Optiscan Imaging Ltd

FY21 Annual Results Presentation

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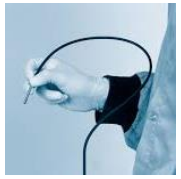
Optiscan Imaging Transformation in FY21

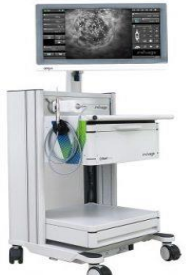
Major advances towards becoming a global medical imaging and diagnostics company

Optiscan at a glance

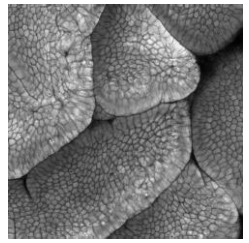
Optiscan Imaging Ltd (ASX:OIL) is a global leader in the development of endomicroscopic technology which enables real-time, 'in vivo' imaging of human tissue for cancer screening, diagnoses and in surgery



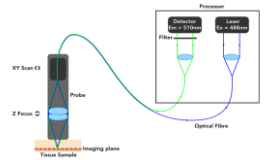
Develops and manufactures hand-held confocal endomicroscopes for medical and research use



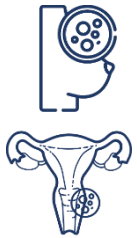
Key clinical device (InVivage®) well progressed down FDA approval pathway for use in oral cancer



Significant doctor and patient benefits through more targeted biopsies and reduced surgical margins



World-leading and patented protected technology



Trials underway for application to other cancers (including breast, cervical, oespohegal)

Co-operation with Carl Zeiss for use of CONVIVO device in neurosurgery

Global market entry and distribution strategy for InVivage® under development

Established distribution network for pre-clinical device FIVE2 across Asia, North America and Australia

Well funded balance sheet to underpin clinical trials and future growth

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Optiscan Key Achievements in FY21

- ✓ **Pathway to US FDA approval for use of InVivage® device in Oral Cancer on track**
  - Oral Cancer Clinical Trial to Support FDA approval process underway
  - Internal and third party device testing progressing
  - US market entry planning
- ✓ **Receipt of Federal Government Support**
  - Almost $1m of funding for Oral Cancer Screening trial in partnership with Melbourne Dental School
- ✓ **Development of Breast Cancer Surgical Margin Assessment clinical application**
  - Commencement and extension of 3 hospital Melbourne trial
- ✓ **Well-funded – Capital Raising of A$9.8m in September 2020**
- ✓ **Board Invigoration – Mr Robert Cooke appointed Chair and new non-executive directors (Mr Ron Song, Professor Camile Farah and Ms Karen Borg)**

Milestones and Recent Share Price Movement

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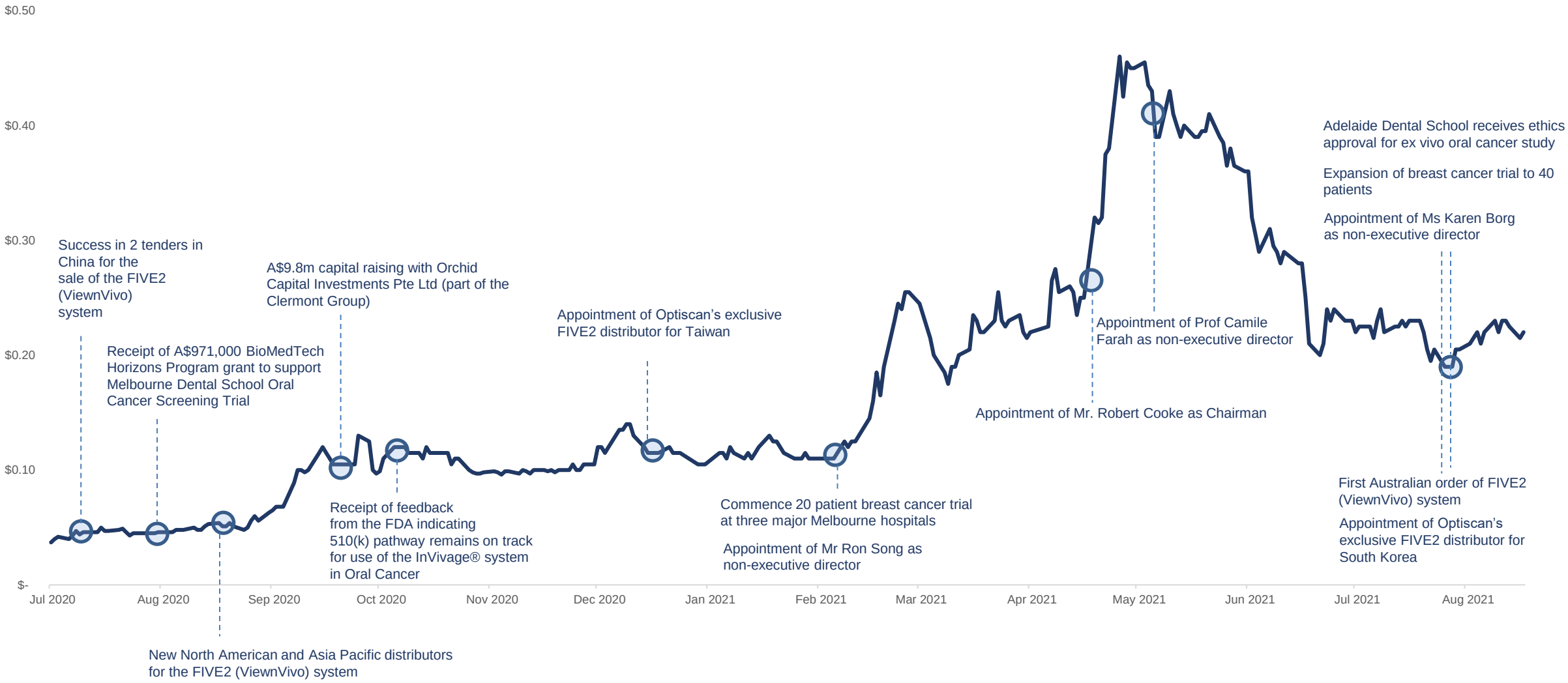

FY21 Financial Highlights

FY21 Total Income (operating revenue and other income) of $2.54m, up ~28% on FY20

- Benefits of new distribution arrangements for FIVE2 - 2 sales in FY21 and order received in July ‘21;
- Continued orders from CZM with sales of $500k as part of CONVIVO® co-operation agreement in neurosurgery
- Income from delivery of InVivage® prototype and product development under BioMedtech Horizons grant

FY21 EBITDA of ($1.85m); FY21 Net operating cash outflow of ($2.13m)

- Cost increase represents expenditure to underpin future growth including increasing scalability in production and quality assurance; spending on clinical trials, testing requirements, prototypes and FDA consultants
- Maintenance of expense discipline around operating costs

Strengthened balance sheet through a capital raising of $9.8m

FY21 Profit and Loss, Balance Sheet and Cash Flow

Profit and Loss*

	FY20	FY21	
Revenue	$940k	$500k	*Carl Zeiss Co-operation*
	$170k	$370k	*FIVE2 Sales*
	$80k	$20k	*FIVE2 Rental and other*
	$1,190k	**$890k**	**Total**
Other Income		$510k	*Melbourne Dental School Grant*
	$790k	$1,120k	*R&D Tax Incentive, Other Govt Support*
		$20k	*Interest*
Total Income	**$1,980k**	**$2,540k**	
Operating Expenses	**($3,150k)**	**($4,200k)**	*5 new staff to support business growth; FDA Consultant and testing costs*
EBITDA	**($1,470k)**	**($1,850k)**	
NPAT	**($1,770k)**	**($2,130k)**	

Cash Flow*

	FY20	FY21	
Cashflow from operations	($1,400k)	($2,130k)	
Cashflow from investing	($20k)	($30k)	
Cashflow from financing	$190k	$10,070k	*Capital Raising and exercise of options*
Total Cashflows	**($1,230k)**	**$7,920k**	

Balance Sheet*

	FY20	FY21	
Current Assets	$2,510k	$10,970k	*Capital Raising and exercise of options*
Non-current Assets	$940k	$730k	
Total Assets	**$3,440k**	**11,700k**	
Current Liabilities	(1,240k)	($970k)	*Repayment of all borrowings*
Non-current Liabilities	($650k)	($510k)	
Total Liabilities	**($1,900k)**	**(1,480k)**	
Net Assets	**$1,550k**	**$10,220k**	
Total Equity	**$1,550k**	**$10,220k**	

* Financials are subject to rounding

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Optiscan devices and current positioning

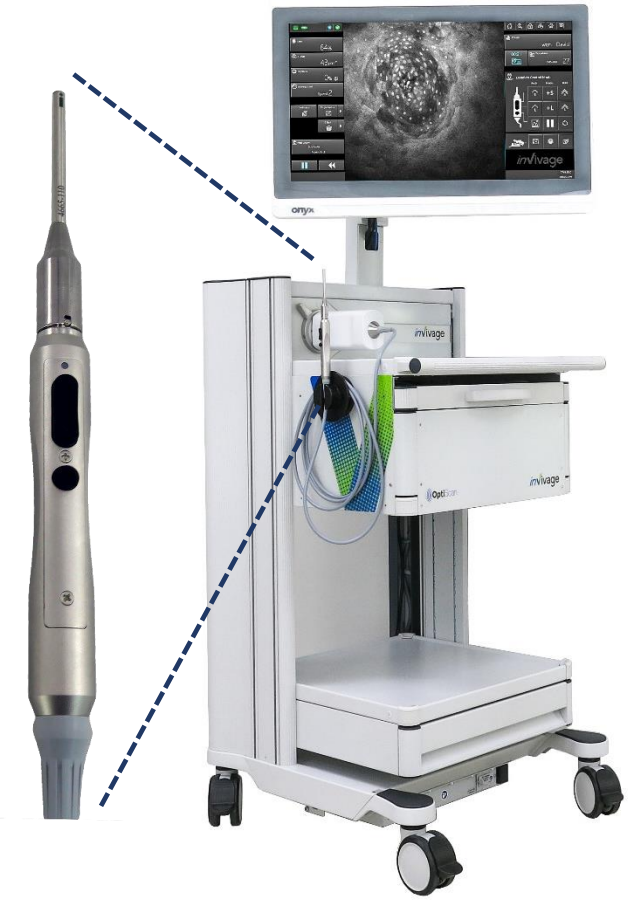
Overview of Optiscan devices

There are currently three devices at different stages of development and marketing, which all use Optiscan's unique hand-held, confocal endomicroscopic technology to deliver real time imaging at sub-cellular level

	InVivage®	FIVE2 (ViewnVivo)	CONVIVO® (co-operation agreement with Carl Zeiss Meditec)
Stage	• Seeking FDA approval for Oral Cancer	• Production and distribution	• Production and distribution
Overview	• Clinical device	• Pre-clinical device used in laboratory and translational experiments	• Co-operation agreement with Carl Zeiss Meditec
Applications and Users	• Oral cancer screening and surgery • Breast cancer surgery • Cervical cancer screening and surgery Hospitals and Cancer Centres	• Pre-clinical and translational research • Ex vivo human studies Medical research facilities and universities	• Neurosurgery / brain cancer Hospitals and Cancer Centres
Status	• Preparing 510(k) application for clearance in US (FDA) • Multiple clinical trials and studies in Australia and US	• Sales of A$370k in FY21 • Distributor network: China, Taiwan, South Korea, North America and Aust • First Australian order received in July 2021	• Sales of A$500k in FY21 • Approved for use in US (FDA) Europe (CE Mark) and Australia (TGA)

Optiscan InVivage® Clinical Device

- Cancer screening and surgical applications
- Miniaturised hand-held probe (4mm diameter tip)
- Instantaneous, sub-cellular resolution imaging
- Enabling more targeted biopsies and reduced surgical margins
- Digital transmission of images
- Initially targeting Oral Cancer Screening and Surgery
- Melbourne Dental Hospital trial of up to 150 patients, 91 sets of imaging completed.

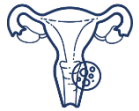


Clinical Applications:

Oral Cancer

Breast Cancer

Cervical Cancer



"Within the next 10 years, the use of digital microscopy will be quite commonplace across many medical specialties"
Dr Tami Yap, Chief Investigator, Melbourne Dental School

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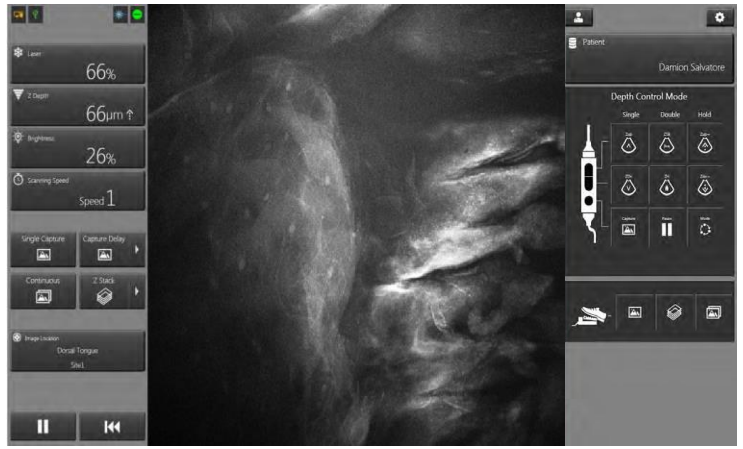
Advantages of InVivage® over Current Standard of Care

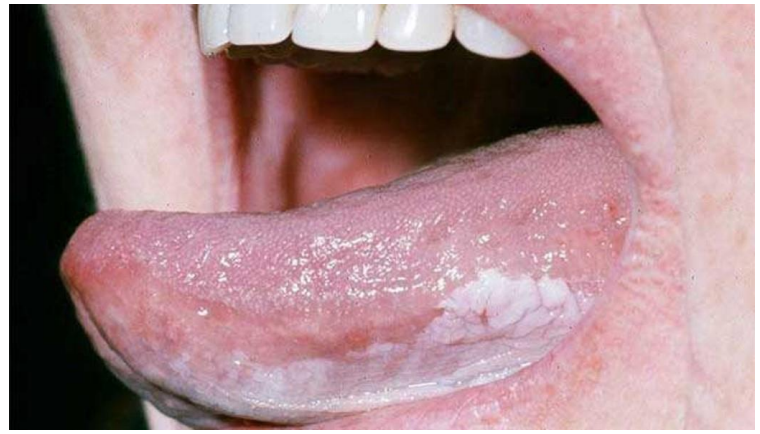
Screening applications (Oral and Cervical)

- Instantaneous, high-resolution images to enable fewer and more targeted biopsies
- Non-invasive image capture encourages screening and early detection
- Changes in cellular architecture not visible to the naked eye can be monitored over time



Surgical applications (Oral and Cervical)

- Tumour margin can be imaged and assessed at microscopic level
- Instantaneous image capture versus 2 or 3 days for pathology results
- Reduced healthy tissue surrounding tumours in sensitive areas (mouth) need to be removed
- Tumourous cells are removed to reduce repeat operations
- 4mm diameter probe tip lends itself to use in multiple parts of body



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InVivage® FDA approval process update

Optiscan is preparing a submission for 510(k) clearance for FDA approval for InVivage® device's use in oral cancer screening and surgery in the United States. Optiscan has successfully passed multiple external and internal tests on its pathway to lodging its submission and is currently completing the remaining tests and activities.

FDA approval process

- 510(k) submission - FDA reduced timeframe pathway
- Demonstrate device is as safe and effective (substantially equivalent) as a similar legally marketed device
- Submission to take place once all validation, verification and clinical trial activities are successfully completed
- Following submission, average time to clearance is approximately six months

Current status

- Q-Submission process undertaken – Optiscan received targeted FDA feedback
- Verification and validation activities are being undertaken internally and with overseas independent contract testing laboratories. Dosing study completed and clinical study underway at Melbourne Dental School.

Optiscan's FIVE2 (ViewnVivo) pre-clinical device

- Designed for translational and pre-clinical research
- Research findings from FIVE2 (ViewnVivo) in the laboratory are transferrable to InVivage®'s use in human patients
- New distribution arrangements commenced in North America, Taiwan and South Korea
- Completed 2 sales in China and received 1st Australian sales order
- Continuing to work closely with overseas distributors and will resume live demonstrations when COVID restrictions permit (a key component of the sales process)

"Optiscan's FIVE2 confocal laser endomicroscope delivers a crisp image of ligament and tendon fibre structure simultaneous with fluorescence imaging in a robust and easy to use package. Do you want the ability to collect "big microscope" data where only a millimetre-scale object can fit? Optiscan's CLE is a powerful tool for tissues research and medical diagnosis"

Prof. Mark M. Banaszak Holl, Professor and Head, Department of Chemical Engineering, Monash University

ZEISS CONVIVO® – Carl Zeiss Meditec AG (CZM) Co-operation

- The ZEISS CONVIVO® demonstrates how Optiscan's confocal imaging technology can be customised for specific medical applications
- Through close collaboration with CZM, Optiscan's technology is now being used in neurosurgery
- In recent years CONVIVO® has received FDA 510(k) clearance, CE Mark and TGA approval
- Current trials underway and approved in Europe, the United States and Australia are expected to increase endorsement and publicity from leading neurosurgeons
- While some marketing activities have been impacted by COVID-19 restrictions, Carl Zeiss have continued to make sales of the CONVIVO in Europe and North America during the pandemic

"This probably is the most exciting technology that I have seen in my career come through the laboratory." *- Dr. Mark C. Preul (MD), Neurosurgeon, Barrow Neurosurgical Institute, Arizona, United States.*

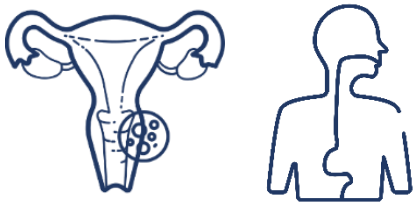
Optiscan – Clinical Studies

Oral Cancer

- 150 patient Oral Cancer Study at Melbourne Dental School (ranked #14 in world) funded by Australian Government BioMedtech Horizons Program. 91 sets of imaging completed
- Oral Cancer Study at Memorial Sloan Kettering Cancer Centre in New York (#2 cancer centre in US)
- Oral Cancer Screening Study at Australian Centre for Oral Oncology Research and Education in Perth
- 30 patient ex vivo study to commence at Adelaide Dental School (ranked #25 in world)

Breast Cancer

- Ex vivo lumpectomy and mastectomy study at Western Australia's largest private hospital.
- Breast Cancer Intraoperative Assessment Trial (ex vivo study) at Royal Melbourne, Frances Perry, Epworth Hospitals: Imaging of 33 of 40 patients completed to date.



Cervical & Oesophageal Cancer

- Ex vivo studies at Memorial Sloan Kettering Cancer Centre with planning for in vivo studies to commence

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Optiscan's relationships and partnerships

Optiscan's established relationships with leading global medical technology companies, universities and hospitals are a strong endorsement of its unique technology. Examples include:

Working with two highest ranked dental schools in Australia

- University of Melbourne (ranked #14 in world)
- University of Adelaide (ranked #25 in world)

Memorial Sloan Kettering, New York (2nd ranked US cancer centre)

- Oral cancer (re-agent trial)
- Cervical and oesophageal cancer studies

Carl Zeiss Meditec AG

Co-operation agreement for CONVIVO®

Breast cancer trial at leading Melbourne hospitals

- Royal Melbourne Hospital
- Frances Perry
- Epworth Hospital

Barrow Neurosurgical Institute, Arizona

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

Tissue culture collaboration

ACL injury study

Improving survival rates for oral cancer through early diagnosis

World Lip & Oral Cavity Cancer Incidence And Mortality

2%
Of all cancer incidence[1]

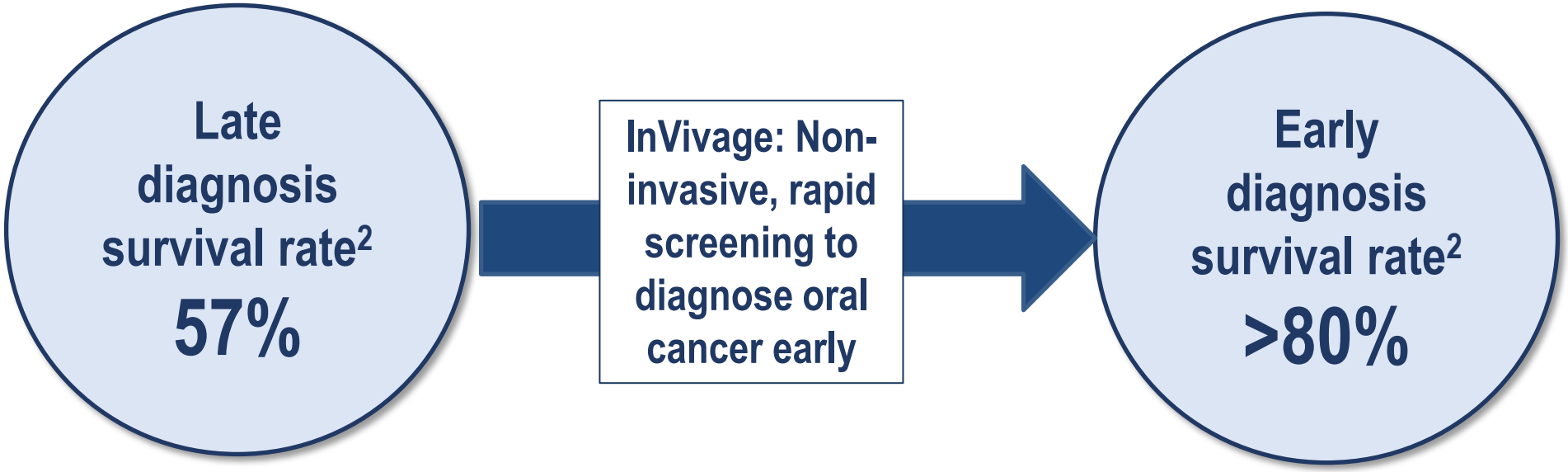
178k
Total deaths 2020[1]

378k
New cases 2020[1]

Early diagnosis is critical due to the rapidly declining survival rates as cancer progresses

Historically patients have delayed screening of oral lesions due to invasive nature of traditional biopsies and benign nature of many lesions

Optiscan's InVivage can provide a new standard of care to assist increased early diagnosis



1. Global cancer statistics 2020: GLOBOCAN estimates
2. Pollaers, K., et al., The economic burden of oral squamous cell carcinoma in Australia. Journal of Oral Pathology & Medicine, 2019. 48(7): p. 588-594. doi: 10.1111/jop.12907. Epub 2019 Jun 27.

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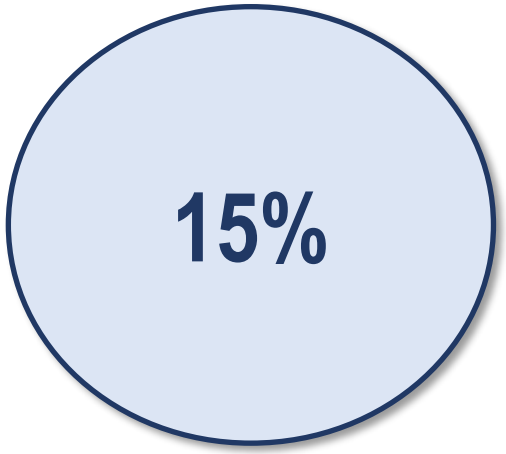
Improving patient and hospital outcomes in breast cancer

Breast cancer is most common cancer in women

2.3 million new worldwide cases of breast cancer in 2020[1]



15% of all new cancer cases in the US are breast cancer[2]

11.1% of all new cancer cases in China are breast cancer[1]

- **20-30% of lumpectomy patients currently require repeat surgery** with current practice (histopathology analysis) often taking 2 to 3 days post initial surgery
- Using InVivage® for detection and treatment of positive tumour margin at the time of surgery will **reduce the requirement for repeat surgeries** with reduced emotional trauma, physical pain and costs for patient and hospital

1. Global cancer statistics 2020: GLOBOCAN estimates
2. American Cancer Society Estimated 2020 statistics

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FY22 priorities and conclusions

FY22 Key Priorities

- Lodgment of FDA 510(k) oral cancer screening and surgical submission
- Finalise distribution strategy for InVivage® into United States market
- Plan regulatory submissions for InVivage® into European and other markets
- Undertake additional clinical studies in oral and other cancer applications
- Enhanced marketing of FIVE2 device in Australia and overseas
- Continue and enhance co-operation with Carl Zeiss Meditec
- Machine-based learning interpretation of images functionality

Conclusions

- Optiscan's technology changing standard of care for human cancer screening and surgery
- Portfolio of world leading patent protected imaging technology
- Well-progressed on FDA approval process for the use of the InVivage® device in oral cancer in US
- Significant interest and endorsement from medical community in InVivage®, with enhanced patient outcomes:
  - Early and less invasive detection
  - Reduced and more targeted biopsies
  - Reduction of tumor margin in surgery
  - Quicker turnaround times for results
- Growing pipeline of sales for FIVE2 pre-clinical device following a strengthening of the distribution network
- Ongoing sales from co-operation agreement with Carl Zeiss Meditec

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

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