

# EU Commercialisation

OncoSil: Advancing  
Pancreatic & Liver  
Cancer Treatment



Daniel Kenny CEO  
Investor Presentation  
November 2015

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# OncoSil Medical - Overview

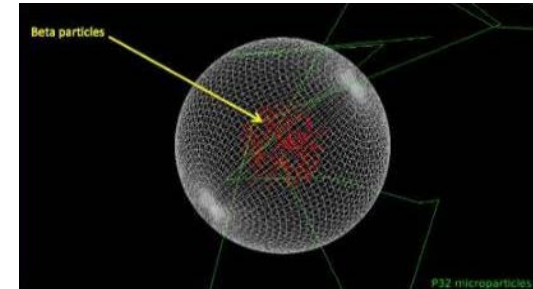


## Developing implantable radiotherapy medical device

- 30 micron silicon particles contain beta emitting phosphorus (P32)<sup>1</sup>
- Safer & stronger medical radiation treatment than external beam radiation

## Successfully developed – preparing for EU commercialisation

- Four pilot clinical studies completed<sup>2</sup>;
  - 2 in primary liver/ hepatocellular carcinoma (HCC)
  - 2 in pancreatic cancer
- Excellent results to support Conformité Européene (CE) Marking 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<sup>2</sup>
- Efficacy data showed that OncoSil™ induces significant reduction in tumour volume in both liver and pancreas cancer and significantly reduces pain<sup>2</sup>



1. Instructions for Use, OncoSil™ ONCSP-32, Document No: RA-IFU01, Sep 2015 Version B. 2. Clinical Evaluation Report, OncoSil™ ONCSP-32, Document No: RA-CER01, 20 Aug 2015 Version B

# OncoSil Medical - Overview

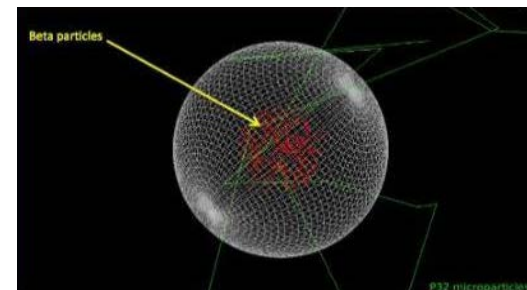


## EU Commercialisation of OncoSil™ remains on schedule for approval in Q4, 2015

- Following the recent granted ISO certification for OncoSil™, filing remains on schedule for Conformité Européene (CE) Marking approval in Q4, 2015
- Commercialisation in the EU 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<sup>1</sup>
- Estimated total market opportunity for OncoSil™ in pancreatic cancer exceeds US\$1bn
- Primary liver cancer is the 6<sup>th</sup> most common cancer in the world, with 782,000 new cases diagnosed in 2012<sup>2,3</sup>
- Value of the primary liver cancer market is expected to exceed US\$1.4bn



1. World Cancer Research Fund International (2012). Accessed 9 Sep 2015, from <http://www.wcrf.org/int/cancer-facts-figures/worldwide-data> 2. Adult Primary Liver Cancer Treatment National Cancer Institute. NIH 31 Jul 2015. Accessed 10 Sep 2015. <http://www.cancer.gov/types/liver/patient/adult-liver-treatment-pdq> 3. World Cancer Report 2014. World Health Organization. Chapter 1.1 ISBN 9283204298

# Board & Management



**Dr. Roger Aston**  
Chairman

Seasoned biotechnology entrepreneur. Inventor on patent for OncoSil™



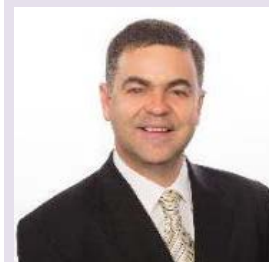
**Dr. Ashish Soman**  
Chief Medical Officer

Former country medical director, AstraZeneca Australia. Over 20 years' experience in clinical practice and the biopharmaceutical industry



**Mr. Daniel Kenny**  
CEO & MD

Former senior Roche & Baxter executive. Accomplished and proven business leader with over 30 years experience. leading multiple \$1bio+ franchises since 2000



**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

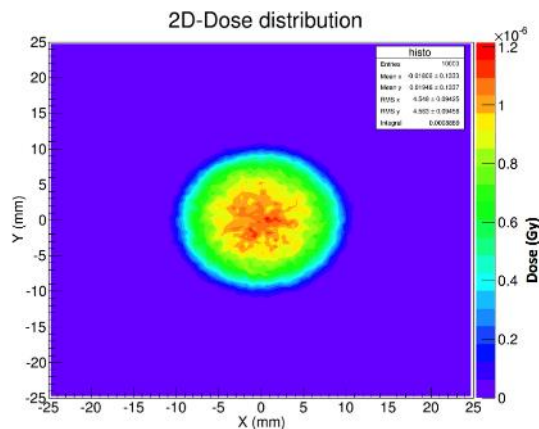


**Aoifa Brogan**  
Vice President, Regulatory Affairs

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



# 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**



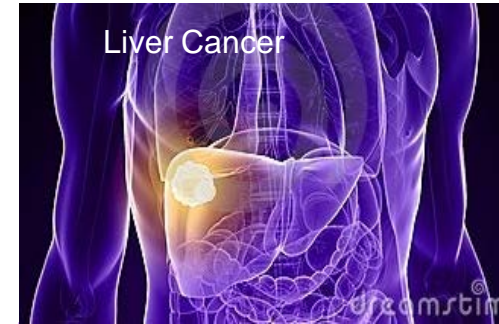
# How OncoSil™ Works



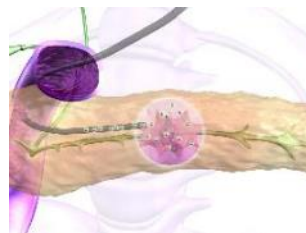
OncoSil™ is suspended in a shielded syringe in the operating theatre where a physician will make the injection of the device into the pancreatic or liver tumour.



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 a needle is extended from the end of the scope into the pancreas and into the middle of the tumour.



Using CT or real-time imaging, the physician guides a 20 gauge introducer needle into the target lesion. The stylet of the introducer needle is removed and a 22 gauge needle with the drug is injected into the tumour.



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

# US\$1bn Pancreatic Cancer



## Unmet medical need

- 338,000 pancreatic cancer incidence yearly world wide<sup>1</sup>
- Approximately 45,000 new patients diagnosed with pancreatic cancer in the US each year<sup>1</sup>
- Poor prognosis - median survival ~8 months and 5 year survival less than 5%<sup>2</sup>



## Target market

- Estimated Global market opportunity for OncoSil exceeds US\$1b<sup>3</sup>
- Current Chemo regime in excess of US\$60,000+ per annum<sup>3</sup>
- Cost of external beam radiation in EU is €9,000<sup>3</sup>



1. World Cancer Research Fund International (2012). Accessed 9 Sep 2015, from <http://www.wcrf.org/int/cancer-facts-figures/worldwide-data> 2. American Cancer Society. 2010. Accessed on 9 September 2015. 3. Datamonitor Healthcare 2013

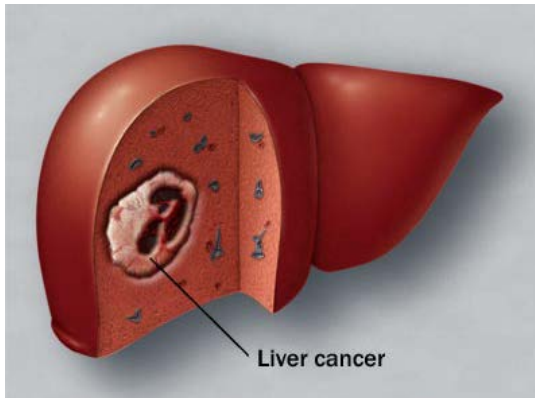


# US\$1.4bn Primary Liver Cancer



## Unmet medical need

- 6<sup>th</sup> most common cancer in the world<sup>1</sup>
- 782,000 new cases diagnosed in 2012<sup>2</sup>
- Due to poor prognosis, 3<sup>rd</sup> leading cause of cancer mortality, 600,000 deaths annually



## Target market

- Entering the primary liver cancer market represents a major new market opportunity and dovetails with pancreatic cancer
- Value of primary liver cancer market expected to exceed US\$1.4b<sup>3</sup>

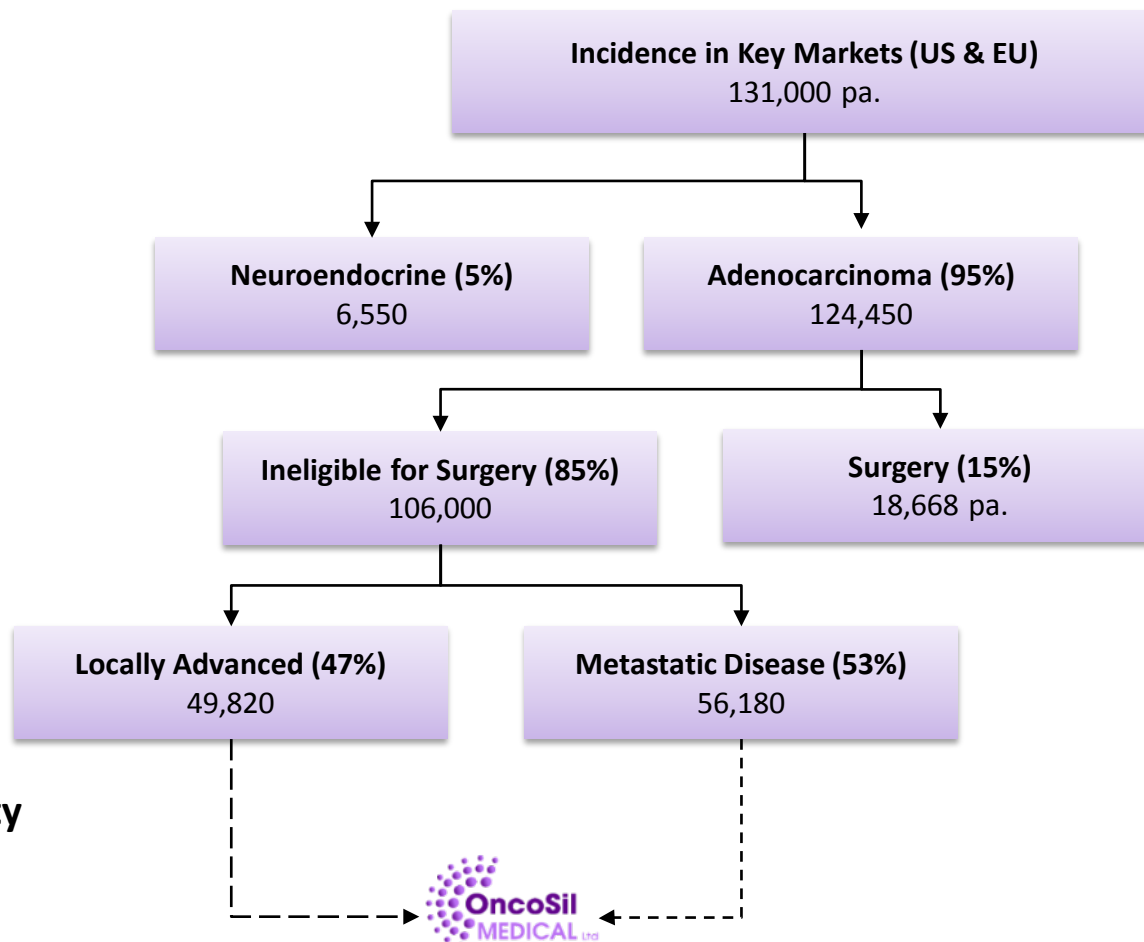
1. Adult Primary Liver Cancer Treatment National Cancer Institute. National Institutes of Health. 31 Jul 2015. Accessed 10 Sep 2015 from <http://www.cancer.gov/types/liver/patient/adult-liver-treatment-pdq> 2. World Cancer Report 2014. World Health Organization. Chapter 1.1 ISBN 9283204298 3. Datamonitor Healthcare 2013

# Pancreatic Cancer: Patient Pool Assumptions – US & EU



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

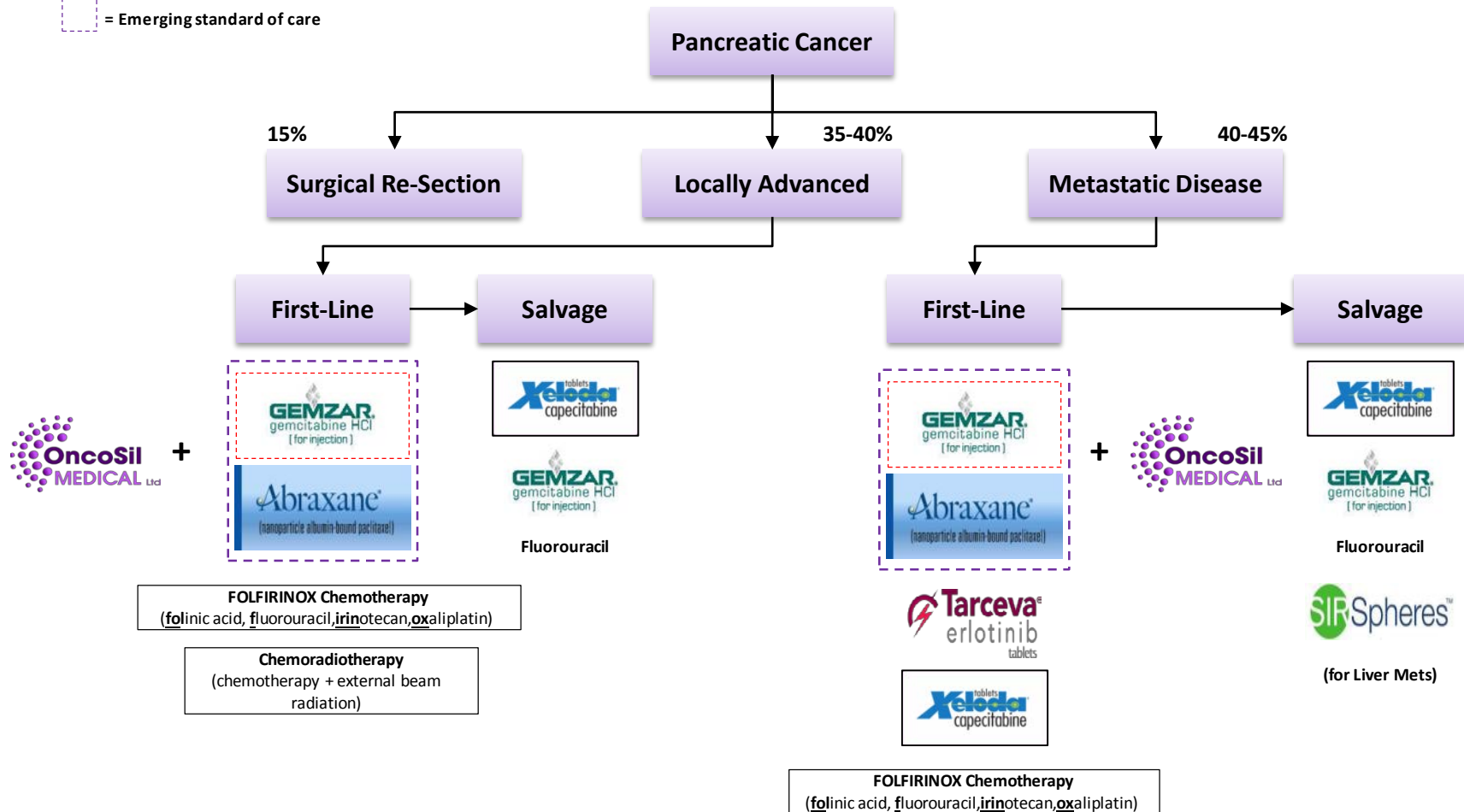
**Potential Market Size**  
(>105,000 pts p.a)

**Total Market Opportunity**  
(>\$1 Billion)



# Pancreatic Cancer Treatment Paradigm

 = Current standard of care  
 = Emerging standard of care



# Clinical Success In Pancreatic Cancer



## Clinical Trial Results (Study DB2- 201)

- 17 locally advanced pancreatic cancer patients in single arm study<sup>1</sup>
- Significant anti-cancer activity – **disease control rate of 82%** : 2 Partial Responses, 12 Stable Disease and 2 Progressive Disease<sup>1</sup>
- 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<sup>1</sup>
- Median overall survival was 309 days or 10+ months<sup>1</sup> (compared with a typical 5.7 months with gemcitabine alone)



1. Ross PJ et al, 2008, "Novel delivery via endoscopic ultrasound of a <sup>32</sup>P brachytherapy device in addition to gemcitabine (G) in advanced pancreatic cancer", ASCO, Chicago, Illinois.

# Target Tumour Response Rate: Pancreas



Study DB2- 201

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%

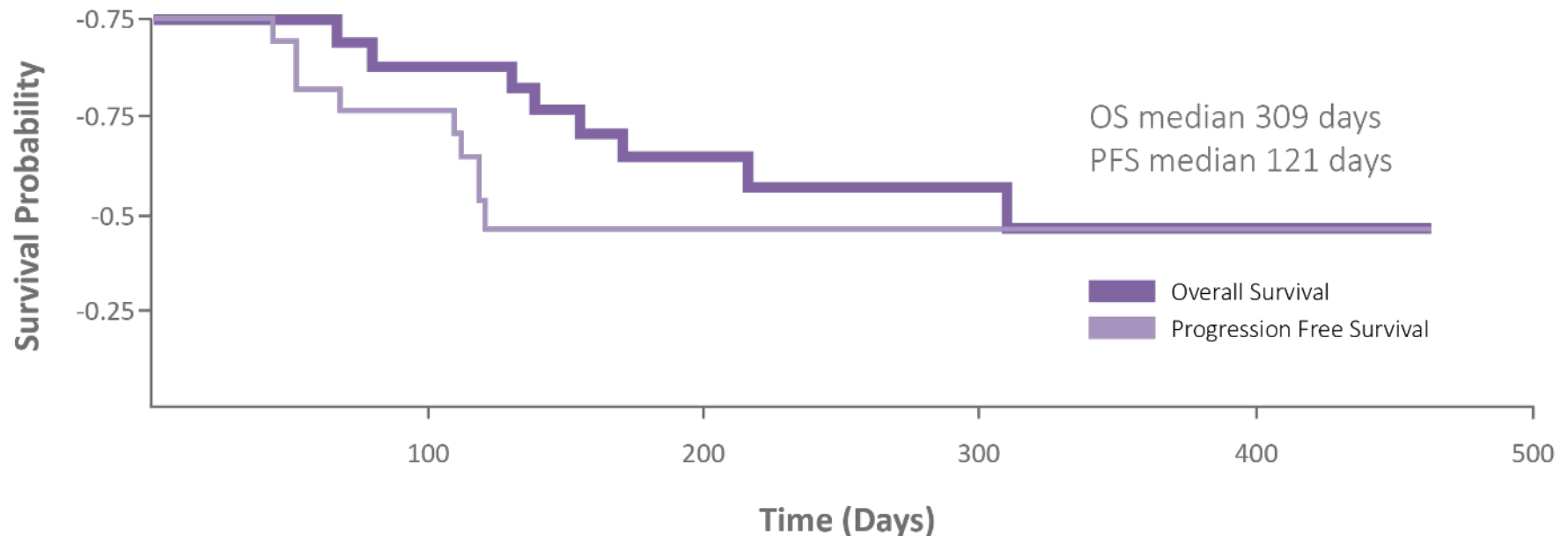


# Results: Pancreatic Cancer

Study DB2- 201



## Overall and Progression Free Survival



Adapted from Ross PJ et al. 2008

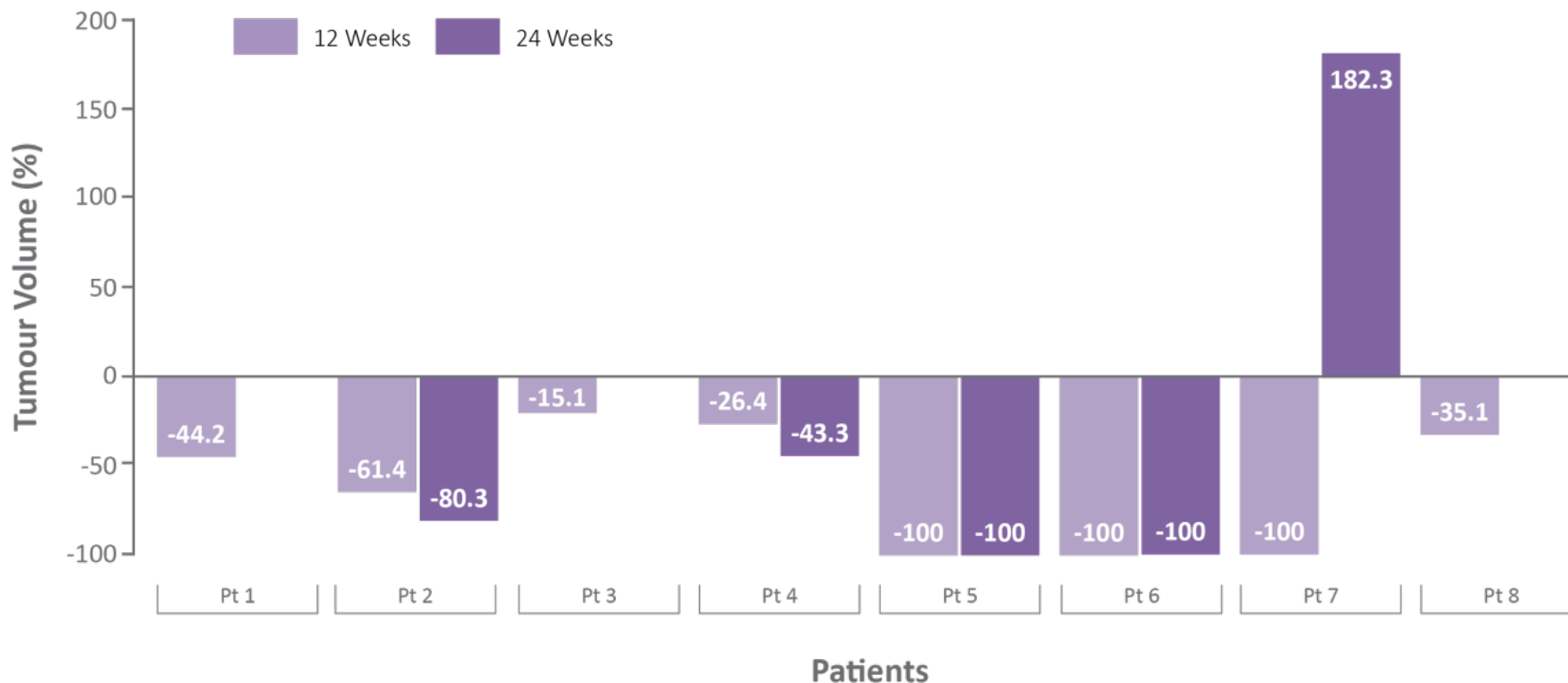
1. Ross PJ et al, 2008, "Novel delivery via endoscopic ultrasound of a  $^{32}\text{P}$  brachytherapy device in addition to gemcitabine (G) in advanced pancreatic cancer", ASCO, Chicago, Illinois.

# Results: Liver Cancer

Study BIOSP-201



## Tumour Volume Response



Adapted from Goh MD 2007. Results from tumour volume regression at week 12 and week 24 by CT scan post implantation. Patient 1,3 and 8 withdrew before the scan at week 24 not due to an adverse events

# Results: Liver Cancer

Study BIOSP-201:



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

Patient Number	% Change in target Tumour Volume	Response <sup>+</sup>
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

1. Clinical Evaluation Report, OncoSil™ ONCSP-32, Document No: RA-CER01, 20 August 2015 Version B

# OncoSil™ Corporate Goals: 2015



- ISO 13485 Certification – granted April 2015
- CE Mark approval by Q4 2015 (original target Q3)
- Commercial Manufacturing readiness by Q3 2015
- Business plan & commercialisation strategy defined by Q4 2015
- First commercial sales in 2015 (dependent on CE Mark granting)
- US FDA 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
US FDA Trial			→				
US FDA IDE	→			Q4 Approval			
CE Marking	→			Q4 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.



# Capital Structure

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<b>ASX code</b>	<b>OSL</b>
<b>Market Cap</b> (Nov, 2015)	<b>\$A57M</b>
<b>Shares on issue</b>	<b>355M</b>
<b>Cash</b> (Sept, 2015)	<b>\$A5.0 M</b>
<b>R&amp;D Credits &amp; Pre-payments</b> (Oct,2015)	<b>\$A2.6 M</b>
<b>Total Cash and Credits</b>	<b>\$A7.6 M</b>

**Average Burn rate: \$A 440K per month**

**Cash reserves to end April 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 25% and five year survival of 5%<sup>1</sup>
  - Primary liver cancer is the 6th most common cancer in the world<sup>2</sup>
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 Q4 2015.
5. EU Commercialisation in 2015 possible following CE Mark authorisation.
6. Upcoming US FDA IDE

1. World Cancer Report 2014. World Health Organization. 2014. Chapter 5.7 ISBN 9283204298 2. World Cancer Report 2014. World Health Organization. Chapter 1.1 ISBN 9283204298

# Thank you !!

Daniel Kenny  
CEO & Managing Director  
OncoSil Medical Ltd  
[www.oncosil.com.au](http://www.oncosil.com.au)