

ASX / Media Release 23rd March 2016

### **OncoSil Medical releases latest Investor Presentation**

**SYDNEY, 23rd March, 2016: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company)** is pleased to release its latest Investor Presentation, delivered at Bell Potter Securities Limited's Emerging Leaders Day in Sydney today.

The presentation provides an overview and update on the Company's activities and operations.

OncoSil Medical is focused on regulatory approval and commercialisation of its OncoSil<sup>TM</sup> brachytherapy technology. It aims to position OncoSil<sup>TM</sup> as an innovative, new medical radiation treatment for pancreatic cancer and other solid tumours – which have major un-met medical needs.

The Company has an Investigational Device Exemption (IDE) filing in progress with the US Food and Drug Administration (FDA) and concurrently is pursuing Conformité Européenne (CE) Mark certification with the European regulatory body for OncoSil<sup>TM</sup>.

The Investor Presentation is attached.

**ENDS** 

**Contact:** 

Mr Daniel Kenny
Chief Executive Officer and Managing Director

E: daniel.kenny@oncosil.com.au

T: +61 2 9223 3344

James Moses Mandate Corporate

E: james@mandatecorporate.com.au

M: +61 420 991 574 T: +61 2 8211 0612

#### **About OncoSil Medical Ltd**

OncoSil Medical Ltd (OncoSil Medical) is a clinical-stage Australian Lifesciences company with the aim is to provide new technologies for safer medical radiation treatments. OncoSil Medical's lead product is OncoSil™ with the first target indication being pancreatic cancer. OncoSil™ is a silicon and P32 (phosphorus) pure beta emitter with the potential to be used medically as a brachytherapy treatment. The OncoSil™ device delivers more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has previously conducted four clinical trials with encouraging results on tolerability, safety and efficacy. There is also potential use for OncoSil™ in other solid tumours outside of pancreatic cancer. FDA and CE Mark approval for pancreatic cancer is the core focus of OncoSil Medical.

#### **Pancreatic Cancer**

Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil™ in pancreatic cancer exceeds \$1b.

#### Hepatocellular carcinoma liver cancer

Hepatocellular carcinoma (HCC) is the 6<sup>th</sup> most common cancer in the world with 782,000 new cases diagnosed in 2012. It's very poor prognosis makes HCC the third leading cause of cancer related mortality responsible for approximately 600,000 deaths annually. Hepatocellular carcinoma can be cured by surgery or transplantation. The vast majority of patients with HCC have disease which is too advanced for surgical intervention and as a consequence survival ranges from a few months to two or more years depending on the liver function at diagnosis and the extent of tumour invasion. The value of the hepatocellular cancer (HCC) market is expected to triple in size to \$1.4b by 2019.

#### References

- Global Industry Analysts 2010
- BIOSDP-201. A single dose, single centre open label Phase I/II Safety Study in Hepatocarcinoma
- Venook et al. The incidence of Epidemiology of Hepatocellular Carcinoma: A Global and Regional Perspective. The Oncologist; 15 Supplement 5-13
- http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/pancreatic-cancer-statistics
- http://www.datamonitorhealthcare.com/hepatocellular-cancer-market-to-treble-in-size-by-2019
- http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/liver-cancer-statistics



# Important Notice



The purpose of the presentation is to provide an update of the business of OncoSil Medical Ltd (ASX:OSL). These slides have been prepared as a presentation aid only and the information they contain may require further explanation and/or clarification. Accordingly, these slides and the information they contain should be read in conjunction with past and future announcements made by OncoSil Medical Ltd and should not be relied upon as an independent source of information. Please contact OncoSil Medical Ltd and/or refer to the Company's website for further information.

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## OncoSil Medical - Overview

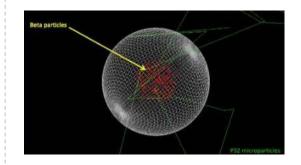


### Developing implantable radiotherapy medical device

- 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<sup>™</sup> is well tolerated in patients with unresectable primary liver and pancreatic cancer<sup>2</sup>
- Efficacy data showed that OncoSil<sup>™</sup> induces significant reduction in tumour volume in both liver and pancreas cancer and significantly reduces pain<sup>2</sup>





<sup>1.</sup> 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

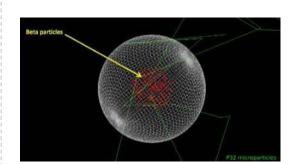


### **CE Mark registration process is ongoing**

- Company confident of CE Mark being granted in the near term
- Company acknowledges that registration process has taken much longer than expected
- CE Mark filing is complex & process complicated
- Submission documentation extends to thousands of pages of reports & data

## 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<sup>TM</sup> 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





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

# **Board & Management**





**Dr. Roger Aston**Chairman



Mr. Daniel Kenny CEO & MD



Dr. Chris Roberts Director



Mr. Martin Rogers Non-Executive Director

Seasoned biotechnology entrepreneur. Inventor on patent for OncoSil™

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

Former Cochlear CEO Highly experienced director and senior executive with 40 years' experience in the Medical innovation space.

A well-recognised Australian biotechnology entrepreneur and executive



Mr. Tom Milicevic Chief Financial officer & Company Secretary





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

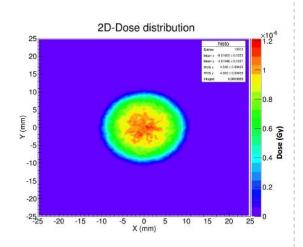


Mr. David James Manufacturing & Operations Manager

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

# OncoSil<sup>TM</sup> - 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

<sup>1.</sup> Clinical Evaluation Report, OncoSil™ ONCSP-32, Document No: RA-CER01, 20 August 2015 Version B 2. Instructions for Use, OncoSil™ ONCSP-32, Document No: RA-IFU01, September 2015 Version B 3. Investor Update.OncoSil™ Medical Ltd. Edition #5: July 2015,

## How OncoSil<sup>TM</sup> 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.

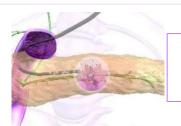


The physician guides an endoscope down the oesophagus, through the stomach and into the first part of the small intestine.

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<sup>TM</sup> suspended in fluid directly into the tumour.

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# **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>

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

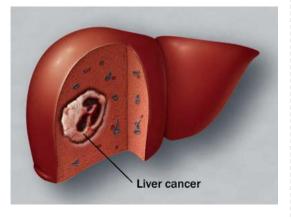
# **US\$1.4bn Primary Liver Cancer**



#### **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





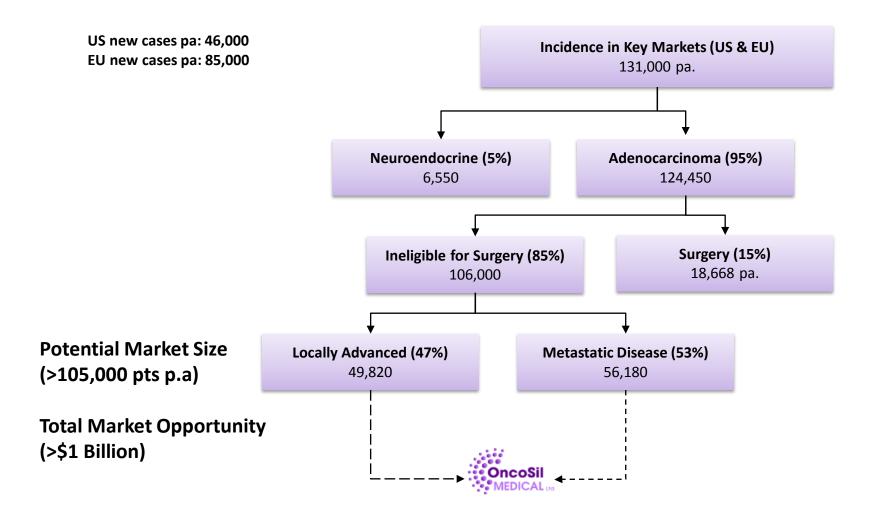
### **Target market**

- 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>

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

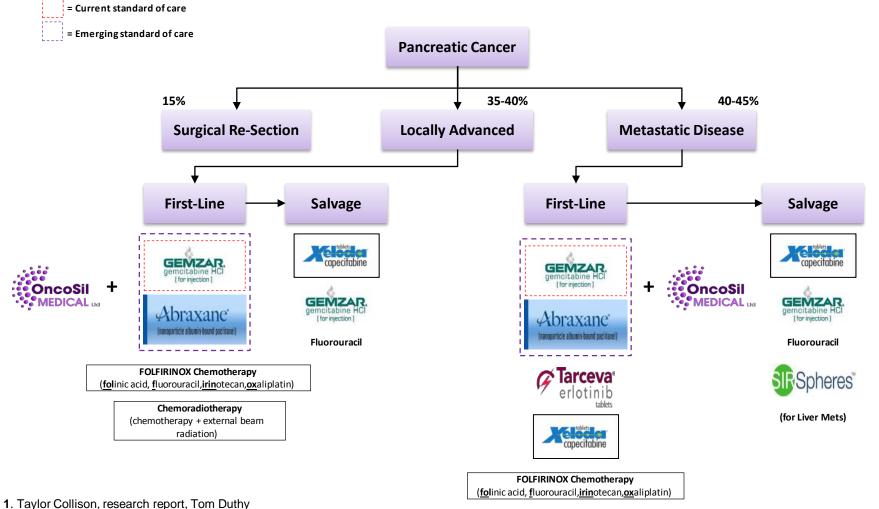
### Pancreatic Cancer: Patient Pool Assumptions – US & EU





### Pancreatic Cancer Treatment Paradigm





### 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)







<sup>1.</sup> 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%

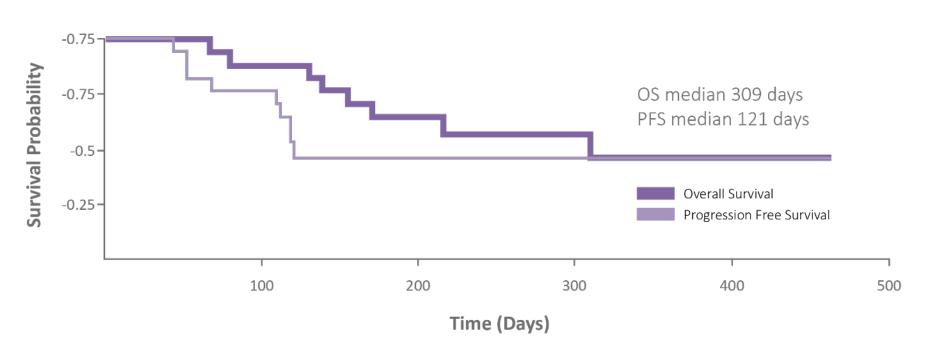
Target Tumour Reduction	5%	10%	15%	20%	25%	30%
Response Rate	68.75%	68.75%	68.75%	62.50%	56.25%	50.00%

### Results: Pancreatic Cancer

Study DB2-201



### **Overall and Progression Free Survival**



Adapted from Ross PJ et al. 2008

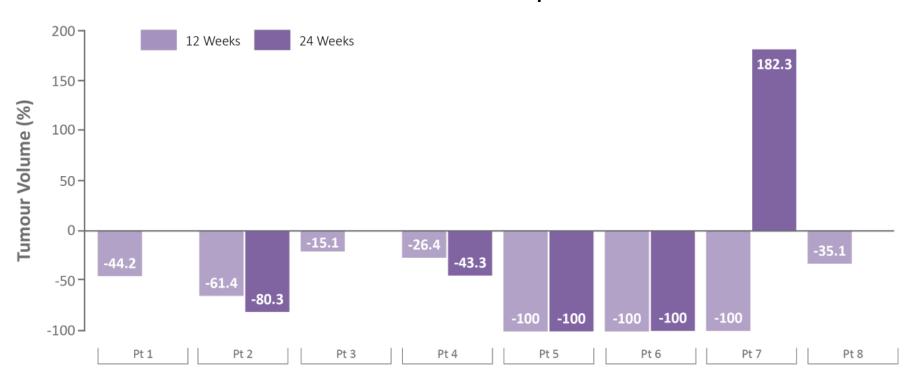
**<sup>1.</sup>** Ross PJ et al, 2008,"Novel delivery via endoscopic ultrasound of a <sup>32</sup>P brachytherapy device in addition to gemcitabine (G) in advanced pancreatic cancer", ASCO, Chicago, Illinois.

### Results: Liver Cancer

Study BIOSP-201



### **Tumour Volume Response**



#### **Patients**

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

1. Goh AS, 2007, Int J Radiat Oncol Biol Phys; 67(3):786-92. Epub 2006 Dec 4

### 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

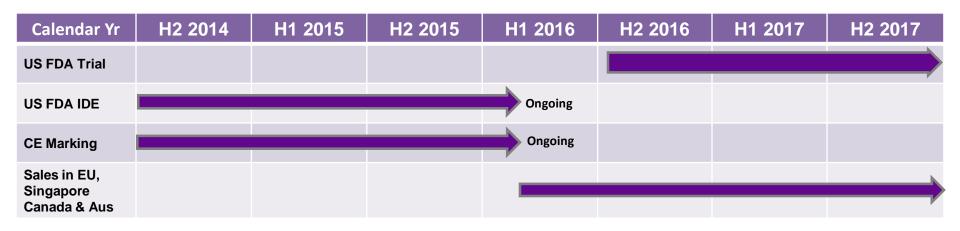
<sup>+</sup>WHO definitions of tumour response \* Denotes investigator's classification A change of -100% indicated total disappearance of target lesions

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

# Global Regulatory Strategy



### **Device Registration Plan for Key Pharmaceutical Markets**



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



		_	Oncosil Medical Ltd Closing Share Price Analysis
ASX Code	OSL	\$0.27	A
Market Cap	<b>A\$70m</b>	\$0.24	<u></u>
Shares on Issue	421m		
Cash as at Sep 15	\$A14.5m	\$0.21	
R & D Credits & Pre-payments	A\$0.5m	\$0.18	
		¥5.125	
Total Cash & Credits	A\$15.0m	\$0.15	
		\$0.12	
		Ψ0.22	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
Avg Burn Rate/month	A\$500k	\$0.09	me Makes
		\$0.06	
Cash reserves to the end of	June 18	30.00 F	Dec't here's serie mais maris maris here's here's serie of the monit occis
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## OncoSil Medical Achievements: 2015



- ISO 13485 Certification granted April 2015
- Filed for CE Mark on July 17, 2015
- Successfully completed US FDA Pre-IDE submission process
- Filed US FDA IDE submission on December 10, 2015
- Built a strong "world-class" Executive Management Team

Achieved a "positive Brand" awareness for OncoSil Medical with the

Investment community







# OncoSil<sup>TM</sup> Corporate Goals: 2016 ConcoSil



- CE Mark approval in near term
- First commercial sales in Ex-US (dependent on CE Mark granting)
- US FDA IDE approval in near term
- Commence Clinical Investigation OncoPac-1 in H2 2016



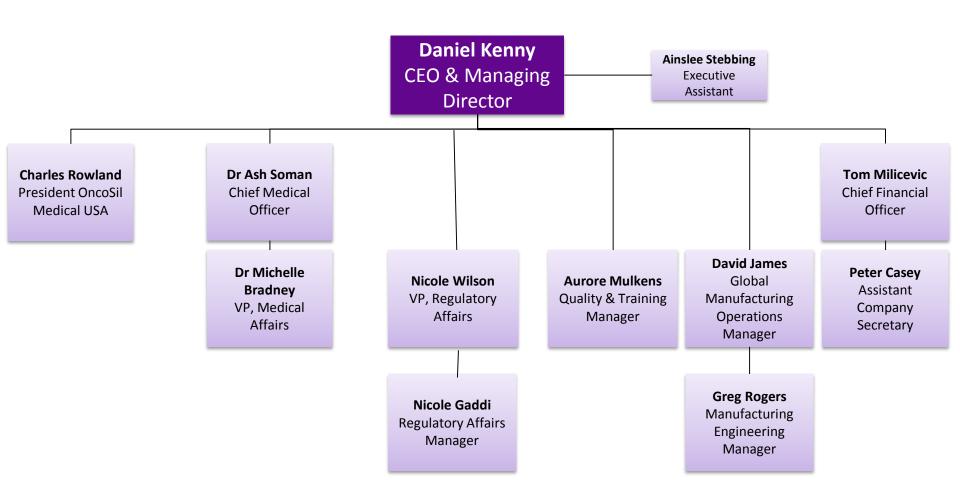
Image 1 (Top left):Microparticle atomiser



Image 2 (to the Right): Microparticle classifier

# **Organisational Chart**





## 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>
- 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 near term.
- 5. EU Commercialisation in 2016 possible following CE Mark authorisation.
- 6. Upcoming US FDA IDE expected in near term

<sup>1.</sup> 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