

EU Commercialisation



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Investor Presentation

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Important Notice



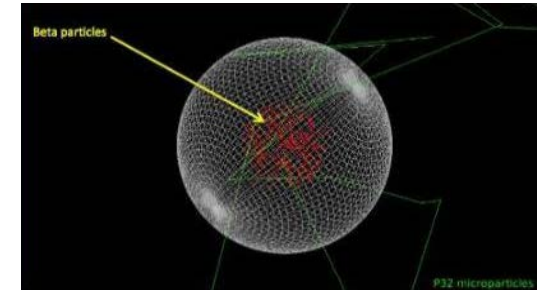
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OncoSil Medical - Overview



- **Developing implantable radiotherapy medical device**
 - 30 micron silicon particles contain beta emitting phosphorus (P32)
 - Safer & stronger medical radiation treatment than external beam radiation
- **Successfully development – preparing for EU Commercialisation**
 - Four previous Pilot Clinical studies completed (two in primary liver or hepatocellular carcinoma (HCC) & two in pancreatic cancer)
 - Excellent results to support CE Mark filings for both Primary Liver and Pancreatic cancer & US FDA IDE submission
 - Safety evaluations suggest that OncoSil™ is well tolerated in patients with unresectable primary liver and pancreatic cancer
 - Efficacy data showed that OncoSil™ induces significant reduction in tumour volume in both liver and pancreas and significantly reduced pain
- **EU Commercialisation of OncoSil™ remains on schedule for approval in Q3, 2015.**
 - Following the recent granted of ISO certification for OncoSil™, filing remains on schedule for Conformité Européenne (CE) Mark approval in Q3, 2015.
 - Commercialisation in the EU and would also facilitate sales in other major markets ex-US.
- **Significant billion dollar market 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 US\$1bn
 - Primary liver cancer is the 6th most common cancer in the world, with 782,000 new cases diagnosed in 2012
 - Value of the primary liver cancer market is expected to exceed US\$1.4bn



Board & Management



Dr. Roger Aston
Chairman

Seasoned biotechnology entrepreneur. Inventor on patent for OncoSil™



Natalie Ruffles
Vice President,
Clinical Research

Former clinical research at leading US medical device company Medtronic Inc. Strong depth and expertise in clinical affairs



Mr. Daniel Kenny
CEO & MD

Ex Roche & Baxter accomplished and proven biopharmaceutical commercial business leader with over 30 years experience.



David James
Manufacturing &
Operations
Manager

Ex Sirtex Medical global operations manager for 6 years. 25 years experience in pharmaceutical manufacturing and operations



Mr. Martin Rogers
Director

A well-recognised Australian biotechnology entrepreneur and executive



Aoifa Brogan
Vice President,
Regulatory Affairs

Ex Medtronic Inc medical device regulatory affairs. 15 years of professional experience in the medical device industry

EU Commercialisation On-Track Q3



- EU Commercialisation of OncoSil™ remains on schedule for approval in Q3, 2015.
- Following the recent granted of ISO certification for OncoSil™, filing remains on schedule for Conformité Européenne (CE) Mark approval in Q3, 2015.
- Regulatory advice for CE Mark approval in pancreatic cancer is to also include primary liver cancer as it strengthens its filing position on clinical data and carries no additional risk.
- OncoSil™ has clinically demonstrated target tumour regression (tumour shrinkage) in both solid tumour indications of pancreatic and liver cancer.
- Commercialisation in the EU and would also facilitate sales in other major markets.
- Global market for Pancreatic Cancer is US\$1Bn and HCC Liver Cancer is an additional US\$1.4Bn

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 (US\$2.4bn acquisition of Algeta) – metastatic to bone
 - Liver cancer – SIR-Sphere, Sirtex Medical
 - Non Hodgkin's Lymphoma – Zevalin, Spectrum Pharmaceuticals – targeted antibody



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

OncoSil™ Benefits

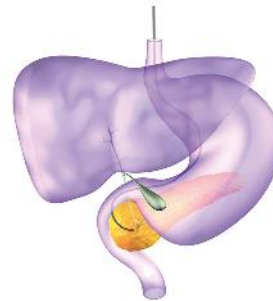
- Localised treatment reduces serious side effects associated with standard radiotherapy
- Classified as a device therefore shorter time to market than traditional drug development
- Synergistic effect with current chemotherapy regime as gemcitabine 'sensitise' cells to radiation therapy



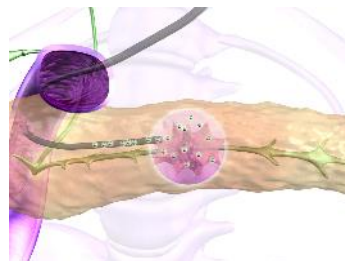
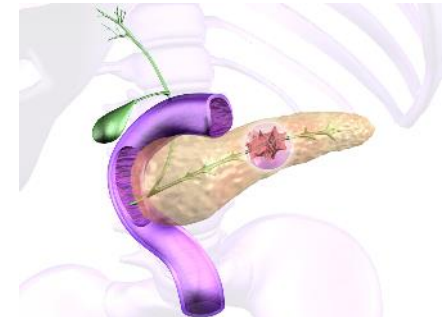
How OncoSil™ Works



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.

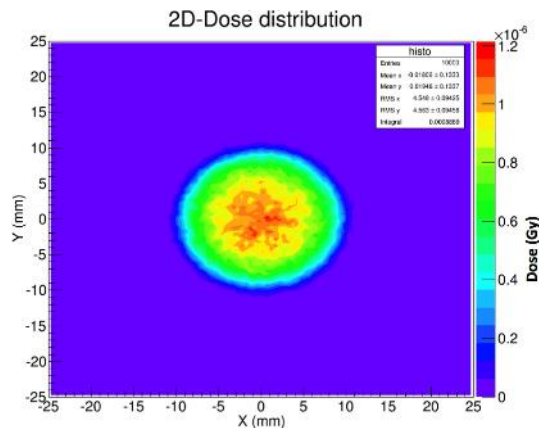


The physician guides an endoscope down the oesophagus, through the stomach and into the first part of the small intestine. Ultrasound is used to image the tumour in the pancreas, then extends a needle from the end of the scope into the pancreas and into the middle of the tumour.



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

US\$1bn 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 US\$1b (2)
- Current Chemo regime in excess of US\$60,000+ per annum
- Cost of external beam radiation in EU is €9,000

Source (1) – 2010 World Cancer Research Fund

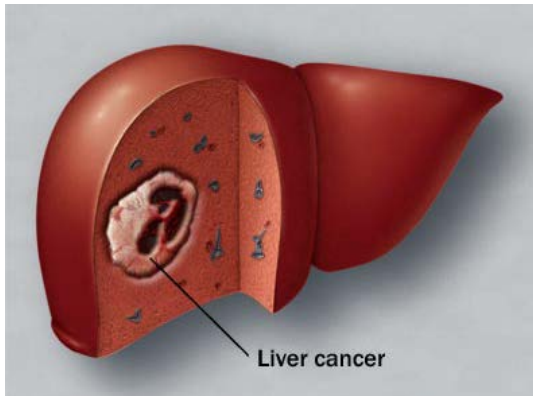
Source (2)– Datamonitor Healthcare 2013

US\$1.4bn 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

Entering the primary liver cancer market represents a major new market opportunity dovetails with pancreatic cancer

Value of primary liver cancer market expected to exceed US\$1.4b (2)

Source (1) – 2012 World Cancer Research Fund

Source (2) – Datamonitor Healthcare 2013

Liver Cancer Expert Professor Pierce Chow



Professor Pierce Chow as Chairman Primary Liver Cancer Scientific Advisory Board

- EU commercialisation also includes primary liver cancer
- Prof Chow is a world leading primary liver cancer expert
- Current leader as principle investigator on the major Sirtex Medical SIR-Spheres™ SIRveNIB trial
- Awarding winning clinician brings great expertise to OncoSil Medical

Prof Chow

“Every now and again you come across a new and exciting approach in medicine that really stands out. OncoSil™ is exactly that in primary liver cancer and I look forward to utilising my skills and expertise in this area to help realise this potential”



Clinical success in pancreatic cancer

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)



Patents, Trademark & Know How



- Multiple granted patents in US, EU, Japan and elsewhere for the therapeutic product and for the manufacturing method (2022 - 2024)
- Potential to expand patent protection
- 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
- Composition of OncoSil™ and nuclear expertise
- Manufacturing and distribution logistics

OncoSil Corporate Goals: 2015



- CE Mark approval by Q3 2015
- Business plan and commercialisation put in place
- First commercial sales in 2015
- US FDA IDE approval by Q4 2015



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%
 - Primary liver cancer is the 6th most common cancer in the world
3. Current pancreatic treatments are lacking.
 - Gemcitabine chemotherapy was approved 18 years ago.
 - Abraxane chemotherapy (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. Upcoming US FDA IDE

Appendices

Global Regulatory Strategy



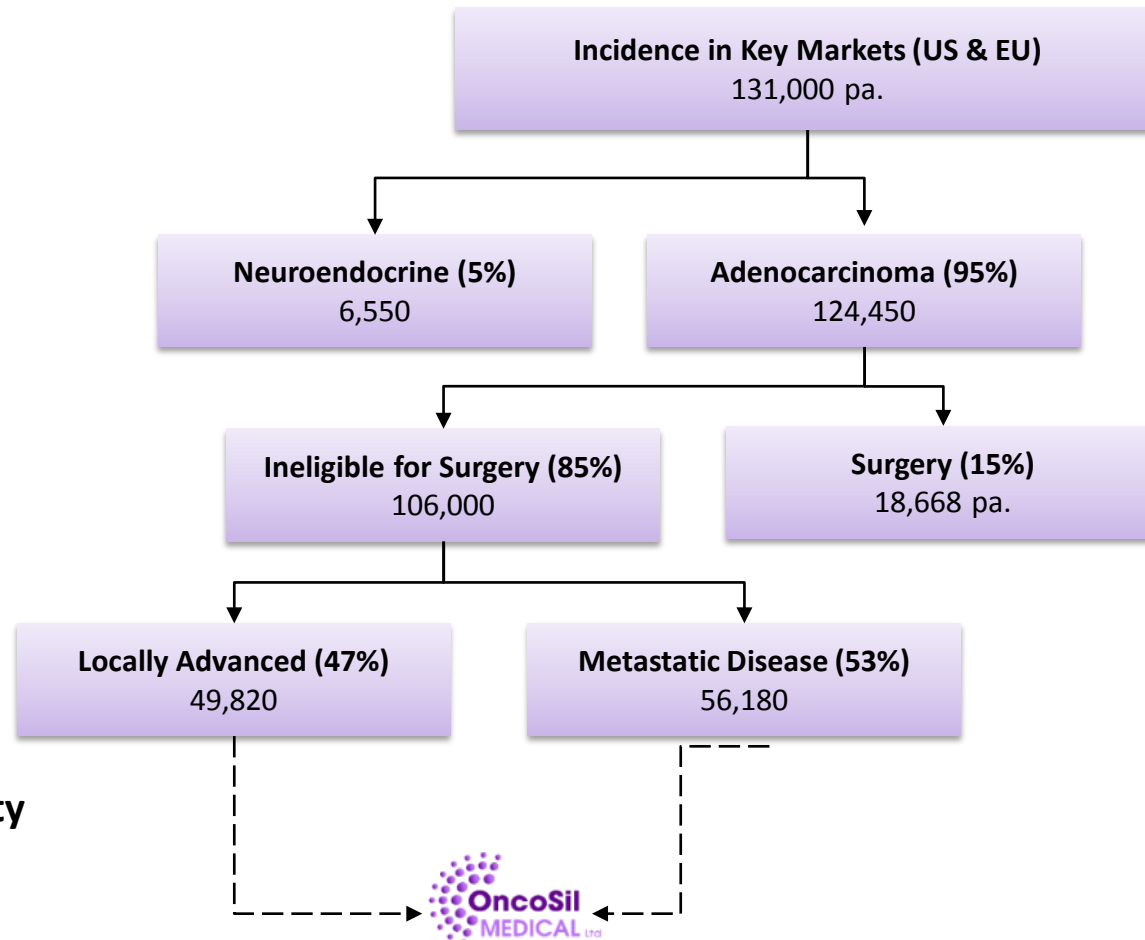
Device Registration Plan for Key Pharmaceutical Markets

Calendar Yr	H2 2014	H1 2015	H2 2015	H1 2016	H2 2016	H1 2017	H2 2017
US Pivotal Trial			→				
US FDA IDE	→		→ Q4 Approval				
US Sales							→
CE Marking	→		→ Q3 Approval				
Sales in EU, Singapore 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.

Pancreatic Cancer: Patient Pool assumptions – US & EU



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

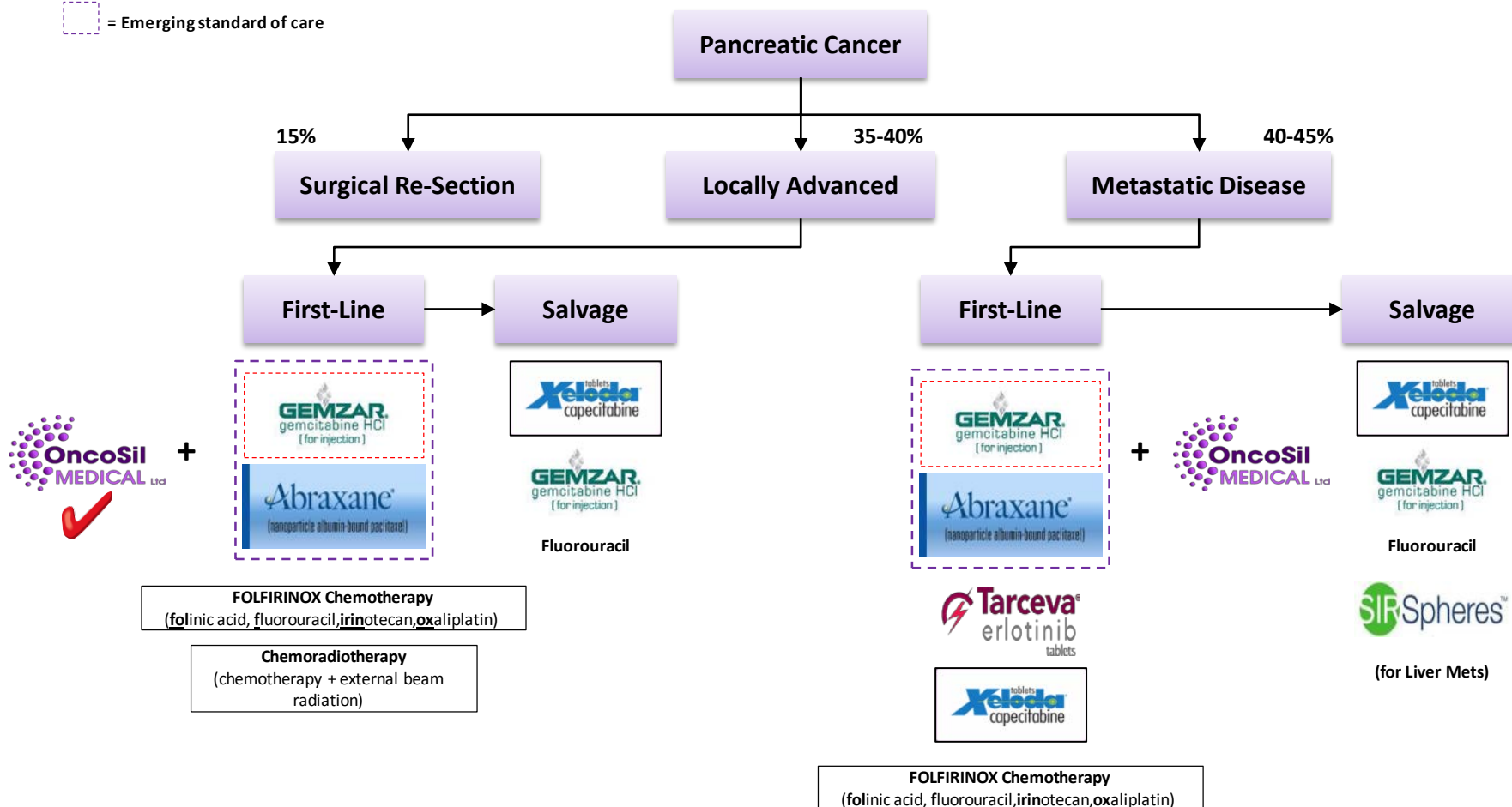


Potential Market Size
(>105,000 pts p.a)

Total Market Opportunity
(>\$1 Billion)

Pancreatic Cancer Treatment Paradigm

 = Current standard of care
 = Emerging standard of care



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

Clinical Trials Completed



- BIOSP-201: A single dose, single centre open label 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, 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, dose escalating safety study in patients with advanced unresectable adenocarcinoma of the pancreas, recruitment 30 Jun 2008 – 12 Aug 2009, 6 patients enrolled