



The Global Leader in Digital Microscopic Imaging





- Global leader in 'in vivo' confocal cellular level imaging for medical, translational and pre-clinical applications
- Est. 1994, ASX listed medical device company
- Unique, patented cutting edge technology:
 - ✓ Sub-cellular, 3D live microscopic imaging
 - \checkmark Real time clinical decision making
 - ✓ Earlier: detection, diagnosis & treatment
- Platform technology with broad applications:
 - \checkmark Gastrointestinal, breast, oral and cervical

Financial Snapshot



HQ | Mulgrave, Victoria, Australia

Market cap | A\$65m

Revenue FY21 | A\$1.0m (+14% YoY)

Cash on hand¹ | A\$4.5m

Last quarter burn¹ | A\$1.4m



Institutional² | Clermont Group 14.4%

Optiscan Price and Volume – 6 months to Oct 4 2022





Optiscan Board



Prof. Camile Farah CEO & Managing Director

Dual trained physician and pathologist. Clinical trial expertise Worldwide top-ten ranked expert in Oral Medicine¹ Robert Cooke Chairman

40-year career in health industry

Executive leadership roles in healthcare companies in Australia, Asia and UK Sean Gardiner Non-Executive Director

Managing Director of Clermont Capital, Singapore 20 years' experience in equity research, senior roles at Morgan Stanley Karen Borg Non-Executive Director

Medtech leader who has held senior executive roles in private and public sector Formerly with Johnson & Johnson in US Ron Song Non-Executive Director

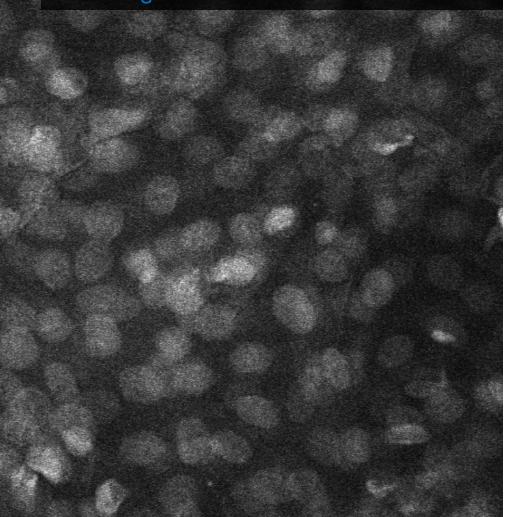
Track record of developing highly profitable ventures Network of global contacts

I. Expertscape



Key Global Challenge

I. High Global Prevalence of Cancer



Oral Cancer: Key Facts¹

- 400m with abnormal oral tissue
- 12-20m with abnormal tissue will have oral cancer
- Annual incidence: 300k people
- Prevalence: 600k people
- 20% of adult population has an oral mucosal lesion,

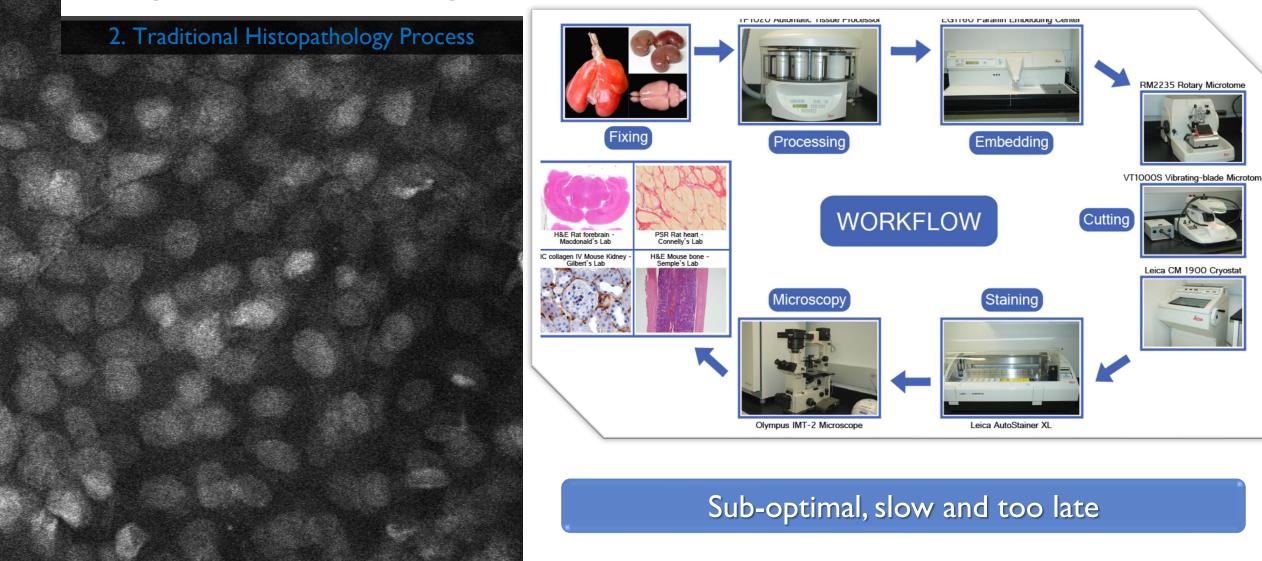
requiring investigation to avoid oral cancer progression

Solution: Early Detection, Diagnosis & Treatment

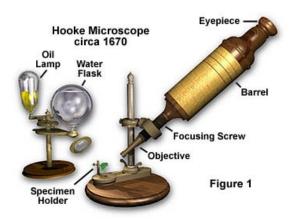
I. Based on Farah, C.S., et al., Oral Mucosal Malignancies, in Contemporary Oral Medicine: A Comprehensive Approach to Clinical Practice, C.S. Farah, R. Balasubramaniam, and M.J. McCullough, Editors. 2018, Springer International Publishing: Cham. p. 1-188. https://doi.org/10.1007/978-3-319-28100-1_21-1



Key Global Challenge



Traditional Histopathology vs. Optiscan Technology



Traditional Histopathology: Challenges

X Hours to days to receive clinical feedback
X 'Single point in time' understanding of tissue status
X Pathologist/Clinicians separated. Communication issues
X Samples only a small fraction of possible diseased area

Traditional Histopathology: Impacts

- x Delayed clinical decisions
- x Negative patient outcomes
- x Increased healthcare system costs
- x Incomplete disease identification



Optiscan technology offers...

- ✓ Real time, *in vivo* clinical feedback. Non-invasive
- ✓ Monitor (same point) over time. Track treatment effects
- ✓ Pathologist / Clinician collaborate via digital workflow
- ✓ Unlimited sampling across diseased tissue

Optiscan technology enables...

- Immediate, informed clinical decisions & collaboration
- ✓ Improved patient outcomes
- ✓ Greater economic efficiencies in healthcare systems
- ✓ Opportunity to continuously image and monitor disease

Immediate Informed Decisions

I. Based on Farah, C.S., et al., Oral Mucosal Malignancies, in Contemporary Oral Medicine: A Comprehensive Approach to Clinical Practice, C.S. Farah, R. Balasubramaniam, and M.J. McCullough, Editors. 2018, Springer International Publishing: Cham. p. 1-188. https://doi.org/10.1007/978-3-319-28100-1_21-1





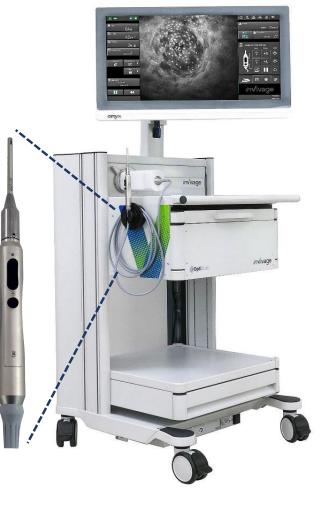
Product Range



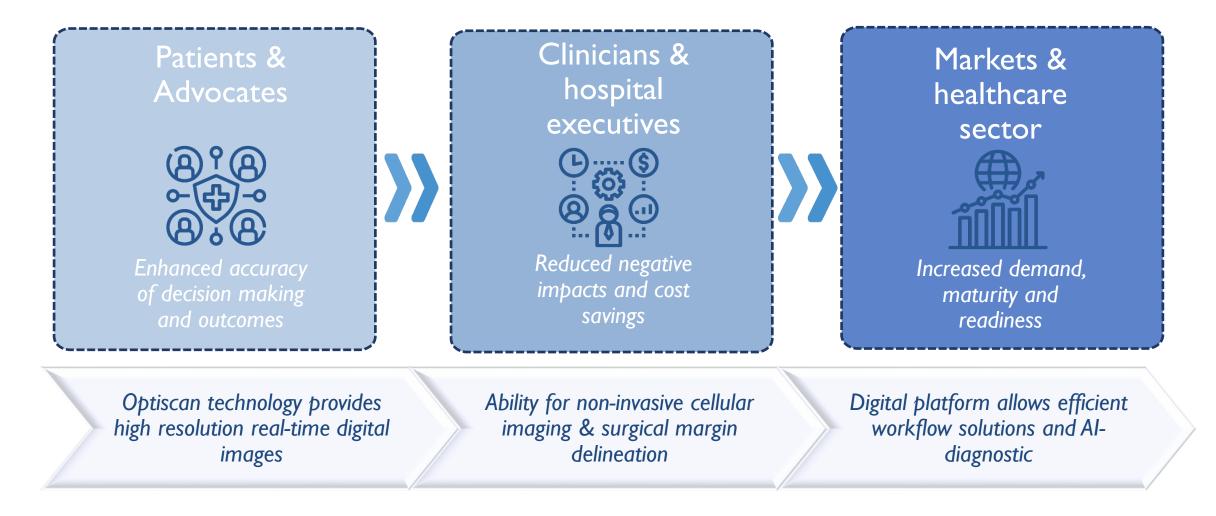
Life Sciences - Research







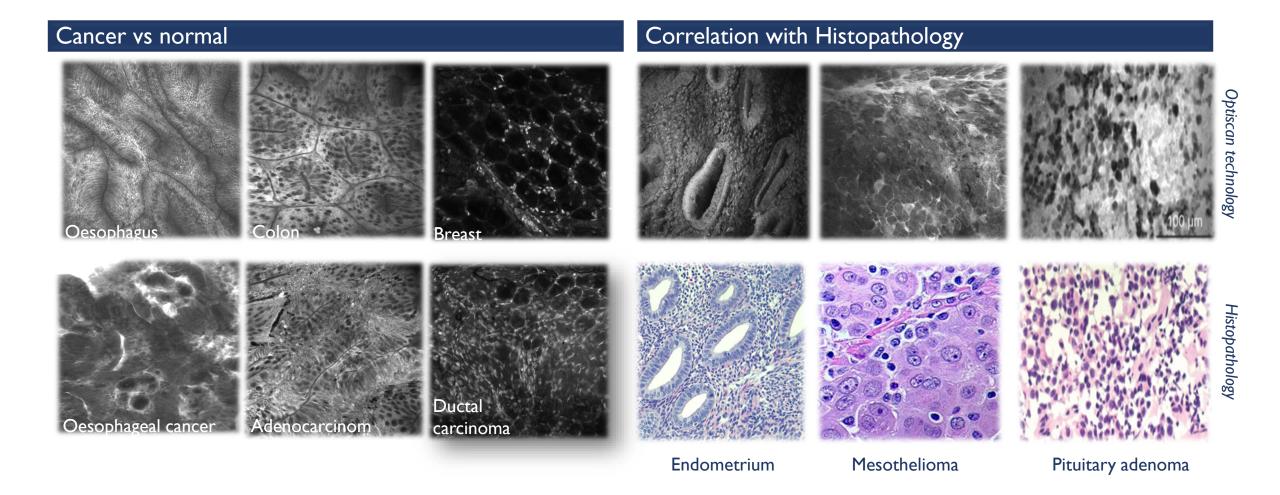
Optiscan Customer Value Proposition



A new standard of care in digital pathology & precision surgery



Excellent Correlation to Conventional Histopathology



Enabling a Digital Workflow within Health Systems





Key Strategic Milestones



Pentax (historical)

- Flexible endoscope
 opportunity
- Carl Zeiss Meditec
- Currently manufacturing CONVIVO (Neurosurgical)

Legacy OEM Portfolio



2 Hero Products

- ViewnVivo[®]: Life Sciences device, launched 2018.
- InVivage[®]: Clinical device (oral cancer) launching 2023

New Optiscan

Imaging Portfolio

Technology Enhancements

Enhanced resolution



Distribution Partners

- Established presence and structure in Asia Pacific
- All partners trained, nurtured and engaged
- Geo-Market Expansion
- US, EU and UK



Clinical Trials

- <u>Australia:</u>WEHI, Melbourne Uni, Adelaide Uni, ACOORE, RMH, Epworth Hospital, Frances Perry House
- <u>US:</u> Barrow Neurological Institute (Arizona), and Memorial Sloan Kettering Cancer Center (NY)

Build

Comprehensive

Clinical Evidence

Program



Diagnostic Alignment with Frozen Section (31 tumours, 10.7k CLE images) • Acc (94%), Sensitivity (94%), Specificity (100%)

Diagnostic Concordance (telepathology s/ware platform in neurology)

96% between CLE video & frozen section

Royal Dental Hosp of Melb

 Imaging multiple oral tissues and lesions with topical fluorescein

Australian Centre for Oral Oncology Research & Ed

- 100% oral cancers diagnosed
- Immediate diagnostic capability of normal, dysplastic & cancer cells, residual cells, margin map, wound resection interrogation

Deliver Digital Pathology Solutions

Strategic evolution into pure-play medical device company

Rapid global expansion

Establish Strong

Distribution

Network

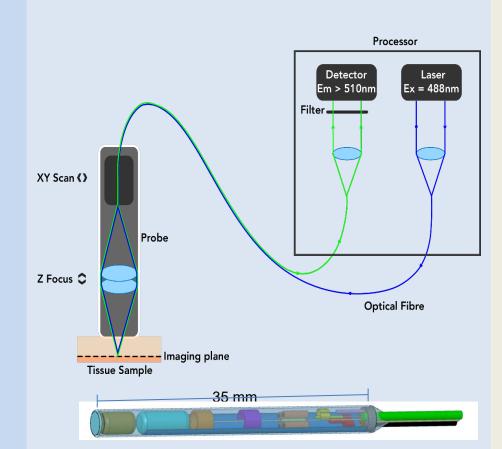
Progress to a new standard of care in precision healthcare



How ((OptiScan technology works

PROCESS

- A single optical fibre projects a pinpoint of laser light into a 'stained' specimen in a scanned raster pattern
- Fluorescence is transmitted back to the detector



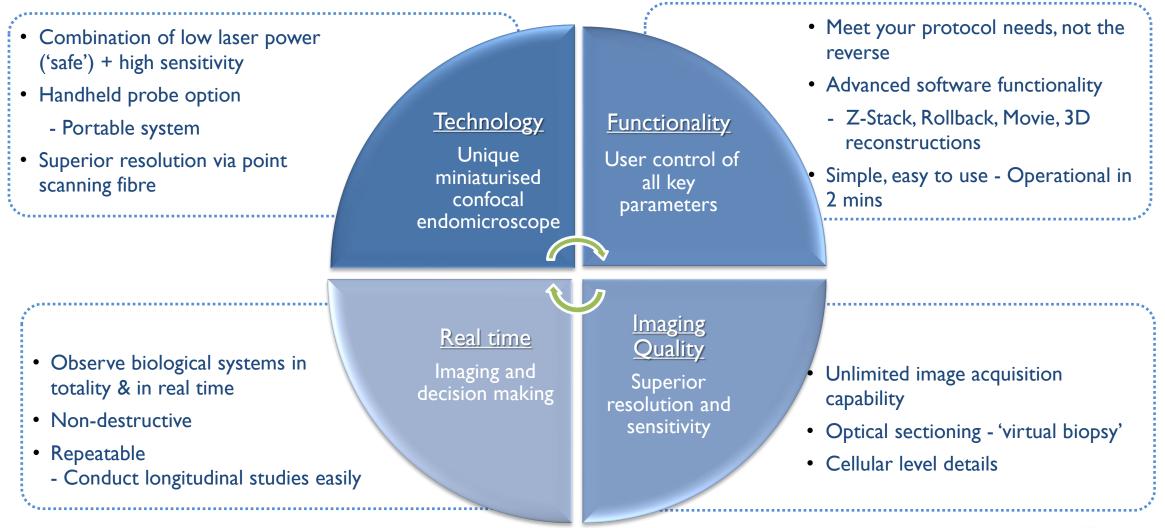


RESULT

- Fluorescence intensity variations are mapped, creating real-time microscopic images
- Moving lenses provide Z-Axis focus ability (3D imaging capability)



Technology Strengths



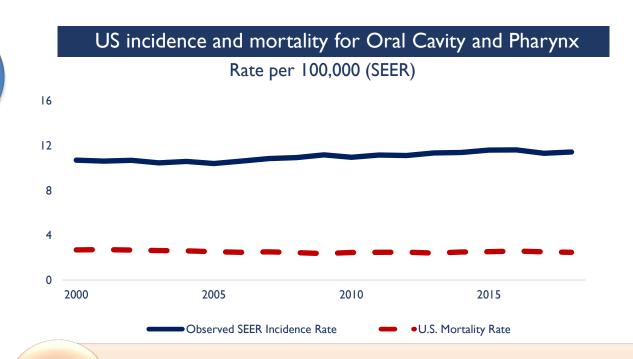




Primary Application: Head & Neck Cancer

KEY FINDINGS

- Head and neck (H&N) cancer is the sixth most common cancer worldwide, 750k patients, 300k deaths annually¹
- US\$16bn market in the US²
- High recurrence rates; 50-60% of patients develop a loco-regional recurrence within 2 years³
- H&N cancer incidence 65k cases annually (US), 13k deaths in 2020
- Annual rate of new cases of laryngeal cancer in US falling by 2-3% (fewer people smoking). Since 2012, declining mortality ~ 2%



HIGH INCIDENCE & MORTALITY RATE MEANS EARLY DETECTION, DIAGNOSIS & TREATMENT VITAL

Optiscan technology

An attractive solution for monitoring post-surgery H&N cancers:

(1) High recurrence rates (2) Virtual biopsy approach - lower patient burden (3) Lower healthcare system costs

- I. Kordbacheh F, Farah CS. Current and Emerging Molecular Therapies for Head and Neck Squamous Cell Carcinoma. Cancers (Basel).
- 2. Annual health care expenditure taking into account impact on patients and the health care system.
- 3. 'Follow-up in Head and Neck Cancer: Do More Does It Mean Do Better? A Systematic Review and Our Proposal Based on Our Experience'



Solution - InVivage[®] Clinical Device



FEATURE

- Miniaturised hand-held rigid probe (4 mm diameter tip)
- Advanced software user interface
- High resolution images, 1000x real magnification
- DICOM-compatible/PACS-enabled





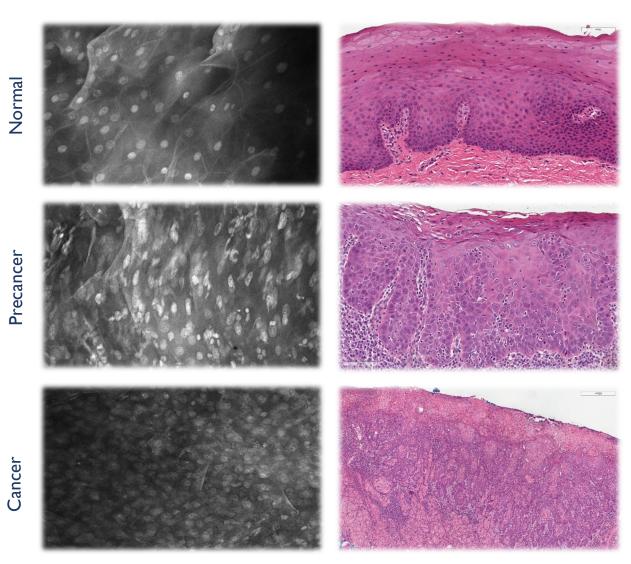
BENEFIT

- Virtual histology and biopsy within health systems
- Real-time, sub-cellular, live microscopic imaging, enabling immediate, informed decision making
- Improved patient outcomes with clearly defined, targeted cancer screening and surgical margin assessment
- Reduced need for traditional histopathology and surgical revision, generating efficiencies within healthcare systems





Proven Correlation for Instantaneous Oral Screening



- Using Optiscan technology, oral cancer can be differentiated from precancer and normal tissue
- Oral tissue/lesion microstructure correlates between confocal images and histopathology
- Future potential for AI applications and computer-assisted oral cancer detection



Prof Camile Farah, Australian Centre for Oral Oncology Research & Education

Competitors: Oral Segment

Blue light with natural tissue fluorescence provides less detail to support clinical decision making compared to Optiscan, however, offers wider field of view, being 'macro level detection'

Clinicians

Ę

• Have questioned value of competitor technology, due to lack of <u>cellular level resolution</u>

Competitors

- Rely on blue light technology and natural tissue fluorescence. Do not use staining agent
- Technology has no visibility at the cellular level, reinforcing above perception of some clinicians

Cost

Relatively inexpensive devices

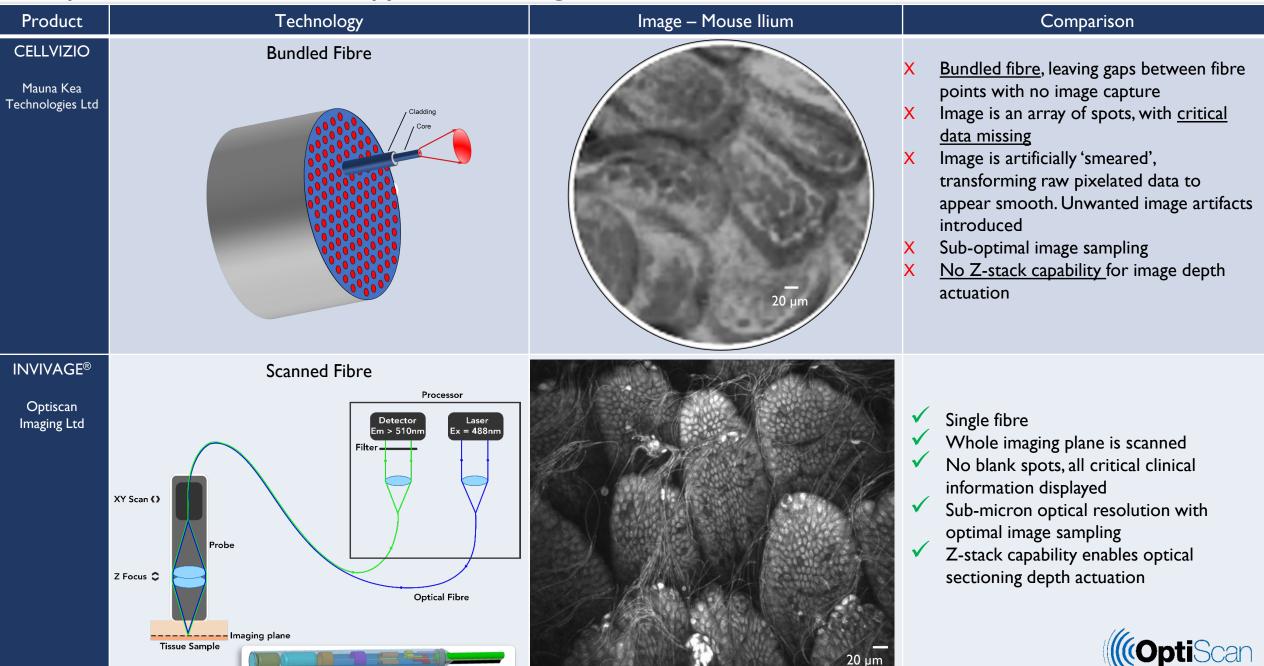
Optiscan Technology

• InVivage[®] is differentiated in its miniaturisation and cellular level digital imaging capabilities

Product	VELSCOPE	IDENTAFI	ORALID	DOE SE			
	Hard of the set of the	With tyr Vector Geen Arabit tyr Vector Identafi Vector Geen Arabit tyr					
Technology	Autofluorescence imaging (AFI)	Multi-spectral fluorescence and reflectance (soft tissue)	Blue light fluorescence technology	Autofluorescence imaging (AFI)			
Use	Detection of Natural Tissue Fluorescence; used in screening and surgery						
FDA Approval	Yes	Yes	Yes	Yes			
Market positioning	Market leader in blue light	Uses "Multi-Spectral Fluorescence" as differentiator	Differentiates on price position, cheaper due to lower lifetime costs, less reliance on consumables	Perceived as inexpensive, quick to implement			

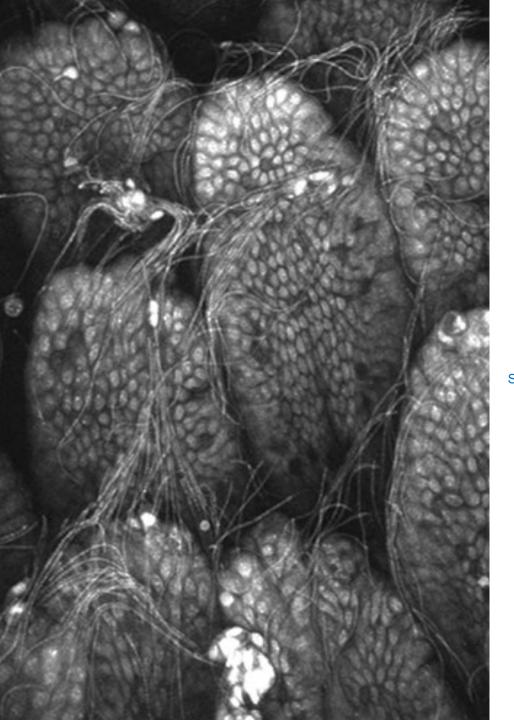


Competitors: Endomicroscopy Product Segment

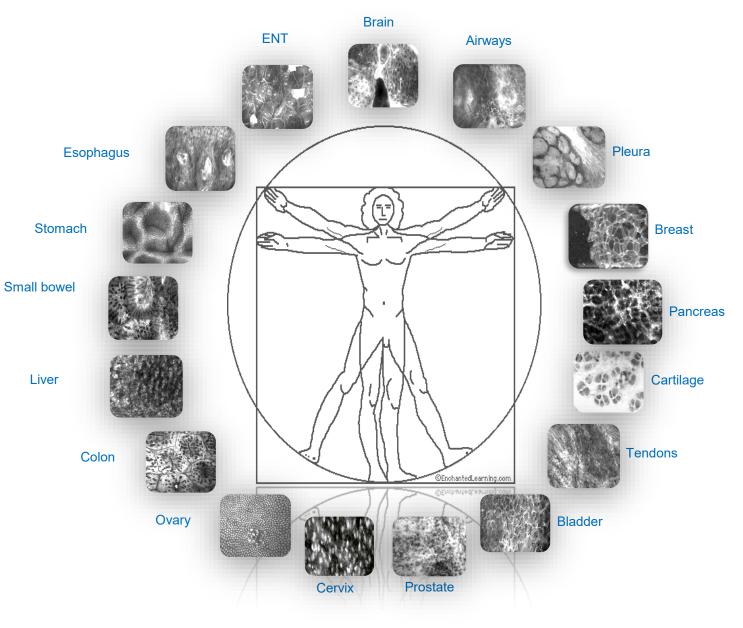




((CoptiScan The Future



((OptiScan: A Platform Technology





Extension Applications

Almost limitless where tissue light transmittance is possible

Current Associated Costs in US (2020)

- Oral and Head & Neck
- Breast: Technology enabled (ease of access touch and see/record) encompassing in vivo or ex vivo tumour margin delineation (studies in progress)
- Cervical
- GI: Partnership opportunities with multiple global endoscope makers

Current Associated Costs in US (2020)							
Measure	Breast	GI	H&N	Cervical	TOTAL		
Total Healthcare Spend (USD)	\$97 b	\$56b	\$16b	\$8 b	\$I77b		
Prevalence (cases)	3.6 m	1.5m	50k	604k	5.75m		
% Overall Cancer Cases	12%	19%	5%	3%	39%		

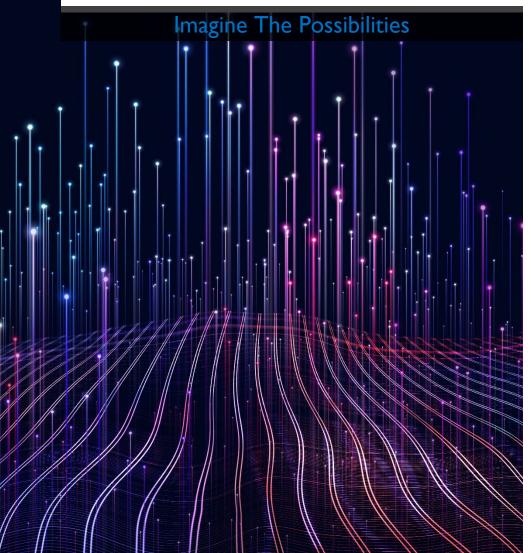
(((OptiScan Technology

✓ Non-invasive, non-destructive, real-time, *in vivo*

- Repeatable monitor disease progression & intervention outcomes
 - Zero incremental cost per image
 - ✓ Greater clinician collaboration



Blue Sky Applications





Real Time AI and algorithmic based identification & diagnostics



Integration with current/future robotics systems



Biopsy channel compatible devices



Molecular imaging

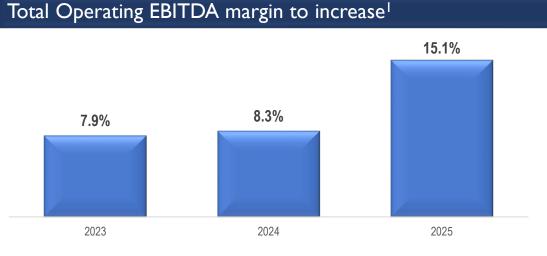
Revolutionising Healthcare

Financial Projection

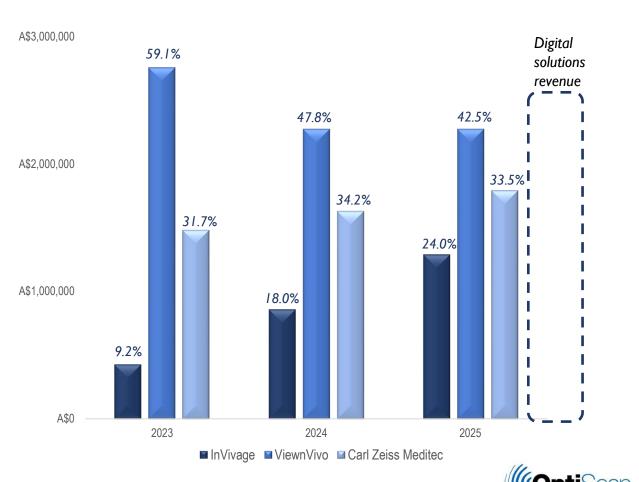
Exciting outlook underpinned by multiple revenue streams

Summary

- Equity, grants, and R&D tax incentives to fund operations and growth strategy
- By 2025, no single product will dominate revenue generation
- Strong innovation contribution 40% of cash invested into R&D
- No debt on balance sheet retaining financial flexibility
- InVivage[®] >80% gross margin
- Future revenue stream being developed for digital and software



Revenue generation – increasing product diversification



1. EBITDA excluding project expenses 2. According to Frost & Sullivan, by 2025, c.80% of healthcare business models will be driven by platform-based healthcare analytics and intelligence solutions



Summary

Optiscan Imaging Ltd (ASX:OIL)



- Global Leader in Digital Microscopic Imaging
- Immediate Informed Decisions
 - ✓ Earlier: Detection, Diagnosis, Treatment
 - ✓ Image-guided surgery
 - ✓ Digital telepathology workflow
 - ✓ Improved patient outcomes
 - ✓ Economic efficiencies for health systems
- Indication Expansion
 - \checkmark Gastrointestinal, breast, oral and cervical
- Establishing Strategic Partnerships
 - ✓ Telepathology, Artificial Intelligence
 - ✓ Molecular Imaging, Robotics
- New Standard in Precision Healthcare







Appendix

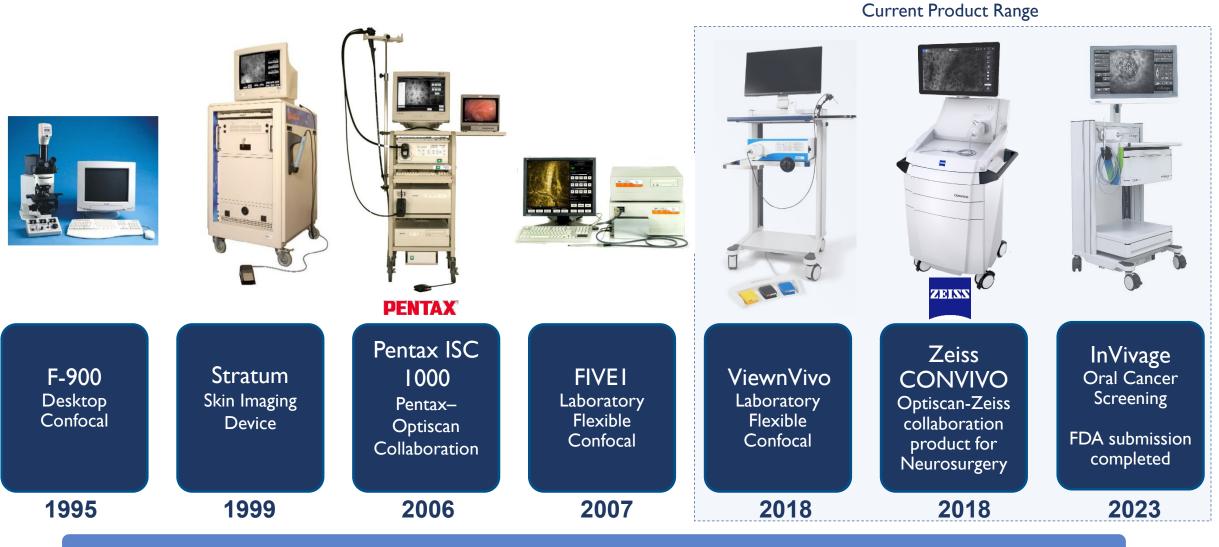
Optiscan Imaging Ltd (ASX:OIL) – Detailed Summary

Who	 Est. 1994. Unique patented protected technology. Focus sectors: Life Science/Research and Clinical (tumour detection and margin detection)
What	 Commercialising core technology for the clinical segment Platform technology delivering a 'digital pathology solution' to improve patient outcomes and theatre workflow throughput and lower overall healthcare system costs and disease burden Significant doctor/patient benefits through a real-time 'virtual biopsy' approach – earlier detection focus Proven technology (Carl Zeiss Meditec using Optiscan technology in neurosurgical device) Clinical studies initiated in Oral and Breast. Potential applications in other Head/Neck, Cervical, GI.
Market	Estimated at US\$177b (Oral/Head & Neck, Breast, GI cancer-related costs)
Target Customers (Users)	Surgeons, Physicians, Pathologists
Payers	Hospital procurement (public, private)
Relationships	Major medical institutions (MSKCC), Carl Zeiss Meditec, Pentax
Trends	Artificial Intelligence (AI) applications, Telepathology, Molecular imaging/disease markers
Products	 InVivage[®] - Clinical handheld miniature microscope system ViewnVivo[®] - for Life Science
Employees	22 FTE across engineering (electrical, software, design), clinical, commercial (marketing, sales), production, quality/safety, finance
Manufacturing	Dedicated manufacturing facility in Melbourne, Victoria with clean room, research, production, warehousing & distribution
Relationships	 Substantial engagement and relationships with clinicians and institutions globally Expanding via priming the market with raised awareness and new connections; building database through attending local and international conferences; building use cases via clinical evidence and publications
Distributors	 Existing, engaged APAC Distribution Partner network In process of finalizing network for US, EU and UK
Regulatory	FDA 510(k) submission (InVivage®) completed (Aug 2022) and under review





Product History



Transition from OEM Supplier into Pure-Play Medical Device Company

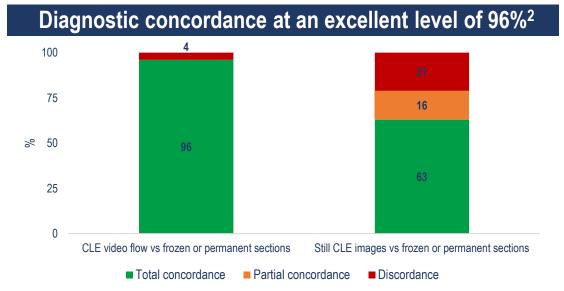


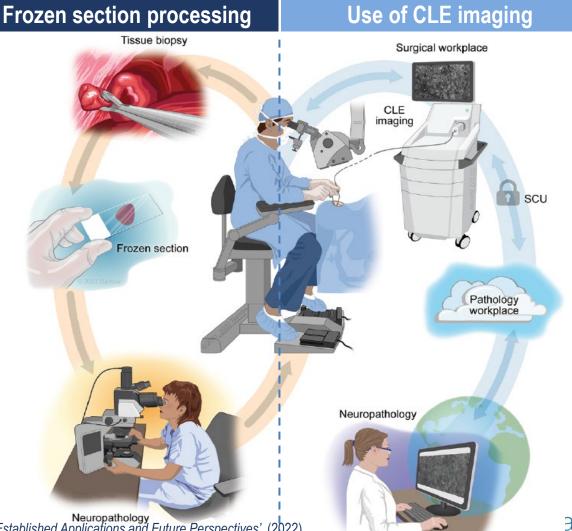
Technology in action: Real-time communication with neurosurgery and pathology

Game changing technology with proven benefits, enabling on-the-fly decision making

The opportunity

- Intraoperative tumor visualization represents one of the most important problems in neuro-oncological surgery¹
- Recent studies have shown use of CLE in conjunction with surgical telepathology software, has significant workflow advantages over standard frozen section analysis²
 - Frozen sections processed within ~23mins vs. ~1min for CLE
 - > 96% concordance achieved between CLE and H&E sections





'Editorial: Intraoperative Fluorescence Imaging and Diagnosis in Central and Peripheral Nervous System Tumors: Established Applications and Future Perspectives' (2022)
 'Real-time intraoperative surgical telepathology using confocal laser endomicroscopy' published in Neurosurgical Focus (2022). Concordance figure has been adapted.

How Optiscan will win in the marketplace

Optiscan is uniquely positioned with few competitors possessing the same capabilities

Overview

- Optiscan Technology is hard to replicate and patent protected
- Closest competitor is Paris/US-based Mauna Kea Technologies
- Point of distinction Mauna Kea Technologies uses Fibre Bundle Imaging whereas single fibre for Optiscan
 - > Optiscan imaging quality is generally superior

Competition in breast application

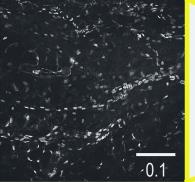
- Optiscan has advantage in higher resolution
- Examples of competitors identified: MarginProbe, OncoRes, Faxitron
 - OncoRes: picks up large compromised margins apparent with the naked eye but no data is available on how accurately it predicts cellular level residual cancer
 - Whereas Optiscan can visualise individual cells and characteristic patterns form when become cancerous, which patterns are very amenable to AI image analysis

Competition in oral application

- Alternatives are blue light with natural tissue fluorescence which provides less detail to support clinical decision making compared to Optiscan, however offers wider field of view, being 'macro detection'
 - Lack of cellular level resolution detail compared to Optiscan
- Examples include: VELscope, Identafi, OralID, DOE SE

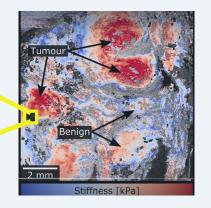
Competition in GI application

The ability to interpret digital biopsies on-the-spot does not currently exist



Comparison of Optiscan image detail vs OncoRes image detail

Optiscan breast cancer trial image



OncoRes breast cancer trial image



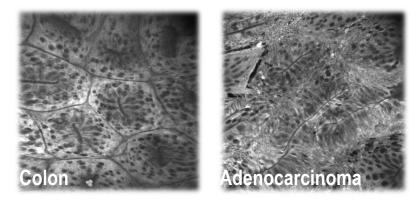
Example of new application: Human gastrointestinal (GI) disease

GI is one of the largest segments in cancer that can benefit from Optiscan's technology value-add

Global Overview

- High incidence in Western countries; especially in US, Australia, Europe
- Approx. 267k new cases of GI cancers, 242k GI deaths, in US p.a.
- GI accounts for 1 in 4 cancer cases, 1 in 3 cancer deaths globally
- International studies typically show high recurrence rates for GI cancer (China study – 60% post resection; European – 37%)
- GI cancer is the most common cancer in Australia
 - > 1,174 deaths from stomach cancer alone in Australia (2019)
 - ▶ In Australia, low 5-year survival rates for GI, at 51%

Optiscan – proven ability to differentiate cancer



US example

- US\$136bn market in the US to capitalise on by total expenditure
- Estimated 17.7m endoscopic procedures are performed annually in the United States (one procedure per 15 adults on average)
- A US stomach cancer patient will give up c.US\$ 130k/year
- Among patients admitted to hospital for GI issues, one in seven will be readmitted within 30 days

The opportunity

- Optiscan was an early pioneer in endomicroscopy for GI
- A large proportion of procedures would benefit by way of time-saving and accuracy from having access to reliable, real-time microscopy
 - Optiscan tech helps decrease likelihood of repeat procedures that are associated with use of standard endoscopy alone, decreasing procedure times and minimising waste
- US CPT codes for real-time digital pathology will unlock significant savings for institutions and surgeons, also benefiting patients
 - Digital biopsy interpreting possible through remote, cloud-based workflow interactions between pathology and operating theatre

Optiscan tech is game-changing for gastroenterologists, patients and the healthcare system

