



ASX:OSL

Advancing Pancreatic & Liver Cancer Treatment

CEO Presentation
18 October 2016

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Revamped leadership team

Dr Chris Roberts

Director & Chairman Elect

Former Cochlear CEO

Highly experienced director and senior executive with 40 years experience in the Medical innovation space



Mr Daniel Kenny

CEO & MD

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



Mr Tom Milicevic

Chief Financial Officer & Company Secretary

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



Dr Ashish Soman

Chief Medical Officer

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



Dr David James

Manufacturing & Operations Manager

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



FY2016

Achievements Delivered

September 2015

- Submission of CE Mark application for OncoSil™

December 2015

- Investigational Device Exemption submitted to the FDA for OncoPac-1 clinical study

February 2016

- \$10 million private placement to Regal Funds Management

May 2016

- OncoSil Medical completes hiring of senior management for the Leadership Team

October 2015

- OncoSil™ CE Mark application granted Fast Track review status

January 2016

- Chris Roberts appointed Independent Non-Executive Director

March - April 2016

- Q-Submissions meeting with FDA
- Responses to CE Mark and FDA questions

June 2016

- IDE Amendment submitted to the FDA for OncoPac-1 clinical study



Device overview

Radiation therapy delivered directly into the tumour



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**

1. 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,



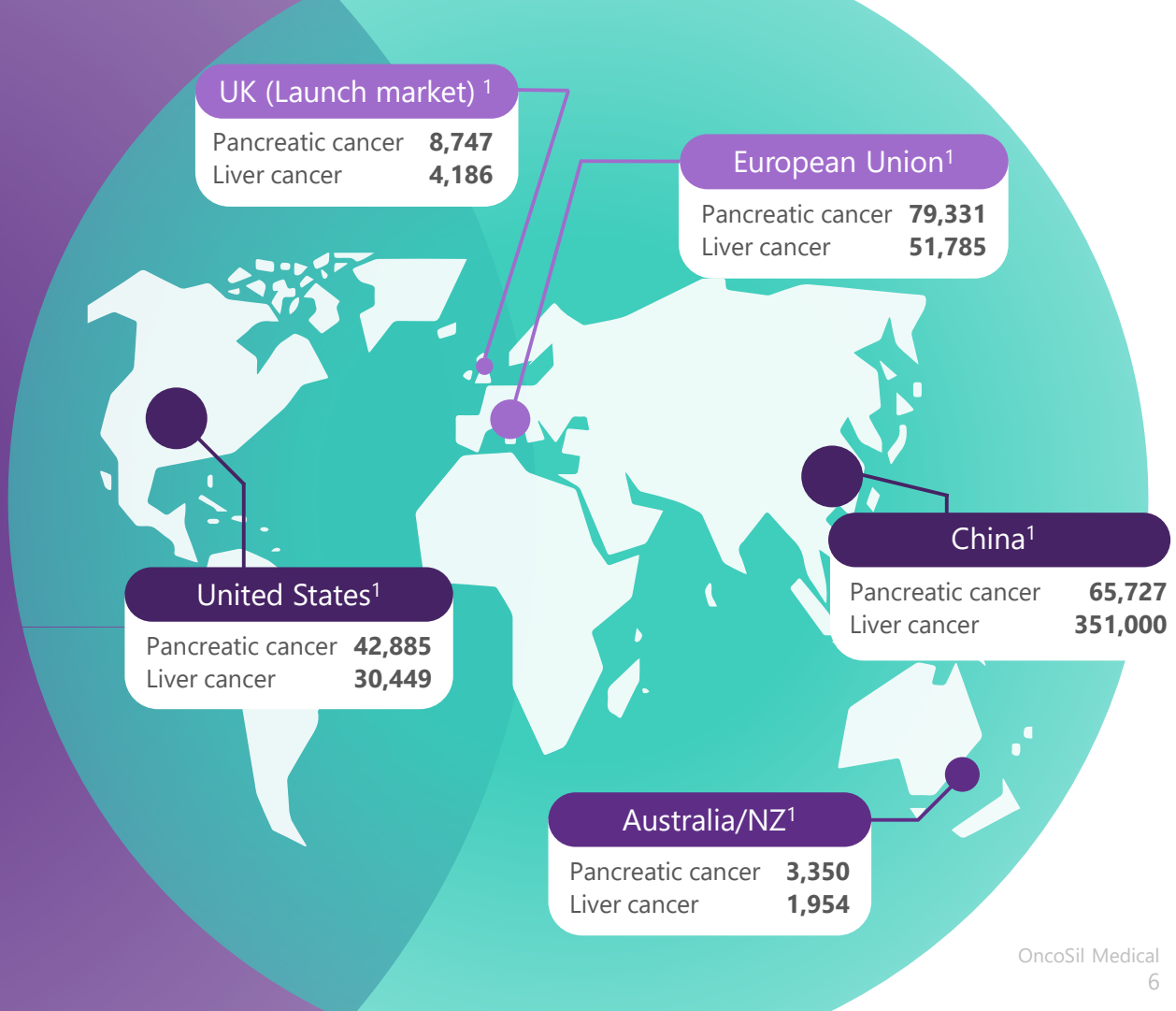
Target markets

Annual incidence

Global opportunity²

Pancreatic cancer	US\$1.0bn
Chemo regime	US\$60,000
External radiation	€9,000
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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



Current
treatments are
limited

**Pancreatic
cancer**

Surgical
re-section
15%

Locally
advanced
35-40%

Metastatic
disease
40-45%

First-line

GEMZAR
gemcitabine HCl
(for injection)

Abraxane
nab-paclitaxel
albumin bound paclitaxel



FOLFIRINOX Chemotherapy

(folinic acid, fluorouracil,
irinotecan, oxaliplatin)

Chemoradiotherapy

(chemotherapy +
external beam radiation)

GEMZAR
gemcitabine HCl
(for injection)

Abraxane
nab-paclitaxel
albumin bound paclitaxel



Tarceva
erlotinib
tablets

Xeloda
capecitabine

FOLFIRINOX Chemotherapy

(folinic acid, fluorouracil,
irinotecan, oxaliplatin)

Salvage

Xeloda
capecitabine

GEMZAR
gemcitabine HCl
(for injection)

Fluorouracil

Xeloda
capecitabine

GEMZAR
gemcitabine HCl
(for injection)

Fluorouracil

SIF-Spheres
microspheres

(for Liver Mets)

*OncoSil™ is not currently approved for commercial sale. OncoSil™ positioning of First-line therapy is illustrative of planned positioning once approved





US market entry – IDE Study approved

Regulatory strategy

Focus on pancreatic cancer indication – potential for future other indications

OncoSil™ will seek Pre-marketing Approval (**PMA**) (Class III device) from the FDA

Pivotal Study underway

Investigational Device Exemption (**IDE**) with agreed trial protocol **approved July 29, 2016**

Patient recruitment to commence early 2017

Randomised Study structure

Pivotal Study of 300 patients, 1:1 randomised OncoSil™ + chemo against standard chemo

~ 30 centres in the U.S. and internationally

20 patient run-in

High profile U.S. Trial centres and PIs at advanced stage of discussions



OncoPac-1

Global Pivotal Study - Overview

- Randomised, safety and efficacy study, OncoSil™ microparticles in **unresectable locally advanced pancreatic cancer**
- N = **300 subjects** (150 per arm) treated at **~30 Centres**
- **Stage 1: 20 patient safety assessment**
- **After Stage 1 patients randomised to OncoSil™ plus chemotherapy or chemotherapy alone**
- Chemotherapy : gemcitabine or gemcitabine + nab-paclitaxel
- OncoSil™ microparticles **administered intra-tumourally** via Endoscopic ultrasonography
- OncoSil™ implantation to occur **during the fourth week** of the **first chemotherapy cycle**
- **IDE protocol** - intended to support PMA Application to FDA



OncoPac-1 Study

Milestones &
Timing



IDE Approval – July 2016

Study preparation securing sites,
and IRB approvals – ongoing

Enrolment of subjects –
2017 - 2018

**Follow up and data
collection** - 2019

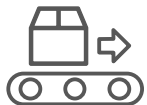
PMA submission to FDA
~2020

FDA approval and U.S. launch

* These dates are estimates and subject to change. There are no guarantees of recruitment rates, trial data or a PMA approval.



Manufacturing & supply chain



Expertise
to manage
execution
risk

In-house expertise

– over 20 years with nuclear medicine products

ISO certified process using **outsourced GMP** manufacturers

3 x Nuclear Reactors

verified for OncoSil
– more to be added

Manufacturing
capacity to
meet needs

Base Material is ultra pure polysilicon and ultra pure red phosphorous

Final product is 30 microns, acid washed and suspended in diluent

Current Inventory is sufficient to meet Clinical Trial commencement and early commercial needs

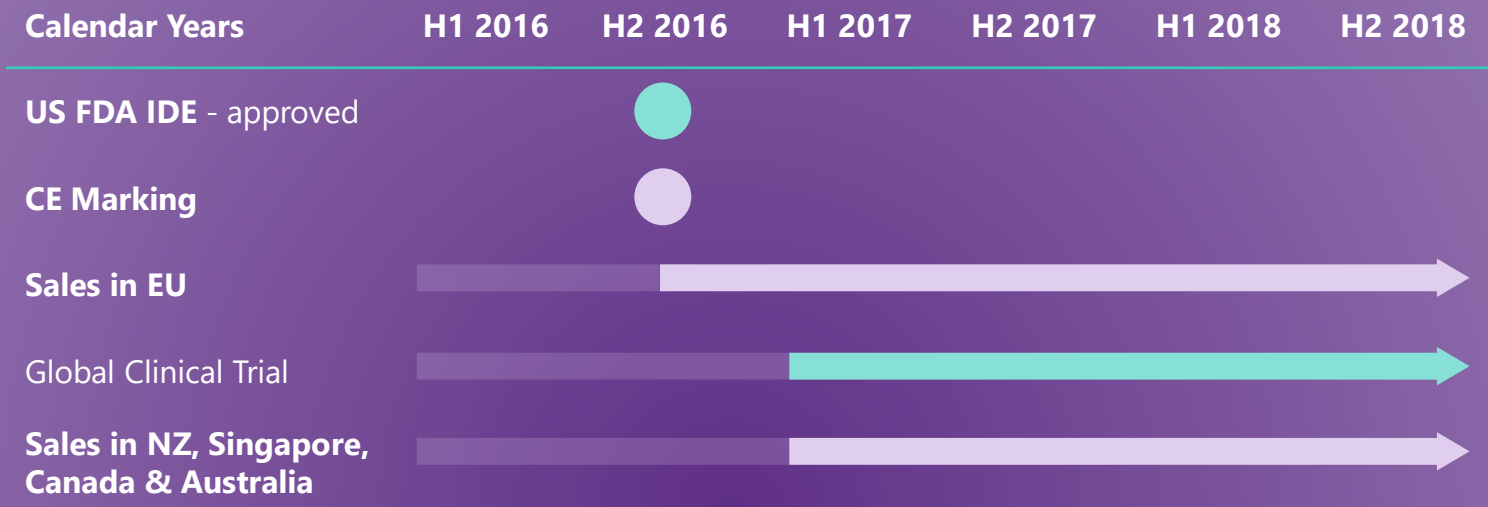
Supply
chain in
place and
validated

Storage, handling & distribution by **partner, Eckhart & Ziegler** in Germany

Validation and hot run at RNS completed in **August 2016**

Margins attractive at scale – **one batch can service 50 treatments**

Targeted milestones



*These Milestones are based on the Company's estimates and may change at any time.



Value proposition

US market entry underway

- IDE granted by FDA in July 2016

Poised for commercial launch

- pending CE Mark in near term

Strong, **revamped leadership** team

- manage execution risk

Proprietary technology platform
provides **a more targeted treatment**

OncoSil™ delivered intra-tumourally -
not to the artery to reach tumour via
bloodflow

Pancreatic cancer is **6th most common cancer** – poor treatment options

Median overall survival ↑ by 2 months to
8.5 months over the past **20 years**

Developing additional **data to support adoption and reimbursement**

Initial target markets offer **significant revenue opportunities**



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