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- Developing an **implantable radiotherapy medical device** ‘**OncoSil™**’ for pancreatic and liver cancer

- **CE Mark targeted in the near term** followed by commercial launch and sales in UK, EU and Australia

- Technology platform suitable for **multiple solid state tumours** providing a **more targeted therapy**

- Global pancreatic cancer market > **US$1B**

- **Global Pivotal Study underway** - **FDA approved IDE** - July, 2016
  - Trial sites being engaged

- **New leadership team**
  - Daniel Kenny CEO (ex Baxter, Roche)
  - Dr Chris Roberts (ex Cochlear CEO), Chairman-elect

- **Proprietary technology with robust patent portfolio**

- **ASX listed ~$69m market cap and $13.4m of cash**

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1. Instructions for Use, OncoSil™ ONCSP-32, Document No: RA-IFU01, Sep 2015 Version B.
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

OncoSil™ procedure*

OncoSil™ is suspended in a shielded syringe in the operating theatre

Endoscope guided into the upper intestine

Using CT or real-time imaging, needle guided into the target lesion

OncoSil™ injected directly into the tumour

* Above procedure is for treating pancreatic cancer. Treatment of liver cancer (HCC) is similar, using needle and imaging to enable OncoSil™ to be injected into the tumour in the liver.
Target markets
Annual incidence

Global opportunity

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Total Market Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic cancer</td>
<td>US$1.0bn</td>
</tr>
<tr>
<td>Liver cancer</td>
<td>US$1.4bn</td>
</tr>
<tr>
<td>Chemo regime</td>
<td>US$60,000</td>
</tr>
<tr>
<td>External radiation</td>
<td>€9,000</td>
</tr>
</tbody>
</table>

2. Datamonitor Healthcare 2013

UK (Launch market) 1
- Pancreatic cancer: 8,747
- Liver cancer: 4,186

European Union 1
- Pancreatic cancer: 79,331
- Liver cancer: 51,785

United States 1
- Pancreatic cancer: 42,885
- Liver cancer: 30,449

Australia/NZ 1
- Pancreatic cancer: 3,350
- Liver cancer: 1,954

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Pancreatic cancer
Unmet need

Patient profile
60 yrs and older Males & females

Symptoms
- Weight loss, malaise, jaundice
- Cancer metastases around the body into lymph nodes, lungs etc.

Causes
- Hereditary
- Type 2 diabetes
- Pancreatitis, often triggered by alcohol

Diagnosis
- CT or ultrasound imaging
- Diagnosis confirmed with biopsy performed with endoscopy

Treatments
- Surgery (resection) if diagnosed early
- Chemotherapy (Gemcitabine) in combination with Paclitaxel
- External Radiation (ablation) therapy

Issues
- Prognosis even with therapy is poor
  - Median survival (8 months and 5 year survival less than 5%) \(^1\)
- Radiation therapy is actually toxic for the patient’s GI tract
- Despite metastatic disease, data suggests uncontrolled local disease kills 30% pancreatic cancer patients

Goal
- Regulators and payers seeking progression free survival

---

Current treatments are limited

Pancreatic cancer

- Surgical re-section: 15%
- Locally advanced: 35-40%
- Metastatic disease: 40-45%

First-line

- FOLFIRINOX Chemotherapy (folinic acid, fluorouracil, irinotecan, oxaliplatin)
- Chemoradiotherapy (chemotherapy + external beam radiation)

Salvage

- Fluorouracil

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Provider</th>
<th>Cancers treated</th>
<th>Delivery</th>
<th>Product</th>
<th>Approvals</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Liver (HCC)</td>
<td>pancreas</td>
<td></td>
<td>FDA</td>
<td></td>
</tr>
<tr>
<td>TheraSphere®</td>
<td>BTG International (LSE:BTG)</td>
<td>●</td>
<td>X</td>
<td>Needle injection into liver artery – into tumour via bloodflow</td>
<td>CE</td>
<td>Limited approval – Humanitarian Device Exemption</td>
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<tr>
<td></td>
<td></td>
<td>Other</td>
<td></td>
<td>Small glass microspheres containing radioactive Y-90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QuiremSpheres®</td>
<td>Quirem Medical (Private)</td>
<td>●</td>
<td>X</td>
<td>Injected by catheter in liver artery – into tumour via bloodflow</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
<td></td>
<td>Radioactive microspheres that treat liver metastases through intra-arterial radioembolisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SIR-Spheres®</td>
<td>Sirtex Medical (ASX:SRX)</td>
<td>●</td>
<td>X</td>
<td>Micro catheter in liver artery – into tumour via bloodflow</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
<td></td>
<td>Y-90 resin microspheres used to selectively deliver a dose of internal radiation to liver tumours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OncosilTM</td>
<td>Oncosil Medical (ASX:OSL)</td>
<td>●</td>
<td>X</td>
<td>Needle on endoscope to enable injection directly into tumour</td>
<td></td>
<td>IDE granted by FDA CE Mark decision expected near term</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
<td></td>
<td>Phosphorus (P32) microparticles suspended in fluid to treat both pancreatic and liver cancer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
OncoSil™ results in pancreatic cancer

Four clinical studies completed
2 x Primary Liver/HCC & 2 x Pancreatic Cancer

Study DB2-201
– Open label, Phase IIa safety study
17 patients with locally advanced pancreatic cancer
Treated with OncoSil™ and gemcitabine chemotherapy

Significant anti-cancer activity
– 82% disease control
4 partial responders and 10 patients with stable disease
2 patients with progressive disease

Average reduction in pain of 35%
69% max. pain reduction – weeks 8 and 11 following implant

Median progression free survival was 121 days
Median overall survival was 10+ months (compared with a typical 5.7 months with gemcitabine alone)

Tumour reduction and Increased survival

Tumour response rate of **81.25%**

Reduction in target tumour volume for 13 of 16 treated patients

- **15%** 11 of the 13 patients
- **50%** 7 of the 13 patients

Overall survival
median 309 days

Progression free survival
median 121 days

4 Pillar Commercial strategy

- **Targeted non-US market entry**
  - Dedicated Clinical Training team
  - Direct+Contract Sales
  - Outlicensing/JV where appropriate

- **Drive Clinical Adoption**
  - IDE Study
  - PMA pathway
  - US commercial launch

- **Leverage Clinical Trial Programme**
  - Trained IDE study sites expand into commercial centres
  - Investigator sponsored studies
  - Patient registry

- **Publications & presentations**
  - Reimbursement approval
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 Trial underway
Investigational Device Exemption (IDE) with agreed trial protocol approved July 29, 2016
Patient recruitment to commence early 2017

Randomised Trial 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
Dosing and Endpoints

Primary Efficacy Endpoint

- **Local Progression Free Survival (LPFS)** within the pancreas
  - improvement in median LPFS from 6 months to 8.5 months
  - powered with significance level set at 0.05

Secondary Efficacy Endpoints

- Progression Free Survival (all sites)
- Overall Survival
- Body weight
- Safety and Tolerability
- Pain Scores
- Quality of Life

A single dose is implanted into the tumour using the final suspension of OncoSil™
Delivering **100 Gy** to the tumour
OncoPac-1 Study

Milestones & Timing

IDE Approval – July 2016

Trial 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.
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

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

Storage, handling & distribution by partner, Eckhert & Ziegler in Germany
Validation and hot run at RNS completed in August 2016
Margins attractive at scale – one batch can service 50 treatments
<table>
<thead>
<tr>
<th>Calendar Years</th>
<th>H1 2016</th>
<th>H2 2016</th>
<th>H1 2017</th>
<th>H2 2017</th>
<th>H1 2018</th>
<th>H2 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>US FDA IDE</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CE Marking</td>
<td>✔️</td>
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<tr>
<td>Sales in EU</td>
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<td></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Global Clinical Trial</td>
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<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Sales in NZ, Singapore, Canada &amp; Australia</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>

*These Milestones are based on the Company’s estimates and may change at any time.*
Revamped leadership team

**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

**Dr Chris Roberts**  
Director & Chairman Elect  
Former Cochlear CEO  
Highly experienced director and senior executive with 40 years experience in the Medical innovation space
### Corporate details – ASX.OSL*

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Share Price</td>
<td>A$0.147</td>
</tr>
<tr>
<td>52 week range</td>
<td>A$0.091-0.270</td>
</tr>
<tr>
<td>Daily Liquidity – 3 months</td>
<td>~$0.10m</td>
</tr>
<tr>
<td>Shares on Issue</td>
<td>468.5m</td>
</tr>
<tr>
<td>Options – expiring 30 June 2017</td>
<td>19.0m</td>
</tr>
<tr>
<td>Market Cap</td>
<td>A$68.9m</td>
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<tr>
<td>Free float</td>
<td>100.0%</td>
</tr>
<tr>
<td>Reported Cash (30 June 2016)</td>
<td>A$13.4m</td>
</tr>
<tr>
<td>Quarterly cash burn</td>
<td>A$2.0m</td>
</tr>
</tbody>
</table>

### Shareholder Base – ASX.OSL

<table>
<thead>
<tr>
<th>Substantial Holders</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regal Funds Management</td>
<td>9.7%</td>
</tr>
<tr>
<td>Webinvest</td>
<td>6.5%</td>
</tr>
<tr>
<td>Management &amp; Directors**</td>
<td>~ 16.4%</td>
</tr>
<tr>
<td>Total Number of Shareholders</td>
<td>~ 2,700</td>
</tr>
</tbody>
</table>

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1. *Closing Price 19 August 2016  ** Includes Loan Shares issued but not options
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
Appendices
Clinical advisory board

Dr. Joseph Michael Herman, M.D., M.Sc.
Johns Hopkins University, Baltimore USA

Co-Director, Pancreatic Cancer Multidisciplinary Clinic, Associate Professor of Radiation Oncology and Molecular Radiation Sciences – The involvement of Dr Herman is important, not only because of his clinical expertise, but also because Johns Hopkins is a high volume, prestigious medical institution in the United States. Its participation in the clinical trial is important for overall credibility and in achieving accelerated recruitment. Dr Herman is a panel member for the NCCN Guidelines on pancreatic cancer.

Professor Pierce Chow
Singapore General Hospital

Professor Chow was recently appointed as Chairman of the Company’s primary liver cancer Scientific Advisory Board. Professor Chow is acknowledged as a global leader in oncology, with particular emphasis on primary liver cancer, and the development of medical devices, and his appointment represents a major endorsement of OncoSil’s plans to actively pursue the primary liver cancer indication. He is Professor at the Duke-NUS Graduate Medical School and Senior Consultant Surgeon at the National Cancer Centre in Singapore and the Singapore General Hospital. Professor Chow is also a member of the OncoSil Pancreatic Cancer Clinical Advisory Board.

Professor Stephen Clarke
Royal North Shore Sydney

Professor Clarke practices in Sydney and has an extensive resume including more than 100 publications in peer reviewed journals.

Professor Dale Bailey
Royal North Shore Sydney

Professor Bailey is the Principle Physicist, Department of Nuclear Medicine, Royal North Shore Hospital, Sydney.

Professor Richard Epstein
St Vincents Sydney

Professor Epstein has an extensive career in Cancer Research and now consults to the Garvan Institute for Medical Research and maintains a practice at St. Vincent’s in Sydney.
Exclusive licence from pSiMedica for 8% net sales royalty

28 patents granted and 6 filed

Patents protect OncoSil™ technology

- Devices & methods for treating cancer
- Material and manufacturing method
- Radioactive solutions for treating cancer

Ongoing patent protection for new IP

Trademark granted for OncoSil™ in key markets UK, EU, Australia, New Zealand, Singapore, Japan and USA
Pancreatic cancer
Patient Pool Assumptions – US & EU

Incidence in Key Markets (US & EU)
131,000 pa.

- Neuroendocrine (5%)
  6,550

- Adenocarcinoma (95%)
  124,450

Ineligible for Surgery (85%)
106,000

- Locally Advanced (47%)
  49,820

- Metastatic Disease (53%)
  56,180

Surgery (15%)
18,668 pa.

US new cases pa: 46,000
EU new cases pa: 85,000

Potential Market Size
(>105,000 pts p.a.)

Total Market Opportunity
(>$1 Billion)
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