



OncoSil Medical

October 2014

ASX: OSL



New Technology To Provide Safer Radiotherapy Treatments

Investor Update

Dr Roger Aston
Executive Chairman

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OncoSil™ - Potential treatment for Pancreatic Cancer

Next Generation Radiotherapy

- OncoSil Medical has an **implantable nuclear medicine (radiotherapy) device** that has commenced 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)
 - Liver cancer – SIR-Sphere, Sirtex
 - Non Hodgkin's Lymphoma – Zevalin, Spectrum Pharmaceuticals



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

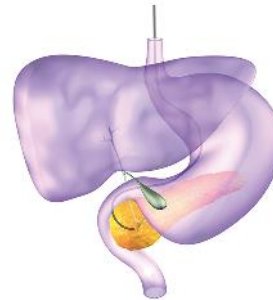
Radiation therapy delivered to the cancer site

- **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**

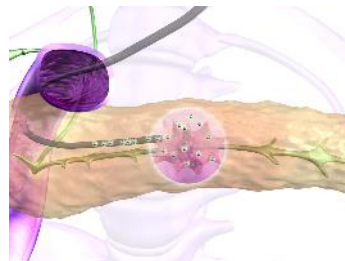
How OncoSil™ Works



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 Abraxane and gemcitabine 'sensitise' cells to radiation therapy



Medical Device Development

Differences between drug and device development

Drugs require Phase I, II and III clinical studies

- Expensive, slow and resource intense
- Typically 10 years to market (from bench)



Devices require Pilot and Pivotal studies

- Faster, fewer patients, no drug interaction work
- Typically 5 years to market



Pancreatic Cancer

Unmet Medical need

- 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%



Target Market

- World market for pancreatic drugs is projected to exceed \$1.2b by 2015 (2)
- Current Chemo regime in excess of \$60,000 per annum

Limited Current Pancreatic Cancer Treatments

Surgery:

Cut out the tumour:

- Only possible in 20% of PC patients



Chemotherapy:

Poison tumour growth, Examples:

- Gemcitabine and Nab-paclitaxel



Immune therapy:

Disrupt growth pathways in the tumour:
Vaccines against tumour antigens



Radiationtherapy: (external beam radiation shown)

Irradiate the body:

- 30 days of radiation
- Many side effects



Clinical data to date

Clinical Trial Results

- 17 locally advanced 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 with the EMA (European Medicines Agency), and with the United States FDA (Food and Drug Administration. IDE: Investigational Device Exemption.

Pivotal Trial for FDA approval

Study Purposes

- Achievement of registration for OncoSil™ in USA
- Create network of Key Opinion Leaders globally
- Establish viable and validated distribution channel for OncoSil™

Study Design

- Randomized open label clinical trial (Gold Standard)
- Combination of OncoSil™ with standard of care (SOC) (gemcitabine, or gemcitabine plus Abraxane™) versus SOC alone
- Single intra-tumoural implant of OncoSil™

Pivotal Trial

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

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



- 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

Executive Chairman:

Dr. Roger Aston

Non-Executive Director:

Mr. Lawrence Gozlan

Non-Executive Director:

Mr. Martin Rogers

Managing Director and CEO:

Dr. Neil Frazer

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

Capital Structure

ASX code	OSL
Market Cap (October 6, 2014)	\$A40m
Shares on issue	355m
Cash (June 30, 2014)	\$A7m



Summary of Investment Profile

Lower Risk

- Medical device
- Internal radiation – next generation of radiotherapy with other products on market demonstrating clinical efficacy
- OncoSil™ has supporting clinical data already

Huge Rewards

- Pancreatic cancer unmet need
- Potential to be used as first line therapy with chemotherapy
- Shorter time lines to regulatory approval drives valuation