

Developing OncoSil™ for Pancreatic & Primary Liver cancer



Daniel Kenny CEO
Investor Update
May 2015

Important Notice



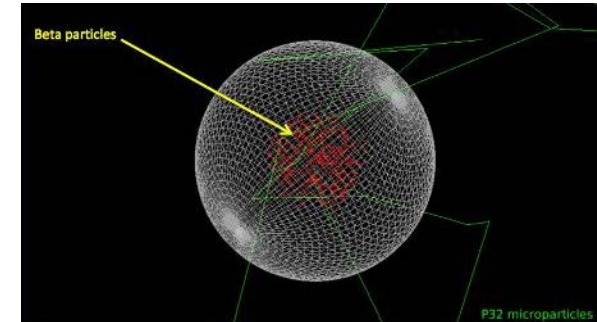
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OncoSil Medical - Overview



- **Developing implantable radiotherapy medical device**
 - 30 micron silicon particles contain beta emitting phosphorus – 32 (P32)
- **Successfully early development – entering into Pivotal Phase for US FDA approval**
 - Four previous Pilot Clinical studies completed (two in hepatocellular carcinoma (HCC) & two in pancreatic cancer)
 - Excellent results to support CE Mark filings for both HCC and Pancreatic cancer & US FDA IDE submission
 - Safety evaluations suggest that OncoSil is well tolerated in patients with unresectable hepatocellular carcinoma and pancreatic cancer
 - Efficacy data showed that OncoSil induces significant reduction in tumour volume in both liver and pancreas
- **Significant and growing unmet medical need**
 - The World Cancer Research Fund estimated that in 2012 338,000 people globally were diagnosed with pancreatic cancer
 - Estimated total market opportunity for OncoSil in pancreatic cancer exceeds \$1b
 - Hepatocellular carcinoma (HCC) is the 6th most common cancer in the world, with 782,000 new cases diagnosed in 2012
 - Value of the HCC market is expected to triple in size to \$1.4b by 2019



Board of Directors



Dr. Roger Aston
Chairman

- Seasoned biotechnology entrepreneur
- Co-founded pSivida Limited. Former CEO of Hospira Australia and CEO of Mayne Pharma Group
- Experience includes FDA and EU product registration, clinical trials, global licensing agreements, fundraising through private placements
- Holds numerous executive and non-executive roles in prominent biotech companies .



Mr. Daniel Kenny
Chief Executive
Officer &
Managing Director

- an accomplished and proven biopharmaceutical business leader with over 30 years experience.
- has developed and successfully driven business with industry leaders such as Roche and Baxter working in Australia, EMEA and the US.
- Extensive global commercialisation experience in launching new and innovative medical devices and pharmaceuticals



**Mr. Martin
Rogers**
Non-Executive
Director

- A well-recognised Australian biotechnology entrepreneur and executive
- Experienced in all aspects of financial, strategic and operational management and has helped raise over \$100m cash equity.
- Chairman of Rhinomed Ltd, Actinogen Medical and non-executive director of Cellmid Ltd.

OncoSil™ - Potential treatment for Pancreatic & Primary Liver Cancer



Next Generation Radiotherapy

- OncoSil Medical has an **implantable nuclear medicine (radiotherapy) device** that has been successfully piloted in pancreatic & liver cancer.
- **Localised radiation therapy** is inherently safe, effective and well tolerated
- 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 & liver cancer patients.

OncoSil™ Benefits

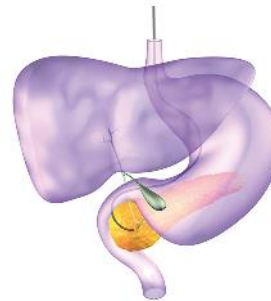
- Localised treatment reduces serious side effects associated with standard radiotherapy
- Classified as a device therefore shorter time to market than traditional drug development
- Synergistic effect with current chemotherapy regime as gemcitabine 'sensitise' cells to radiation therapy



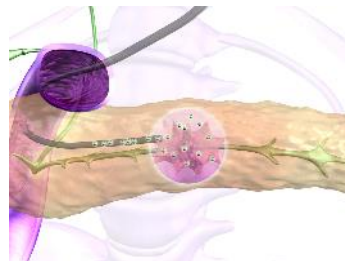
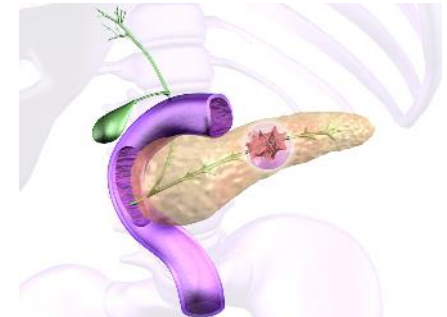
How OncoSil™ Works



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.

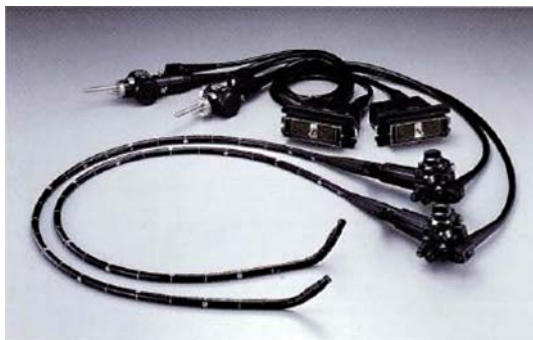
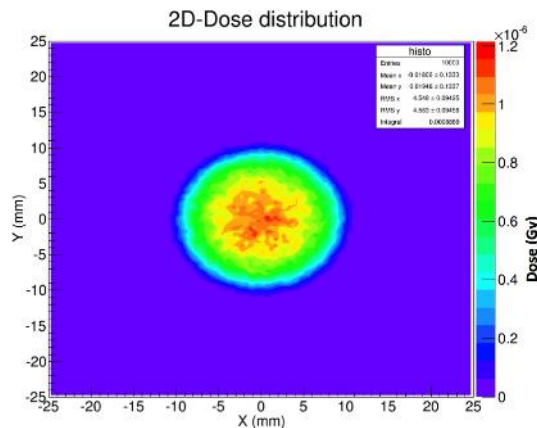


The physician guides an endoscope down the oesophagus, through the stomach and into the first part of the small intestine. Ultrasound is used to image the tumour in the pancreas, then extends a needle from the end of the scope into the pancreas and into the middle of the tumour.



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

OncoSil™ - Device Overview



Radiation therapy delivered to the cancer site

- **Pure “soft 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**

Currently no other intra-tumoral device approved for pancreatic cancer

Device technology platform capable of use in two solid tumour types

Pancreatic Cancer

Unmet Medical need

- 338,000 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

- Estimated Global market opportunity for OncoSil exceeds \$1b (2)
- Current Chemo regime in excess of \$60,000 per annum

Source (1) – 2010 World Cancer Research Fund

Source (2)– Datamonitor Healthcare 2013

Primary Liver Cancer

Unmet Medical need

- 6th most common cancer in the world
- 782,000 new cases diagnosed in 2012 (1)
- Due to poor prognosis, 3rd leading cause of cancer mortality, 600,000 deaths annually

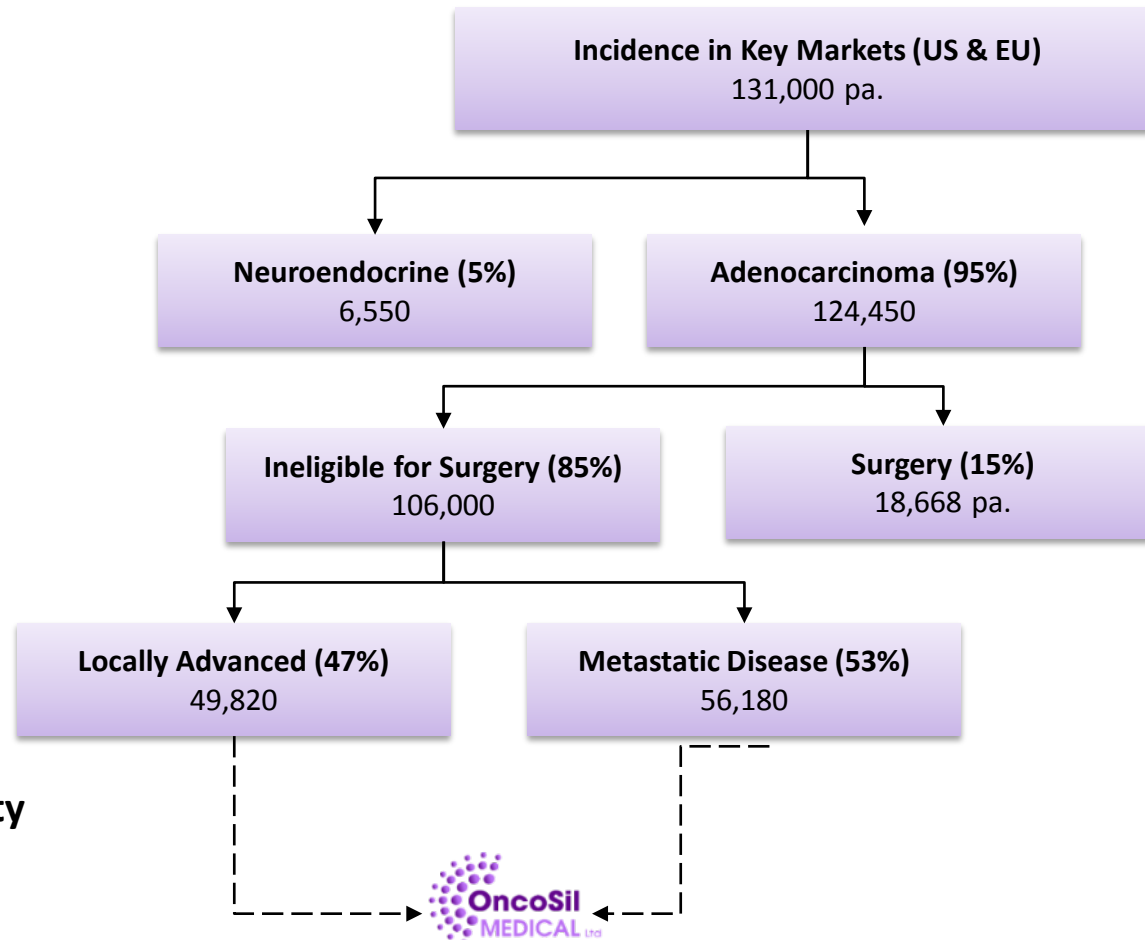


Target Market

Value of HCC market expected to triple in size to \$1.4b by 2019 (2)

Pancreatic Cancer: Patient Pool assumptions – US & EU



US new cases pa: 46,000
EU new cases pa: 85,000

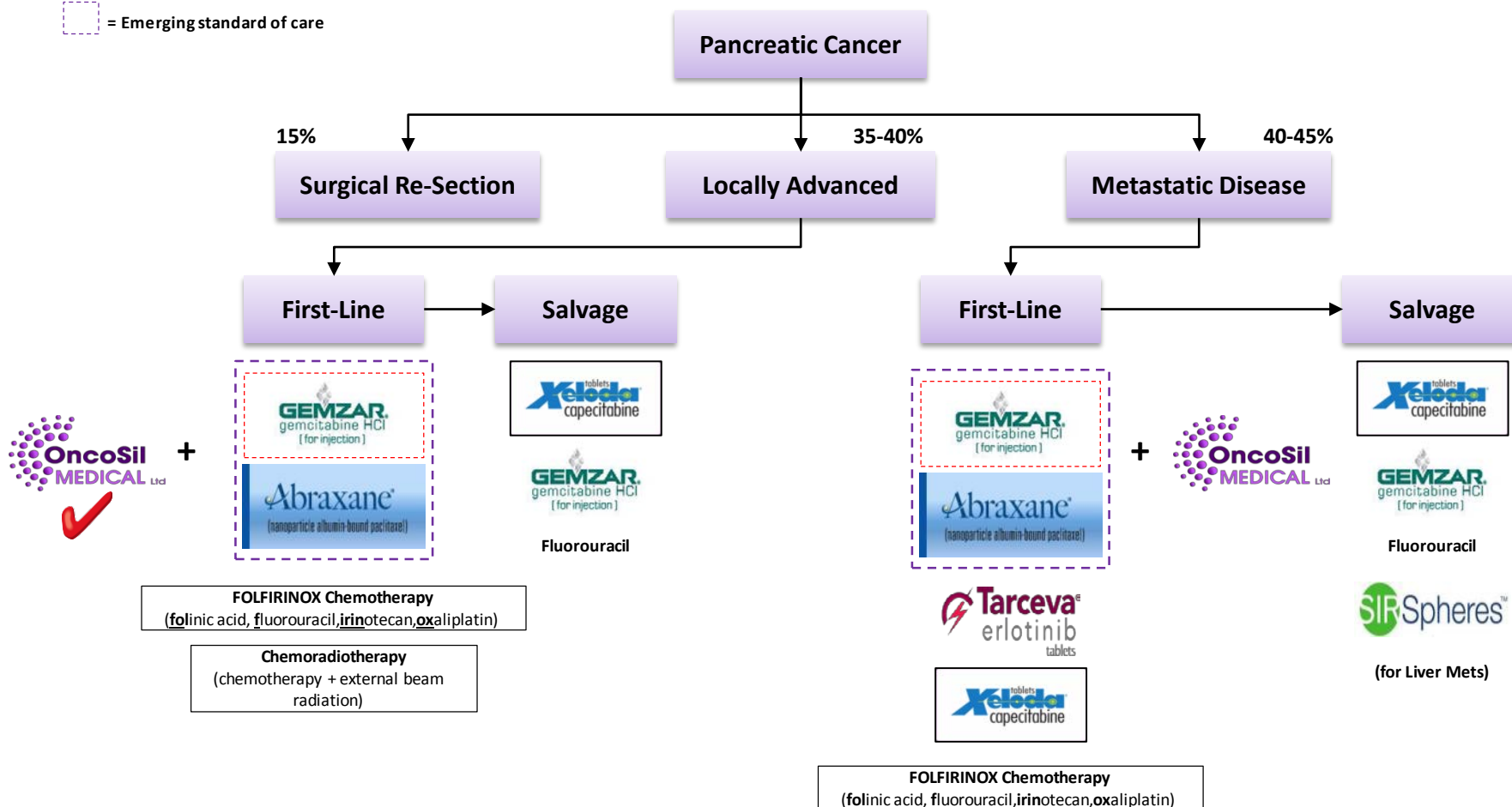


Potential Market Size
(>105,000 pts p.a)

Total Market Opportunity
(>\$1 Billion)

Pancreatic Cancer Treatment Paradigm

 = Current standard of care
 = Emerging standard of care



Clinical Trials Completed



- BIOSP-201: A single dose, single centre open label phase I/II safety study in hepatocarcinoma, recruitment 31 May 2004 – 09 March 2005, 8 patients enrolled
- BIOSP-202: A multi-centre, dose escalating study in hepatocarcinoma, recruitment 17 Oct 2005 – 27 Sept 2006, 11 patients enrolled
- DB2-201: A multi-centre, open label, phase IIa, safety study in patients with advanced unresectable adenocarcinoma of the pancreas, recruitment 16 Sept 2006 – 21 Jan 2008, 17 patients enrolled
- DB2-202: A multi-centre, open label, phase IIb, dose escalating safety study in patients with advanced unresectable adenocarcinoma of the pancreas, recruitment 30 Jun 2008 – 12 Aug 2009, 6 patients enrolled

Pancreatic cancer: 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)



Target Tumour Response rate: Pancreas



- Target tumour response rate: 81.25%
- 13/16 treated patients experienced a reduction in target tumour volume
- Of the 13 patients with a reduction in target tumour volume only 2 had less than a 15% reduction
- 50% of responders achieved target tumour volume reduction of >30%

Target Tumour Reduction	5%	10%	15%	20%	25%	30%
Response Rate	68.75%	68.75%	68.75%	62.50%	56.25%	50.00%

Best Response of HCC Target Tumour after Single Fixed Dose of OncoSil™



Patient Number	% Change in target Tumour Volume	Response ⁺
001	-44%	Stable Disease
002	-80%	Partial Response
003	-16%	Stable Disease
004	-43%	Partial Response
005	-100%	Complete Response
006	-100%	Complete Response
007	-100%	Complete Response
008	-35%	Stable Disease

+WHO definitions of tumour response * Denotes investigator's classification A change of -100% indicated total disappearance of target lesions

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

OncoSil Corporate Goals: 2015



- Finalize design of Pivotal Study for Pancreatic cancer by end of Q2 2015
- Recruit 1st patient in Pivotal Study by end of Q3 2015
- CE Mark approval by end Q3 2015
- IDE approval by Q4 2015



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	→			Q4 Approval			
FDA							→
CE Marking	→			Q3 Approval			
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.

Capital Structure



ASX code	OSL
Market Cap (April, 2015)	\$A40m
Shares on issue	355m
Cash (31 March, 2014)	\$A7.2m
R&D Credits & Pre-payments	\$A2.55 M
Total Cash and Credits	\$A9.75M

Average Burn rate: \$A 460K per month

Cash reserves to Q1 2017

Investment Thesis



1. OncoSil Medical has strong leadership
 - New management, energised and focused.
2. High unmet medical need.
 - Pancreatic cancer has one year survival of 26% and five year survival of 6%
 - HCC is the 6th most common cancer in the world
3. Current treatments are lacking.
 - Gemcitabine was approved 18 years ago.
 - Abraxane (approved 2013)
 - Median overall survival has increased by 2 months to 8.5 months over the past 20 years
4. Sufficient Clinical Data to secure CE mark in Q3 2015.
5. EU Commercialisation in 2015 possible following CE Mark authorisation.
6. Single Pivotal Study sufficient to secure FDA PMA approval.
7. Pivotal Study to commence 'active recruitment' in Q3 2015.