

ASX/ Media Release
8 March 2018

OncoSil Company Update Presentation

Sydney, Australia, 8 March 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, is pleased to release a new company investor presentation. The presentation outlines OncoSil's compelling investment case and strategy following the release of new positive clinical data and will be used to support ongoing investor and commercial licensing discussions.

Key highlights:

- Clear mission to commercialise a **breakthrough implantation radiation treatment** for Pancreatic cancer
- **Targeting a >\$2bn market opportunity** to improve standard of care
- **Current and previous clinical studies show excellent local disease control and safety**
- **Manufacturing and logistics optimised for commercialisation**
- **US FDA-approved IDE in place, safety run-in underway**
- **Submission of 16 week 20 patient data to EU Notified Body by 31 May 2018**

- ENDS -

Company	Media
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About OncoSil

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

Treatment with the OncoSil™ 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™ 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™ 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 6th 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 forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.

Company Update

March 2018

Advancing Pancreatic
Cancer Treatment

OncoSil Medical | Investment Highlights

1 **Clear mission** Commercialising a breakthrough implantation radiation treatment for Pancreatic cancer

2 **Sound science** Current and previous clinical studies demonstrate:

- **Excellent Local Disease Control**
- **Significant reduction** in tumour size and volume
- **Excellent safety and tolerability** profile
- **Ease of implantation**

3 **Clear strategic path**

- Targeting **>\$2bn market opportunity** to improve standard of care
- **US FDA-approved IDE** in place, safety run-in underway
- **EU regulatory approval**, CE Marking expected near-term
- **Highly experienced management team**; strong clinical and commercial pedigree
- Manufacturing and logistics **optimised for supply of commercial quantities**
- At a potential value inflection point with multiple paths to commercialisation

OncoSil Medical

OncoSil™ 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 micro-particles 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

Share price (as at 6-Mar-18) A\$0.14

52 week range A\$0.08-0.18

Shares on Issue 484.9m

Market capitalisation A\$67.9m

Cash (31 December 2017) A\$5.2m

Debt (31 December 2017) Nil

Enterprise value A\$62.7m

Share price performance (1 year)



Substantial shareholders

Regal Funds Management	7.5%
Webinvest	5.1%
Management and Directors	14.1%

About the OncoSil™ device

An implantable radiotherapy medical device targeting pancreatic cancer

- ⊕ OncoSil™ is a **single-use brachytherapy device**
- ⊕ Delivered through **microparticles**: 30-micron silicon particles contain beta-emitting Phosphorus-32 (^{32}P)
- ⊕ OncoSil™ Microparticles are inserted **directly into the tumour**
- ⊕ 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

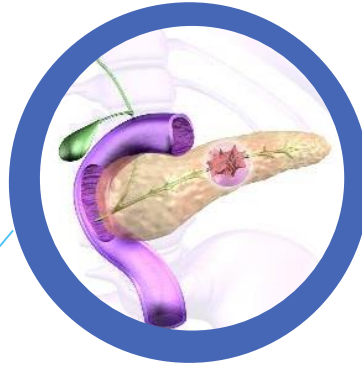


Implantation procedure

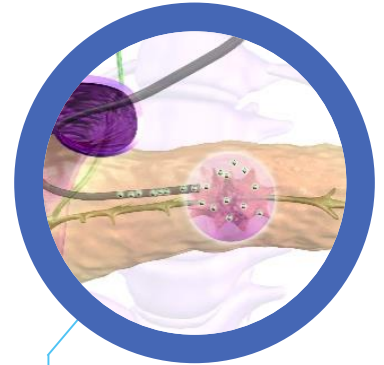
Studies continue to show the device implantation is technically straightforward



OncoSil™ 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

OncoSil at a potential value inflection point

The Company is well positioned to realise value of OncoSil™ device

Current focus

Before 2015:
Demonstrate potential

- 4 studies show potential of OncoSil™ to treat pancreatic & primary liver (HCC) cancer

2016 to 2018:
Satisfy regulatory obligations

- Secured **US FDA IDE approval**
- Initiated PanCO & OncoPac-1 clinical studies
- **Highly positive early safety, efficacy and implant delivery data** consistent with results from previously completed studies

2018 onwards:
Path to commercialisation

- Secure **strategic partnerships and licensing agreements** in all key geographies
- Secure **licensing agreements** in unique geographies
- Leverage potential for **broader distribution, capital and market support and exposure**

Clinical pathway overview

PanCO and OncoPaC-1 to inform future studies

Phases:

Current focus

2 concurrent trials, targeting 65 patients total

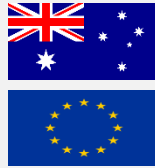
Future focus

Studies to drive clinical adoption (EU & global)
and secure US FDA approval

Trials:

PanCO – 45 patients

Open label study in patients with
unresectable locally advanced
pancreatic cancer with Oncosil given in
combination with SOC chemotherapy



OncoPaC-1 – 20 patients

Open label study in patients with
unresectable locally advanced
pancreatic cancer with Oncosil given in
combination with SOC chemotherapy



Current
trials inform
future trials*

Company exploring clinical study
options in **resectable, borderline
resectable and locally advanced**
pancreatic cancer indications.



Final decision on future studies to
be taken based on data received
from ongoing studies and feedback
from US FDA*



**Future trials to drive clinical
adoption in EU and to generate
data for US FDA approval (PMA)**

Regulatory milestones:

CE Mark: Company to provide
16 week data for first 20 patients
to EU Notified Body by 31 May 18

FDA approval

PanCO study – positive results to date

Positive clinical data on 20 patients (at Week 8) and 14 patients (at Week 16)

Patients recruited and implanted

- ✓ **38 patients** enrolled in the study¹
- ✓ **28 patients** implanted¹

Clinical performance

- ✓ Excellent local Disease Control Rate (DCR) of **100% (Week 8)** and **87% (Week 16)**
- ✓ **4 out of 20 implanted patients have achieved a Partial Response**
(Partial Response defined as a reduction in tumour longest diameter of at least 30% from baseline)
- ✓ **3 out of 20 implanted patients now considered for surgical resection**
(Resection is the only potential cure for pancreatic cancer, demonstrating possibility of improved outcomes in patient group deemed inoperable at time of study entry)
- ✓ **Substantial tumour volumetric reduction** observed in patients
 - ✓ Up to **73% volumetric reduction** at Week 8 (median volumetric reduction 29%)
 - ✓ Up to **72% volumetric reduction** at Week 16 (median volumetric reduction 39.5%)

Safety

- ✓ **No Serious Adverse Events (SAEs)** attributed to device or implantation procedure
(SAEs related to chemotherapy or cancer progression)
- ✓ **No evidence of radiation toxicities**
- ✓ **No other safety concerns identified to date**

Implantation procedure

- ✓ OncoSil™ device delivery via EUS considered **straightforward for implantation**

1. As at 7-Mar-18

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 months¹
 - 5 year survival less than 5%¹
- 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

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



12TH 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	  CEDARS-SINAI MEDICAL CENTER.	 
	Johns Hopkins, Maryland		
	Moffitt Cancer Centre Florida		
	Cedars Sinai Hospital, LA		
	Guy's & St Thomas', London	 Hammersmith Hospital	 Addenbrooke's 
	University of Leicester		
	Hammersmith, London		
	Addenbrookes, Cambridge		
	Monash, Melbourne	 	   
	St Vincent's, Sydney		
	Westmead Hospital, Sydney		
	RNS Hospital, Sydney		
	Royal Adelaide		
	The Austin Hospital, Melbourne		
	Jules Bordet Institute Hospital, Brussels		

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

Over 130,000 patients diagnosed with pancreatic cancer in US and EU every year

Potential paths to market



Strategic licensing partners in all key geographies



EU
US



Additional licensing partners in unique geographies



China
Japan
India

2018 marks the start of this journey



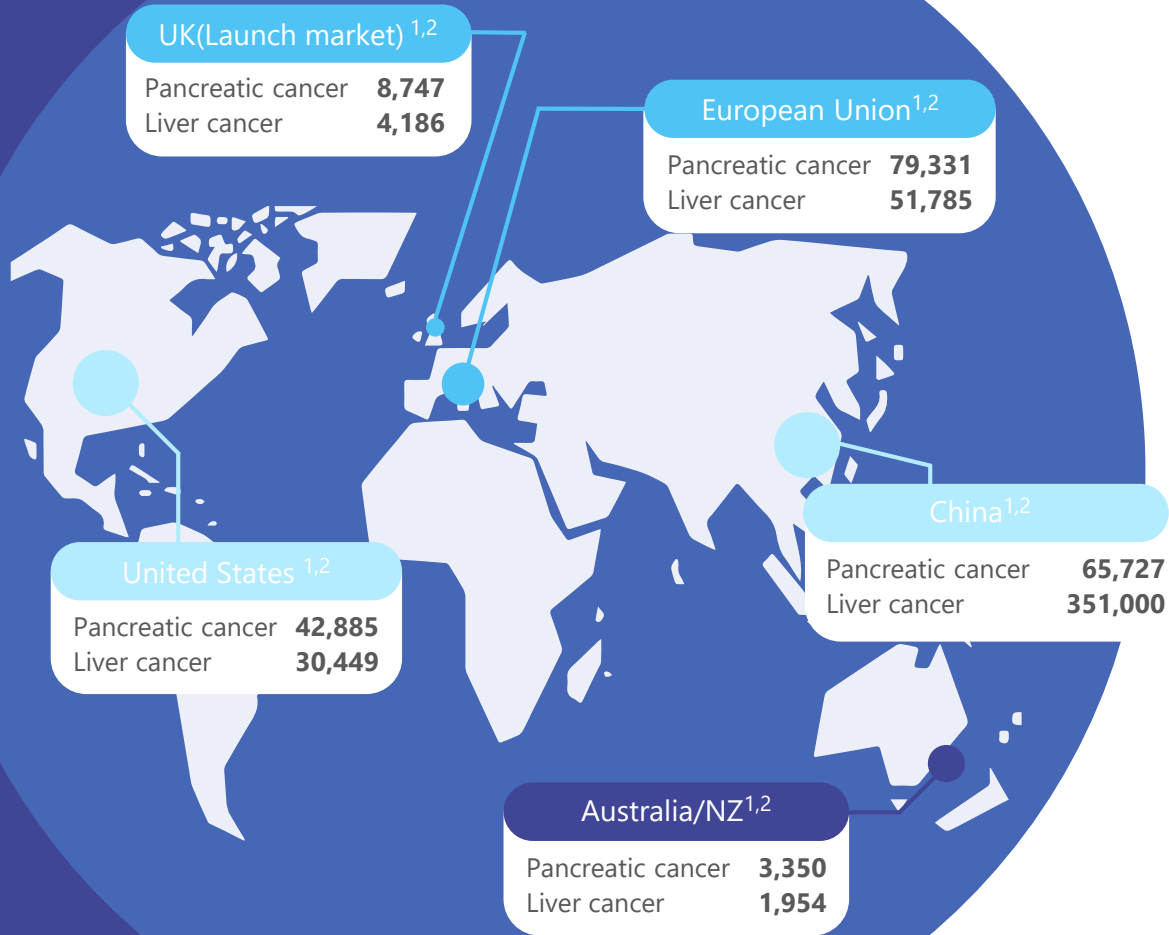
Target markets

Annual incidence

Global opportunity

Pancreatic cancer US>\$2.0bn

Liver cancer US\$1.4bn



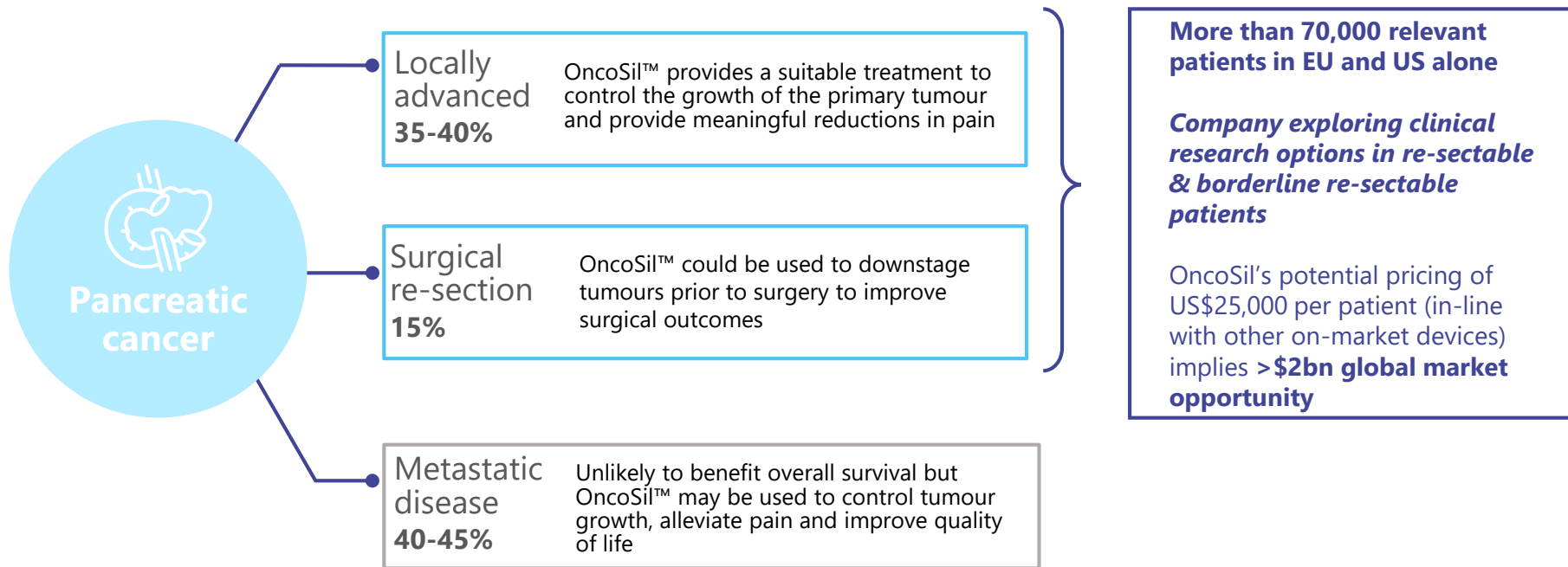
1. GLOBOCAN 2012: Estimated Cancer Incidence Worldwide in 2012 (IARC/WHO), Accessed 22 Apr 2016, from http://globocan.iarc.fr/Pages/fact_sheets_population.aspx

2. Datamonitor Healthcare 2013

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

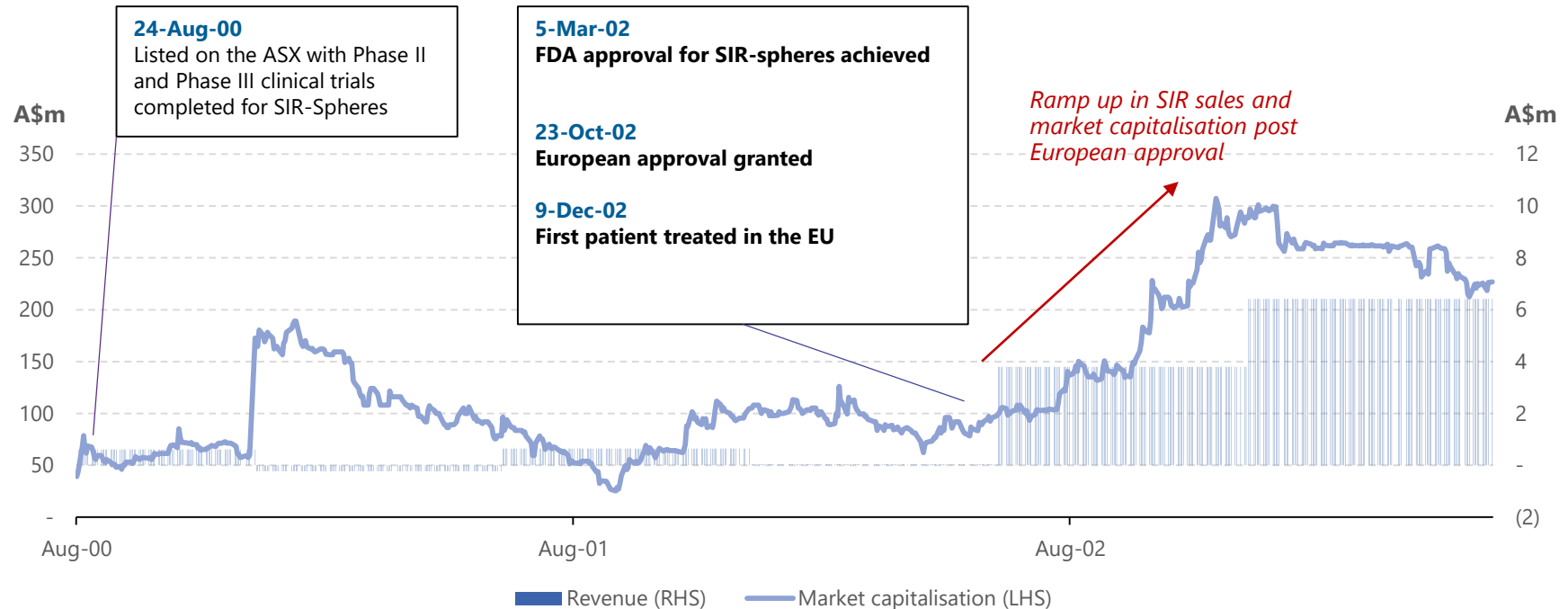
Global Commercial opportunity in excess of \$2bn

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








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

Acquiree	 varian	 <small>Developers of Oncolytic Immunotherapies</small>	
Acquirer			
Consideration	A\$1.6 billion¹	A\$502 million¹	A\$120 million¹
Date	30 Jan 2018	22 Feb 2018	6 Feb 2018
Premium	60% (1 month VWAP) ²	160% (1 month VWAP) ²	Private company
Technology	Brachytherapy	Oncolytic immunotherapy	Injectable tropoelastin
Deal status	Complete	Currently under offer	Subject to FIRB approval

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 Warrenner
Global Sales & Marketing
Director

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

Key catalysts in CY 2018

CE Mark

- Target submission of 16 week 20 patient supplemental data to BSI by 31-May-18
- Target CE Mark certification
- Target EU first sales

Global Pancreatic Clinical Study programme

- Continued recruitment into the Global Pancreatic Cancer clinical study program, (PanCO & OncoPaC-1): 38 patients currently enrolled
- OncoPaC-1 trial progress
- Congress presentation of latest patient data from clinical programme

Strategic partnerships

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

Important notice

This Presentation has been prepared by OncoSil Medical Ltd (ASX:OSL) (**OncoSil** or the **Company**) to provide an overview of the Company. This Presentation and the information contained may require further explanation and/or clarification. Accordingly, this Presentation and the information contained should be read in conjunction with past and future ASX announcements made by OncoSil and should not be relied upon as an independent source of information. Please contact OncoSil and/or refer to the Company's website www.oncosil.com.au for further information.

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Forward-Looking Statements

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