



# OncoSil Medical

28<sup>th</sup> November 2014

ASX: OSL



New Technology To Provide Safer Radiotherapy Treatments

Shareholder Update  
AGM 2014

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# OncoSil™ - Potential treatment for Pancreatic Cancer

## Next Generation Radiotherapy

- OncoSil Medical has an **implantable nuclear medicine ( radiotherapy) device** that is commencing a pivotal study in pancreatic cancer.
- **Localised radiation therapy** is inherently safe, effective and well tolerated and matches well with the features of pancreatic cancer.
- There are highly **commercially successful precedents** for radiation therapy in:
  - Prostate cancer - Xofigo, Bayer (\$2.4bn acquisition of Algeta) – metastatic to bone
  - Liver cancer – SIR-Sphere, Sirtex
  - Non Hodgkin's Lymphoma – Zevalin, Spectrum Pharmaceuticals – targeted antibody



**Localised radiotherapy is a potential new approach for pancreatic cancer patients.**

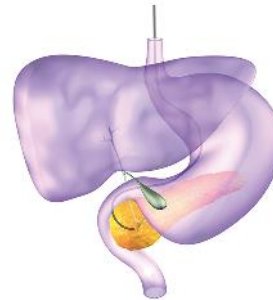
## Radiation therapy delivered to the cancer site

- **Pure beta radiation source (P32)** to avoid systemic side effects
- **Localised radiation therapy** using “sticky” microparticles
- **Carrier particles are inert silicon**
- **Particles are suspended in fluid** to allow direct injection into the tumour
- **Single Injection** under anesthesia takes 30 minutes
- **Local radiation in the tumour lasts around 3 months**

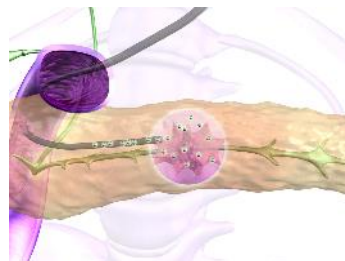
# How OncoSil™ Works



**OncoSil™ is suspended in a shielded syringe in the operating theatre where a physician will make the injection of the device into the pancreatic tumour.**



**The physician guides an endoscope down the oesophagus, through the stomach and into the first part of the small intestine. Ultrasound is used to image the tumour in the pancreas, then extends a needle from the end of the scope into the pancreas and into the middle of the tumour.**



**The physician then injects the OncoSil™ suspended in fluid directly into the tumour.**

# OncoSil™ Benefits

- Localised treatment reduces serious side effects associated with standard radiotherapy
- Classified as a device therefore shorter time to market than traditional drug development
- Synergistic effect with current chemotherapy regime as gemcitabine 'sensitise' cells to radiation therapy





# Unmet Medical need



## Unmet Medical need

- Current treatment \$60,000/patient
- 280,000+ pancreatic cancer incidence yearly world wide (1)
- Approximately 45,000 new patients diagnosed with pancreatic cancer in the US each year
- Poor prognosis -Median survival ~8 months and 5 year survival less than 7%

# Clinical data to date

## Clinical Trial Results

- 17 inoperable pancreatic cancer patients in single arm study
- Significant anti-cancer activity – disease control rate of 82% : 4 Partial Responses, 10 Stable disease and 3 Progressive Disease
- Average reduction in pain of 35% - with a maximum reduction of 69% between weeks 8 and 11 following implant
- Median progression free survival was 121 days
- Median overall survival was 309 days or 10+ months (compared with a typical 5.7 months with gemcitabine alone)





# Global Regulatory Strategy

## Device Registration Plan for Key Pharmaceutical Markets

Calendar Yr	H2 2014	H1 2015	H2 2015	H1 2016	H2 2016	H1 2017	H2 2017
OncoSil™ Pivotal study							
IDE							
FDA							
CE Marking							
Sales in EU, Canada & Aus							

OncoSil's global registration strategy is with CE (Conformité Européenne) mark, and with the United States FDA (Food and Drug Administration). IDE: Investigational Device Exemption.

# Pivotal Trial

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## Endpoints

### Primary:

- Overall survival (time from randomization to death)

### Secondary:

- Progression free survival (time to clinical or radiological confirmed progression)
- Quality of Life (EORTC Scale)
- Pain (Brief Pain Index, point of time and 24 hours)

## Challenges

- No prior state-of-the art studies to reference
- Investigator buy-in
- Global Study design
- Supply logistics and global co-ordination

# Pivotal Trial – Why the Delay

1. We announced that we had approval to begin a pivotal trial in Australia
2. Protocol being amended to meet US and EU regulatory recommendations
3. Trial design is being modified to increase the statistical powering
4. Manufacturing and logistical process is being finalised to comply with local importation requirements



# OncoSil™ Manufacturing

## Starting material

- Mix Silicon and Phosphorus at 1480°C
- Atomise with water to create Si-P micro particles

## Create 32P Micro particles

- Grade particles to 30 microns
- Etch with acid to create porosity
- Place in a high neutron reactor

## Dosing

- Package and ship in lead containers
- Pharmacist reconstitutes OncoSil™
- Patient is dosed

# Patents, Trademark & Know How

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- Multiple granted patents in US, EU, Japan and elsewhere for the therapeutic product and for the manufacturing method (2022 - 2024)
- Trademark protection granted for OncoSil™ in Australia, New Zealand, UK, EU, USA, Japan and Singapore

## **Know-How, Expertise and Trade Secrets**

- Brachytherapy clinical trial management
- Manufacturing and distribution logistics

# Board Management Slide

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Executive Chairman:

Dr. Roger Aston

Non-Executive Director:

Mr. Lawrence Gozlan

Non-Executive Director:

Mr. Martin Rogers

Managing Director and CEO:

Mr. Daniel Kenny

Financial Controller & Company  
Secretary:

Mr. Peter Casey

Head of EU Operations:

Dr. Drew Ferguson

Chief Scientific Officer:

Dr. Peter Knox

VP Clinical Research:

Ms. Natalie Ruffles