

ASX/ Media Release 2 May 2018

### Oncosil Medical Presents at Finance News Network Investor Event Updated Corporate Presentation

**Sydney, Australia, 2 May 2018:** OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**) a medical device company focused on localised treatments for patients with pancreatic and liver cancer, today announced that Chief Executive Officer, Daniel Kenny will present at the Finance News Network Investor Event in Sydney 2 May 2018.

The Company's updated Presentation which will be presented at the conference is attached and is also available at the Company's website <u>www.oncosil.com.au</u>.

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#### About OncoSil

OncoSil<sup>™</sup> is a clinical-stage medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil<sup>™</sup> is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with the OncoSil<sup>™</sup> is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical trials with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil<sup>™</sup> in the European Union (EU) is under review with commercial launch planned subject to approval.

The U.S Food and Drug Administration granted an Investigational Device Exemption (IDE) in July 2016 with approval to conduct a clinical study of the OncoSil<sup>™</sup> device. The aim of the study will be to collect safety and effectiveness data required to support a Premarket Approval (PMA) application.

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 \$2b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6<sup>th</sup> most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.



#### **Forward Looking Statements**

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil is providing this information as of the date of this document and does not assume any obligation to update any forwardlooking statements contained in this document as a result of new information, future events or developments or otherwise.



### Company Update May 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

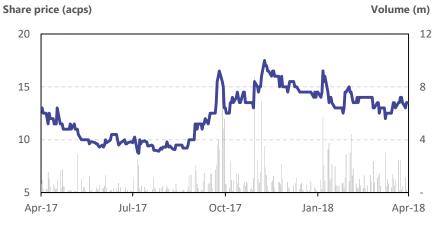
### First in class technology

- 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\$69.1m
Debt (31 March 2018)	Nil
Cash (31 March 2018) <sup>2</sup>	A\$10.7m
Market capitalisation	A\$79.8m
Shares on Issue <sup>1</sup>	590.9m
52 week range	A\$0.08-0.18
Share price (as at 30-Apr-18)	A\$0.135

### Share price performance (1 year)



#### Substantial shareholders

Regal Funds Management	10.6%
Management and Directors	12.3%

Note: 1. 33.3m Tranche 2 placement shares expected to be issued following Extraordinary General Meeting to be held on 14 May 2018. 2. 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**
- $\oplus$
- 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

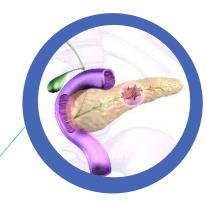


### **Implantation procedure**

Studies continue to show the device implantation is technically straightforward

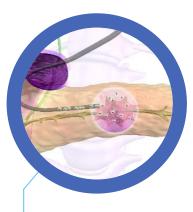


OncoSil<sup>™</sup> dose is suspended in a specially formulated fluid for implantation



Endoscope guided into the upper intestine

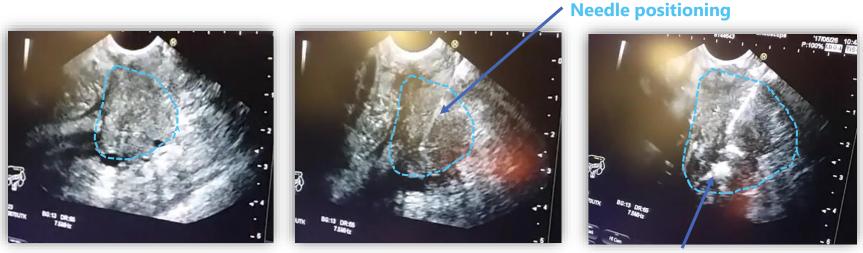
Using CT or real-time imaging, the needle is guided into the target lesion (tumour)



OncoSil<sup>™</sup> injected directly into the tumour

### **Real-Time Visualisation**

Needle Positioning in Pancreatic Mass via Endoscopic Ultrasound (EUS)



**OncoSil<sup>™</sup> deposition** 

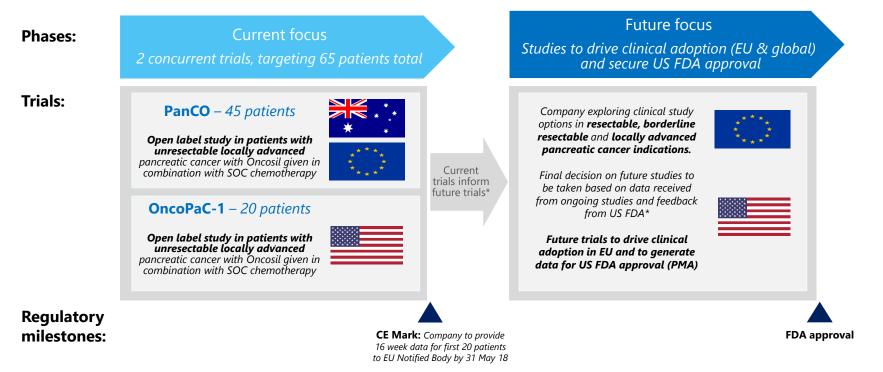
## **OncoSil at a potential value inflection point**

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>46</b> patients enrolled <sup>1</sup>	<b>33</b> patients implanted <sup>1</sup>	
Clinical performance	<ul> <li>Disease Control Rate (DCR) of 100% (Week 8) and 87% (Week 16)</li> <li>4 out of 20 implanted patients achieved a Partial Response</li> <li>5 out of 20 implanted patients have undergone Surgical Resection</li> </ul>	<ul> <li>Partial Response – a reduction in tumour longest diameter of at least 30% from baseline</li> <li>Resection – the only potential cure for pancreatic cancer, demonstrating possibility of improved outcomes in patient group deemed inoperable at time of study</li> </ul>	
	<ul> <li>Up to 73% and 72% tumour volumetric reduction at Week 8 and 16 respectively</li> <li>Median volumetric reduction of 29% (at week 8) and 39.5% (as week 16)</li> </ul>	entry. A further 3 study participants are being assessed for possible surgical 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 30-Apr-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

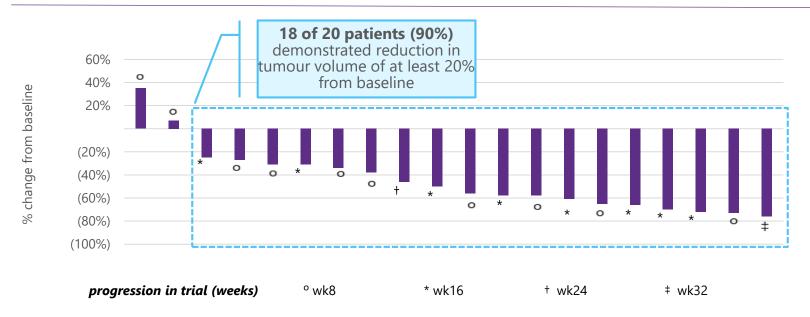
But <15% of all diagnosed pancreatic cancer patients will be eligible for surgical resection

#### 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	MOFFI CANCER CE	TT
	Johns Hopkins, Maryland	Cancer Center	CANCER CE	
	Moffit Cancer Centre Florida	COS	A IOHNS	S HOPKINS
	Cedars Sinai Hospital, LA	CEDARS-SINAI MEDICAL CENTER.	<b>М</b> е	DICINE
	Guy's & St Thomas', London	UNIVERSITY OF	UNIVERSITY OF Curves and St Thomas' NHS Foundation Trust	
	University of Leicester	LEICESTER		
	Hammersmith, London		Addenbroo	oke's NHS
	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

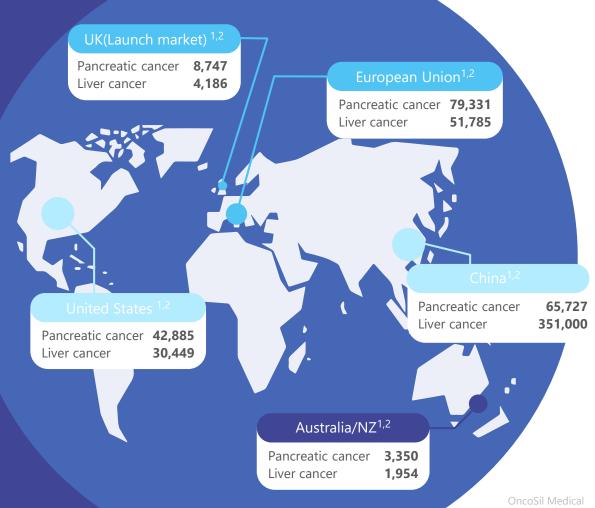


### 2018 marks the start of this journey

# Target markets Annual incidence

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



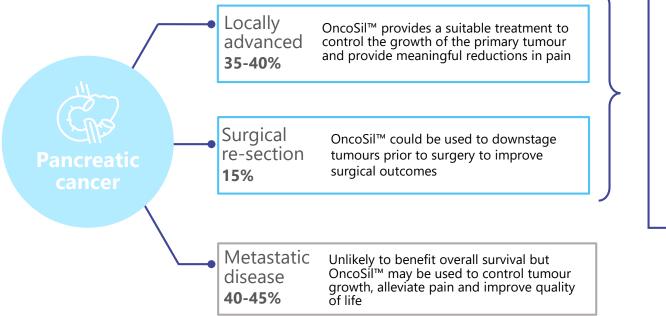
1. GLOBOCAN 2012: Estimated Cancer Incidence Worldwide in 2012 (IARC/WHO). Accessed 22 Apr 2016, from http://globocan.iarc.fr/Pages/fact\_sheets\_population.aspx

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



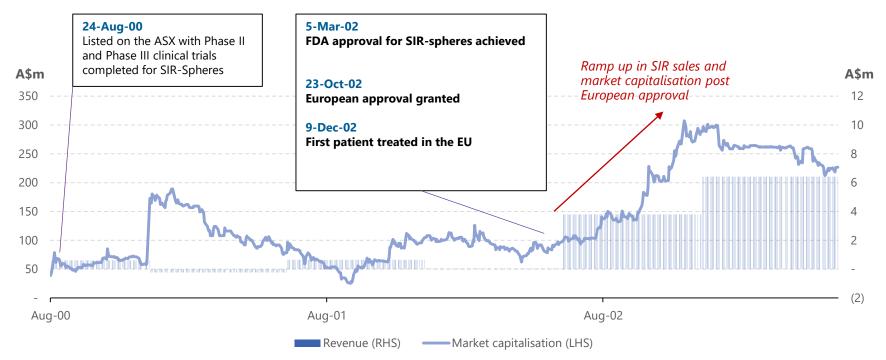
More than 70,000 relevant patients in EU and US alone

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

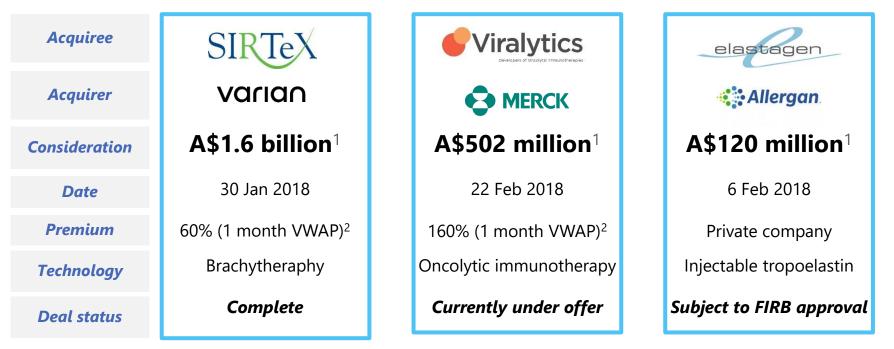
# **OncoSil's commercial path has precedent**

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

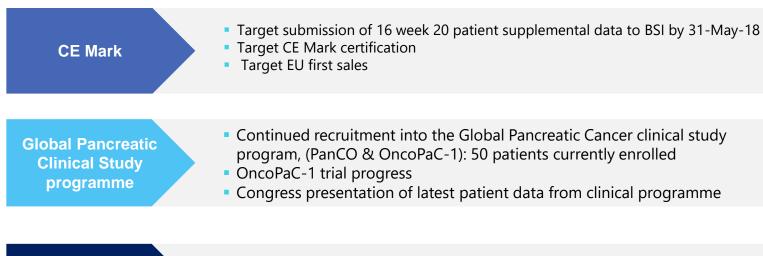
- Regulatory affairs specialist focused on quality compliance and marketing registrations in the Asia, South America and middle East.
- Principal for the regulatory approvals in Brazil, Argentina and UAE for Sirtex.



#### 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

### **Important notice**

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