

ONCOSI MEDICAL ASX.OSL

# Advancing Pancreatic & Liver Cancer Treatment

Australian Biotech Invest 2017 October 24<sup>th</sup> Melbourne

OncoSil Medical

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# **Investment Highlights**

- Developing a **breakthrough implantable radiation treatment** for Pancreatic and Liver cancer
- Current and previous clinical studies demonstrate **significant reduction in tumour size & volume, good safety and tolerability profile and ease of implantation**
- US FDA-approved IDE in place, safety run-in underway
- Targeting a **\$1bn market opportunity** to improve standard of care
- Manufacturing and logistics are optimized for supply of commercial quantities
- Highly experienced management team with strong clinical and commercial pedigree
- Planning **commercial launch in Europe**, pending CE Mark

# **OncoSil Medical**

# OncoSil<sup>™</sup> is a first in class medical device for the treatment of unresectable locally advanced pancreatic cancer

### First in class technology

- Proprietary brachytherapy device that emits cancer-killing radiation into a tumour without damaging healthy surrounding tissues
- Patent protected class III medical device meaning it needs less clinical work, funding and time to get to market compared to drug development

### Significant clinical achievements to date

- Previous Phase IIa study (DB2-201)
  - Significant anti-cancer activity
    - Target Tumour response rate 23.5%
    - Target Tumour control rate 82.4%
    - Median progression free survival 121 days
  - Acceptable safety profile and device well tolerated
  - Significant progress in FDA approval; IDE granted in July 2016
  - Global Pancreatic Cancer Study underway
    - Early data to be presented at EANM, Vienna October 2017

#### **Financial information**

Enterprise value	A\$67.5m
Debt (31 September 2017	Nil
Cash (31 September 2017)	A\$8.5m
Market capitalisation	A\$76m
Shares on Issue	487.5m
52 week range	A\$0.08-0.16
Share price (as at 16-Oct-17)	A\$0.16

#### Substantial shareholders

Regal Funds Management	9.7%
Webinvest	5.9%
Management and Directors <sup>1</sup>	14.6%

### **OncoSil<sup>TM</sup> device overview**

An implantable radiotherapy medical device targeting pancreatic and liver cancers



OncoSil<sup>TM</sup> is a **single-use brachytherapy device** 



Delivered through **microparticles**: 30-micron silicon particles contain beta-emitting Phosphorous<sub>32</sub> (P32)

OncoSil<sup>TM</sup> microparticles are inserted **directly into the tumour** 



Radiation **kills cancer cells directly**, with 98% of all radiation delivered within 81 days of injection

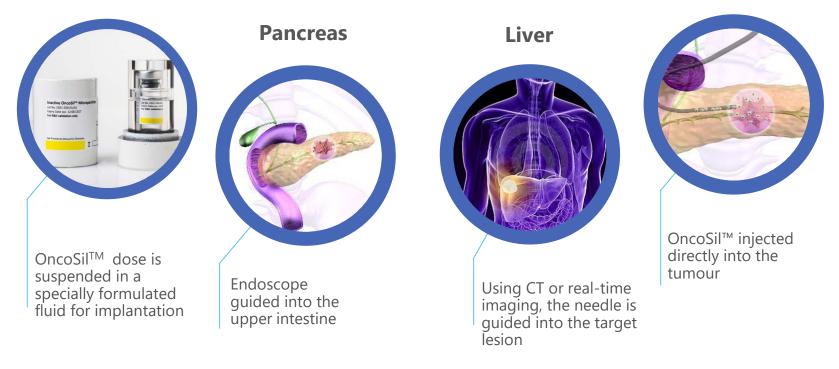


Inert microparticles stay in the tumour permanently



### **OncoSil<sup>™</sup> procedure**

The procedure is minimally invasive and allows for targeted radiation



# EANM Congress – Early study results

### Early results presented at European Association of Nuclear Medicine on 21-Oct-17

### **Clinical Performance**

- Excellent local disease control Disease Control Rate (DCR) 100% @ Week 8
- Early and substantial tumour volume reductions up to 73% volumetric reduction observed 4 weeks post implant, Median volumetric reduction 34.5% at 4 weeks post implant
- No serious Adverse Events attributed to device or implantation procedure

### Safety

Reassuring safety profile as conformed by First Independent Safety Review Committee meeting

- No SAEs attributed to device or implantation procedure
- SAEs related to chemotherapy or complications arising from cancer progression
- No evidence of radiation toxicities
- No other safety concerns identified to date

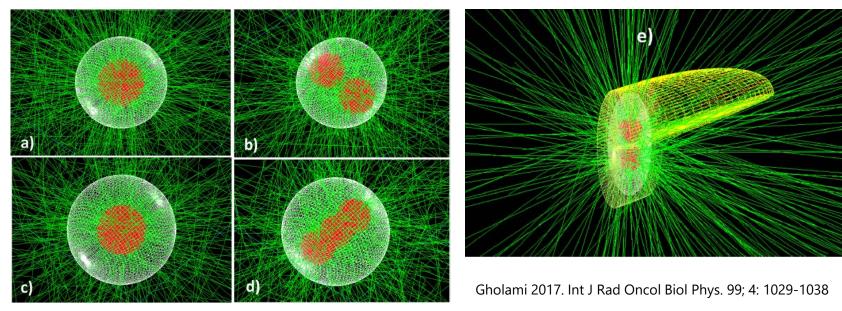
### **Implantation Procedure**

• Continuing to refine and optimise implantation technique. OncoSil<sup>™</sup> device delivery via EUS is considered easy to use for implantation.

# Delivering a single dose of OncoSil<sup>™</sup> microparticles

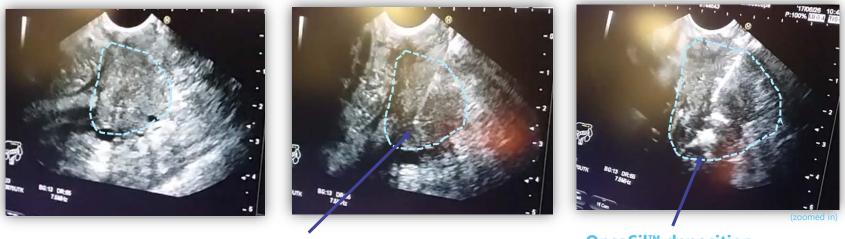
### A single dose is implanted into the body of the tumour

Delivers 100 Gy of radiation to the tumour mass



### Implantation via Ultrasound guided endoscopy EUS

**OncoSil™ device delivery via EUS is considered easy to use for implantation** 

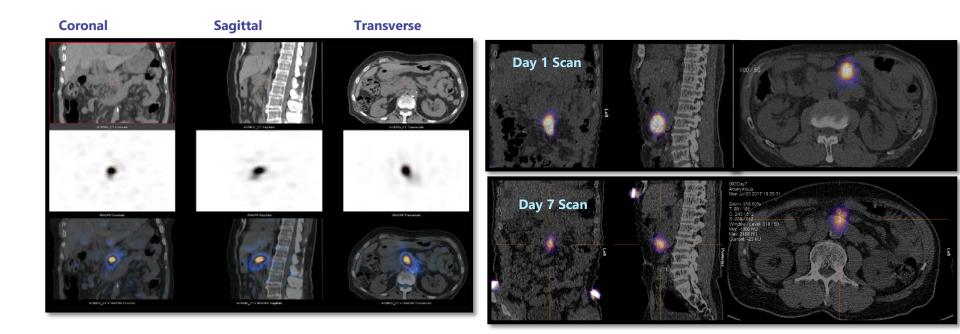


**Tumour Outline** 

**Needle positioning** 

**OncoSil<sup>™</sup> deposition** 

### **Images post implantation**

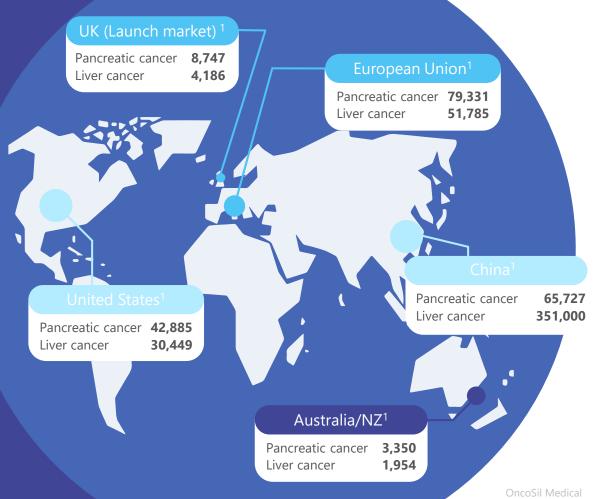


# Target markets Annual incidence

Liver cancer	US\$1.4bn
Chemo regime External radiation	US\$60,000 €9,000
Pancreatic cancer	US\$1.0bn
Global opportunity <sup>2</sup>	

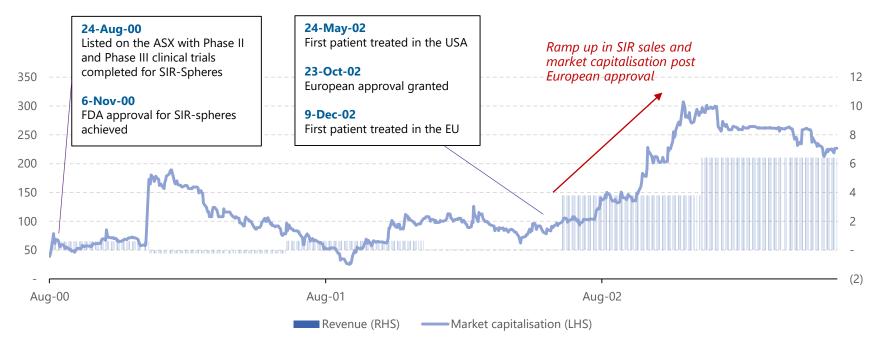
1. GLOBOCAN 2012: Estimated Cancer Incidence Worldwide in 2012 (IARC/WHO). Accessed 22 Apr 2016, from http://globocan.iarc.fr/Pages/fact\_sheets\_population.aspx

2. Datamonitor Healthcare 2013



# **OncoSil's commercial path has precedent**

SirTex provides a useful case study to demonstrate the potential commercial journey for OncoSil due to similarities in addressable market



# **Highly credentialed 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



Martin Cross Non Executive Director

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

# **Deeply 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 • 15+ 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, AstraŽeneca 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

- 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

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OncoSil Medical 15