

## **Annual General Meeting**

Thursday, 20 January 2022 at 11.00am (AEDT)



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## Agenda

- 1. Welcome & Opening
- 2. Introductions
- 3. Apologies
- 4. Notice of Meeting
- 5. Format of Meeting
- 6. Chairman's Address
- 7. CEO/Managing Director's Presentation
- 8. General Questions
- 9. Voting Procedure
- 10. Items of Business
- 11. Proxies
- 12. Financial Statements & Reports
- 13. Resolutions



#### **Chairman's Address**





Mr Robert Cooke, Non-Executive Chairman



## **Optiscan Board**







**Camile Farah** 



**Phil Currie** 



**Ron Song** 



**Karen Borg** 



#### **Chairman's Address**

- 2021 was a year of significant progress for Optiscan from both a commercial and governance prospective
- Optiscan's technology has the potential to the change standard of care for human cancer screening and surgery which is well recognised by medical community
  - Significant Board invigoration over last 12 months
    - Mr Robert Cooke appointed Chair on 19 April 2021 and new non-executive directors appointed Mr Ron Song [February 2021] and Ms Karen Borg [July 2021]
    - Professor Camile Farah appointed as a non-Executive Director in [May 2021], followed by his appointment as CEO/MD in December 2021 to replace outgoing MD Mr Darren Lurie
    - Mr Graham Mutton [July 2021] and Dr Phil Currie [following this AGM] resigned from the Board of Optiscan
  - Board structures have been reviewed and key sub-committees are being established including a Risk and Audit committee, and a Remuneration committee
  - The Company is well-funded Capital Raising of A\$9.8m in September 2020



#### **Chairman's Address**

- In the last six months the Board undertook a company wide review which included a number of internal and external presentations the findings from this review will form the basis to finalise our operational and strategic focus going forward under the new Board and Management
- Good progress was made in relation to the commercialization of Optiscan's key products
- Optiscan's established relationships with leading global medical technology companies, universities and hospitals are a strong endorsement of its unique technology
- The Board is committed to broadening and strengthening staff resources to enable accelerated regulatory, growth and sales strategies
- Optiscan is on the verge of the next stage in its exciting journey, as it seeks FDA approval for its InVivage® device for use in oral cancer, and trials are continuing in relation to other cancers and applications



## **Managing Director's Report**



Prof Camile Farah, PhD MBA MAICD FAIM CEO & Managing Director



## **Optiscan - Optimising for Growth**

## **Key Themes**

Technology is proven and differentiated

Clinical studies are providing opportunity to expand application footprint

Innovation and clinical data will accelerate market entry into USA



### Optiscan - Global leader in endomicroscopic imaging

# Differentiated Technology

World-leading miniaturized imaging technology

Hand-held confocal endomicroscopes for medical and research use

Highest quality images with significant doctor and patient benefits

# **Application Opportunities**

Clinical device (InVivage®) well progressed down FDA approval pathway

Clinical studies underway for cancer applications including oral, breast, cervical, esophageal



## **Market Expansion**

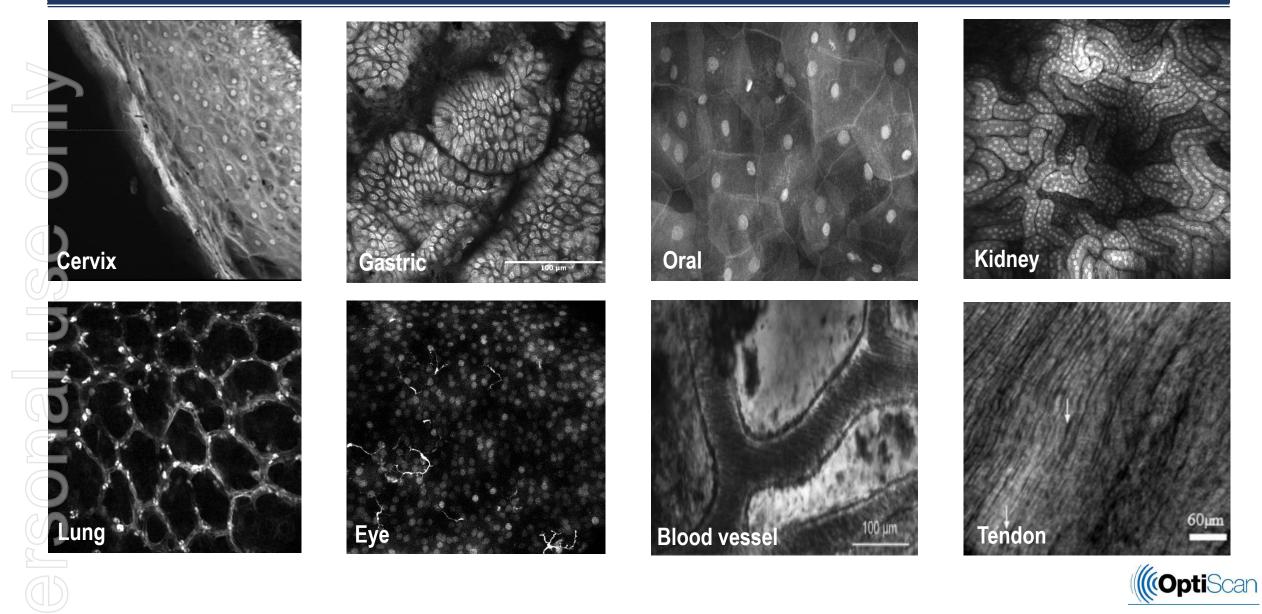
Strong balance sheet and shareholder support

International distribution network for research device in Asia, N. America & Australia

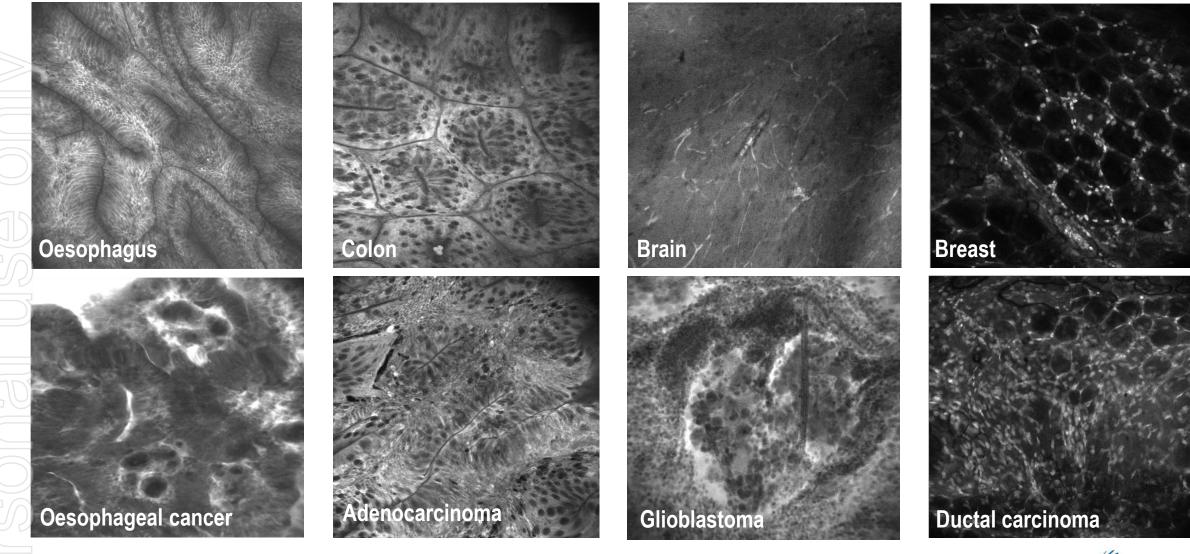
Global market entry & distribution strategy for clinical launch



## Unique ability to image different tissues

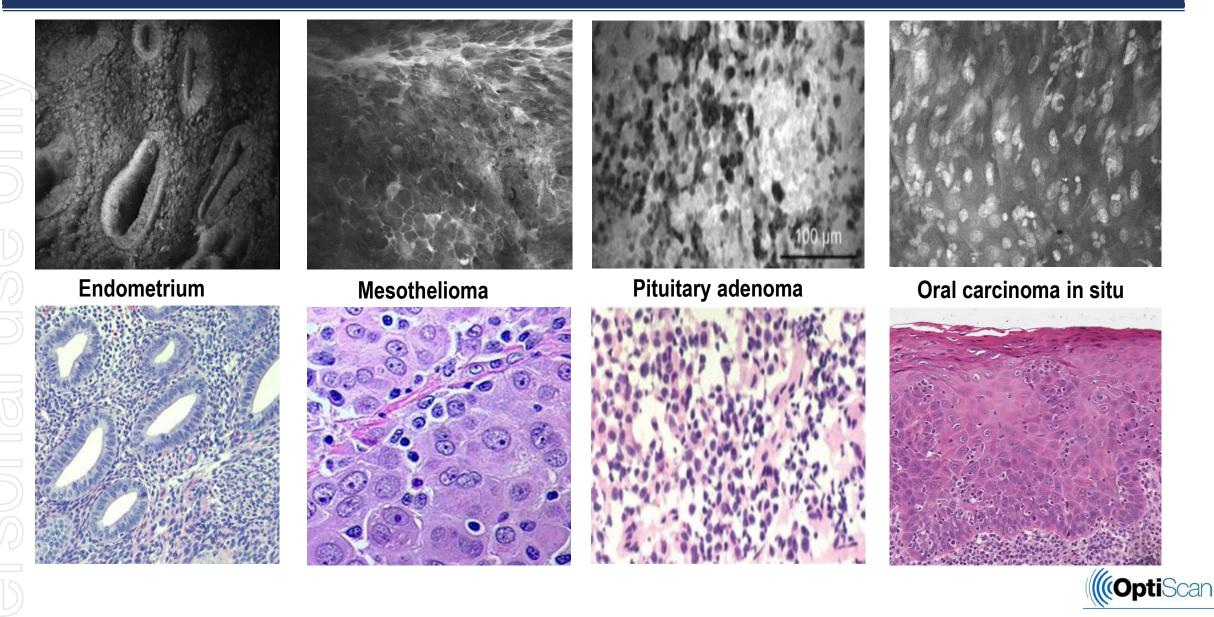


### Proven ability to differentiate cancer vs normal





## **Excellent correlation with current gold standard histopathology**



## **Strong Relationships and Partnerships**

Established relationships with leading global medical technology companies, universities and hospitals



Leaders in neurosurgery with digital pathology workflow recently approved by FDA



MELBOURNE



Memorial Sloan Kettering Cancer Center



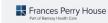




**Breast cancer study at leading Melbourne** hospitals









One of most highly regarded neurological centres in US Neurosurgery clinical studies

#### Other applications













- ACL injury
- Tissue culture
- Eye health
- Fish health

#### **Funding partners**











## Selected 2021 publications demonstrating Optiscan technology

#### Brain



Redosing of Fluorescein Sodium Improves Image Interpretation During Intraoperative Ex Vivo Confocal Laser Endomicroscopy of Brain Tumors

#### Brain



Molecular Imaging of Glucose Metabolism for Intraoperative Fluorescence Guidance During Glioma Surgery

#### Cervical



PARP1: A Potential Molecular Marker to Identify
Cancer During Colposcopy Procedures

#### Brain



Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey

#### Brain

### FOCUS FOCUS

Intraoperative imaging of brain tumors with fluorescein: confocal laser endomicroscopy in neurosurgery. Clinical and user experience

#### Tendon



A multiscale study of morphological changes in tendons following repeated cyclic loading

#### Brain



Confocal Laser Microscopy in Neurosurgery: State of the Art of Actual Clinical Applications

#### **Head & Neck**



Fluorescein-Guided Panendoscopy for Head and Neck Cancer Using Handheld Probe-Based Confocal Laser Endomicroscopy: A Pilot Study

#### Gut



Rapid testing of gut permeability using oral fluorescein and confocal laser endomicroscopy in Zambian adults



#### Optiscan – Positioned for unique clinical impact

Patients & Advocates

Enhanced accuracy of decision making and outcomes

Clinicians & hospital executives

Reduced negative impacts and cost savings

Markets & healthcare sector

Increased demand, maturity and readiness

Optiscan
technology
provides high
resolution real-time
digital images

Ability for noninvasive cellular imaging & surgical margin delineation Digital platform allows efficient workflow solutions and Aldiagnostics



#### Differentiated research and clinical devices for market diversification

#### FIVE2



**Research Device** 

#### **InVivage®**



**Clinical Device** 



#### FIVE2 Sales, Rentals and Loans

FIVE2 sales achieved

FIVE2 units on site

**FIVE2** demos in progress



brighter together









### InVivage® Clinical Device

#### **Overview**

- Miniaturized hand-held rigid probe (4mm diameter tip)
- Real-time, sub-cellular live microscopic imaging
- High resolution images, 1000x real magnification
- Advanced software user interface
- DICOM-compatible/PACS-enabled
- Targeting cancer screening and surgical margin assessment

#### **Clinical Applications**

**Oral Cancer** 

**Breast Cancer** 

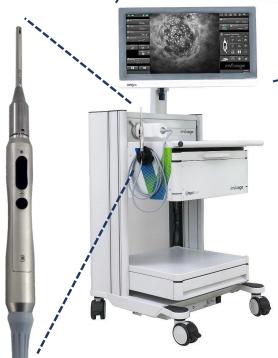
**Cervical Cancer** 













### InVivage® FDA submission process update

#### FDA approval process

- InVivage 510(k) submission through the FDA reduced timeframe pathway
- Aim to receive approval for use of images by clinicians, paving the way for follow-up FDA approval
- Submission to take place once all validation, verification and clinical activities are successfully completed
- Following submission, average time to clearance is approximately six months

#### **Progress update**

- Successfully passed multiple internal and external quality and safety tests
- Currently completing remaining tests, dedicating more resources for swift completion.
- Dosing study completed and significant progress made in clinical study at Melbourne Dental School



## **Key Achievements in 2021 (1/2)**

- ✓ Strengthening leadership and Board capabilities
  - Appointment of Mr Robert Cooke, Ms Karen Borg and Mr Ron Song to Board
  - Appointment of Prof Camile Farah as CEO & Managing Director

- ✓ Accelerating preparation for FDA application for InVivage approval in the US
  - Progress in Melbourne Dental School imaging sets
  - Advancement of internal and external and quality and safety testing for InVivage®
- U.S. FOOD & DRUG

- ✓ Progression of US market entry planning
  - Engagement with potential logistics and 3PL providers
  - Development of marketing collateral for launch











## Key Achievements in 2021 (2/2)

- ✓ Ongoing clinical studies to support oral/head & neck clinical applications
  - Advancement of in vivo screening study at Australian Centre for Oral Oncology in Perth
  - Commencement of 30 patient ex vivo study at University of Adelaide using FIVE2







- ✓ Completion of imaging for Breast Cancer Margin Assessment study
  - Completed patient recruitment and imaging component of breast cancer margin assessment study (ex vivo) at Royal Melbourne Hospital, Frances Perry House and Epworth Hospital – 38 patients



- ✓ Sales of 2 FIVE2 systems to leading Australian Research Institutions
  - Swinburne University as part of Victorian Government MedTechVic partnership
  - The Walter and Eliza Hall Institute





## **FY21 Financial Highlights**

- ✓ Strengthened balance sheet through a capital raising of \$9.8m
  - Backing of Clermont Group as major shareholder
- ✓ FY21 Total Income (operating revenue and other income) of \$2.54m, up ~28% on FY20
  - Increased distribution channels for FIVE2
  - Continued orders from Carl Zeiss Meditec
  - Grant income from InVivage® prototype and development

- ✓ FY21 EBITDA of (\$1.85m); FY21 Net operating cash outflow of (\$2.13m)
  - Spending to underpin future growth including scalability in production, prototypes, and clinical studies







## Oral Cancer study at Melbourne Dental School (1/2)

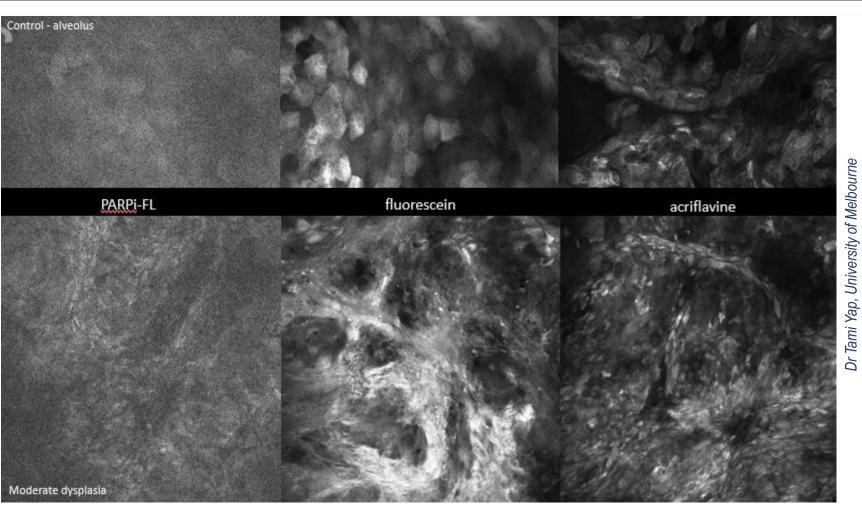
Results will assist with InVivage® FDA submission and open up clinical applications and markets

Summary	Summary	
Aims	<ul> <li>Triage and monitor oral tissue health and escalate the diagnosis of oral cancer</li> <li>Validate use of fluorescent probe and mouth map software in performing digital biopsy</li> </ul>	
Key investigators	Dr Tami Yap & Professor Michael McCullough	
Collaborators	<ul> <li>Royal Melbourne Hospital, Memorial Sloan Kettering Cancer Center, Peter MacCallum Cancer Centre</li> </ul>	
No. of patients	<ul> <li>Up to 150 patients between Q4 2020 and Q4 2022</li> </ul>	
Current progress <sup>1</sup>	<ul> <li>40 patients imaged with topical fluorescein showing a variety of pathologies to be used in FDA submission</li> <li>Progress with other imaging dyes (49 with PARPi-FL, 46 with acriflavine)</li> </ul>	



## Oral Cancer study at Melbourne Dental School (2/2)

#### Comparison of oral imaging using three dyes



- Using Optiscan
  technology, clinically
  abnormal areas can
  be identified as either
  precancerous or
  cancerous compared
  to normal tissue
- Multiple potential dye applications demonstrating similar disease profiles
- Future potential for oral cancer screening and detection



ormal

## Oral Screening study at Australian Centre for Oral Oncology (1/2)

Results will assist with development of machine learning and artificial intelligence algorithms for diagnostic applications

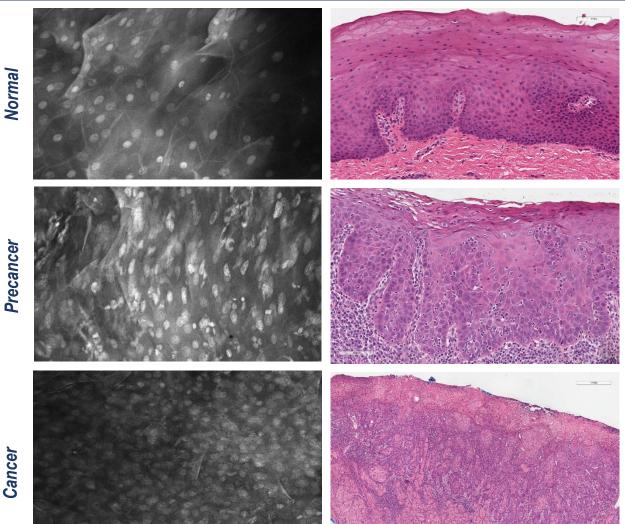
Summary	
Aims	<ul> <li>Image a range of oral lesions (cancer, precancer, benign) compared to normal</li> <li>Determine accuracy of correlation with standard histopathology</li> <li>Build artificial intelligence platform for computer-assisted diagnosis</li> </ul>
Key investigators	Professor Camile Farah, Oral Physician & Maxillofacial Pathologist
Collaborators	• University of Texas MD Anderson Cancer Centre, Harvard University, Claritas HealthTech,
No. of patients	123 patient datasets to Q4 2021
Current progress <sup>1</sup>	<ul> <li>Image analysis and histopathology correlation of topical acriflavine images</li> <li>Image annotation and curation for machine learning analysis</li> </ul>



## Oral Screening study at Australian Centre for Oral Oncology (2/2)

Centre for

#### Oral screening: Optiscan CLE technology vs. Histopathology



- 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 Al applications and computer-assisted oral cancer detection



## **Breast Cancer Margin Assessment study (1/2)**

Results from the breast study will open up a new clinical application and market offering

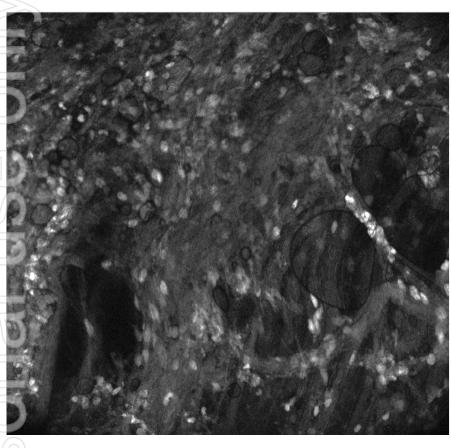
	Summary	
	Aim	Determine if intraoperative imaging of excised breast tissue can detect positive surgical margins compared to standard pathology
	Key investigators	Professor Bruce Mann, Royal Melbourne and Royal Women's Hospital
	Collaborators	<ul> <li>Dr Anand Murugasu, Dr Philip Currie, Lee McKerracher (Breast Cancer Network Australia),</li> <li>Frances Perry House, Epworth Freemasons</li> </ul>
N	No. of Patients	<ul> <li>Imaged 38 patients and 44 discrete tumors and related cavity shaves</li> </ul>
	Current progress <sup>1</sup>	Image analysis and comparison to histopathology with encouraging findings

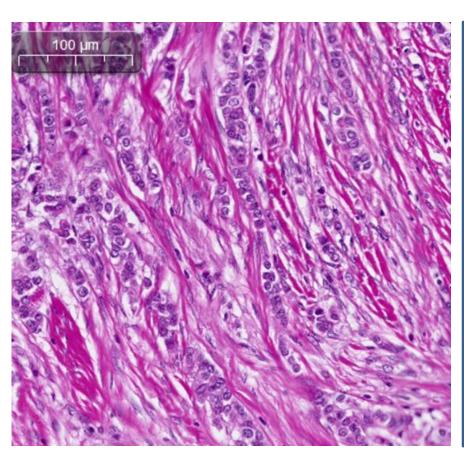


# Individual cells (0.5mm x 0.5mm)

## **Breast Cancer Margin Assessment study (2/2)**

#### Invasive Carcinoma of the Breast: Optiscan CLE technology vs. Histopathology





- Optiscan images mirror the current gold standard
- Optiscan technology can provide precise identification of cancer cells at surgery
- Future clinical studies are required to advance the path to commercialisation



#### **Optiscan - Immediate Priorities**

1

- Accelerate FDA approval of InVivage®
- Progress focused US launch

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- Enhance product functionality
- Drive product R&D

3

- Expand clinical applications
- Drive sales revenue through market growth



#### **Optiscan - Future Perspectives**

1

Expand development of InVivage® platform

2

- Advance miniaturization and dye alternatives
- Explore molecular imaging applications

3

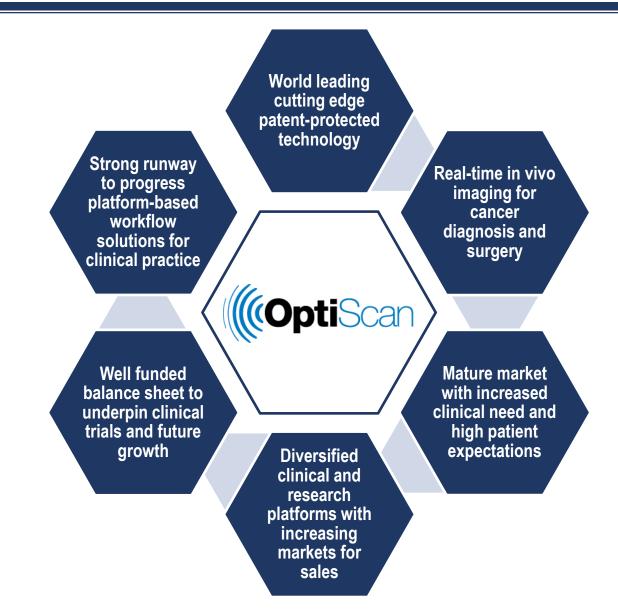
Target artificial intelligence applications<sup>1</sup>

2. Source: BCG 2019

Drive Al-related diagnostics<sup>2</sup>



#### Optiscan – Towards global leadership in medical imaging & diagnostics





#### **Question & Answer**

## Thank You





Thank you for your attendance

