oncosil MEDICAL
ASX.OSL

Company Update
July 2018

Advancing Pancreatic Cancer Treatment

OncoSil Medical | Investment Highlights

1 **Clear mission**

Commercialising a breakthrough implantation radiation treatment for Pancreatic cancer

2 **Sound science**

Current and previous clinical studies demonstrate:

- **Excellent Local Disease Control**
- **Significant reduction** in tumour size and volume
- **Excellent safety and tolerability** profile
- **Ease of implantation**

3 **Clear strategic path**

- Targeting **>$2bn market opportunity** to improve standard of care
- **U.S. FDA-approved IDE** in place, safety run-in underway
- **EU regulatory approval**, CE Marking expected near-term
- **Highly experienced management team**; strong clinical and commercial pedigree
- Manufacturing and logistics **optimised for supply of commercial quantities**
- At a potential value inflection point with multiple paths to commercialisation

OncoSil Medical

OncoSil™ is a medical device for the treatment of unresectable locally advanced pancreatic cancer

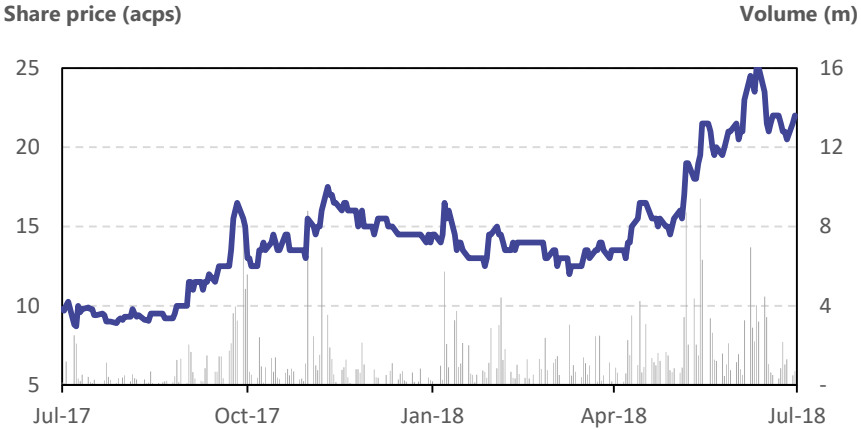
First in class technology

- Proprietary brachytherapy (internal radiation) medical device
- Cancer is treated by implantation of radioactive Micro-particles into a tumour via ultrasound guided endoscopy with negligible surrounding healthy tissues damage
- Patent protected in all major geographies
- Class III Medical device in the US and AIMD in EU

Financial information

Share price (as at 25-Jul-18)	A$0.22
52 week range	A$0.09 - 0.25
Shares on Issue	624.2m
Market capitalisation	**A$137.3m**
Cash (30 June 2018)	A$15.2m
Debt (30 June 2018)	Nil
Enterprise value	**A$122.1m**

Share price performance (1 year)



Substantial shareholders

Regal Funds Management	10.0%
Management and Directors	12.3%

About the OncoSil™ device

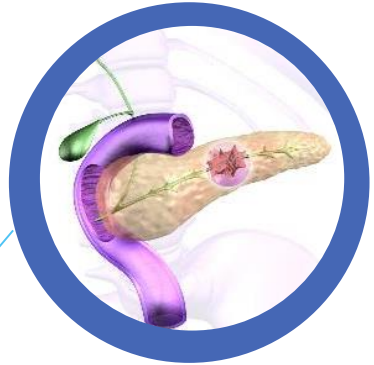
An implantable radiotherapy medical device targeting pancreatic cancer

- OncoSil™ is a **single-use brachytherapy device**
- Delivered through **Microparticles**: 30-micron silicon particles contain beta-emitting Phosphorus-32 (^{32}P)
- OncoSil™ Microparticles are inserted **directly into the tumour**
- Radiation from the Microparticles causes direct damage to cancer cell DNA. The device being active for approximately 3 months after implantation
- Microparticles stay in the tumour permanently

Implantation procedure

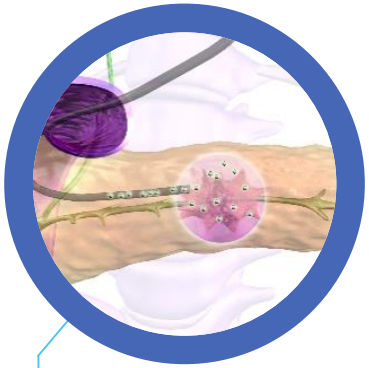
Studies continue to show the device implantation is technically straightforward

OncoSil™ dose is suspended in a specially formulated fluid for implantation



Endoscope guided into the upper intestine

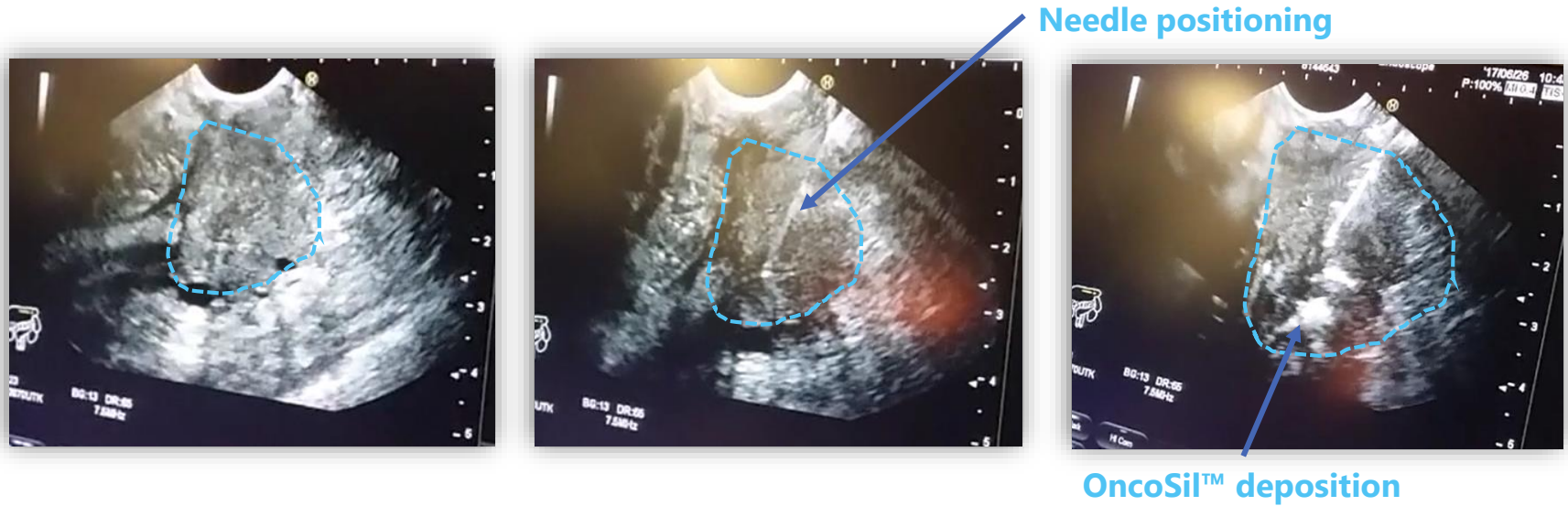
Using CT or real-time imaging, the needle is guided into the target lesion (tumour)



OncoSil™ injected directly into the tumour

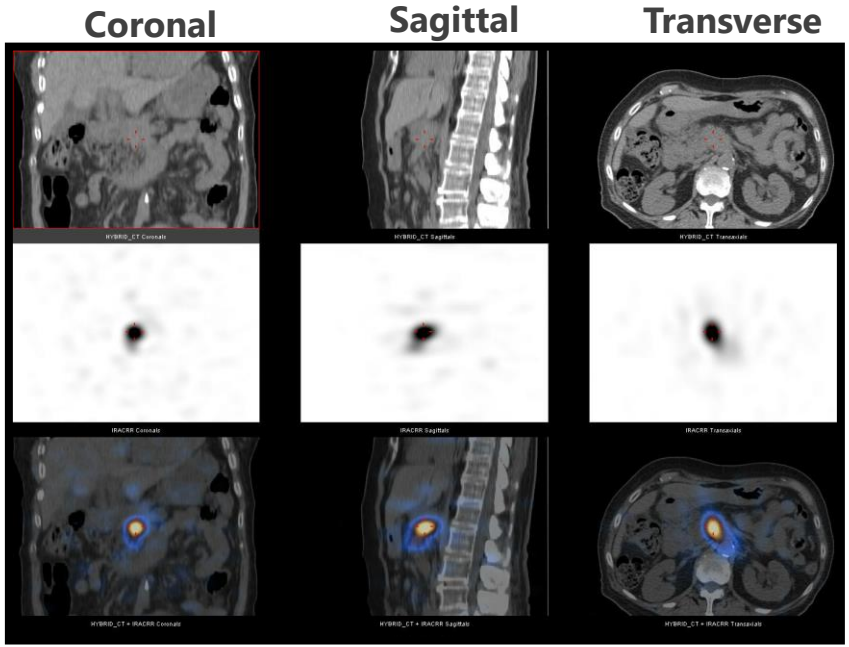
Real-Time Visualisation

Needle Positioning in Pancreatic Mass via Endoscopic Ultrasound (EUS)



SPECT-CT Bremsstrahlung Imaging

Used to Confirm Localisation of OncoSil™



Interaction of beta particles with tissue can produce bremsstrahlung x-rays which can be imaged with a gamma camera.

Single 'hot spot' signifies localised treatment

OncoSil at a potential value inflection point

The Company is well positioned to realise value of OncoSil™ device

Current focus

Before 2015: *Demonstrate potential*

- **4 studies show potential of OncoSil™ to treat pancreatic & primary liver (HCC) cancer**

2016 to 2018: *Satisfy regulatory obligations*

- Secured **US FDA IDE approval**
- Initiated PanCO & OncoPac-1 clinical studies
- **Highly positive early safety, efficacy and implant delivery data** consistent with results from previously completed studies

2018 onwards: *Path to commercialisation*

- Secure **strategic partnerships and licensing agreements** in all key geographies
- Secure **licensing agreements** in unique geographies
- Leverage potential for **broader distribution, capital and market support and exposure**

Clinical pathway overview

PanCO and OncoPaC-1 to inform future studies

Phases:

Current focus

2 concurrent trials, targeting 65 patients total

Future focus

Studies to drive clinical adoption (EU & global) and secure US FDA approval

Trials:

PanCO – *45 patients*

Open label study in patients with unresectable locally advanced *pancreatic cancer with OncoSil given in combination with SOC chemotherapy*

OncoPaC-1 – *20 patients*

Open label study in patients with unresectable locally advanced *pancreatic cancer with OncoSil given in combination with SOC chemotherapy*

Current trials inform future trials*

Company exploring clinical study options in ***resectable, borderline resectable*** *and* ***locally advanced pancreatic cancer indications.***

*Final decision on future studies to be taken based on data received from ongoing studies and feedback from US FDA**

Future trials to drive clinical adoption in EU and to generate data for US FDA approval (PMA)

Regulatory milestones:

CE Mark: *Company to provide 16 week data for first 20 patients to EU Notified Body by 31 May 18*

FDA approval

**FDA granted OncoSil an IDE (July 2016) and has requested 20 patient safety run. 10 patients must come from OncoPaC-1*

PanCO study – positive results to date

Positive clinical data on 35 patients (at Week 8) and 30 patients (at Week 16)

Study progress overview

50 patients enrolled[1]

41 patients implanted[1]

Clinical performance

- Disease Control Rate (DCR) of **100%** (Week 8) and **87%** (Week 16)
- **9** implanted patients so far have achieved a **Partial Response**
- **6** implanted patients so far have undergone **Surgical Resection**
- **Up to 73% and 80% tumour volumetric reduction at Week 8 and 16 respectively**
- Median volumetric reduction of 25% (at week 8) and 33% (as week 16)

Partial Response *– a reduction in tumour longest diameter of at least 30% from baseline*

Resection *– the* ***only potential cure*** *for pancreatic cancer, demonstrating possibility of improved outcomes in patient group deemed inoperable at time of study entry.*

Safety & implantation

- Well tolerated with reassuring safety profile confirmed by independent Safety Review Committee
- OncoSil™ device delivery via EUS considered straightforward for implantation

1. *As at 5-Jul-18*

Tumours successfully resected

Recap of study context

- Study population drawn from patients with **unresectable** locally advanced pancreatic cancer
- Primary objective of treatment with OncoSil™ for these patients is to control tumour growth

- 6 implanted patients so far have undergone surgical resection **with curative intent** (undergoing the Whipple procedure)
- 5 patients have achieved R0 surgical margins (Clear Margins): R0 a recognised marker of improved survival

SIGNIFICANT MILESTONE FOR PanCO STUDY

Demonstrates improved outcomes in group of patients deemed inoperable at time of enrolment

RESECTION IS THE ONLY CURE FOR PANCREATIC CANCER

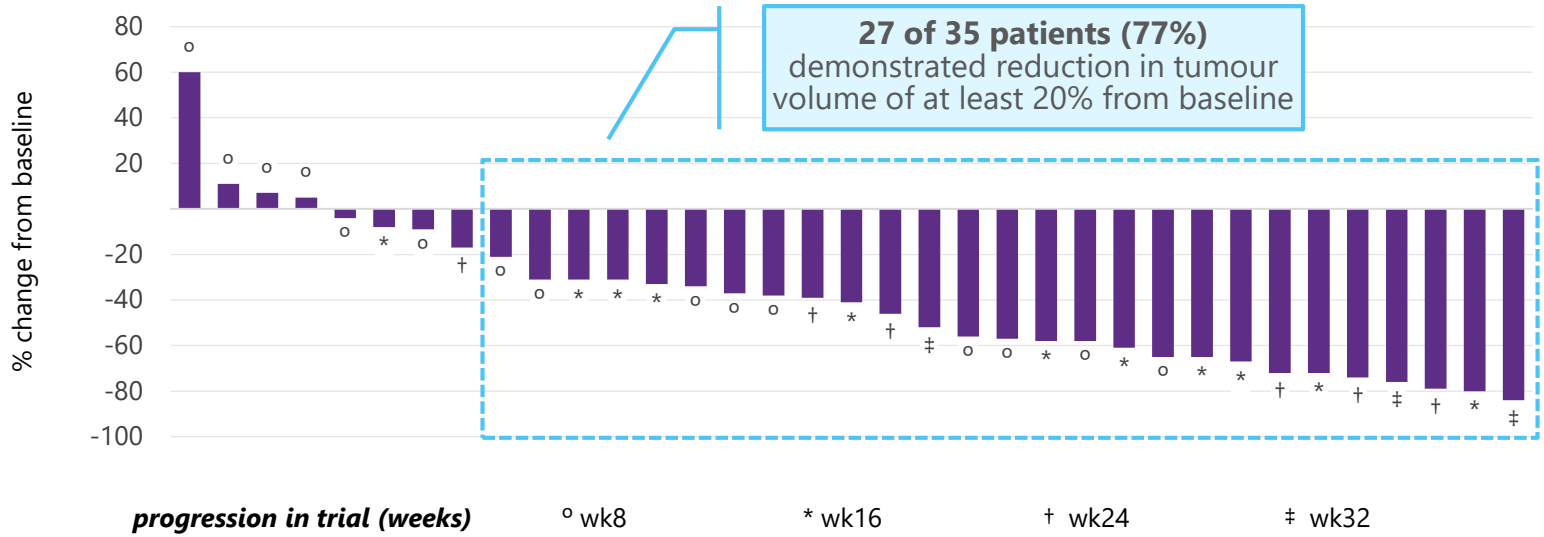
But <15% of all diagnosed pancreatic cancer patients will be eligible for surgical resection

CONTINUED PROGRESS WILL BE CLOSELY MONITORED

Down-staging patients to resection is not an objective endpoint in the PanCO study, however will be closely followed as more data is collected.

Substantial tumour volumetric reduction

Best tumour volumetric change in first 35 implanted patients



Significant opportunity for OncoSil

Current available treatment for pancreatic cancer

- Surgery (resection), if diagnosed early enough
- Chemotherapy (Gemcitabine & Abraxane, FOLFIRINOX)

GEMZAR gemcitabine HCl (for injection) Abraxane® nanoparticle albumin bound paclitaxel

- External radiation therapy

Issues with current standard of care

- Symptoms often unnoticed until cancer has metastasised; poor prognosis even with therapy:
  - Median survival ~8 months[1]
  - 5 year survival less than 5%[1]
- Surgery not feasible in 85% of patients
- Chemotherapeutic treatments limited effectiveness and are very toxic
- Radiation therapy is toxic to the patient's GI tract

The opportunity for OncoSil

- Only two drugs to have made significant improvements in pancreatic cancer in over 20 years:
  - Gemcitabine approved over 21 years ago and Abraxane approved in 2013
  - Median overall survival has increased by only 2 months (to 8.5 months) over the past 20 years

Significant opportunity for OncoSil to become standard of care in combination with Chemotherapy

1. **American Cancer Society 2010 Accessed on 9 September 2015**

Positive reception at key conferences

Early study data presented at 3 leading conferences:

European Association of Nuclear Medicine Annual Congress 2017

Digestive Disease Week 2018

European Society of Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer 2018

EANM® European Association of Nuclear Medicine

✓ The EANM is the **largest organisation** dedicated to Nuclear Medicine in Europe

DDW Digestive Disease Week®

Digestive Disease Week
Washington, June 2018

✓ DDW is the **leading annual US conference** in the field of **gastroenterology**

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO World Congress on Gastrointestinal Cancer, Barcelona, Spain June 2018

✓ ESMO is Europe's **leading non-profit medical oncology organisation**

12TH WORLD CONGRESS OF THE WORLD FEDERATION OF NUCLEAR MEDICINE AND BIOLOGY
20–24 April 2018 | MELBOURNE, AUSTRALIA

World Congress of the World Federation of Nuclear Medicine and Biology - *Melbourne, April 2018*

OncoSil data presentations by two research groups at WFNMB 2018

Future conference presentations in 2018

UNITED EUROPEAN GASTROENTEROLOGY ueg

United European Gastroenterology is a professional non-profit organisation **combining all the leading European societies** concerned with **digestive health**.

Early study data selected for oral presentation

United European Gastroenterology Week, Vienna, Austria – October 2018

EANM® European Association of Nuclear Medicine

EANM 2018, Dusseldorf, Germany – October 2018

Presentation by UK research group

Partnering with leading cancer centres

15 leading cancer centres participating in Global Pancreatic Cancer clinical programme

Region	Centre
	MD Anderson, Texas
	Johns Hopkins, Maryland
	Moffit Cancer Centre Florida
	Cedars Sinai Hospital, LA
	Guy's & St Thomas', London
	University of Leicester
	Hammersmith, London
	Addenbrookes, Cambridge
	Monash, Melbourne
	St Vincent's, Sydney
	Westmead Hospital, Sydney
	RNS Hospital, Sydney
	Royal Adelaide
	The Austin Hospital, Melbourne
	Jules Bordet Institute Hospital, Brussels

Clear pathway to commercialisation

Strategic partners provide multiple paths to market to optimise value

Well positioned for commercialisation

Broad technology platform
Treatment for multiple solid tumours

Excellent clinical results
Pancreatic and primary liver cancer

EU regulatory approval
CE Mark certification for pancreatic cancer expected near-term

Significant unmet clinical need
Over130,000 patients diagnosed with pancreatic cancer in US and EU every year

Potential paths to market

Strategic licensing partners in all key geographies
- EU
- US

Additional licensing partners in unique geographies
- China
- Japan
- India

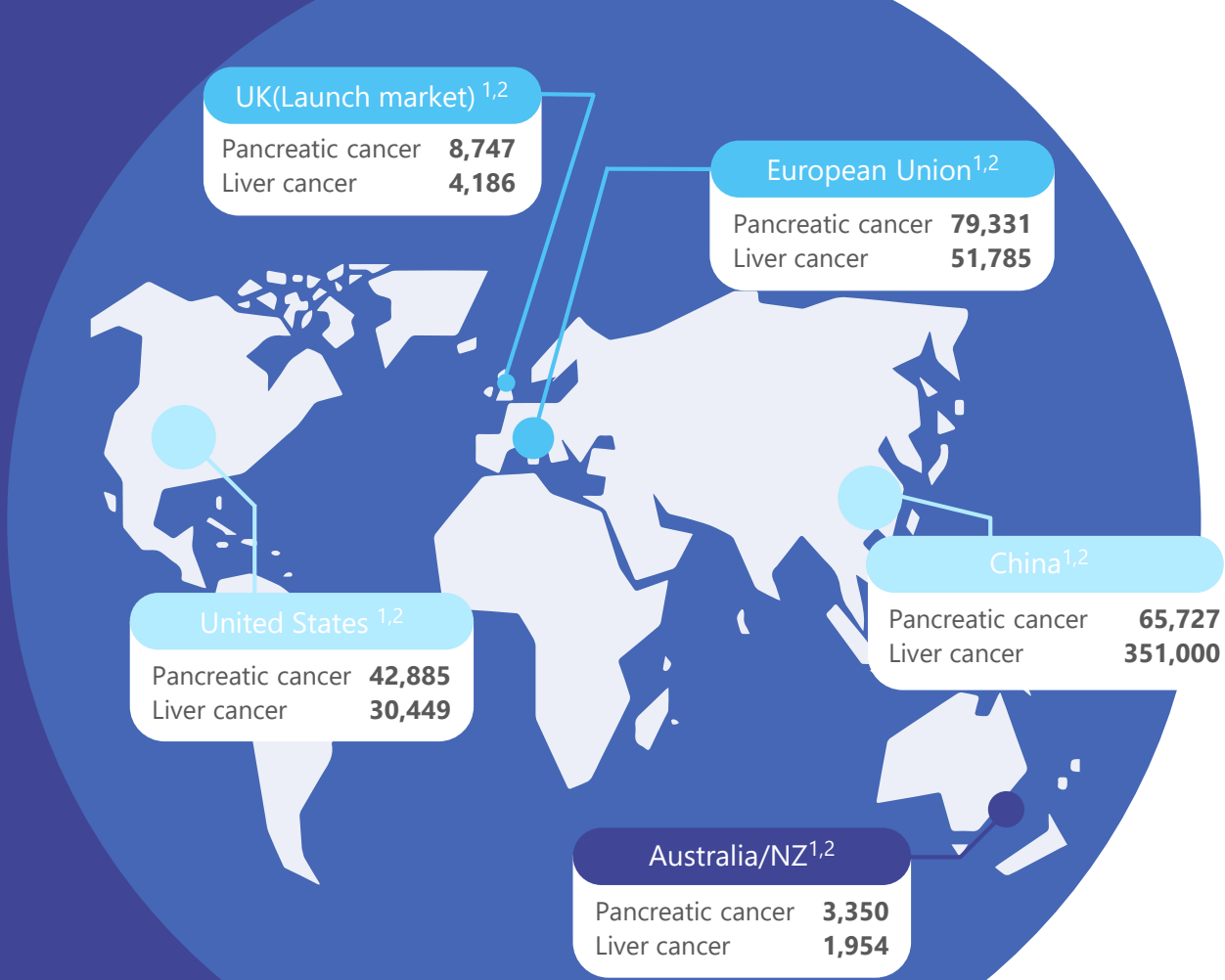
2018 marks the start of this journey

1. GLOBOCAN 2012: Estimated Cancer Incidence Worldwide in 2012 (IARC/WHO). Accessed 22 Apr 2016,from http://globocan.iarc.fr/Pages/fact_sheets_population.aspx

Target markets

Annual incidence

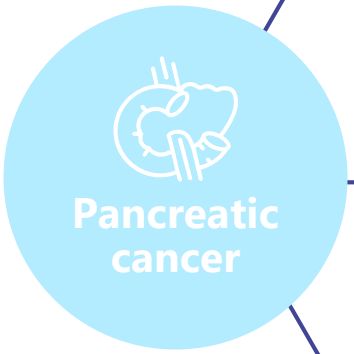
Global opportunity	
Pancreatic cancer	US>$2.0bn
Liver cancer	US$1.4bn



1. GLOBOCAN 2012: Estimated Cancer Incidence Worldwide in 2012 (IARC/WHO). Accessed 22 Apr 2016, from http://globocan.iarc.fr/Pages/fact_sheets_population.aspx
2. Datamonitor Healthcare 2013
3. OncoSil dose pricing, $USD 25,000

Global Commercial opportunity in excess of $2bn

130,000 cases per year in US+EU alone: more than 70,000 of these could benefit from OncoSil™



Locally advanced
35-40%

OncoSil™ provides a suitable treatment to control the growth of the primary tumour and provide meaningful reductions in pain

Surgical re-section
15%

OncoSil™ could be used to downstage tumours prior to surgery to improve surgical outcomes

Metastatic disease
40-45%

Unlikely to benefit overall survival but OncoSil™ may be used to control tumour growth, alleviate pain and improve quality of life

More than 70,000 relevant patients in EU and US alone

Company exploring clinical research options in resectable & borderline resectable patients

OncoSil's potential pricing of US$25,000 per patient (in-line with other on-market devices) implies **>$2bn global market opportunity**

Sector M&A trends

Over A$2bn of acquisitions in February 2018 highlights attraction of early-stage Australian biotech to global pharmaceutical players

Acquiree	SIRTeX	Viralytics Developers of Oncolytic Immunotherapies	elastagen
Acquirer	GDH INVESTMENTS 鼎晖投资	MERCK	Allergan
Consideration	**A$1.9 billion**[1]	**A$502 million**[1]	**A$120 million**[1]
Date	22 May 2018	22 Feb 2018	6 Feb 2018
Premium	78% (29 Jan 2018)[3]	160% (1 month VWAP)[2]	Private company
Technology	Brachytherapy	Oncolytic immunotherapy	Injectable tropoelastin
Deal status	***In progress***	***Complete***	***Subject to FIRB approval***

Note:

1. *Based on disclosed consideration*
2. *Based on disclosed premium to target's volume weighted average price prior to announcement*
3. *Undisturbed Sirtex Share price the day prior the initial Varian takeover bid*

Board of Directors

- Board and management are experienced leaders in the pharmaceutical and medical device space, having held senior positions at **Cochlear** (ASX:COH), **Sirtex Medical** (ASX:SRX), ABIVAX, Baxter International, Roche and more
- Extensive leadership experience guiding products from clinical development to commercialisation
- **120+ years collective experience** in the health care industry

Dr Chris Roberts
Chairman

- Former CEO/President of Cochlear (ASX:COH)
- 40+ years' industry experience
- Former Chairman of Sirtex (ASX: SRX) & Executive Vice-President of ResMed (ASX: RMD)

Mr Daniel Kenny
CEO & MD

- Proven biopharma professional, leading multiple $1bn+ franchises
- 30+ years industry experience
- Commercial development at ABIVAX & global strategic marketing & business development at Roche

Dr Roger Aston
Non Executive Director

- Biotech & pharma entrepreneur
- 20+ years industry experience
- Founder & former CEO of pSiMedica & pSiOncology
- FDA & EU registration, global licensing & equity capital raisings experience

Dr Martin Cross
Non Executive Director

- Former Chairman of Medicines Australia
- Highly regarded pharmaceutical executive with 30+ years experience in corporate & industry leadership roles

Highly experienced management team

- Management team experienced leaders in the medical device space having held senior positions at **Sirtex Medical** (ASX:SRX)
- Extensive leadership experience in clinical studies, commercialisation and manufacturing & operations

Mr Daniel Kenny
CEO & MD

- Proven biopharma professional, leading multiple $1bn+ franchises
- 30+ years industry experience
- Commercial development at ABIVAX & global strategic marketing & business development at Roche

Mr Tom Milicevic
Chief Financial Officer & Company Secretary

- Seasoned CFO with over 18+ years experience in the Medical Device sector
- Experience in investor relations and also Company Secretary duties

Dr Ashish Soman
Chief Medical Officer

- Former country medical director, AstraZeneca Australia.
- 20+ years' experience in clinical practice & the biopharmaceutical industry

Dr David James
Manufacturing & Operations Manager

- Ex Sirtex Medical global operations manager for 6 years
- Established Sirtex's manufacturing and operations
- 25 years experience in pharmaceutical operations

Nicole Wilson
VP Regulatory Affairs & Quality

- Regulatory affairs specialist focused on quality compliance and marketing registrations in the Asia, South America and middle East.
- Principal for the regulatory approvals in Brazil, Argentina and UAE for Sirtex.

Michael Warrener
Global Sales & Marketing Director

- Former Sirtex Medical Senior Executive
- Introduced Sir-Spheres in Australia, EU and Middle East markets

Key catalysts in CY 2018

CE Mark

- Target CE Mark Certification
- Target EU first sales

Global Pancreatic Clinical Study programme

- Completion of PanCO clinical study, with 50 patients currently enrolled
- OncoPaC-1 trial progress: 6 patients currently enrolled
- Congress presentation of latest patient data from clinical programme
- New clinical studies planned for CY2019

Strategic partnerships

- Securing strategic partnerships and licensing agreements in key geographies
- Additional Licensing partners in unique geographies

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