Optiscan

*Immediate Informed Decisions*

# A validated imaging platform *taking its own products to market*

**Optiscan Imaging Limited**

**ASX: OIL**

INVESTOR PRESENTATION

NOVEMBER 2026

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Regulatory status statements are as at the date of this presentation. Submission and clearance timing for InVue™ and InForm™ is anticipated and subject to regulatory review; no assurance is given that any clearance will be obtained or obtained within any particular timeframe. Veterinary market entry and human 510(k) clearance are separate regulatory pathways and one is not a predictor of the other. Statements regarding reimbursement are not within the Company's control.

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# Meet the CEO



**Dr Camile Farah**

Chief Executive Officer

Dr Camile Farah (PhD, MBA, MAICD, FAIM, FLWA) is CEO & Managing Director of Optiscan Imaging Ltd and its US subsidiary Optiscan Imaging, Inc. Camile is a medtech executive and board director with a background in healthcare, medical research, industry and academia spanning 25 years. Camile holds multiple degrees and fellowships in pathology, oncology, higher education, business management and leadership, and is a prolific author and international speaker. Camile has held various senior leadership roles in public and private clinical, research and academic institutions in dentistry, maxillofacial medicine, oncology, and head and neck pathology.

Under Camile's leadership, Optiscan is undergoing a digital transformation developing digital pathology and precision surgery hardware and software solutions enabling live optical biopsy for diagnostic and surgical applications including cloud-based telepathology and AI/ML solutions for intraoperative digital workflows, an endomicroscopic imaging system for robotic-assisted surgery, and a growing portfolio of point-of-care products to tackle large addressable markets including oral, breast, gastrointestinal, and veterinary imaging. Camile has expanded Optiscan's geographical footprint and raised millions of dollars in dilutive and non-dilutive capital and overseen the establishment of strategic partnerships and collaborations. He is a shareholder of the Company.

# 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 previously cleared partner-branded devices (Pentax, Carl Zeiss). 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.

# 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 Patents**
- **IP & Know-how**
- **Manufacturing**
- **Clinical validation**
- **Regulatory files**

NOW

**Built and sold by Optiscan**

**InSpecta™**
Vet · launched

**InForm™**
Pathology · filed

**InVue™**
Surgery · filed




The long build is an asset. A$106 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. Delivering unrivalled sub-cellular resolution that is >1000x that of a CT or MRI.

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

# See it in use – Watch the device in theatre and in the lab

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inVue by Optiscan

InVue™ Product Video

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INFORM by Optiscan

InForm™ Product Video

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# Validated by tier 1 institutions

The clinical studies behind both FDA submissions run at these institutions, on top of an independent literature base of more than 150 peer-reviewed papers.

## Mayo Clinic

TIER 1 · MAYO CLINIC, UNITED STATES

Two research agreements (2026). InVue™ and InForm™ in breast and head & neck cancer surgery, up to 35 US patients each.

Know-how agreement for robotic-assisted surgery imaging (2024-2026).

"Over the past two years, the collaboration with Optiscan has provided an important opportunity to explore how real-time microscopic imaging may be integrated into robotic-assisted surgery workflows. The progress achieved to date reflects a strong combination of clinical insight and technical development, and we look forward to continuing to evaluate the potential of Optiscan's technology to support more informed intraoperative decision-making in the future."

Dr Mara Piltin,
Breast & Robotic Surgeon



## OTHER CLINICAL PARTNERS

### The Royal Melbourne Hospital

Breast cancer surgery · InVue™ and InForm™ · 40 of 50 patients, ongoing

### St John of God Murdoch Hospital

Head & neck cancer surgery · InVue™ and InForm™ · 20 of 50 patients, ongoing

### Universitätsmedizin Mainz

GI observational study · flexible endomicroscope prototype · up to 50 patients, ongoing

### Australian Clinical Labs

InForm™ across multiple tissue and pathology types · >85 datasets, ongoing

**150+** peer-reviewed publications, built by third-party researchers and clinicians; a significant competitive advantage against new entrants

**2** global OEM partners (Pentax, Carl Zeiss) put the optics through their own engineering and regulatory scrutiny

**5+** clinical and academic institutions across robotic surgery, breast, head & neck and GI

Minimum study progress as reported in the quarterly activities report to 30 September 2026. OEM arrangements are historical.

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# Strong management track record

Clinical, commercial and capital-markets experience in place. The US commercial lead is the critical hire; the search is under way. COO will own operations and scale manufacturing; search under way. Strong alignment between Board and Management.

## MANAGEMENT



### Dr Camile Farah

Chief Executive Officer

Dr Camile Farah (PhD, MBA, MAICD, FAIM, FLWA) is CEO & Managing Director of Optiscan Imaging Ltd and its US subsidiary Optiscan Imaging, Inc. Camile is a medtech executive and board director with a background in healthcare, medical research, industry and academia spanning 25 years. Camile holds multiple degrees and fellowships in pathology, oncology, higher education, business management and leadership, and is a prolific author and international speaker. Camile has held various senior leadership roles in public and private clinical, research and academic institutions in dentistry, maxillofacial medicine, oncology, and head and neck pathology.



### Darius Ooi

Chief Financial Officer

Darius Ooi is the Chief Financial Officer at Optiscan Imaging. With extensive experience in the MedTech industry, Darius is passionate about translating commercial success into improved patient outcomes. He has led several finance transformation projects, resulting in significant efficiencies and savings through technology. At Optiscan, Darius continues to build the finance team and infrastructure, positioning the company for global scalability.



### Sanchitha Fernando

Chief Technology Officer

Dr Sanchitha Fernando (PhD) is the Chief Technology Officer at Optiscan Imaging. With a doctorate in Micro Electro Mechanical Systems, he has a proven track record in solving complex engineering problems. Sanchitha's experience spans semiconductors, electronics, optics, signal processing, software, navigation, acoustics, telecommunications, and solar energy. He excels in leading interdisciplinary projects and has built public-private partnerships to commercialize research outcomes, making significant advancements in the field of medical technology.



### Jessica Ward

Director of Clinical and Regulatory Affairs

Jessica Ward is the Director of Clinical and Regulatory Affairs at Optiscan Imaging. With over 20 years of experience in clinical research and medical affairs, she brings extensive expertise from both the medical device and academic sectors. Known for her dynamic and engaging leadership style, Jessica has built and led high-performing, diverse clinical affairs teams that consistently deliver exceptional results. Her teams have played a crucial role in supporting new product launches, securing regulatory clearances, and advancing reimbursement and market access initiatives across various medical specialties. Previously, Jessica was the Manager of Medical Affairs and Clinical Affairs at Stryker. Prior to Stryker, she was engaged in preclinical and clinical research initiatives as well as physician training programs at Atrium Health, a North Carolina-based hospital system and part of the third-largest nonprofit health system in the United States.

## BOARD

**Robert Cooke · Non-Executive Chair**

Former MD and CEO, Healthscope
Current Chair, GenesisCare

**Karen Borg · Non-Executive Director**

CEO, SomnoMed; former ResMed President APAC & ME

**Ron Song · Non-Executive Director**

Former Managing Director, Premium Automobiles (Singapore)

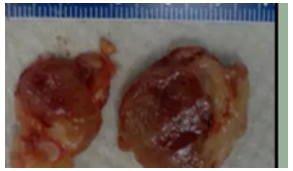
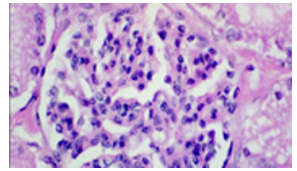
**Russell Low · Non-Executive Director**

Clermont Group; Singapore

# The answer arrives after the decision

**WHERE CONVENTIONAL PATHOLOGY LEAVES A GAP; TYPICALLY, 2–7 DAYS · treatment waits on the laboratory**

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 ▲

## THE VALUE

### SURGEONS: Decisions made without a cellular view

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

### PATIENTS: 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.

### HOSPITALS: Theatre time and costs

Intra-operative sampling adds time under anaesthesia. US operating room time costs ~$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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# Pathology has not had its radiology moment

Radiology went digital at the point of capture and software followed. Pathology only digitises at the end of an analogue workflow. Optiscan starts digital.

### RADIOLOGY · DIGITISED AT THE POINT OF CAPTURE

**1980s–90s**
**Film gives way to digital detectors**

**1993**
**DICOM standard published**

**2015 ONWARD**
**Algorithms read alongside the radiologist**

### PATHOLOGY · DIGITISED AT THE END OF THE WORKFLOW

**TODAY**
**Tissue still travels as glass**

**2017**
**First FDA clearance for whole-slide imaging**

**NOW**
**Scanning digitises the output only**

### FDA AI-ENABLED AUTHORISATIONS TO DEC 2025




Algorithms follow digital images. Pathology has not built that base.

### EVERYONE ELSE · DIGITISES THE OUTPUT

| | | | |
|---|---|---|---|
| Resection | Fixation | Processing | Embedding |
| Sectioning | Staining | Glass slide | Slide scanning |

STILL 2–7 DAYS · more equipment, consumables and handling

### OPTISCAN · STARTS DIGITAL

| | |
|---|---|
| Tissue imaged in situ or freshly excised | Digital image at the point of capture |

SECONDS · no block, no slide, no scanner

**Optiscan is not another slide scanner competing at the back end. It sits at a point in the workflow a scanner cannot reach.**

**Optiscan starts where radiology started. The image is digital at capture, so telepathology and AI algorithms can sit directly on it.**

An analogy, not a forecast. Source: FDA AI-enabled medical device list to December 2025. Turnaround varies by institution, specimen and service. Comparison prepared by Optiscan from publicly available information.

# How Optiscan works, and why it is hard to copy

## HOW IT WORKS

### 01 A probe contacts the tissue

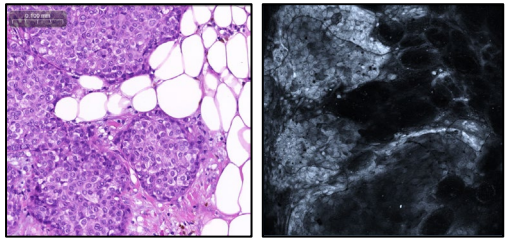
A miniaturised confocal probe images tissue where it is, in the body or freshly excised. The scanner sits at the tip, so resolution holds at the point of contact.

### 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.
H&E: Hematoxylin and eosin microscopy: the gold-standard histological technique in clinical pathology. CLE: Confocal laser endomicroscopy, also known as an "optical biopsy"

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# One imaging core, deliberately prioritised

One miniaturised confocal core, packaged for three settings: operating theatre, pathology laboratory, clinic.

**ONE IMAGING CORE**



## CORE PRODUCT PORTFOLIO

| | | |
|---|---|---|
| **InVue™** | Surgery — intraoperative cellular imaging | FDA-gated. The largest addressable markets, and the full recurring stack of console, consumable (OptiSheath™) and software. |
| **InForm™** | Pathology — digital, real-time reads | |

## ABILITY TO EXECUTE

| | | |
|---|---|---|
| **InSpecta™** | Veterinary — launched in market (US) | Regulatory execution demonstrated; distributor to be appointed. Generates revenue and usage evidence ahead of the human franchises. |

## FUTURE SCALABLE GROWTH

| | | |
|---|---|---|
| **Telepathology** | SaaS tool allowing real-time remote consultation | MVP Completed. Allows surgeons ability to consult with a pathologist in real-time. Medium term opportunity. |
| **AI/ML** | Decision-support algorithms in development | Faster, more accurate clinical decisions. Each algorithm requires its own regulatory review. |
| **Robotics** | Integrated into the surgical workflow itself | Opens up minimally invasive surgery; integration demonstrated; robotic-manufacturer agnostic. |
| **Flexible scope** | Next-generation endoscopy platform | Further miniaturised; opens up colonoscopy, endoscopy and bronchoscopy; scope manufacturer agnostic. |

Product status as at the date of this presentation. Pre-clinical and life-sciences programs are no longer a resourcing priority. OptiSheath™ is subject to its own FDA clearance pathway. No market size, revenue or timing is asserted.

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# InVue™: Starting where the margin question is sharpest

InVue™ puts a cellular view in the surgeon's hand during the procedure. It starts in breast, head and neck cancer surgery, with other tissue types to follow, under a general imaging (not diagnostic) indication sought from FDA.

WHERE IT STARTS

## Breast, head, and neck cancers

Breast-conserving surgery and head & neck cancer surgery: high volumes, a margin decision made by eye and touch, and a costly second operation or additional treatment when it is wrong.

Initial beachhead markets within the 510(k) for imaging (not diagnostic), with success in 3 tissue types as supportive of a broader tissue approval.

>350,000 breast cancer cases pa

>70,000 head and neck cancer cases pa

WHERE IT GOES

## Other solid-tumour surgery

A general, tissue- and cancer-agnostic imaging indication sought, so further surgical indications do not need a new device.

Future studies in colorectal and genitourinary will support broader use.

HOW IT GROWS

## Open, robotic, flexible

Open surgery first. The same probe is being integrated with DaVinci surgical robots, and a flexible format is in development: the same core reaching more procedures.

1,800 US oncology centres; 250–500 cases per site each year (breast and head and neck). The initial addressable base, before any further indication.

Indication scope is subject to FDA review. Robotic integration and flexible formats are in pre-clinical development. Site and case counts are Company estimates and are not a penetration assumption. Not a forecast.

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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

**30–45 min**
added under anaesthesia by traditional frozen section per cycle

**25–30%**
of breast-conserving surgeries need re-excision; 15-25% positive margin rates in head and neck cancers

**$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.<br>Cost of each frozen section cycle from is $65. | Read inside procedure reduces time and OR costs.<br>Reduces cost of each section cycle to $41 (37%).<br>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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# InForm™: a faster read, and a better margin for the lab

InForm™ images fresh or fixed tissue in the pathology lab and gives a digital read in seconds, ahead of the slide workflow.

WHERE IT STARTS

## Tier 1 hospital labs

Labs handling surgical specimens, starting with breast and head & neck tissue, where a fast answer changes the surgical decision.

WHERE IT GOES

## More tissues, more labs

A tissue- and cancer-agnostic indication sought; a wide range of tissues has been imaged and presented to FDA.

HOW IT GROWS

## Telepathology and AI

The image is digital at capture, so a remote pathologist can read it live and algorithms can sit on it. Each needs its own clearance.

### THE LAB IS PAID FOR THE REPORT, NOT THE INPUTS

| | TODAY | WITH INFORM™ |
|---|---|---|
| **Cassettes per case** | 30 | 3 |
| **Consumables per case** | $330 | $33 |
| **Technician input** | 8 min / cassette<br>$6 / cassette | 80% less time/case,<br>$162 saved/case,<br>~50% gain in tech time |
| **Turnaround** | 2–7 days | Seconds to first read |

**IF THE REPORT AND FEE ARE UNCHANGED**

Lower cost per case, so a higher margin on every report.

More cases through the same staff and equipment, less consumables.

Frozen lab: doubles throughout, 30% reduction capex and service costs, 60% reduction in consumable costs, 50% savings average overall.

Histo lab definitive path savings per case: $309

**2,400 US Tier 1 laboratories as the initial addressable base; a further 4,000 community laboratories over time.**

Cassette numbers, costs and turnaround figures are Company modelling and general practice estimates. Lab reimbursement varies by jurisdiction and payer. Indication scope is subject to FDA review. Not a forecast.

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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 by October 2027, subject to FDA review. InForm™ may clear before InVue™. Commercial preparation commencing now.

## 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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# In practice: what surgeons and pathologists say

Clinicians who have used the devices in Optiscan's studies, and the leaders who will champion them.

**SURGEON · INVUE™**

"Despite the prevalence of breast cancer surgery globally, surgeons still have limited access to immediate, detailed information during procedures."

"We are pleased with the progress of this study, particularly its exploration of real-time tissue assessment during surgery. These technologies may give surgeons more immediate insight during procedures and open up new possibilities to potentially reduce the need for re-operative surgeries."



Professor Bruce Mann
Breast Surgeon, Royal Melbourne Hospital

**PATHOLOGIST · INFORM™**

"Having InForm™ operating within our anatomical pathology laboratory provides a unique opportunity to evaluate real-time, slide-free cellular imaging in a genuine clinical environment. Importantly, our pathologists and laboratory scientists are able to assess the technology across a diverse range of tissue types and clinical scenarios, while providing direct feedback on its potential integration into everyday pathology workflows."



Associate Professor Marissa Muller
Clinical Director & Anatomical Pathologist,
Australian Clinical Labs

**KEY OPINION LEADER**

"If we can then tag those fluorescent dyes with specific molecular labels to actually label the cells that this probe system can see, that is nearly a holy grail in terms of identifying these malignant cells that we need to get out. That would be an incredible advantage for these patients."



Professor Mark Preul
Neurosurgeon and Director of Neurosurgery Research, Barrow Neurological Institute

Testimonials reflect the views of the individuals named and are not a clinical claim.

# No single alternative covers the whole workflow

Other approaches are strong on individual attributes, mostly in breast only. Optiscan covers all four, in theatre and in the lab, from one core.

| IN THE THEATRE · IN VIVO | Live or fresh tissue | Sub-cellular resolution | Result within the procedure | Digitally native | INDICATION SCOPE |
|---|---|---|---|---|---|
| **Optiscan InVue™ (indication sought)** | ● | ● | ● | ● | In vivo, tissue and cancer agnostic |
| **Mauna Kea (Cellvizio®, proximal pCLE)** | ● | ○ | ● | ● | Endoscopic indications, GI |
| **Perimeter (Claire™ OCT)** | ● | ○ | ● | ● | Breast specific |
| **Dilon (MarginProbe® RF spectroscopy)** | ● | – | ● | ○ | Breast specific |
| **Lumicell (Lumisight™ fluorescence)** | ● | – | ● | ○ | Breast specific |
| **OncoRes (OCT + elastography)** | ● | – | ● | ○ | Breast specific |
| **IN THE LABORATORY · EX VIVO** | | | | | |
| **Optiscan InForm™ (indication sought)** | ● | ● | ● | ● | Ex vivo, tissue and cancer agnostic |
| **SamanTree (Histolog® confocal scanner)** | ○ | ○ | ● | ● | Broad margin indication |
| **Frozen section (rapid analogue)** | ○ | ● | ○ | – | Broad, but out of field |
| **Whole-slide imaging scanners** | – | ● | – | ● | Broad, ex vivo only |
| **Invenio (NIO® Simulated Raman Histology)** | ● | ● | ● | ● | Destructive, small samples required |

### The indication argument

Most alternatives are breast only. Optiscan seeks a tissue- and cancer-agnostic indication in one submission per device, rather than building indication by indication.

### Complementary, not just competing

Digital pathology platforms, AI developers, surgical robotics and reference labs are adjacent categories where the platform adds to the workflow.

● full ○ partial or indication-limited – not applicable

Optiscan scored on design and indication sought; others on marketed indications as publicly described. SamanTree Histolog® received FDA 510(k) clearance in 2024. Indication scope is subject to FDA review. NIO® CE but not FDA cleared.

# 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.

# The US commercial opportunity

Sized from the number of sites that could realistically use each product, and the recurring revenue each site generates.

SURGERY · InVue™

**1,800**

**US oncology surgical centres**
**Capital equipment or leasing model**

| | |
|---|---|
| **Procedures per year** | 250–500 per site; estimate >500,000 total |
| **Consumable opportunity** | USD$150 per procedure; >USD$75M market opportunity annually |
| **Maintenance opportunity** | USD$40K indicative base fee per device based on closest competitors |

PATHOLOGY · InForm™

**2,400**

**US Tier 1 laboratories**
**Capital equipment or leasing model**

| | |
|---|---|
| **Further labs, longer term** | 4,000 community laboratories |
| **Service opportunity** | USD$40K indicative base fee per device based on closest competitors |
| **Software opportunity** | Subject to separate clearance; not yet sized |

**Every console placed opens recurring sheath (InVue™ only) and service revenue; telepathology software and AI sits on top once cleared.**

Site counts and procedure volumes are Company estimates and are indicative of addressable scope, not of pipeline, target or penetration. Dollar figures to be derived from Company pricing assumptions. Not a forecast.

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# Limited market release: five US reference sites first

The console goes in first and the capital decision comes later, so procedures and consumable revenue start sooner. The team is sized to the release.

**01**
### Clinical champion
A surgeon or pathologist sponsors evaluation.
Pre-clearance

**02**
### Reference site appointed
Brand-name academic site joins; pre-clearance use limited to authorised studies.
1H 2027

**03**
### Console placed
No capital request. Sheath and service from the operating budget.
First 12 months

**04**
### Evidence and VAC
Outcomes published; the committee reviews benefit, workflow and cost.
~12 months after placement

**05**
### Purchase, lease or return
Purchase plus consumable, or leasing. Declined consoles are redeployed.
From late 2028

**06**
### Expand within the site
More service lines and consoles; utilisation builds.
Ongoing

## SUPPORTING TEAM

| ROLE | WHERE | NO. | WHAT THEY DO |
|---|---|---|---|
| **Chief Commercial Officer** | US | 1 | Leads the US release; search concluding Q2FY27 |
| **Clinical specialists** | US | 5 | One per reference site: training and early adoption |
| **Field service technician** | US | 1 | Installation and maintenance |
| **Chief Operating Officer** | Melbourne | 1 | Manufacturing scale-up; search concluded Q2FY27 |
| **Manufacturing technicians** | Melbourne | 3 | Three appointed Q2FY27 |

## GEOGRAPHY

### United States
The focus: reference sites and the placement release.

### Australia
HQ, R&D and manufacturing. Australian reference sites: RMH, SJOG, ACL

### Rest of world
Partnerships or licensing considered after FDA clearance.

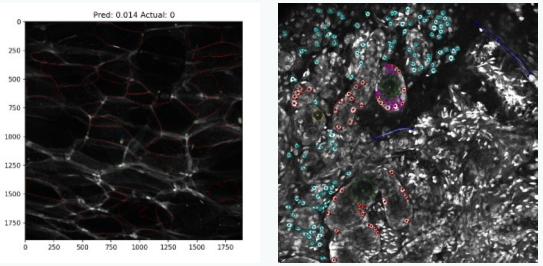
Indicative of US hospital practice; cycle lengths vary by institution. The placement model, its duration and team sizing remain subject to Company confirmation. Appointments are searches in progress. Not a forecast.

# Technology pipeline: the same core, taken further

Each stage builds on the one before. The case rests on the device and the consumable; the pipeline is upside investors are not being asked to fund.

SOFTWARE · SAAS LAYER

## Telepathology and AI




Cloud telepathology: MVP completed 2025. Anticipated 510(k) pathway 2028 post device clearance.

Decision-support algorithms in breast and head & neck first followed by GI. First likely De Novo.

Optiscan creates, processes and stores its own images, so the data is proprietary and grows with utilization and the installed base.

ROBOTIC INTEGRATION

## Probe on the robotic arm



Cellular detail reaches the surgeon without leaving the robot console.

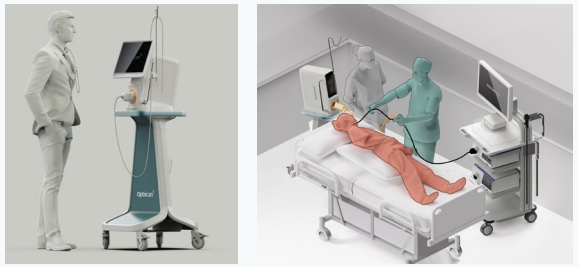
Vendor-agnostic. Intuitive da Vinci first target.

Know-how agreement with Mayo Clinic.

Engineering integration completed. Preclinical and clinical studies to be commenced.

FLEXIBLE SCOPES · GI

## Next-generation endomicroscope



Sized for the working channel of a standard flexible scope.

Prototype in an observational GI study at Universitätsmedizin Mainz (up to 50 patients).

Potential reach to c.10,000 US endoscopy sites.

Applicable for colonoscopy, endoscopy and bronchoscopy in addition to minimally invasive procedures and robotics.

**CORE** InVue™ · InForm™ · OptiSheath™ · InSpecta™

**ADJACENT** Telepathology · AI-assist

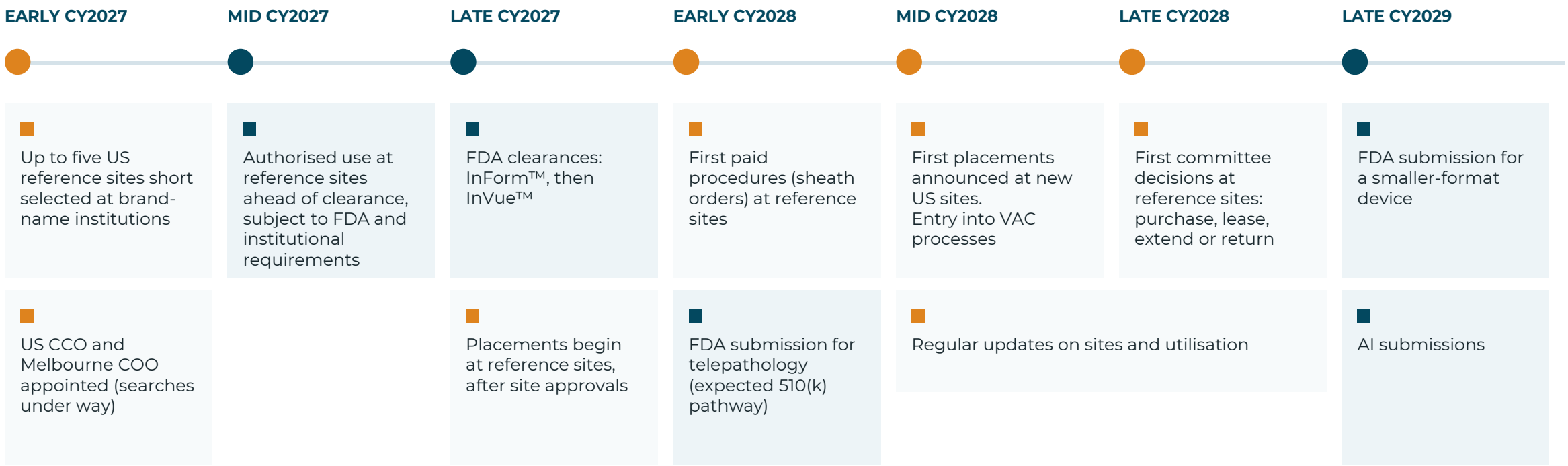
**PLATFORM** Robotics · flexible GI

Programs are pre-clinical or in development, evidence-gated and subject to regulatory review and funding. No market size, revenue or timing is asserted.

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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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