

Optiscan<sup>o</sup>

Annual General Meeting

23 November 2023



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# Chairman's Address



**Mr Robert Cooke**  
Non-Executive Chairman

# Optiscan Board: Experienced Leadership



Robert Cooke  
Board Chair

- 40-year career in health industry
- Executive leadership roles in healthcare companies in Australia, Asia and UK



Dr Camile Farah  
CEO & MD

- Proven track record in organisational leadership and excellence in the healthcare industry with expertise in building successful businesses
- Dual trained physician and pathologist with strong global market linkages



Sean Gardiner  
Non-Executive Director

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



Karen Borg  
Non-Executive Director

- Medtech leader who has held senior executive roles in private and public sectors
- Formerly with Johnson & Johnson USA



Ron Song  
Non-Executive Director

- Track record of developing highly profitable ventures with a network of global contacts
- Formerly managed BMW & Audi dealerships in APAC

# Chairman's Address

## OPTISCAN CHAIRMAN'S AGM ADDRESS

**Optiscan Imaging Limited (ASX: OIL)** ('the Company' or 'Optiscan') provides the following Chairman's address which will be made to the Annual General Meeting of shareholders today.

During FY23, the Company continued to build on its foundations whilst working to secure partnerships to promote the Company's products. The Company has focussed its efforts for expansion on the large US market, where it has set up a commercial operation and taken on sales staff to expand sales of its technology and devices.

Concurrently with a focus on the US market, the Company continues to deliver high quality product to Carl Zeiss Meditec with all deliveries occurring either on time or ahead of schedule. In parallel, the Company delivered a research device to a large US-based pharmaceutical company, and has received new orders from its China-based distributor, following distributor consolidation within the Asia Pacific region.

The Company continued to work through its FDA De Novo application for the InVivage® with submission of a research dossier based on FDA feedback undertaken, and a planned meeting with the FDA towards the end of the 2023 calendar year. Depending on the outcome of that meeting, the Company is optimistic about its De Novo submission during FY24.

The Company continued to work with our partner, Prolucid Technologies, to develop cloud infrastructure as well as to update device software. Regulatory requirements are being pursued from the outset, to streamline future regulatory submissions. At the same time, work continued on the Company's oral imaging Artificial Intelligence (AI) algorithm, with ongoing work on data curation and cell segmentation.

Work has commenced to enhance the Company's core technology, starting with feasibility studies, considering not only technology but also manufacturability and regulatory aspects. Pathways identified in these studies will feed future product development activities.

Concurrently, work commenced on the Company's new surgical device to be used for open breast surgery in the first instance, but which can be adapted to other surgical applications with distinct probe designs to come. This approach is part of the Company's planned technology roadmap where hardware and software product development will occur in parallel to accelerate the Company's product development, clinical testing and regulatory submissions allowing for earlier future commercialisation.

During the financial year, the Company launched a partially underwritten renounceable entitlement offer to raise \$16.7M to fund its strategic portfolio expansion. The Offer was structured to raise up to \$16,698,816 by the issue of up to 208,735,201 Shares in the capital of the Company at an issue price of \$0.08 per Share. The Company engaged substantial shareholders, Peters Investments Pty Ltd (Peters) and Orchid Capital Investments Pte. Ltd (Orchid) to partially underwrite the Offer. The Company achieved its target capital raise of \$16,698,816.

The Company has also continued to increase its manufacturing capabilities as transforms itself into a pure play medical device manufacturer and service provider, enhancing its processes and de-risking the business with new staff recruitments and upskilling of existing staff.

The Company is well positioned to be able to capitalise on its future objectives with the increase in these key appointments and increase in manufacturing capabilities.

I would like to thank our executive team and employees for their significant contributions during the year as the Company continues to develop into a global leader in its field.

On behalf of the Board, I would like to thank our shareholders for their continued and much valued support over the past year.

# Managing Director's Report



**Dr Camile Farah**  
**CEO & Managing Director**

# Acknowledgement of Country

I begin today by acknowledging the Traditional Owners of the land on which we meet, the Wurundjeri and the Boon Wurrung people of the Kulin Nation, and pay my respects to their Elders past, present and emerging.



# Optiscan: Building Momentum

**PURPOSE:** To positively transform lives through our leading imaging technology.

**MISSION:** To enable informed decisions for optimised global healthcare.

**VISION:** To be a global leader in digital healthcare solutions.



## STRATEGIC PILLARS



# Improving Cancer Outcomes with Digital Pathology & Precision Surgery

	1	2	3	4	5
Challenge	High, growing cancer rates are a huge burden on society	Cancer treatment lacks accuracy and results in high recurrence rates	Frozen section procedure is time-consuming, costly and inaccurate	Traditional histopathology is not instantaneous	Access to quality healthcare is disperse and varies significantly across geographies
Solution	Non-invasive early detection, diagnosis and treatment	Intraoperative microscopic-guided surgery	Live, in-vivo, microscopic imaging	Real-time digital pathology	AI assisted diagnosis & telepathology services
Optiscan					

Improving cancer outcomes requires accessible digital pathology service solutions for anyone, anywhere and anytime

# Healthcare Ecosystem Value Proposition



## Patients, Families & Advocates

Enhanced accuracy, faster decisions, better outcomes

Superior experience and clinical journey

Less anxiety & uncertainty



## Clinicians & Hospital Executives

Real-time digital microscopic imaging & diagnostic software

Physicians: earlier detection  
Surgeons: unprecedented vision  
Pathologists: unparalleled collaboration

Enhanced operating theatre efficiency & utilisation



## Insurers & Healthcare Providers

Established CPT reimbursement codes for GI applications

Simple, secure software integration into health infrastructure

Significant cost savings and economic efficiencies across health systems

Optiscan technology helps surgeons, pathologists, and physicians optimise patient outcomes by enhancing productivity, reducing diagnostic inaccuracies, and improving practice efficiencies

# Optiscan: Competitive Advantage



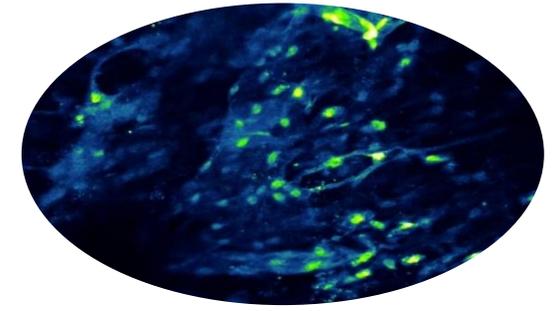
## Digital imaging solutions for operating rooms of the future

- Real-time feedback in the Operating Room
- Removal of diseased tissue while preserving normal structures
- Increased precision decreases likelihood of repeat surgeries
- Significant workflow improvement from remotely engaging pathologists
- Workflow efficiencies lead to system economies



## Novel imaging solutions for contemporary clinical practice

- Digital microscopic imaging and diagnosis on-the-fly
- Speed of image delivery and ability to share images is crucial to *immediate, informed decision making*
- Reduces need for biopsy or glass slide pathology
- Allows functional studies not previously possible



## New standard of precision healthcare

- Non-invasive imaging for patients
- Unlimited sampling
- Visually monitor disease over time
- Track disease treatment impact
- Clinician-Pathologist digital collaboration

Optiscan Hardware & Software Solutions : Transforming Pathology and Precision Surgery

# Our Hardware: Differentiated Clinical & Research Devices

## InVivage® Oral Imaging Device



### FEATURES

- High resolution images, 1000x real magnification
- Software user interface with AI and Telepathology compatibility
- DICOM-compliant / PACS-enabled
- Ergonomic surgical handpiece for easy operator use

### USE CASES

- Detection and treatment of oral cancer
- Selective virtual biopsies with higher diagnostic yield
- For use by physicians, surgeons and pathologists

## ViewnVivo® Research Device



### FEATURES

- Our original precision engineered platform technology
- Miniaturised hand-held probe with 4 mm diameter tip
- Comprehensively patented with high intrinsic value
- Compatible with multiple dyes and contrast agents

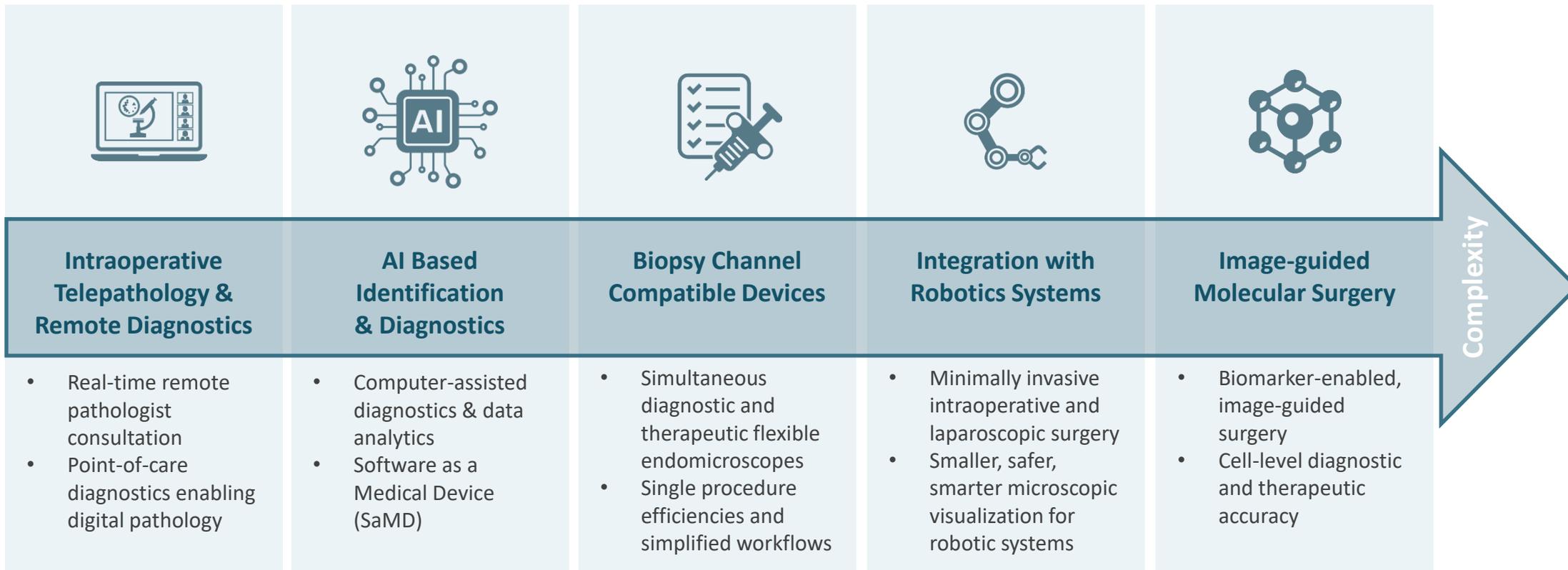
### USE CASES

- Non-destructive small animal imaging
- Real-time anatomic, physiologic and metabolic research
- Accelerates drug discovery research

Developing new clinical devices to enable image guided surgery and digital pathology for large addressable markets

# Expanding Areas of Clinical Application

## Expanding Applications ... Revolutionising Healthcare



# Optiscan: Towards Proprietary Digital Solutions

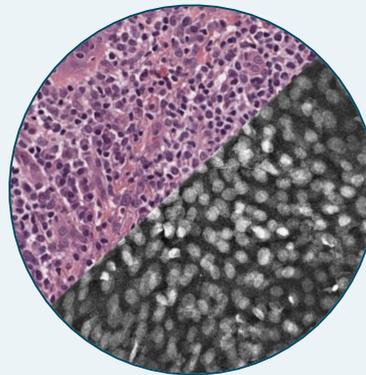


## Unique Hardware

Handheld, miniaturised confocal laser endomicroscopes

Evolution from OEM into medical device company and digital solutions provider

Multiple devices for highly addressable markets (Oral, Breast, Pathology, Vet, GI)

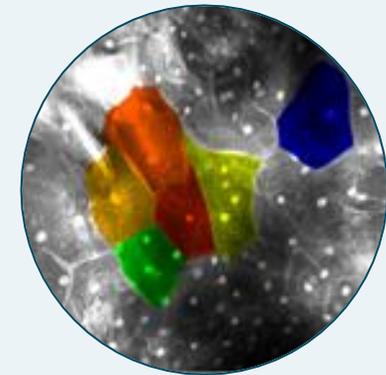


## Clinical Practice

Conventional histopathology unchanged for > 100 years

Slide-free, biopsy-free pathology

Health system efficiencies and significant cost savings



## Proprietary Software

Developing proprietary AI and Telepathology capability

Digital pathology for anyone, anywhere, anytime

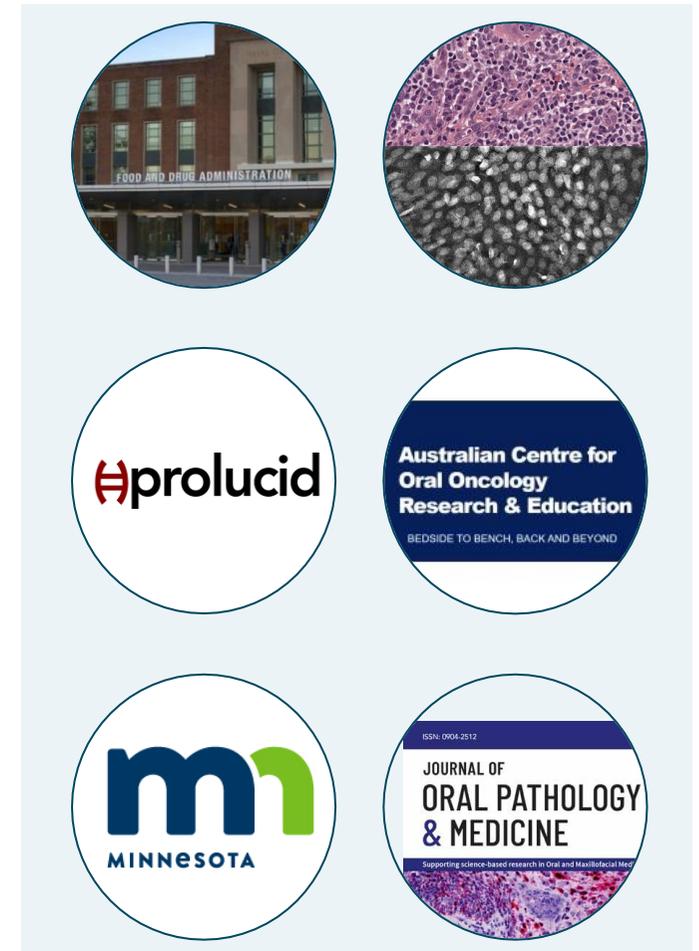
A new standard of digital pathology & precision surgery

Transforming the Company and Changing the Pathology Paradigm

# Key Achievements - Building Foundations in FY23

## Key Achievements FY2023

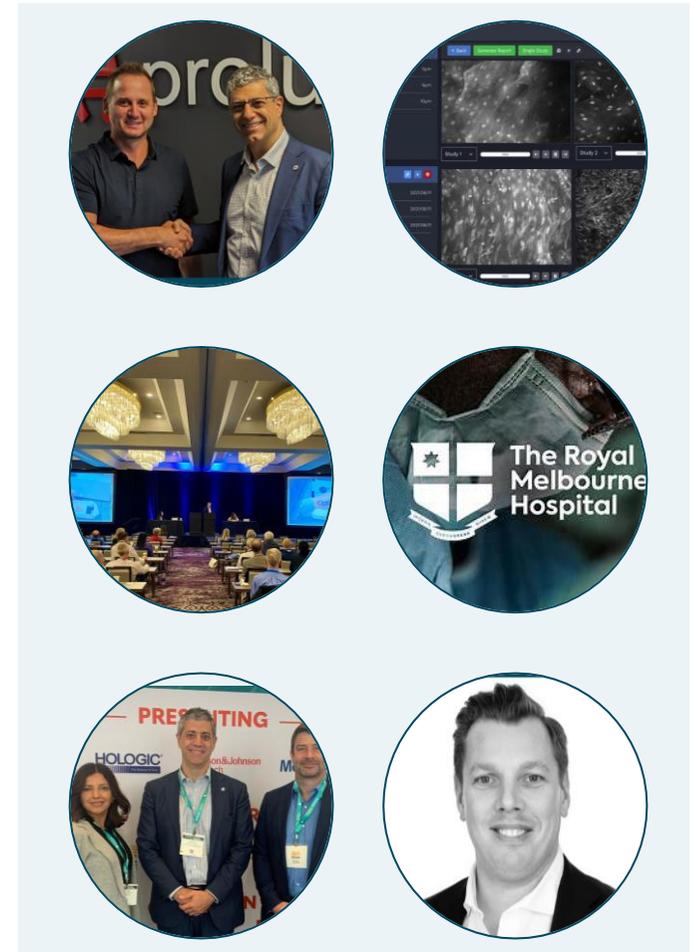
<b>Regulatory</b>	<p><b>InVivage FDA Application</b> Original FDA application submitted as planned</p>	<b>Aug 2022</b>
<b>Clinical</b>	<p><b>Optiscan Acquires Intellectual Property</b> Acquisition of 228 clinical and histopathological matched patient libraries containing oral cancer, precancer subtypes, and normal tissues. Utilised for AI algorithms.</p>	<b>Oct 2022</b>
<b>Product Development</b>	<p><b>Prolucid Technologies Partnership</b> Developing AI and Telepathology software using 228 clinically matched datasets owned by Optiscan</p>	<b>Jan 2023</b>
<b>Regulatory</b>	<p><b>Optiscan Pursues De Novo Pathway for InVivage®</b> Valuable feedback from FDA on first-in-class nature of InVivage® means De Novo clearance is now being pursued</p>	<b>Jan 2023</b>
<b>Clinical</b>	<p><b>Australian Centre for Oral Oncology Research &amp; Education Oral Imaging Interim Results</b> Optiscan technology is highly accurate for oral cancer diagnosis</p>	<b>March 2023</b>
<b>Commercialisation</b>	<p><b>Optiscan Establishes US Commercial Operation in Minnesota</b> Implementation of direct market model in the US with a new team and business entity, Optiscan Imaging Inc</p>	<b>April 2023</b>
<b>Clinical</b>	<p><b>Optiscan Oral Study Published in Prestigious Journal</b> Australian Centre for Oral Oncology Research &amp; Education study published in highly ranked international Journal of Oral Pathology and Medicine</p>	<b>May 2023</b>



# Key Achievements - Achieving Significant Milestones into FY24

## Key Achievements FY2024

<b>Product Development</b>	<b>\$16.7m Entitlement Issue</b> Successful completion of a \$16.7m capital raise to develop new clinical devices and product innovations	<b>July 2023</b>
<b>Clinical</b>	<b>Key International Congress Presentations</b> Presented at the 11th International Conference of the American Head and Neck Society (AHNS) in Montreal, Canada, & 48th Brazilian Congress of Stomatology and Oral Pathology (SOBEP) in Curitiba, Brazil	<b>July 2023</b>
<b>Clinical</b>	<b>Melbourne Dental School Study published in Frontiers</b> "Acquisition and Annotation in High-Resolution In Vivo Digital Biopsy by Confocal Microscopy for Diagnosis in Oral Precancer and Cancer", successfully demonstrated the utility of InVivage® in detecting and differentiating between normal and diseased oral mucosal tissues	<b>July 2023</b>
<b>Product Development</b>	<b>Telepathology Milestone</b> Project with Prolucid passes proof of concept ahead of schedule	<b>Aug 2023</b>
<b>Clinical</b>	<b>Breast Study Milestone</b> Optiscan technology correlates with histology in interoperative assessment study at the Royal Melbourne Hospital, Frances Perry & Epworth Hospitals	<b>Sept 2023</b>
<b>Commercialisation</b>	<b>Key appointments for US operation</b> Shayra Leon and Tim Rowe appointed as Business Development Managers for North America (East / West)	<b>Oct 2023</b>
<b>Commercialisation</b>	<b>Brendan Fafiani Appointed Chief Operating Officer</b> Significant leadership experience & success in product development & commercialisation of medical devices	<b>Oct 2023</b>



# FY23 Financial Highlights

## Accelerating commercialization and innovation



### **FY23 Revenues from ordinary activities up ~66% on FY22 to \$1.68m**

- Convivo – Carl Zeiss Meditec: Sales more than doubled from previous year to \$1.3m
- Pre-clinical system, ViewnVivo®, US commercial sale to a large pharmaceutical company



### **Increased commercialization and business activities**

Prudent cost control resulted in lower business expenses (excl. R&D) by 4% to \$3.37m despite increased business activity and US expansion:

- Setup of US commercial operations in Minnesota, USA
- Increased commercial presence globally through strategic partnerships, keynote presentations, and research publications



### **Focus on innovation that will accelerate commercialization**

Increased R&D resources by 13% to \$2.4m on strategic activities such as:

- Acquiring intellectual property being used for AI algorithms
- Further product development for wider clinical applications (breast, GI, Vet)

# FY24 Year to date

## CASH



Capital raised

**\$16.7m**

R&D tax refund

**\$670k\***

*\*Estimate to be received by Jan24*

## Value of orders received to date

**\$720k**



**\$990k**

(60% of last year's revenue)

**\$270k**



ViewnVivo®

### Key takeaways

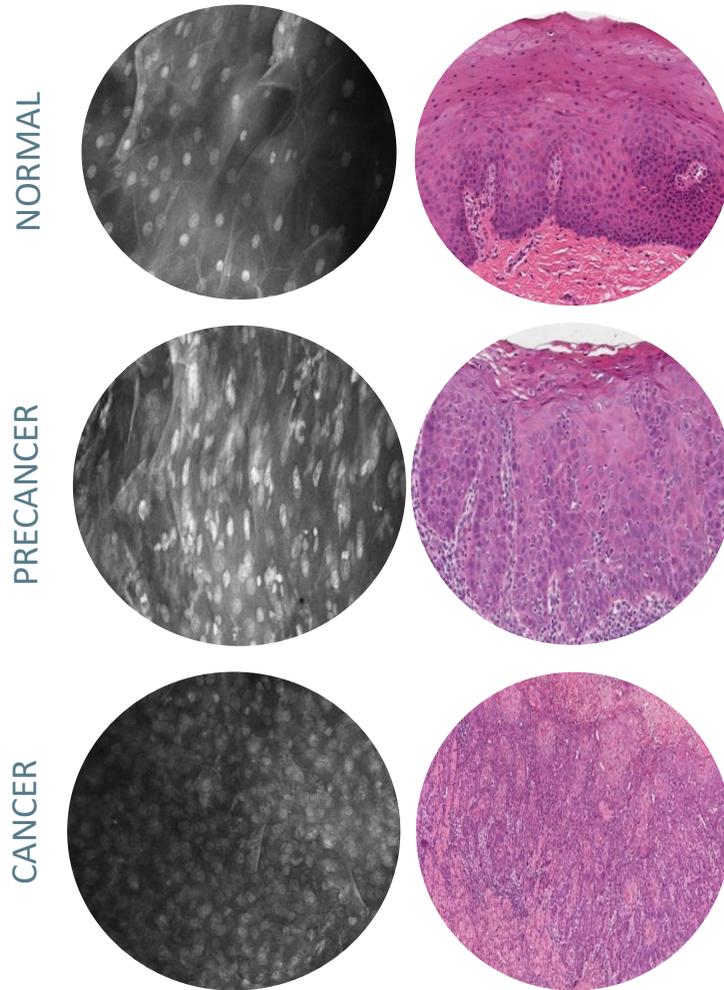
- High value of sales orders secured within 5 months of FY24 (60% of FY23 revenue)
- Further Zeiss Convivo orders anticipated
- Demand for ViewnVivo® in China and US projected to increase in H2FY24

# Optiscan – Future Product Family Vision



Optiscan has selected Design and Industry (D+I), Australia's leading Complete Design and Development company as its product realization partner, to create Optiscan's Future Product Family Vision, and have begun delivery of the product roadmap.

# Oral Device



- Highly accurate and easy to use technology for the diagnosis of oral cancer & precancer
- Proven ability to detect oral cancer & precancer
- Unparalleled ability to diagnose oral cancer and precancer on-the-fly
- Sensitivity 86.8%
- Specificity 92%
- Positive predictive value 94.3%
- Negative predictive value 82.1%
- Overall accuracy 88.9%
- Cancers diagnosed correctly 100%
- First candidate for AI/ML SaMD and telepathology service
- Secondary applications in oral surgical and pathology

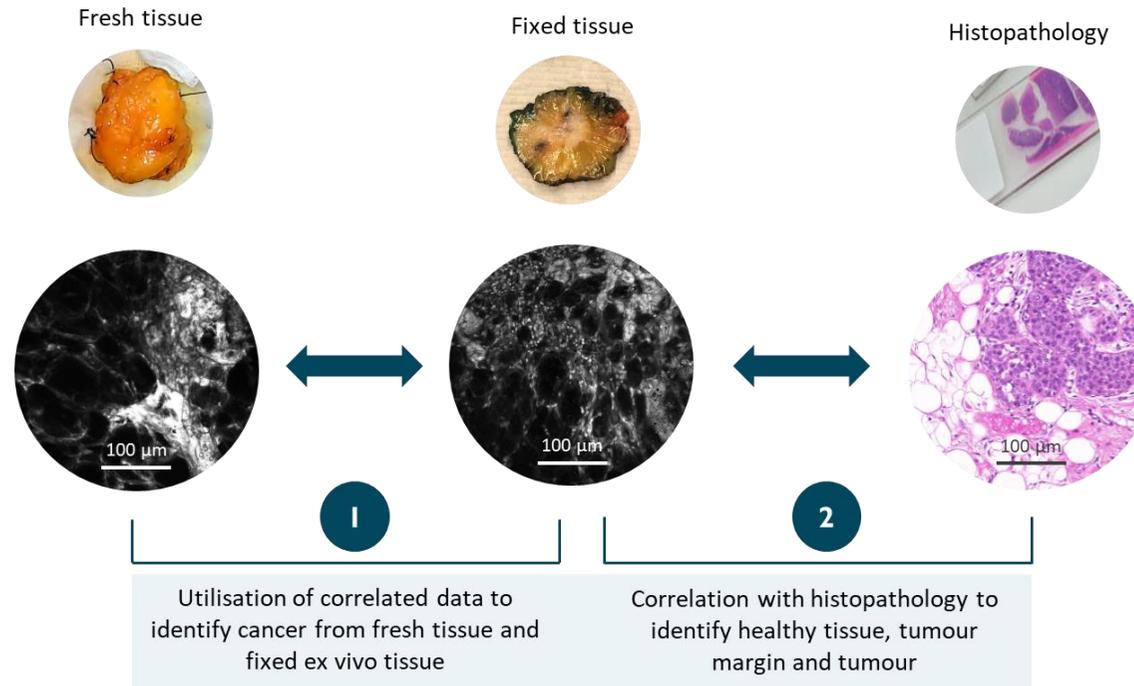
# Surgical Device



		BREAST		ORAL	
				PRECANCER	CANCER
PRECLINICAL	SURFACE				
	MARGIN				
	CANCER				
CLINICAL	SURFACE				
	MARGIN				
	SURGICAL BED				

Intraoperative live in vivo imaging for immediate surgical decision making.  
 Rigid scope design for open breast surgery and later laparoscopic surgical approaches.  
 Near perfect concordance with frozen section biopsy.

# Pathology Device



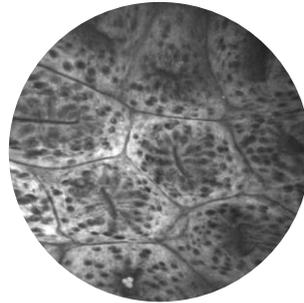
The digital replacement of the frozen section, unchanged since 1905

- Ex vivo bedside imaging
- Specimen-driven frozen section replacement
- Can be used on fresh or fixed tissue
- Applications in any soft tissue type
- Demonstrated applicability in neurosurgery, oral and breast cancer
- Multiple applicable dyes allow differentiation of distinct nuclear and cellular features

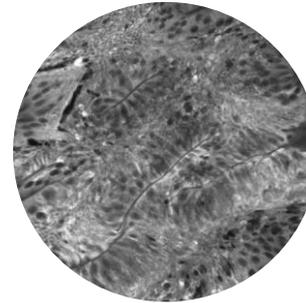
# GI Device



First and longest lasting product with most developed evidence base and reimbursement options



NORMAL



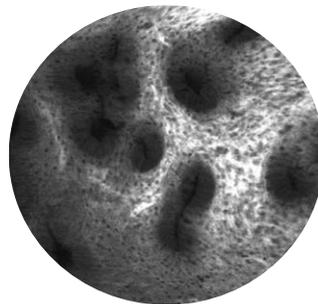
CANCER

- Development of 2<sup>nd</sup> generation device
- Flexible scope for colonoscopy, gastroscopy and endoscopy
- Based on previous FDA-cleared Pentax closed system device
- Down the working channel open system device
- Agnostic to endoscope manufacturer
- CPT codes for immediate utility
- Proven ability to identify cancer with >95% accuracy
- Additional utility in functional imaging for food allergy and bowel diseases

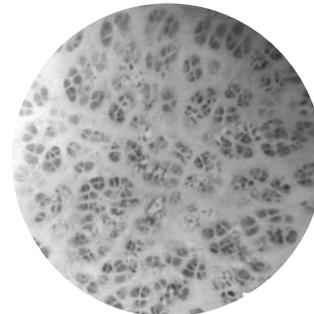
CPT Code	Description
43206	Esophagoscopy flexible, transoral; with optical endomicroscopy
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscope
88375	Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session
0397T	Endoscopic retrograde cholangiopancreatography (ercp), with optical endomicroscopy (list separately in addition to code for primary procedure)



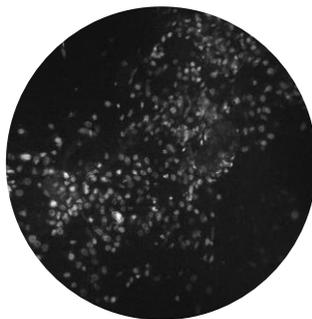
Developing first device specifically designed for the needs of the veterinary sector



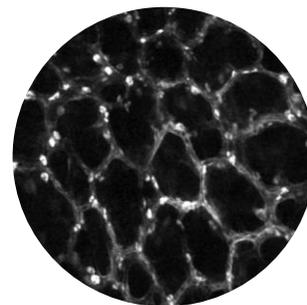
MARE ENDOMETRIUM



SHEEP CARTILAGE



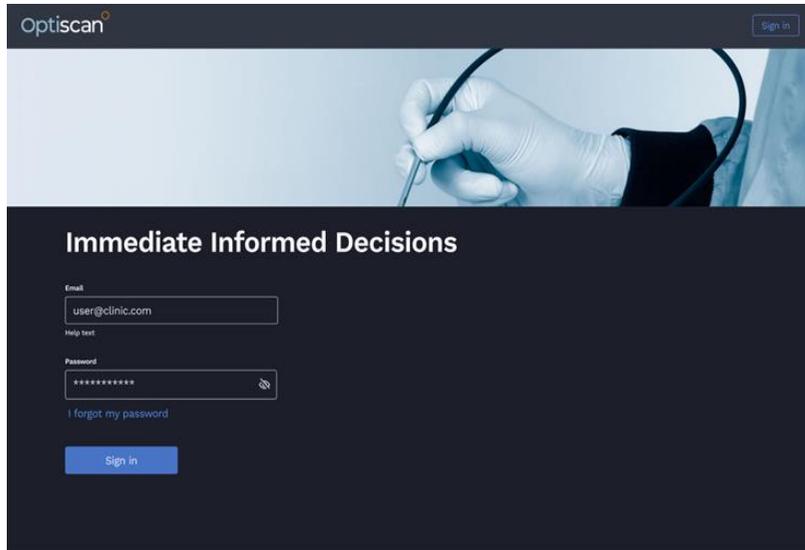
SHEEP CERVIX



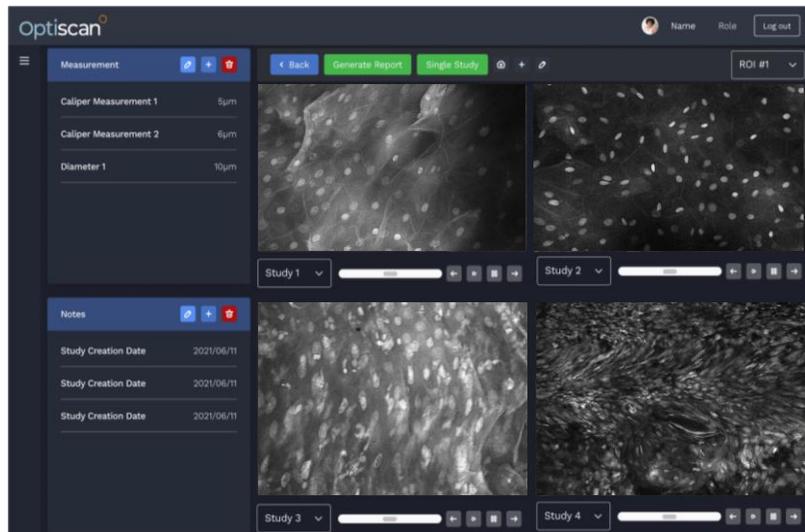
RAT LUNG

- Large addressable market with unmet surgical and pathology need
- Varied clinical applications in small animal veterinary practice and specialized large animal facilities
- Extensive prior experience and experimentation supporting clinical applications
- Rigid and flexible scope combo
- Lower regulatory burden
- Value in microscopic imaging akin to that of diagnostic radiology imaging for correct application
- In discussions with various veterinary schools and hospitals on long term collaborations and partnerships

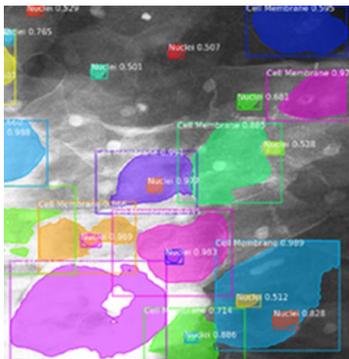
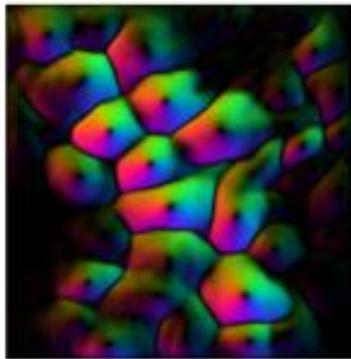
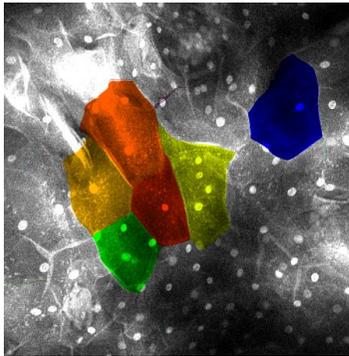
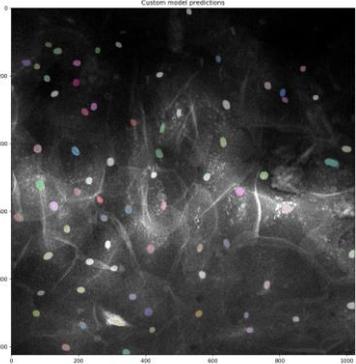
# Telepathology


Enabling digital pathology for anyone, anywhere, anytime



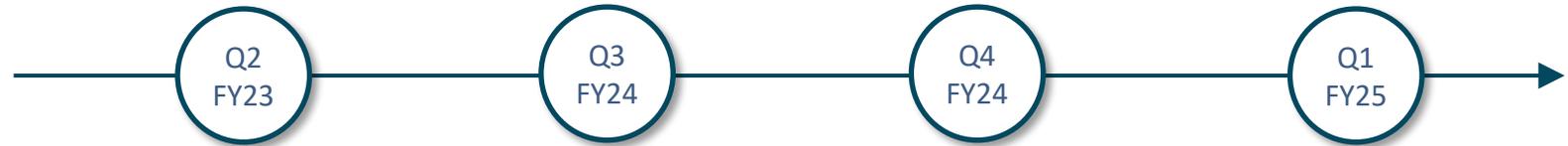
- Cloud hosted webapp utilizing microservice based architecture for device management, security, storage, and data processing
- Custom pathologist web portal interface for data access, real-time telepathology support, historical data review, and reporting
- Video streaming utilizing various services for real-time remote image viewing/reviewing
- Executed of proof-of-concept iterations to validate technology solutions for:
  - Ability to transfer images in real-time from the device to N-clients.
  - Ability for devices/clients to authenticate with the server to view live image streams.



Instantaneous diagnostic capability of pre-cancer and cancer with AI solutions

- Machine learning and image processing pipeline running directly on the device to process images in real-time
- Pipeline broken down into multiple ML and traditional computer vision algorithms for:
  - Image pre-processing, filtering, and masking
  - Nuclei extraction
  - Cell boundary segmentation
  - Feature extraction and results interpretation
- Design and Discovery iteration to capture requirements and identify MVP release to prove out functionality and gather early feedback
- Model selection, training, and testing iterations completed to quantify performance of a variety of models on acquired image data
- Pipeline prototyping using images from various dye-stained tissues to quantify capability and outline ML pipeline requirements

# Certification Timetable




FDA Approval Process for InVivage®

- |   |   |  |  |
|---|---|--|--|
| <ul style="list-style-type: none"> <li>• Progress AI/ML and telepathology portal</li> <li>• Analysis of oral images to determine path for alternative contrast agent utility for topical use</li> </ul> | <ul style="list-style-type: none"> <li>• Planned submission to FDA for De Novo classification</li> <li>• Prepare for oral cancer intraoperative imaging surgical study</li> </ul> | <ul style="list-style-type: none"> <li>• Real world testing of AI/ML and telepathology applications</li> <li>• Activate oral cancer intraoperative imaging surgical study</li> </ul> | <ul style="list-style-type: none"> <li>• Anticipated FDA clearance</li> <li>• Launch commercial sales in US</li> </ul> |
|---|---|--|--|



Other FDA Submissions

- |   |  |   |   |
|---|--|---|---|
| <ul style="list-style-type: none"> <li>• Analysis of breast cancer ex vivo imaging study</li> <li>• Prepare for in vivo breast cancer clinical study</li> </ul> | <ul style="list-style-type: none"> <li>• Activate in vivo breast cancer clinical study</li> <li>• Assess telepathology portal for breast cancer utility</li> </ul> | <ul style="list-style-type: none"> <li>• Commence AI/ML integration for breast cancer assessment</li> <li>• Continue telepathology breast assessment</li> </ul> | <ul style="list-style-type: none"> <li>• Continue in vivo breast cancer clinical trial</li> <li>• Prepare for FDA submission for breast cancer utilization</li> </ul> |
|---|--|---|---|

# Expanding our Operation for Commercial Growth



## Melbourne: Global Headquarters

R&D and Innovation

Marketing & Communications

Engineering

HR & Finance

Manufacturing and Operations

Regulatory & Quality

## APAC: Distributor Network



## Minnesota: Commercial Hub

Business Development, Sales, Applications, Clinical Studies, Corporate Development

Exploring additional regional and resource expansion in FY24

# Sales Strategy – Aligned for Revenue Growth



## Distributor Consolidation

- APAC distributor review
- Consolidation from 4 into 2 partners for greater focus
- Partnership-first approach to grow ViewnVivo® in China



## US Commercial Operation

- Direct market model in North America. Commercial hub (Minnesota), regional office (San Francisco).
- 2x Business Development Managers North America
- Further appointments planned



## Outbound Sales & Marketing

- Outbound digital marketing lead generation
- Buildout of new customer database for future outbound engagement
- Defined sales and marketing strategies in AU, China and USA



## Market Development

- Market development to explore new jurisdictions
- Sales pilots and entry assessment

Accelerating Revenue Growth in FY24

# Marketing & Communications – Increasing Brand Recognition



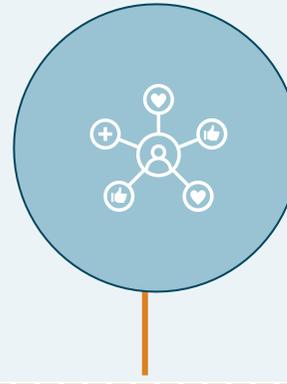
## Increasing Brand Awareness

- Conferences, publications, brand initiatives, forums
- >100 customer facing activities in FY23



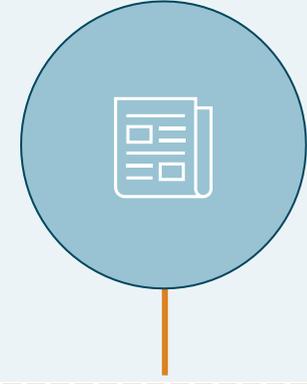
## Revenue Generation

- Lead generation activities
- Building opportunity pipeline
- Marketing preparation for InVivage®



## Increasing Communication Reach

- 21k reached with email marketing, 4x to open rate benchmarks
- 168k reached with social media
- Media channel followers doubled
- 2x over-indexing to engagement rate benchmarks



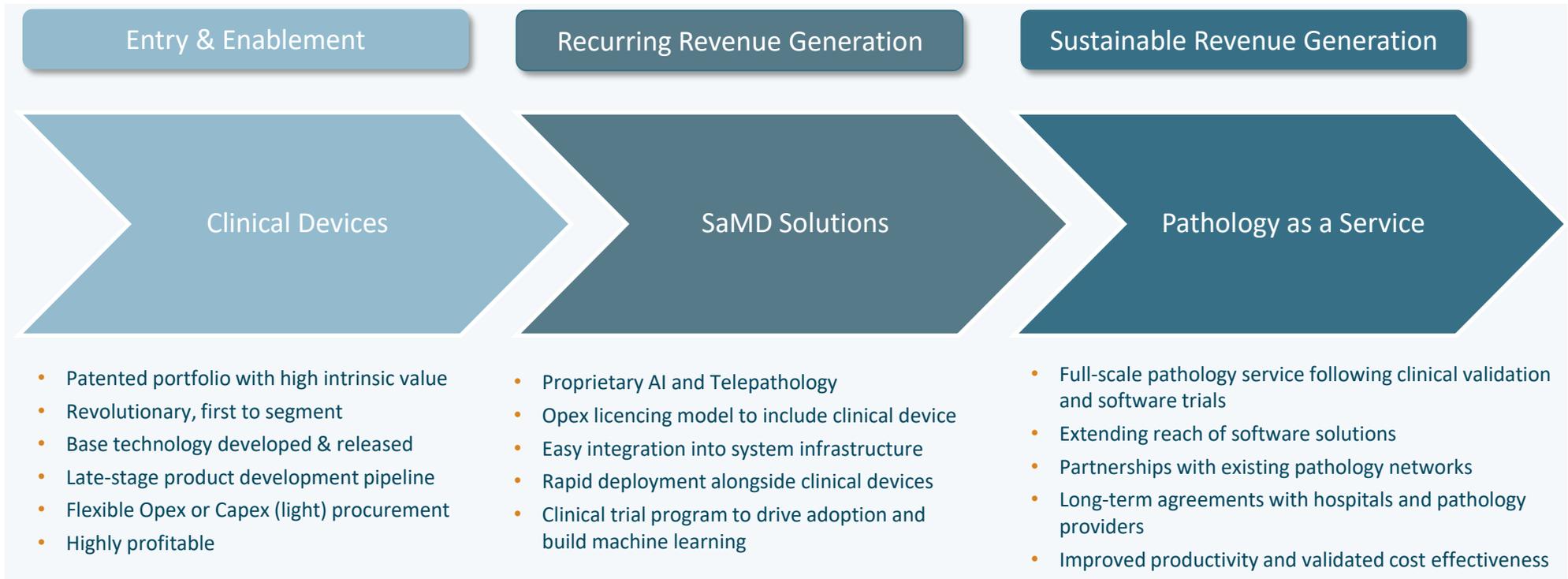
## Expanding Media Presence

- Coverage in the AFR, Bulls N' Bears, The West Australian & other media partners in the popular & MedTech market press
- Stockhead engagement in FY24



Communicating more, expanding reach, maintaining engagement, generating revenue

# Business Model: Progressing to Sustainable Revenue Generation



Sustainable revenue generation through end-to-end digital pathology service

# Summary



## Company

- Slide-free, biopsy-free live microscopic digital imaging solutions for oral, breast, GI and vet
- InVivage (oral) and proprietary AI & Telepathology software
- Highly patented technology with high intrinsic value
- Large addressable markets



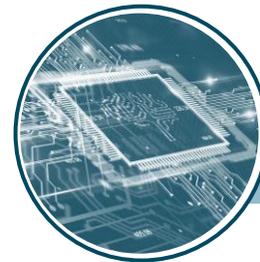
## Users

- Image guided surgery & digital pathology at the single cell level
- Early detection for physicians
- Revolutionary vision for surgeons
- Bringing pathologists directly into the OR



## Health Systems

- 23% saving in the OR
- Reducing physical slide processing, biopsy collection, ancillary logistics and pathology materials
- Closer clinical collaboration optimising patient outcomes



## Evolution

- New clinical devices for open, laparoscopic and endoscopic surgery
- Recurring revenue with AI and Telepathology software
- Sustained revenue with pathology as a service

Setting a new standard of care in precision surgery and digital pathology

Thank You

Questions?