Optiscan

Annual General Meeting November 2022

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Chairman's Address



Mr Robert Cooke, Non-Executive Chairman



Chairman's Address

Good morning shareholders and welcome to the Optiscan 2022 Annual General Meeting.

The past year has seen a number of changes to the Company with the appointment of Professor Camile Farah as Managing Director in December 2021, and the appointment of additional executive positions to help drive the Company's growth and objectives.

Over the past year the Company successfully lodged its FDA 510(k) pre-market notification application for the InVivage[®] device intended for oral tissue imaging. This was a key milestone for the Company and we look forward to finalising regulatory approval in due course. This will enable the Company to continue to commercialise its InVivage[®] device.

The Company and its newly appointed executives continue to market the Company and its technology. As discussed in the Managing Director's report, we have engaged with a number of medical institutions and have raised awareness at a number of international medical conferences and trade exhibitions.

We have also increased our manufacturing capabilities as we shape the Company for the future.

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.

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

I would now like to hand over to our Managing Director, Prof Camile Farah, to provide an update on the Company and its activities.



Optiscan Board: Experienced Leadership



Dr Camile Farah CEO & MD

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- 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



Robert Cooke Board Chair

- 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, 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



Managing Director's Report



Dr Camile Farah, CEO & Managing Director



Welcome to 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.





Acknowledgement



Vale Peter Delaney

As one of the founders of Optiscan, Peter served in senior management roles including Chief Executive Officer, Chief Technology Officer, and board member for over 25 years.

Peter's wisdom, knowledge, and deep understanding of Optiscan's technology and its applications will be missed by all employees past and present, and collaborators around the world who had the pleasure of working with him.



Optiscan: Imaging in the palm of your hand

Global leader in 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
- Real time clinical decision making
- ✓ Earlier: detection, diagnosis & treatment

Platform technology with broad applications:

Gastrointestinal, breast, oral and cervical





Technology: Excellent Correlation to Conventional Histopathology





Improving Cancer Outcomes: A Global Challenge







Patients & Advocates

High resolution, real-time digital microscopic imaging

Enhanced accuracy of decision making and better treatment outcomes





Non-invasive diagnostic imaging and better surgical outcomes

Enhanced healthcare efficiencies and better operating theatre utilisation



Insurers & Healthcare Providers

Established CPT reimbursement codes for immediate GI applications

Cost savings on diagnostic and surgical procedures with better doctor-on-time efficiency

Optiscan is setting a new standard of care in digital pathology and precision surgery



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 pathology slides
- Allows functional studies not previously possible
- Less invasive for patients

The next generation of digital diagnostic and functional pathology solutions



Digital imaging solutions for operating rooms of the future



- Real-time feedback in the Operating Room
- Empowers precision medicine ultimate outcome in cancer treatment is removal of diseased tissue while preserving normal structures
- Significant workflow improvement from remotely engaging pathologists
- Increased precision decreases likelihood of repeat surgeries

Live imaging improves patient outcomes and generates efficiencies within healthcare systems



Opportunity to establish new standard of precision healthcare



- Real time feedback
 Visually monitor over time
 Track disease treatment impact
 Pathologist / Clinician digital collaboration
 Unlimited sampling
- Workflow efficiencies lead to system economies

Traditional histopathology is inefficient – will not meet future demands



Product Range: Differentiated Clinical & Research Devices

InVivage® Clinical Device	
<image/>	
FEATURES Push-button handpiece for easy operator use Advanced software user interface High resolution images, 1000x real magnification DICOM-compliant / PACS-enabled 	

USE CASES

- Selective virtual biopsies with higher diagnostic yield
- Multiple clinical applications including oral, cervical and breast
- For use by physicians, surgeons and pathologists



FEATURES

- Miniaturised hand-held probe with 4 mm diameter tip
- Variable-length rigid probes for different applications
- Portable with small footprint
- 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



Key Achievements in 2022

On a growth trajectory, in preparation for launch into overseas markets



Submission of FDA 510(k) application for InVivage® approval in US

• Submitted application for premarket clearance in late August 2022



Completion of oral cancer imaging studies

- In vivo dosing and imaging studies at Melbourne Dental School
- In vivo on-the-fly diagnosis study at Australian Centre for Oral Oncology
- Ex vivo oral cancer imaging at Adelaide Dental School



Transformation of structure and brand

- Completed brand transformation for company and products
- Exhibited at major international conferences and trade fairs
- Gearing up for international expansion and new partnerships



FY22 Financial Highlights

On a growth trajectory, in preparation for launch into overseas markets



FY22 Revenues from ordinary activities up ~14% on FY21 to \$1.01m

- Pre-clinical system, ViewnVivo®, had first few sales recorded for Australia
- Convivo Carl Zeiss Meditec: Increased sales by 28%



Increased R&D tax incentive refund by c. \$100k to \$942k

• Focus on R&D to ensure ongoing technological advantage remains strong



FY22 expenses of (\$6.5m)

• Spending on regulatory processes in US, clinical studies, additional staff



Selected 2022 publications using Optiscan technology

Neurology



Real-time intraoperative surgical telepathology using confocal laser endomicroscopy



Intraoperative confocal laser endomicroscopy: prospective in vivo feasibility study of a clinicalgrade system for brain tumors



Characterization of ex vivo and in vivo intraoperative neurosurgical confocal laser endomicroscopy imaging



Intraoperative Fluorescence Imaging and Diagnosis in Central and Peripheral Nervous System Tumors: Established Applications and Future Perspectives



nature communications

JEO

Science Advances

Life Sciences & Clinical

Ligand-switchable nanoparticles resembling viral surface for sequential drug delivery and improved oral insulin therapy

Anterior cruciate ligament microfatigue damage detected by collagen autofluorescence in situ

Bioinspired large Stokes shift small molecular dyes for biomedical fluorescence imaging

A biomimetic and bioactive scaffold with intelligently pulsatile teriparatide delivery for local and systemic osteoporosis regeneration

Confocal microscopy in oral cancer and oral potentially malignant disorders: A systematic review





Optiscan^O Strategic Pillars

New strategic pillars

Building momentum





Internal positioning for growth

New strategy

- New business strategy and sales/marketing plans
 - Enhanced via support from Australian
 Government Entrepreneurs' Programme
- Headcount growth by 30% in 2022
 - Appointment of Commercial, Marketing, Quality
 Assurance & Finance managers







Implementation

- Refurbishments of existing spaces
- Leasing of additional space for production
 - Increased production staff for future demand
- New ERP system with plans to integrate new engineering software platforms



Optiscan

Our Mission & Vision

OUR MISSION

To enable informed decisions for optimised global healthcare.

OUR VISION

To be a global leader in digital healthcare solutions.





Our Values



Bold and courageous



Empower each other



Commercial mind and warm heart



Continuous improvement



Customer focused



Responsible and accountable

We have a strong purpose of transforming people's lives through earlier and less invasive diagnosis and treatment of diseases with use of our leading endomicroscopic technology



Sales strategy update – Life Sciences

Fresh approach

- Dedicated distributor partners South Korea, China, Taiwan
 - > Appointment of new China distributor
 - Implementation of new training programs with positive feedback
 - > Distributors engaged for commercialisation rollout
- Preparing for engagement of US and Europe based distributors

Partnership opportunities

• Several rental devices worldwide including:

QuantiDoc Norway-based Quantidoc – aquaculture & mammalian mucosal barrier function

Non-disclosable multinational pharmaceutical company

• Partner users of tech:



Walter and Eliza Hall Institute – animal models of cancer



Swinburne University of Technology – tissue culture

View





Expanded marketing capabilities - InVivage®

Increased international engagement and proximity to customers and industry influencers





Expanded marketing capabilities - Optiscan.com



About Us

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- Website embeds new lead capture mechanism linking to new CRM system
- Live, dynamic company updates
- Incorporates new branding





Expanded marketing capabilities

Brand identity

- Circle as focal element representing precision and single optical fibre, key features of our technology
- New byline Immediate Informed Decisions

Media coverage

• Australasian College of Health Services, Health Leader TV, ASM Media, AusBiotech, BioMelbourne Network

Lead capture

- Lead capture marketing automation, facilitating customer engagement
- Capture both targeted segments

Lead nurture

- CRM system with segmented customer profiling
- Formalised lead funnel to enable sales focus







Optiscan^O Key Studies

Melbourne Dental School

Study showed dysplastic and cancerous tissue can be identified with InVivage®

Aim	•	Triage, monitor tissue health & escalate diagnosis Validate use of fluorescent probe & mouth map software
Investigator	•	Dr Tami Yap, Professor Michael McCullough
Patients	•	71 patients
Progress	•	Study completed



- Precancerous and cancerous tissue can be identified
- Results included in InVivage® FDA 510(k) submission
 - Data analysis and publication of results ongoing



Findings

Australian Research Centre for Population Oral Health at University of Adelaide

Study further validates InVivage® ability to identify cancerous tissue

Aim	•	To assess ability of Optiscan technology to detect oral squamous cell carcinoma in ex-vivo surgical resections
Investigator	•	Dr Sneha Sethi, Dr Lisa Jameson, Dr Paul Sambrook
Patients	•	20 patients
Progress	•	Imaging completed. Image analysis ongoing

- High accuracy of ex vivo image classification for tumor tissue
- Encouraging for in vivo screening of suspicious lesions
 - Encouraging for in vivo intraoperative diagnosis





Findings

Australian Centre for Oral Oncology Research & Education

Study proved diagnostic decisions can be made on the fly using InVivage®

Aim	•	To assess ability of Optiscan technology to assist with on-the-fly diagnosis of oral cancer and precancer
Investigator	•	Professor Camile Farah
Patients	•	228 patients
Progress	•	Imaging completed. Image analysis ongoing

- Oral cancer diagnosed correctly in 100% of cases
- Oral precancer diagnosed correctly in >90% of cases
- Technology able to image intraoperatively with topical contrast agents
- Imaging not impacted by blood or saliva in surgical field





Findings

Breast Cancer Margin Assessment study (1/2)

Results will unlock a new clinical application and market offering

Aim	 Determine if intraoperative imaging of excised breast tissue can detect positive surgical margins pre- pathology
Investigator	Professor Bruce Mann, Dr Anand Murugasu
Patients	 50 patients. 42 patients and 48 discrete tumors and related cavity shaves imaged (Oct 22).
Status	 Expanded study to include imaging of fresh tissue and subsequent imaging during pathology cut-up of fixed tissue
	 Breast cancer image atlas to develop from tissue comparison
	 Data collection completion due Q4 2022



Optiscan

Optiscan helps reduce recall rate in breast surgery from positive margins

Breast Cancer Margin Assessment study (2/2)

Extended study workflow resulting in robust correlation between images and histopathology



Correlation of Optiscan images with histopathology to identify healthy tissue, tumour margin and tumour.





Utilisation of correlated data to identify breast cancer from fresh tissue and fixed ex vivo tissue





Optiscan^O The Future

Optiscan: Platform Technology





Extension Applications

Almost limitless where tissue light transmittance is possible



Oral and Head & Neck



Breast



Gastrointestinal

Cervical

Size of US cancer burden in 2020

Optiscan is targeting markets worth over US\$62.4bn for some of the world's most severe cancer problems.





Future Applications: Huge Potential





Roadmap



Product Evolution

Core products

- ViewnVivo®
- InVivage®
- Other

Tech upgrades

• Enhanced resolution

New Portfolio



Distribution Partners

Established presence and structure in Asia-Pacific

Geographic Expansion



Establish Distribution

Network





THE UNIVERSITY ofADELAIDE

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Memorial Sloan Kettering Cancer Center.

Clinical Studies





Digital Pathology Solutions

- Immediate diagnostic capability
- Exploring business models for ٠ 'Digital Pathology as a Service'

Build Comprehensive Clinical Evidence

Hospital

Deliver Digital Pathology Solutions

Evolution into pure-play medical device company

Global expansion

Conclusion

Global leader in digital microscopic imaging

US regulatory approval submitted for oral device

Internal capacity build-out undertaken

Potential for indication expansion

✓ Gastrointestinal, breast, oral and cervical

Scoping for strategic partnerships

- Telepathology, artificial intelligence
- Molecular imaging, robotics

New precision healthcare digital solutions





Thank You

Questions?