA engagement	Q-Sub Q250588 submission 3/3/2025; meetings held 8/5/2025 and 12/11/2025

40
breast patients,
Royal Melbourne Hospital

18
head & neck patients,
St John of God

3
tissue types imaged in vivo

InForm™

PATHOLOGY · FILED 1 OCT 2026

Predicate	Saman Tree Medical Histolog® Scanner (K241275) flatbed confocal system; cleared with topical acridine orange dye
What is different	InForm™ scans at the probe tip in seconds without image stitching; Histolog® uses multi-scanner images stitched to create final image; lower image resolution and FOV; addressed through performance testing.
Performance	Pathologist determined image quality, clinical benefit and concordance against histology for multiple tissue types. Sensitivity and specificity data not required or requested. Assessment made on imaging performance.
FDA engagement	Q-Sub Q253726 submission 23/12/25: written feedback 9/3/2026

>85
datasets, Australian Clinical Labs

>10
anatomies

>15
pathologies imaged
in the path lab

Common to both. Quality system and manufacturing exercised through the Pentax and Zeiss programs and InSpecta™. Optiscan's core sits in the predicate chain. The vet pathway is separate and does not predict human clearance.

Regulatory status as at the date of this presentation. Clearance is subject to FDA review; no assurance is given that it will be obtained, or within any timeframe.

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Place the console, earn on every procedure

In the first years, consoles are placed to drive procedures and adoption. Revenue comes from the sheath and service, then capital sales or leasing, with software and AI on top once cleared.

GROW INSTALLED BASE AND CONSUMABLES

HARDWARE · PLACED

Console

Place at 5 reference sites, InVue™ and InForm™

Option to rent, to remove the capital hurdle

Moves to purchase or lease after committee review

Indicative capital cost USD$250K-350K based on closest competitors

CONSUMABLE · PER PROCEDURE

Sterile sheath

Sale price USD$150 per procedure, InVue™ only

Gross margin >80%

OptiSheath™ FDA pathway: 510(k) submission H1CY27, clearance expected H2CY27 (must follow InVue™)

MAINTENANCE · ANNUAL

Service contract

Annual fee 15% cost of console

Gross margin 50%+

Tied to the installed base

SOFTWARE · LATER

Telepathology + AI

Subscription, SaaS model

Separate FDA clearances needed

Not in the near-term revenue line

REIMBURSEMENT IS AN ACCELERANT, NOT A DEPENDENCY

LAYER 1 · TODAY

No new code assumed

In the placement phase, the site is expected to fund the device rental, consumable and service from its existing budget.

LAYER 2 · EXISTING CODES

Where they apply

Confocal endomicroscopy has CPT Medicare coverage precedent in GI procedures (via Pentax® device). CPT 43206 (ACS $809 / Outpatient $1,662) & CPT 43252 (ACS $834 / Outpatient $1,687). CPT 88375 pathology reporting ($45).

LAYER 3 · OVER TIME

Dedicated coding

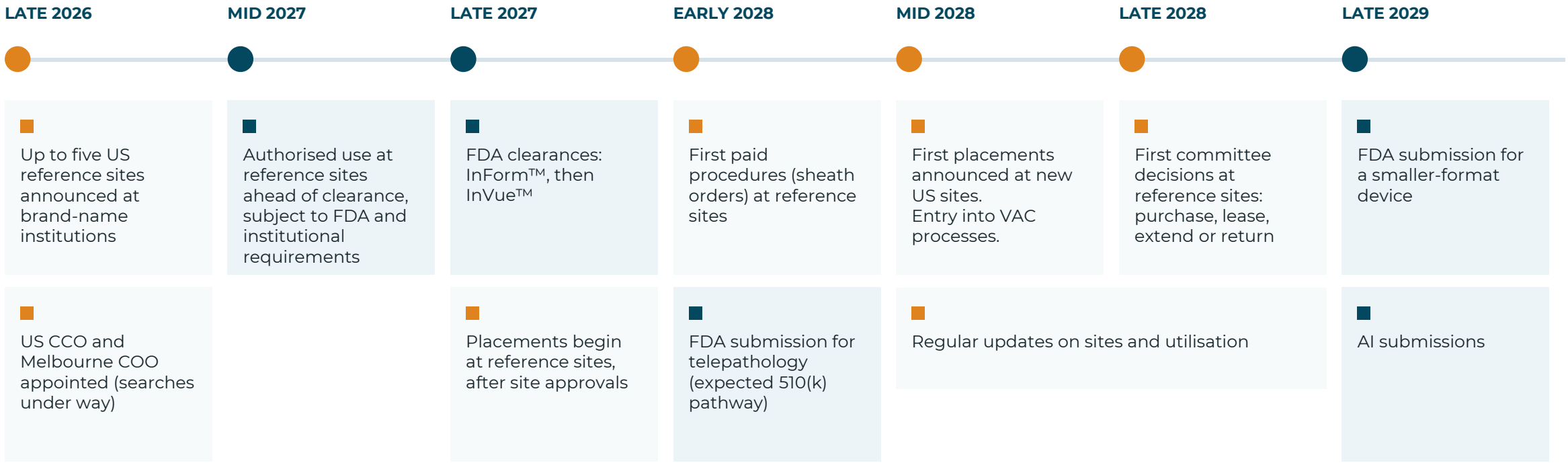
Coding specific to digital tools continues to evolve. Progression follows evidence and larger pools of health economic data, and evidence follows the reference-account program. Coding strategy will evolve over time.

Pricing, margins and placement terms are Company assumptions, not final. Reimbursement and coding outcomes are not within the Company's control. CPT applicability to breast, head & neck or laboratory settings is not assumed. Software revenue is subject to separate FDA clearance. Not a forecast.

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Milestones begin in 1H 2027, ahead of clearance

Indicative sequence. Each milestone depends on FDA review, site agreements and execution; regulatory and commercial events are shown separately.



Sequence and timing as assessed by the Company and indicative only. Clearance timing is subject to FDA review; ethics approvals and site appointments are not within the Company's sole control. No quantum or probability is asserted. Not a forecast.



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