BioShares Presentation

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ASX: OSL

OncoSil MEDICAL Ltd

New Technology To Provide Safer Radiotherapy Treatments

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ONCOSIL™ - POTENTIAL TREATMENT FOR PANCREATIC CANCER

MAJOR UNMET NEED

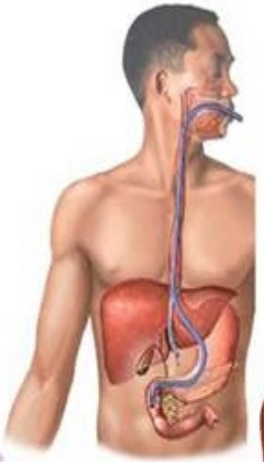
- OncoSil Medical has an **implantable nuclear medicine device** that has commenced a pivotal study in pancreatic cancer.
- **Localised radiation therapy** is inherently safe, effective and well tolerated, ideal for pancreatic cancer.
- There are highly **commercially successful precedents** for localised radiation therapy in liver cancer and prostate cancer

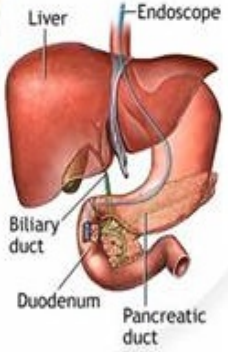
… therefore OncoSil™ as a **localised radiation therapy** for **pancreatic cancer** is a major opportunity for patients and investors

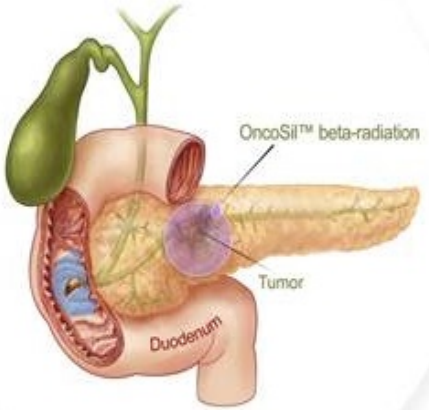
ABOUT ONCOSIL™

- **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 anaesthesia takes 30 minutes
- **Local radiation in the tumour lasts around 3 months**

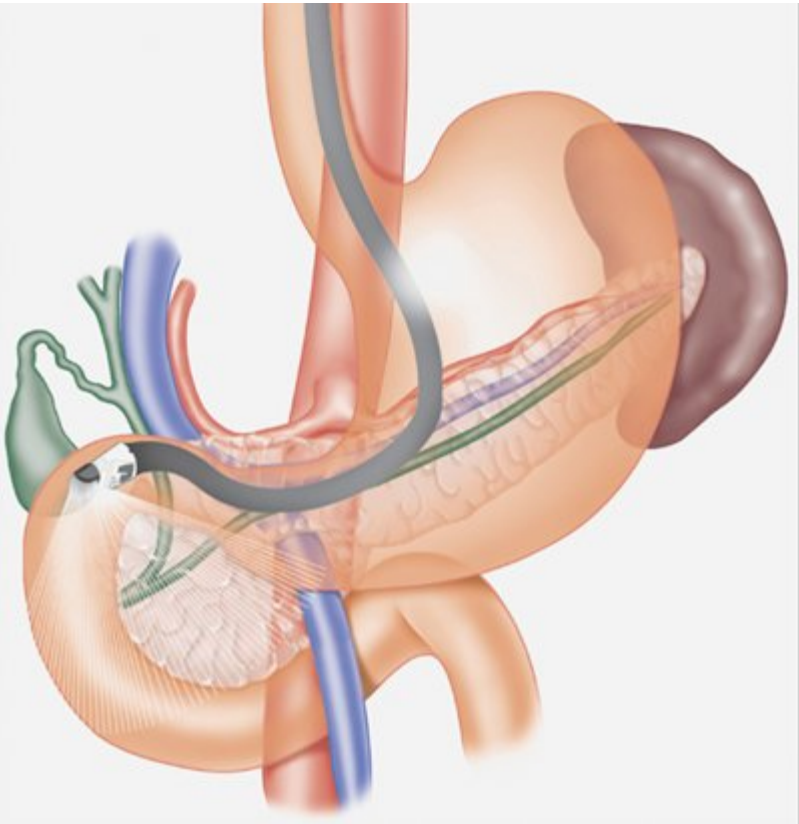
HOW ONCOSIL™ WORKS

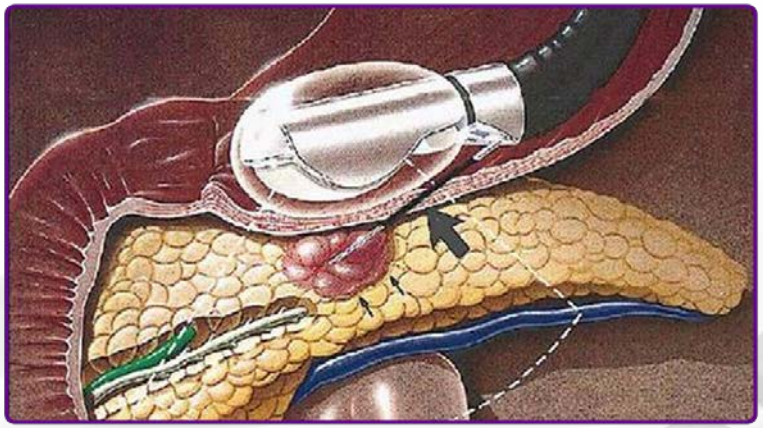






ONCOSIL™ ADMINISTRATION





Endoscopic ultrasound positions the injection of OncoSil™ in the pancreatic tumour

COMPLETED PILOT STUDY

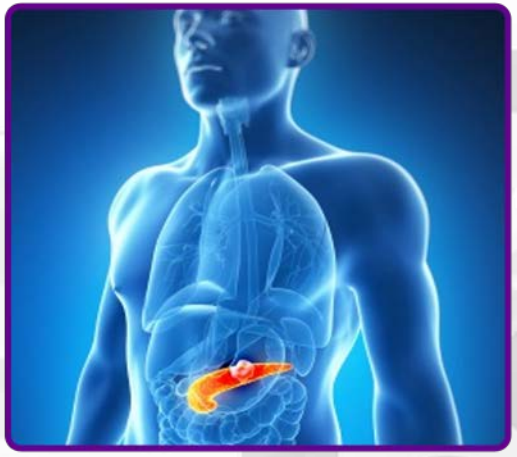
RESULTS:

- 17 locally advanced pancreatic cancer patients
- Significant tumouricidal activity with a 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)

PANCREATIC CANCER

MAJOR UNMET CLINICAL NEED

- 280,000+ pancreatic cancer incidence yearly world wide (1)
- Median survival ~8 months and 5 year survival less than 7%
- Severe abdominal and back pain is a significant complication in patients who develop pancreatic cancer
- Approximately 45,000 new patients diagnosed with pancreatic cancer in the US each year
- World market for pancreatic drugs is projected to exceed $1.2b by 2015 (2)



Source (1) – 2010 World Cancer Research Fund Source (2)– Global Industry Analysis

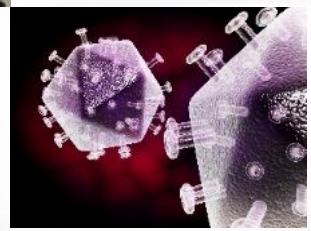
TREATMENT CHOICES FOR MOST HUMAN CANCERS

Surgery: Cut out the tumour:
- Only possible in 20% of PC patients

Chemotherapy: Poison tumour growth
Examples: Gemcitabine and Nab-paclitaxel

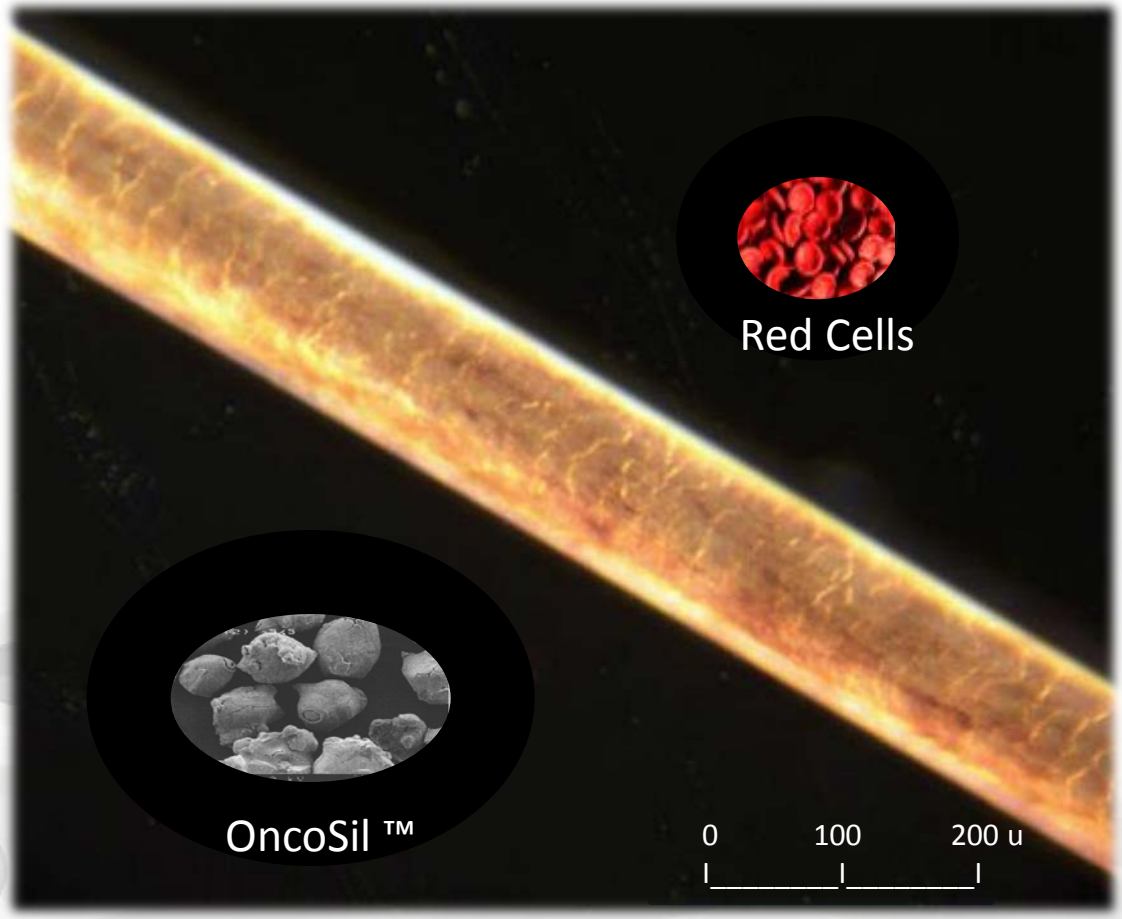
Radiation therapy:
(external beam radiation shown)
Irradiate the body
- 30 days of radiation
- Many side effects

Immune therapy: Disrupt growth pathways in the tumour
- Vaccines against tumour antigens



ONCOSIL™ Micro Particles

OncoSil™ particles compared with a human hair and red blood cells



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

REGISTRATION STUDY: PANCREATIC CANCER

STUDY PURPOSES

- Achievement of registration for OncoSil™ in key global markets
- Create state-of-the-art publication to influence key opinion leaders in treatment of pancreatic cancer
- Establish international credibility for OncoSil™
- Create network of Key Opinion Leaders globally
- Establish viable and validated distribution channel for OncoSil™

REGISTRATION STUDY: PANCREATIC CANCER

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
- Chemotherapy commenced within four weeks prior to implantation, or within three days following implantation
- 150 patients, randomized 100 to OncoSil™ plus SOC and 50 to SOC alone
- Single intra-tumoural implant of OncoSil™

SITES

- Experienced multidisciplinary medical team
- Nuclear Medicine capabilities
- Up to 20 in EU, USA, Australasia

REGISTRATION STUDY: PANCREATIC CANCER

STUDY DESIGN (Inclusion/ exclusion)

- Pancreatic cancer, locally advanced, non-resectable
- Concomitant chemotherapy (gemcitabine, or gemcitabine plus Abraxane™)
- Chemotherapy commenced within four weeks prior to implantation, or within three days following implantation
- Metastases limited to lung and/or liver, with none life threatening or greater than 5cm diameter
- Informed consent
- Life expectancy of at least three months

EXCLUSION

- Pregnant
- ECOG 3 or 4
- Prior radiation therapy

REGISTRATION STUDY: PANCREATIC CANCER

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)

POTENTIAL RECRUITMENT RATE

- Peaks at 12 patients per month (0.6 p/s/m)
- Predicted overall recruitment 12 months from 1st patient
- Note: Interim PFS analysis planned for ONC-301 for the first 30 patients at 6 months after their commencement of the study

REGISTRATION STUDY: CHALLENGES

To Boldly Go……

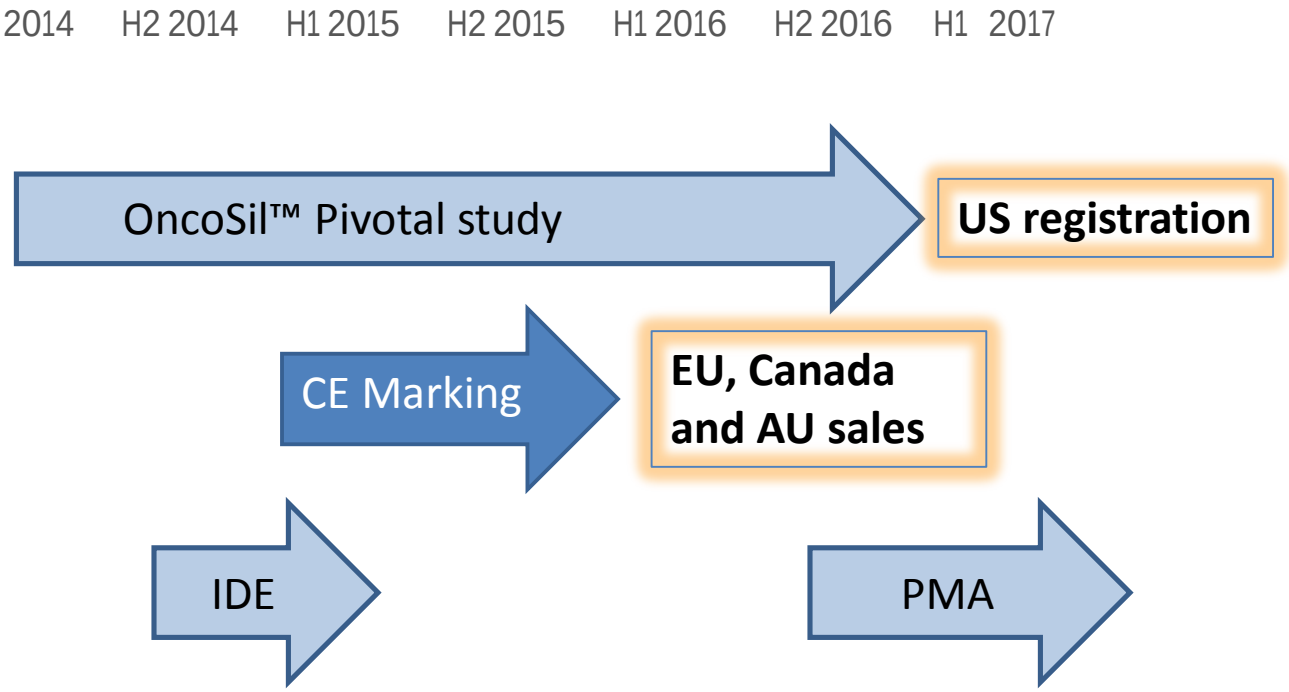
- No prior state-of-the art studies to reference
- Study design for registration is open for discussion
- Investigator buy-in
- Global Study design
- Supply logistics
- Global coordination
- Opinion Leaders/ Opinionated Leaders
- Funding is king

…. Where No Oncology Device Study has gone before

- Unmet need overcomes all obstacles
- If the KOI's buy-in the product will likely succeed
- Risk/ Benefit ratio critical

REGULATORY STRATEGY

PLAN FOR GLOBAL DEVICE REGISTRATION



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 PMA (pre-marketing approval). IDE: Investigational Device Exemption. PMA: Pre Marketing Approval

CONCLUSIONS

- Device studies are different to drug studies
- No requirement for ADME and drug interaction studies
- Predictable device life
- No long term safety issues
- Building on existing technology
- No change of existing medical practice
- Strong KOL buy in to technology in this area
- Regulatory paths are different for devices and drugs
- A strong cash balance increases investor confidence