

### **Company Update** June 2018

Advancing Pancreatic Cancer Treatment

**OncoSil** Medical

# **OncoSil Medical | Investment Highlights**

1	Clear mission	Commercialising a breakthrough implantation radiation treatment for Pancreatic cancer	
2	Sound science	<ul> <li>Current and previous clinical studies demonstrate:</li> <li>Excellent Local Disease Control</li> <li>Significant reduction in tumour size and volume</li> <li>Excellent safety and tolerability profile</li> <li>Ease of implantation</li> </ul>	
3	Clear strategic path	<ul> <li>Targeting &gt;\$2bn market opportunity to improve standard of care</li> <li>US FDA-approved IDE in place, safety run-in underway</li> <li>EU regulatory approval, CE Marking expected near-term</li> <li>Highly experienced management team; strong clinical and commercial pedigree</li> <li>Manufacturing and logistics optimised for supply of commercial quantities</li> <li>At a potential value inflection point with multiple paths to commercialisation</li> </ul>	

# **OncoSil Medical**

# OncoSil<sup>™</sup> is a first in class medical device for the treatment of unresectable locally advanced pancreatic cancer

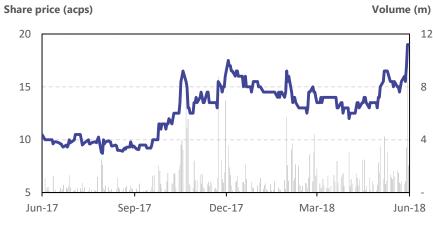
#### First in class technology

- Proprietary brachytherapy (internal radiation) medical device
- Cancer is treated by implantation of radioactive microparticles into a tumour via ultrasound guided endoscopy with negligible surrounding healthy tissues damage
- Patent protected in all major geographies
- Class III Medical device in the US and AIMD in EU

#### **Financial information**

Enterprise value	A\$107.9m
Debt (31 March 2018)	Nil
Cash (31 March 2018) <sup>1</sup>	A\$10.7m
Market capitalisation	A\$118.6m
Shares on Issue	624.2m
52 week range	A\$0.08-0.19
Share price (as at 1-Jun-18)	A\$0.19

#### Share price performance (1 year)



#### Substantial shareholders

Regal Funds Management	10.0%
Management and Directors	12.3%

Note: 1. Cash balance as at 31 March 2018 does not include capital raised in OSL's April 2018 Tranche 2 placement (\$4.0m) and SPP (\$4.0m)

### About the OncoSil<sup>™</sup> device

An implantable radiotherapy medical device targeting pancreatic cancer



- OncoSil<sup>TM</sup> is a **single-use brachytherapy device**
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- Delivered through **microparticles**: 30-micron silicon particles contain beta-emitting Phosphorus-32 (<sup>32</sup>P)
  - OncoSil<sup>TM</sup> Microparticles are inserted **directly into the tumour**
- $\oplus$
- Radiation from the microparticles causes direct damage to cancer cell DNA. The device being active for approximately 3 months after implantation



Microparticles stay in the tumour permanently



### **Implantation procedure**

Studies continue to show the device implantation is technically straightforward

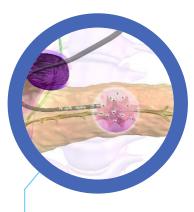


OncoSil<sup>™</sup> dose is suspended in a specially formulated fluid for implantation



Endoscope guided into the upper intestine

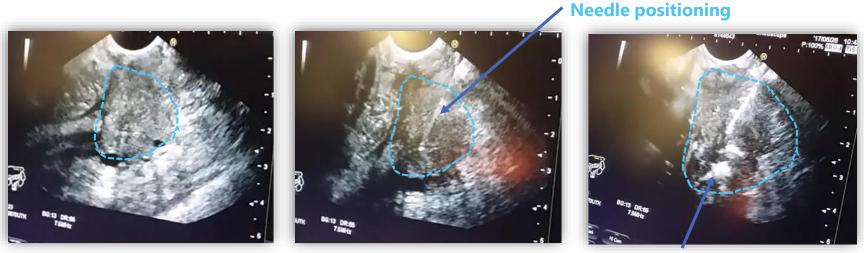
Using CT or real-time imaging, the needle is guided into the target lesion (tumour)



OncoSil™ injected directly into the tumour

### **Real-Time Visualisation**

Needle Positioning in Pancreatic Mass via Endoscopic Ultrasound (EUS)



**OncoSil<sup>™</sup> deposition** 

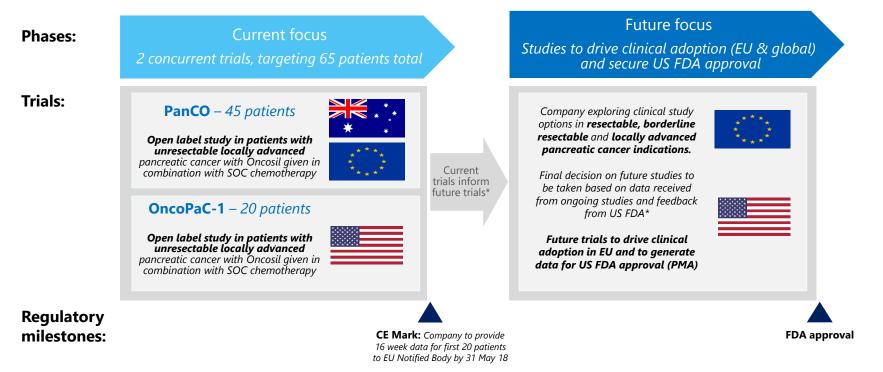
# **OncoSil at a potential value inflection point**

The Company is well positioned to realise value of OncoSil<sup>™</sup> device

	Current focus		
Before 2015: <b>Demonstrate</b> potential	2016 to 2018: Satisfy regulatory obligations	2018 onwards: <b>Path to</b> commercialisation	
<ul> <li>4 studies show potential of OncoSil™ to treat pancreatic &amp; primary liver (HCC) cancer</li> </ul>	<ul> <li>Secured US FDA IDE approval</li> <li>Initiated PanCO &amp; OncoPac-1 clinical studies</li> <li>Highly positive early safety, efficacy and implant delivery data consistent with results from previously completed studies</li> </ul>	<ul> <li>Secure strategic partnerships and licensing agreements in all key geographies</li> <li>Secure licensing agreements in unique geographies</li> <li>Leverage potential for broader distribution, capital and market support and exposure</li> </ul>	

# **Clinical pathway overview**

PanCO and OncoPaC-1 to inform future studies



## **PanCO study – positive results to date**

Positive clinical data on 20 patients (at Week 8) and 20 patients (at Week 16)

Study progress overview	<b>47</b> patients enrolled <sup>1</sup>	<b>36</b> patients implanted <sup>1</sup>	
	<ul> <li>Disease Control Rate (DCR) of <b>100%</b> (Week 8) and <b>87%</b> (Week 16)</li> </ul>	Partial Response – a reduction in tumour longest diameter of at least 30% from baseline	
	<ul> <li>5 out of 20 implanted patients achieved a Partial Response</li> </ul>		
Clinical performance	<ul> <li>5 out of 20 implanted patients have undergone Surgical Resection</li> </ul>	Resection – the only potential cure for pancreatic cancer, demonstrating possibility of improved outcomes in patient group deemed inoperable at time of study entry. A further 3 study participants are being assessed for possible surgical resection	
	<ul> <li>Up to 73% and 80% tumour volumetric reduction at Week 8 and 16 respectively</li> </ul>		
	<ul> <li>Median volumetric reduction of 29% (at week 8) and 39.5% (as week 16)</li> </ul>	resection	
Safety & implantation	<ul> <li>No Serious Adverse Events (SAEs) attributed to device or implantation<sup>2</sup></li> <li>No evidence of radiation toxicities, or other safety concerns identified to date</li> <li>OncoSil<sup>™</sup> device delivery via EUS considered straightforward for implantation</li> </ul>		

1. As at 28-May-18

2. SAEs related to chemotherapy or cancer progression

### **Tumours successfully resected**

#### **Recap of study context**

- Study population drawn from patients with unresectable locally advanced pancreatic cancer
- Primary objective of treatment with OncoSil for these patients is to control tumour growth
- To date, 5 out of 20 implanted patients have undergone surgical resection with curative intent (undergoing the Whipple procedure)

#### SIGNIFICANT MILESTONE FOR PanCO STUDY

Demonstrates improved outcomes in group of patients deemed inoperable at time of enrolment

#### RESECTION IS THE ONLY CURE FOR PANCREATIC CANCER

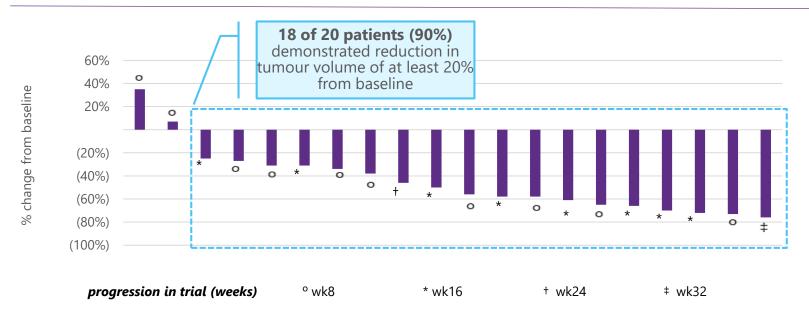
But <15% of all diagnosed pancreatic cancer patients will be eligible for surgical resection

#### CONTINUED PROGRESS WILL BE CLOSELY MONITORED

Down-staging patients to resection is not an objective endpoint in the PanCO study, however will be closely followed as more data is collected.

### Substantial tumour volumetric reduction

#### Best tumour volumetric change in first 20 implanted patients



# Significant opportunity for OncoSil

#### Current available treatment for pancreatic cancer

- Surgery (resection), if diagnosed early enough
- Chemotherapy (Gemcitabine and Abraxane)



External radiation therapy

#### Issues with current standard of care

- Symptoms often unnoticed until cancer has metastasised; poor prognosis even with therapy:
  - Median survival ~8 months<sup>1</sup>
  - 5 year survival less than 5%<sup>1</sup>
- Surgery not feasible in 85% of patients
- Chemotherapeutic treatments limited effectiveness and are very toxic
- Radiation therapy is toxic to the patient's GI tract

#### The opportunity for OncoSil

- Only two drugs to have made significant improvements in pancreatic cancer in over 20 years:
  - Gemcitabine approved over 21 years ago and Abraxane approved in 2013
  - Median overall survival has increased by only 2 months (to 8.5 months) over the past 20 years

Significant opportunity for OncoSil to become standard of care in combination with Chemotherapy

1. American Cancer Society 2010 Accessed on 9 September 2015

# **Positive reception at key conferences**

Early study data presented at European Association of Nuclear Medicine (EANM) Annual Congress and European Society of Medical Oncology (ESMO)



The EANM is the **largest organisation** dedicated to Nuclear Medicine in Europe



OncoSil presented early study results to EANM Annual Congress in Vienna on 21 October 2017



ESMO is Europe's **leading non-profit medical oncology organisation** 



OncoSil presented details of its trial design to ESMO World Congress on Gastrointestinal Cancer in Barcelona in July 2017

#### Future conference presentations in 2018



12<sup>TH</sup> WORLD CONGRESS OF THE WORLD FEDERATION OF NUCLEAR MEDICINE AND BIOLOGY 20-24 April 2018 | MELBOURNE, AUSTRALIA

World Congress of the World Federation of Nuclear Medicine and Biology Melbourne, April 2018



Digestive Disease Week®

Digestive Disease Week Washington, June 2018

### **Partnering with leading cancer centres**

15 leading cancer centres participating in Global Pancreatic Cancer clinical programme

Region	Centre			
****	MD Anderson, Texas	the university of texas MDAnderson <del>Cancer</del> Center	MOFFITT	
	Johns Hopkins, Maryland			
	Moffit Cancer Centre Florida	COS	A JOHNS	S HOPKINS
	Cedars Sinai Hospital, LA	CEDARS-SINAI MEDICAL CENTER.	<b>М</b> е	DICINE
	Guy's & St Thomas', London	UNIVERSITY OF LEICESTER	Guy's and St Thomas' NHS Foundation Trust	
	University of Leicester			
	Hammersmith, London	Hammersmith Hospital	Addenbrooke's <b>NHS</b>	
	Addenbrookes, Cambridge			NHS Trust
	Monash, Melbourne	Monash <b>Health</b>		
	St Vincent's, Sydney		WESTMEAD HOSPITAL	Royal Adelaide
	Westmead Hospital, Sydney		HUSFILL	Hospital
* *	RNS Hospital, Sydney	Austin Health	ST VINCENT'S	Royal North
	Royal Adelaide		ST VINCENT'S HOSPITAL	Shore Hospital
	The Austin Hospital, Melbourne			
	Jules Bordet Institute Hospital, Brussels	•		

JULES BORDET

# **Clear pathway to commercialisation**

Strategic partners provide multiple paths to market to optimise value

### Well positioned for commercialisation



**Broad technology platform** *Treatment for multiple solid tumours* 



**Excellent clinical results** *Pancreatic and primary liver cancer* 



**EU regulatory approval** *CE Mark certification for pancreatic cancer expected near-term* 



#### Significant unmet clinical need

Over130,000 patients diagnosed with pancreatic cancer in US and EU every year

### Potential paths to market



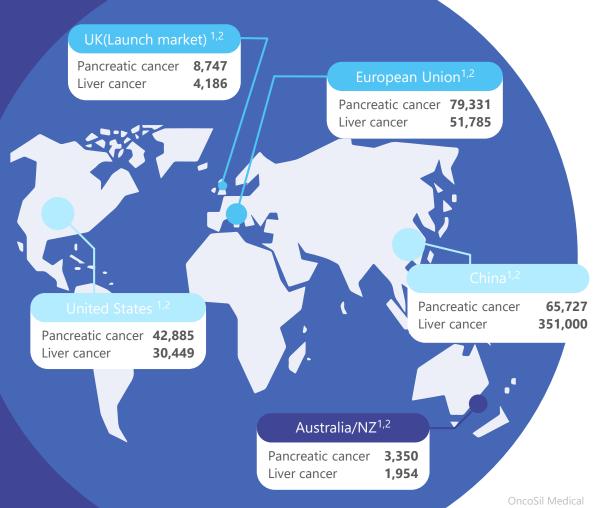
### 2018 marks the start of this journey

1. GLOBOCAN 2012: Estimated Cancer Incidence Worldwide in 2012 (IARC/WHO). Accessed 22 Apr 2016,from http://globocan.iarc.fr/Pages/fact\_sheets\_population.aspx

# Target markets Annual incidence

Globa	opportunity	/
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Pancreatic cancer	US>\$2.0bn	
Liver cancer	US\$1.4bn	



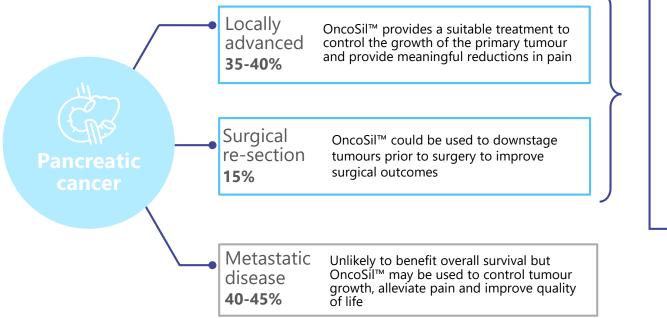
1. GLOBOCAN 2012: Estimated Cancer Incidence Worldwide in 2012 (IARC/WHO). Accessed 22 Apr 2016, from http://globocan.iarc.fr/Pages/fact\_sheets\_population.aspx

2. Datamonitor Healthcare 2013

3. OncoSil dose pricing, \$USD 25,000

# **Global Commercial opportunity in excess of \$2bn**

130,000 cases per year in US+EU alone: more than 70,000 of these could benefit from OncoSil



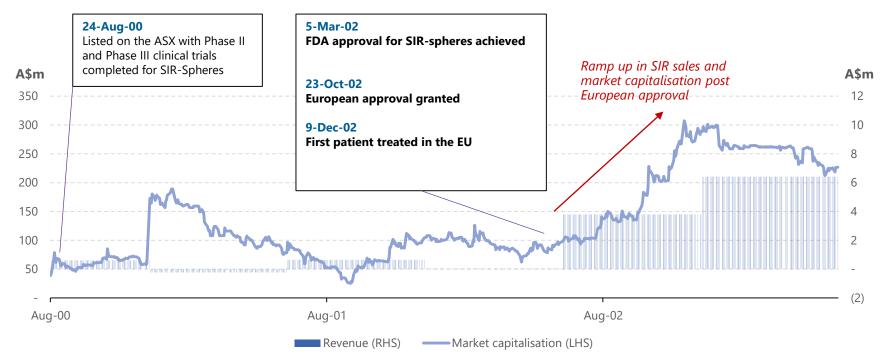
More than 70,000 relevant patients in EU and US alone

Company exploring clinical research options in re-sectable & borderline re-sectable patients

OncoSil's potential pricing of US\$25,000 per patient (in-line with other on-market devices) implies >**\$2bn global market** opportunity

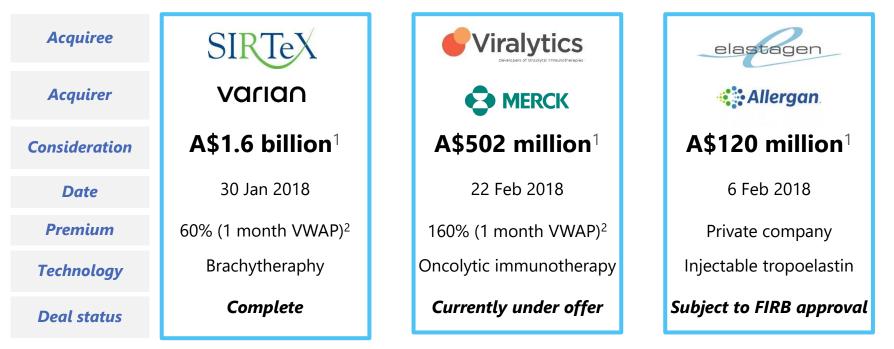
# **OncoSil's commercial path has precedent**

Sirtex provides a useful case study to demonstrate the potential commercial journey for OncoSil due to similarities in addressable market



### Sector M&A trends

Over A\$2bn of acquisitions in February 2018 highlights attraction of early-stage Australian biotech to global pharmaceutical players



Note:

1. Based on disclosed consideration

2. Based on disclosed premium to target's volume weighted average price prior to announcement

### **Board of Directors**

- Board and management are experienced leaders in the pharmaceutical and medical device space, having held senior positions at **Cochlear** (ASX:COH), **Sirtex Medical** (ASX:SRX), ABIVAX, Baxter International, Roche and more
- Extensive leadership experience guiding products from clinical development to commercialisation
- 120+ years collective experience in the health care industry



Dr Chris Roberts Chairman

- Former CEO/President of Cochlear (ASX:COH)
- 40+ years' industry experience
- Former Chairman of Sirtex (ASX: SRX) & Executive Vice-President of ResMed (ASX: RMD)



Mr Daniel Kenny CEO & MD

- Proven biopharma professional, leading multiple \$1bn+ franchises
- 30+ years industry experience
- Commercial development at ABIVAX & global strategic marketing & business development at Roche



**Dr Roger Aston** Non Executive Director

- Biotech & pharma entrepreneur
- 20+ years industry experience
- Founder & former CEO of pSiMedica & pSiOncology
- FDA & EU registration, global licensing & equity capital raisings experience



Martin Cross Non Executive Director

- Former Chairman of Medicines Australia
- Highly regarded pharmaceutical executive with 30+ years experience in corporate & industry leadership roles

# Highly experienced management team

- Management team experienced leaders in the medical device space having held senior positions at Sirtex Medical (ASX:SRX)
- Extensive leadership experience in clinical studies, commercialisation and manufacturing & operations



#### Mr Daniel Kenny CEO & MD

- Proven biopharma professional, leading multiple \$1bn+ franchises
- 30+ years industry experience
- Commercial development at ABIVAX & global strategic marketing & business development at Roche



#### **Mr Tom Milicevic** Chief Financial Officer & Company Secretary

- Seasoned CFO with over 15+ years experience in the Medical Device sector
- Experience in investor relations and also Company Secretary duties



#### **Dr Ashish Soman** Chief Medical Officer

- Former country medical director, AstraZeneca Australia.
- 20+ years' experience in clinical practice & the biopharmaceutical industry



#### **Dr David James** Manufacturing &

Operations Manager

- Ex Sirtex Medical global operations manager for 6 years
- Established Sirtex's manufacturing and operations
- 25 years experience in pharmaceutical operations



#### **Nicole Wilson** VP Regulatory Affairs & Quality

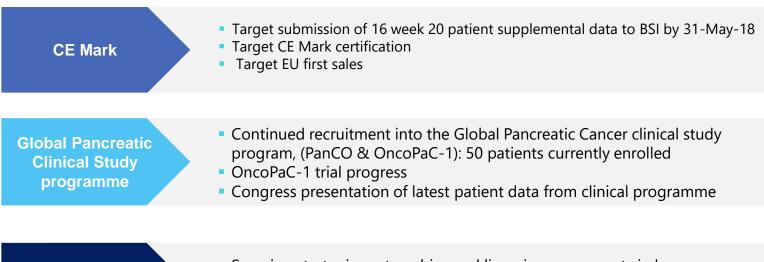
- Regulatory affairs specialist focused on quality compliance and marketing registrations in the Asia, South America and middle East.
- Principal for the regulatory approvals in Brazil, Argentina and UAE for Sirtex.



#### **Michael Warrener** Global Sales & Marketing Director

- Former Sirtex Medical Senior Executive
- Introduced Sir-Spheres in Australia, EU and Middle East markets

### Key catalysts in CY 2018



Strategic partnerships

- Securing strategic partnerships and licensing agreements in key geographies
- Additional Licensing partners in unique geographies

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