



New Technology To Provide Safer Radiotherapy Treatments

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@Dr_Neil_Frazer

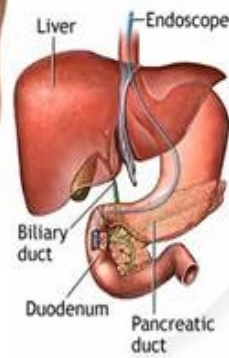
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HOW ONCOSIL™ WORKS



BOARD AND MANAGEMENT

Board Chairman:	Mr. Martin Rogers
Executive Director:	Mr. David McAuliffe
Non-Executive Director:	Dr. Roger Aston
Managing Director and CEO:	Dr. Neil Frazer
General Counsel & Company Secretary:	Ms. Jillian McGregor
Management:	Dr. Neil Frazer
Head of EU Operations:	Dr. Drew Ferguson
Chief Scientific Officer:	Dr. Peter Knox

A **management team** with experience to guide products through the global **development** and **regulatory** process

ONCOSIL MEDICAL: Australian Biotech Company



ASX
Market Cap (18th July, 13) **\$A21m**
Shares on issue **242m**
Cash June 30th, 2013 **\$A3.4m**
No. of Shareholders **~550**



Major holders:	TISIA NOMINEES PTY LTD	6.47%
	JK NOMINEES PTY LTD	6.47%
	DENLIN NOMINEES PTY LTD	6.25%
	WEBINVEST PTY LTD	4.97%

New management in place since June 2013.

Management and directors own ~16% shareholders equity

ONCOSIL MEDICAL OFFERS POTENTIAL TREATMENT FOR PANCREATIC CANCER, A MAJOR UNMET NEED

- **OncoSil Medical** has a medical device in development that is ready for a registration study
- Registration will be sought in all major markets as a **medical device**
- **Medical devices** have a fraction of the development cost compared to drugs and are faster to register; making a better return on investment
- **Pancreatic cancer** remains a huge challenge for physicians
- **Localised radiation therapy** is inherently safe, effective and well tolerated.
- There are highly **commercially successful precedents** for localised radiation therapy in liver cancer and prostate cancer

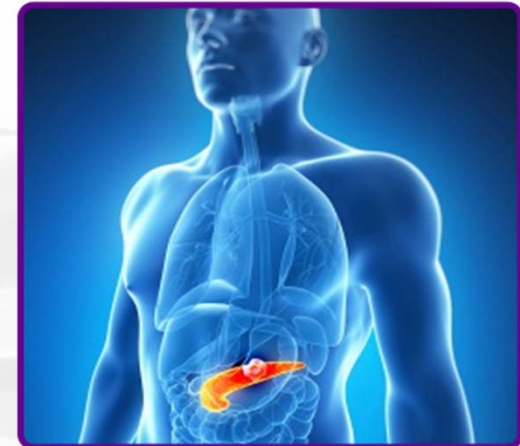


... therefore OncoSil as a **localised radiation therapy**
for **pancreatic cancer** is a major opportunity for
patients and **investors**

PANCREATIC CANCER

MAJOR UNMET CLINICAL NEED

- ▶ 280,000+ pancreatic cancer incidence yearly world wide ⁽¹⁾
- ▶ Median survival 4-6 months and 5 year survival less than 5%
- ▶ 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⁾
- ▶ The prognosis for patients diagnosed with pancreatic cancer regardless of stage is generally poor; the five year survival for all stages combined is around 5%

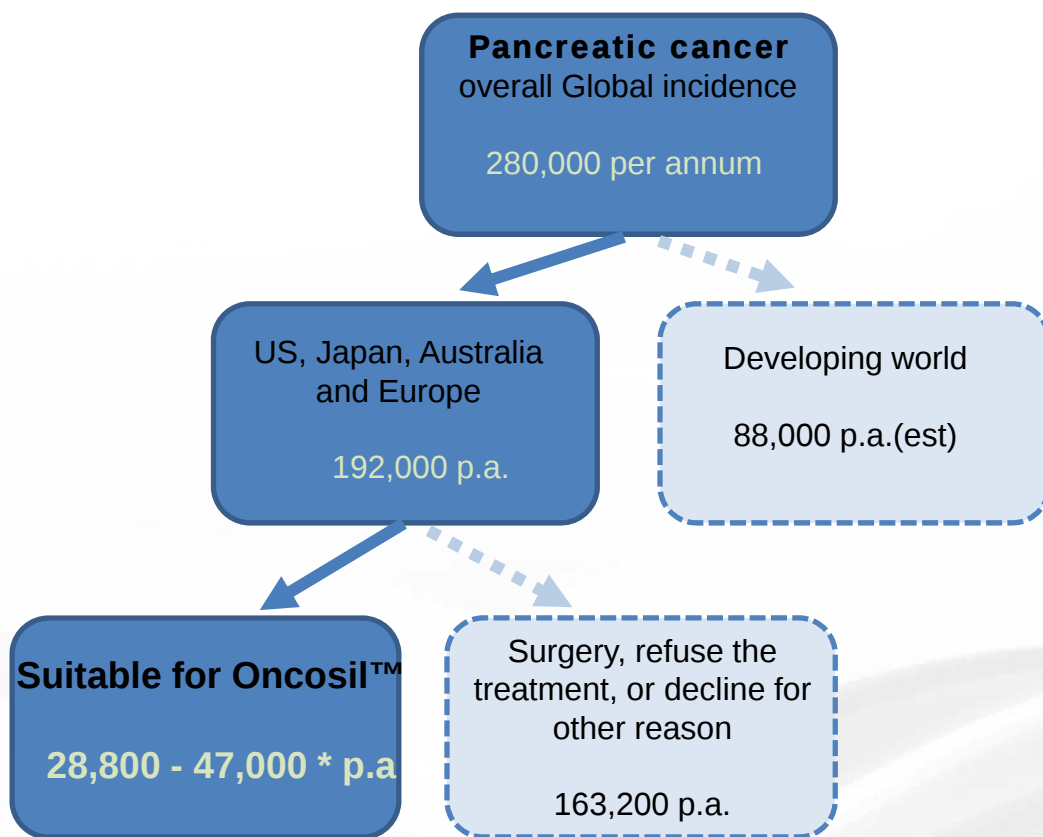


PANCREATIC CANCER



- ▶ Gemcitabine (Roche) is the standard treatment with median survival < 6 months
- ▶ Side effects include: Fever, Fatigue, Vomiting, Hair Loss, Mouth Sores and Diarrhea
- ▶ Erlotinib (Roche) is currently the last line therapy
- ▶ “Whipple” surgery is applicable in only 10-20% of cases and has 5-15% mortality rate
- ▶ Generic chemotherapy drugs include 5 fluoro-uracil (5-FU) and leukovorin (LV)
- ▶ **External beam radiation therapy** is delivered daily over a 6 week period, but has systemic side-effects and many physicians don't use it because of the side-effects for patients
- ▶ OncoSil™ is a **localised radiation therapy** potential solution for pancreatic cancer

MARKET FOR ONCOSIL™



- *28,800 – 47,000 Low to high level assumptions on peak annual sales
- Price estimate US\$15,000 per treatment, 1-2 treatments per patient

TREATMENT CHOICES FOR MOST HUMAN CANCERS

Surgery: Cut out the tumour



Chemotherapy: Poison tumour growth



Radiation therapy: Irradiate the body
(external beam radiation shown)



Immune therapy: Disrupt growth pathways in the immune system



FOR PANCREATIC CANCER THESE ARE LESS EFFECTIVE

Surgery:
(20% of tumours)



Chemotherapy:
(no K-ras mutation)



EB Radiation therapy:



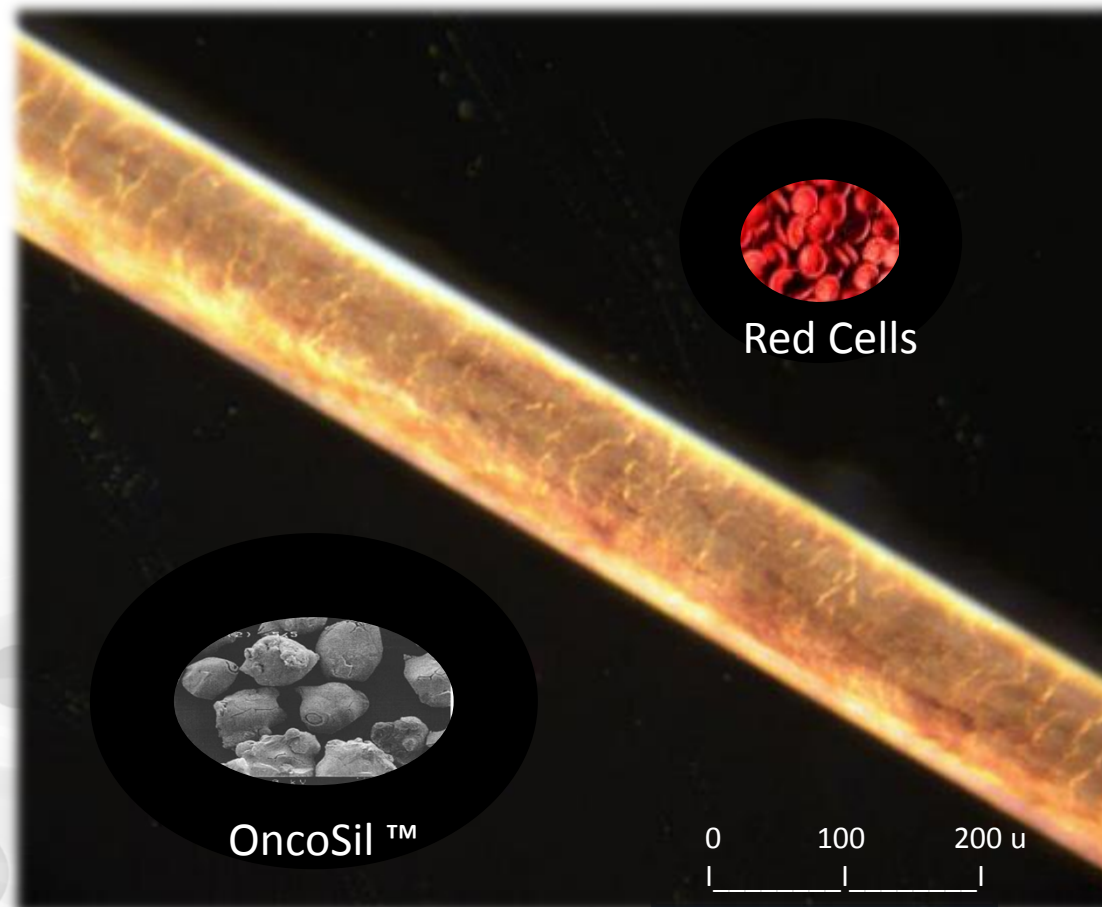
Immune therapy:
(experimental only)



Fractionated External Beam Radiation therapy (EB) may be used in combination with chemotherapy but evidence of effectiveness is controversial, and toxicity is a problem. Physicians shy away from offering traditional external beam radiation for this reason to their patients. OncoSil™ offers a localised radiation therapy treatment option for the patient that avoids the toxicity problem.

ONCOSIL™ Micro Particles

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



ONCOSIL™ MANUFACTURE



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

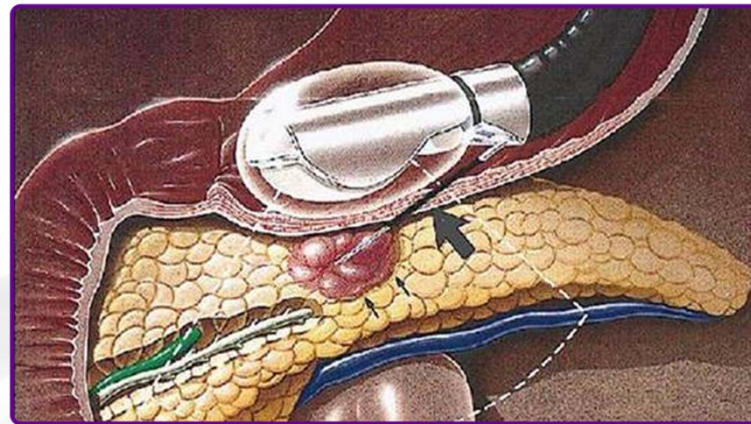
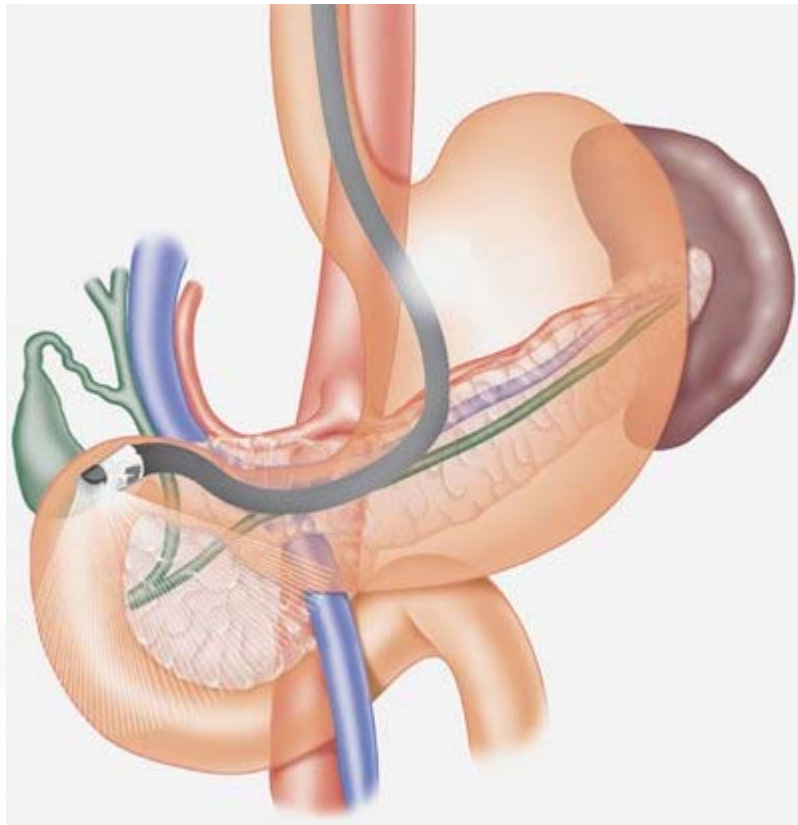
ONCOSIL™ INJECTION

**PHARMACY
RECONSTITUTES
ONCOSIL™**



**ENDOSCOPIC
ULTRASOUND GUIDED
TUMOUR INJECTION**

ONCOSIL™ ADMINISTRATION



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

- ▶ Technology has approximately US\$25 million already invested
- ▶ Technology is ready for a registration trial in pancreatic cancer
- ▶ A management team highly experienced in oncology and commercialisation
- ▶ Two key patent families covering manufacture and composition of matter
- ▶ OncoSil™ is a **class III medical device**, not a drug therefore potentially:
 - Significantly less funding and time is required to undertake a registration study
 - Faster approval is possible

CONVENIENCE

- ▶ The treatment is an outpatient visit or overnight stay
- ▶ Hospital radio-pharmacies prepare the device prior to use
- ▶ 30 minute endoscopic procedure by skilled gastrointestinal endoscopists, radiologists, radiation oncologists or surgeons
- ▶ Only 1 or 2 treatments per patient.

COST EFFECTIVENESS AND HIGH POTENTIAL MARGINS

- ▶ High gross margins due to cost of raw materials in relation to expected sales price (expected to be ~ \$15k per treatment)
- ▶ Peak sales 28,800-47,000 patient treatments p.a. (low and high estimate)
 - low cost of goods and high expected margins

- ▶ OncoSil™ uses a micro particle radioactive technology
- ▶ OncoSil™ is targeting pancreatic cancer
- ▶ OncoSil™ has P-32 as a source of beta particle radiation with much longer duration of radiation, killing more dividing cells and potentially cancer stem cells as well
- ▶ OncoSil™ is injected directly into the tumour
- ▶ OncoSil™ micro particles remain locally in the tumour and do not migrate round the body
- ▶ OncoSil™ or P32 has a 14.3 day half life. Y90 has a 2.7 day half life. The longer life has multiple advantages

MEDICAL DEVICE DEVELOPMENT REQUIRES FOUR KEY INGREDIENTS

Key steps in getting a drug or device to commercialization

Clinical
Development
(product discovery)

Level 1
effectiveness
(demonstrates
efficacy)

Regulatory
Approval
(permits
commercialisation)

Reimbursement by
Payers
(Physicians accept
use)

Differences between drug and device development

Drugs: Phase 1,2 and 3 trials

Devices: Pilot and Registration trials

Therefore:

- less clinical trial work to approval
- less funding required
- faster approval process

Drugs and Devices:

- Controlled clinical study
 - Publication in peer reviewed journal
- Therefore:
- effective communication with physicians

Drugs: FDA, EMA, TGA

Devices: FDA, CE Mark, TGA

Devices have a relatively easier path
to regulatory approval

Drugs and Devices:

Medicare, Medicaid
Private insurers provide
reimbursement

PILOT TRIAL UNDERTAKEN IN PANCREATIC CANCER (1)

STUDY DESIGN:

- ▶ A fixed dose study in 17 patients with pancreatic cancer
- ▶ A single intra-tumoural implantation of OncoSil™ (100 Gy)

Gemcitabine commenced within 2 weeks prior to implantation, or within three days following implantation
- ▶ Patients were followed for safety for up to 24 weeks, with assessments of response at weeks 8, 16 and 24



PILOT STUDY (2)



RESULTS:

- ▶ Analysis of patients demonstrated significant tumouricidal activity with a disease control rate of 82%
- ▶ Over the 24 week period of the trial, patients experienced an 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)
- ▶ Efficacy: 4 Partial Responses, 10 Stable disease and 3 Progressive Disease

2nd PILOT STUDY

STUDY DESIGN:

- ▶ A dose escalating study in 6 patients with pancreatic cancer
- ▶ Ascending doses; a single intra-tumoural implantation of Oncosil™ (up to 400 Gy)
- ▶ Gemcitabine commenced within two weeks prior to implantation, or within three days following implantation.
- ▶ Patients were followed for safety for up to 24 weeks, with assessments of response at weeks 8, 16 and 24.

RESULTS:

- ▶ Note: study was stopped early due to change of focus of prior owner of the product
- ▶ 400Gy well tolerated – no device related adverse events
- ▶ Tumour control rate 100% (6 out of 6 patients): stabilisation of tumour growth (RECIST).

Source - Clinical Study Report DB2-202, January 2010

PLANNED REGISTRATION STUDY: PANCREATIC CANCER



STUDY DESIGN

- ▶ Randomised open label clinical trial (Gold Standard)
- ▶ Combination with standard of care (gemcitabine) versus gemcitabine alone
- ▶ Gemcitabine commenced within two weeks prior to implantation, or within three days following implantation
- ▶ Approximately 100-300 patients (statistical analysis to be completed)
- ▶ Majority of patients to be recruited within 12 months
- ▶ Single intra-tumoural implantation of OncoSil™

END POINTS

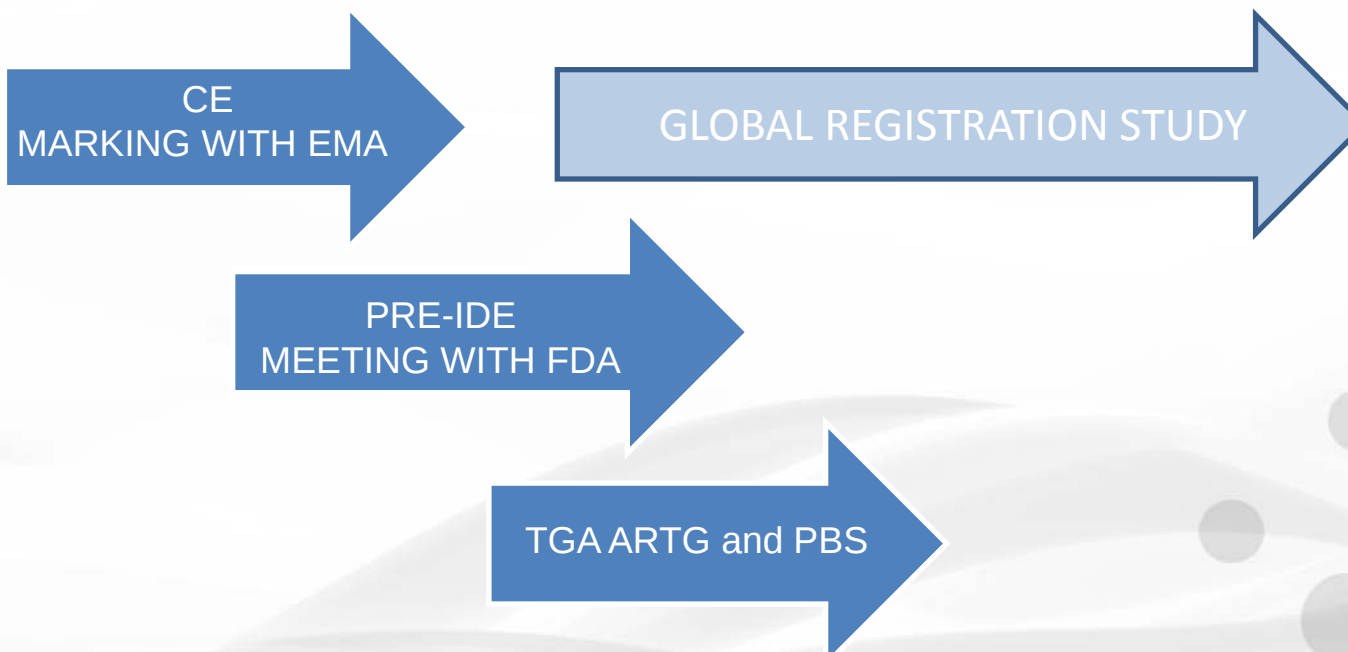
- ▶ Progression free survival, overall survival
- ▶ Quality of life – substantial pain relief
- ▶ Product safety
- ▶ Validation of device supply logistics

REGULATORY STRATEGY



PLAN FOR GLOBAL DEVICE REGISTRATION

Q3 2013 Q4 2013 Q1 2014 Q2 2014 Q3 2014



OncoSil's global registration strategy is with CE (Conformité Européenne) mark with the EMA (European Medicines Agency), with the United States FDA (Food and Drug Administration) and in Australia with the TGA (Therapeutic Goods Administration) for ARTG(Australian Register of Therapeutic Goods) and with the PBS (Pharmaceutical Benefits Scheme)

*proposed start dates are subject to change

PATENTS, TRADEMARKS AND KNOW HOW

- ▶ Multi-layered protection from multiple granted patents in US, EU, Japan and elsewhere on therapeutic product and on manufacturing method
- ▶ 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
- ▶ Core technologies and full toxicology package
- ▶ Detailed professional Market Research Data (Navigant Consulting Inc.)

VALUE INFLECTION POINTS NEXT 6-12 MONTHS



- ▶ OncoSil Medical establishing a global strategic manufacturing alliance
- ▶ US FDA gap analysis for IDE process
- ▶ Pre-IDE meeting with FDA
- ▶ European strategy of EMA and CE marking requirements
- ▶ Registration Study design with key opinion leaders and bio-statisticians
- ▶ Commence global Registration Study
- ▶ Australian ARTG and PBS strategy

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