

# Non-Renounceable Entitlement Offer & Top Up Facility

17 March 2023



**Targeted Approach • Positive Impact** 

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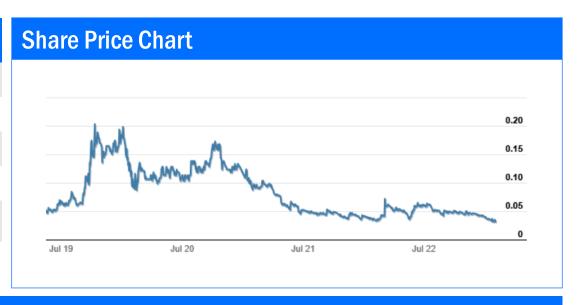
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# Company Overview

Capital Structure	
ASX Code	OSL
Share Price (at 16 March 2023)	\$0.031
Shares on Issue	989,242,262
Market Capitalisation	\$30.67m
Cash in bank (31 December 2022)	\$5.76m
Top 20 shareholders	33.74%



#### **Board of Directors Nigel Lange Brian Leedman Otto Buttula** Non-Executive Chairman Managing Director and CEO Non-Executive Director · Extensive financial, investment and biotech • 30+ years experience in medical • 15+ years experience in the experience device industry biotechnology sector · Served as Group COO and Interim Co-founder and CEO of IWL (ASX: IWL); · Founder of ResApp Diagnostics and Founder / former CEO of Investors Mutual Group CEO of Sirtex Medical **Biolife Sciences** · Chairman of Rhythm (ASX: RHY) and HITIQ Served as VP, investor relations for (ASX: HIQ) pSivida Corp.

# Indicative Timetable of Entitlement Offer

Key Details of the Offer	
Offer to Eligible Shareholders	<ul> <li>1 New Share for every 1 Share held at the Record Date at the Issue Price plus:</li> <li>1 Option for every 1 New Share subscribed under the Offer;</li> <li>Option means a New Option to purchase a Share with an exercise price of 3c and an Expiry Date of 30 April 2027;</li> <li>A Top-Up Facility for Shareholders who subscribe for their full Entitlement for Additional Shares</li> </ul>
Issue Price per New Share	\$0.01 or 1 cent per New Share payable in full on Application
Existing Shares as at the date of the Offer	989,242,262
Maximum number of New Shares issued under the Offer	989,242,262
Maximum proceeds from the Offer (excluding costs associated with the Offer)	Approximately \$9.9 million (before expenses and costs of the issue)
Maximum number of shares on issue following the Offer	1,978,484,524

## Indicative Timetable of Entitlement Offer

Important dates*	
Entitlement Offer announcement	Friday, 17 March 2023
Record Date (to determine Entitlement of Eligible Shareholders to participate in the Offer)	Wednesday, 22 March 2023
Opening Date of Rights Issue Offer – Dispatch of the Prospectus and Entitlement Form to Eligible Shareholders	Thursday, 23 March 2023
Closing Date for acceptances under the Entitlement Offer	5pm, Thursday 27 April 2023
Shortfall (if any) announced to the ASX	Tuesday, 2 May 2023
Allotment and Issue of the New Shares and New Options	Thursday, 4 May 2023
Trading (T+2) if New Shares expected to commence	Friday, 5 May 2023

<sup>\*</sup> The above dates are indicative only and subject to change. The Company reserves the right, subject to the Corporations Act and the Listing Rules, to extend the Closing Date or to withdraw the Offer at any time without prior notice, in which case all Application Monies will be refunded (without interest) as soon as practicable. Any extension of the Closing Date will have a consequential effect on the issue date of New Shares. All dates and times are references to Sydney, Australia time.

### Use of Funds

# The Entitlement Offer seeks to raise a maximum of \$9.9m and will be used for the following purposes:

Use of funds*	
Sales and marketing resources to support commercialisation activities for the OncoSil device in Europe and the United Kingdom	\$4.4m
Clinical trial expenditure to expand the use of the OncoSil™ device in combination with FOLFIRINOX chemotherapy and other trials	\$2.6m
Manufacturing and supply chain optimisation projects	\$1.4m
Day to day working capital requirements and capital raising costs for the Offer	\$1.5m
Maximum funds raised under the Offer	\$9.9m

Where the Company raises less than the maximum of \$9.9 million it intends to scale back the above expenditure proportionally.

<sup>\*</sup> The Company reserves the rights to pay cash commission to AFSL Holders or authorised representatives of AFSL Holders who introduce participants to take up any or all of the Shortfall. Any such commission costs have not be taken into account in the use of funds above.

# How to Apply



# You may only take up all of part of your Entitlement by

- Making payment by Bpay® corresponding the component (part or all) of your Entitlement you with to accept,
- Making payment by Bpay corresponding to all of your Entitlement, plus an application for Additional Shares you wish to accept, or
- By completing the Entitlement & Acceptance Form and attaching payment by cheque, bank draft or money order to reach Boardroom (Share Registry) at the following address:

OncoSil Medical Limited Entitlement Offer C/- Boardroom Pty Limited GPO Box 3993 Sydney NSW 2001

By no later than 5:00pm (AEST) on the Closing Date.

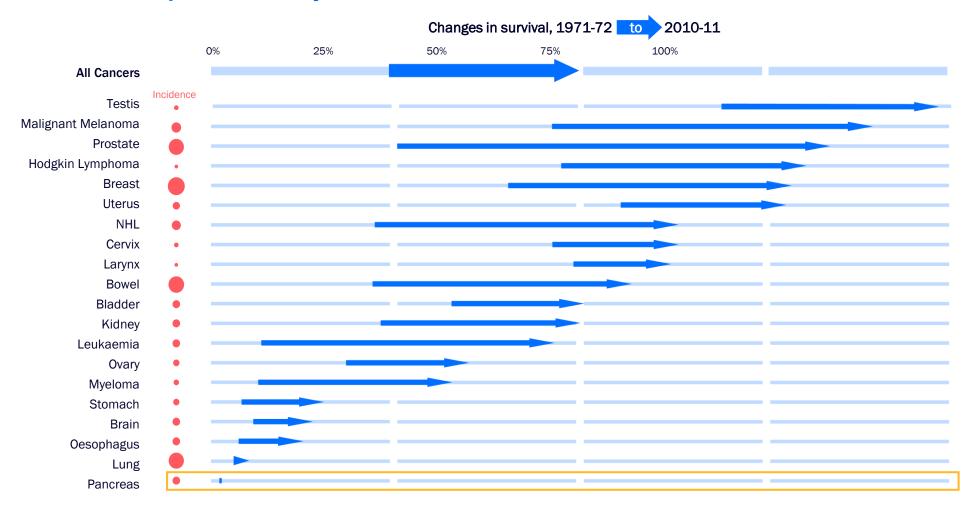


#### Contact

For any queries concerning your Entitlement please contact the Company's Share registry on 1300 737 760 (within Australia) or +61 2 9290 9600 (outside Australia.

## Introduction

The prognosis for pancreatic cancer patients has remained almost unchanged for over 40 years<sup>1</sup> with a reported five-year survival rate for the disease of 10%<sup>2</sup>





# Executive Summary

OncoSil<sup>™</sup> is a commercial-stage breakthrough device delivering targeted radiotherapy for pancreatic cancer



- Implanted device delivers targeted radiation to pancreatic tumour
- Breakthrough designation received in the EU/UK, US and Singapore

Experienced management, sales, clinical and R&D team in place



- Experienced management, sales, clinical and R&D team with appropriate background and experience to pursue market access and sales opportunities
- Approved for sale in 34 countries
- Sales team in Europe and the UK now have greater access to sites and staff to accelerate sales activity

Large global addressable market



- Global population of ~130k per annum
- Area of high unmet need with limited competition from what are considered effective treatments
- Market access and clinical development teams working on multiple activities to expand the addressable market

# Board and Management Team with Experience and Expertise



Nigel Lange Managing Director & CEO

30+ years experience in medical device industry Served as Group COO and

Interim Group CEO of

Sirtex Medical



Otto
Buttula
Non-executive
Chairman

Extensive experience in investment research, funds management and IT and previously a director of Imugene (ASX:IMU) and currently Chairman of Rhythm Biosciences (ASX:RHY) & HITIQ (ASX: HIQ)



Brian Leedman Non-executive Director

Experienced company director, Investor Relations specialist and biotechnology entrepreneur. Co-founded five healthcare companies on the ASX including ResApp Health (ASX:RAP) acquired by Pfizer in 2022



Dr Jon Bell MD Chief Medical Officer

8+ years experience as an Interventional Radiologist and an internationally recognised expert in Interventional Oncology



David Turner Head of Medical Affairs

40+ years experience in pharmaceutical, medical device and health technology industries



Henk Tissing Director of Clinical Development

25+ years industry experience in oncology with pharmaceuticals and medical devices.

Senior Clinical development roles at Sirtex Medical, BTG, A-Z & Sanofi Aventis



Karl Pechmann Chief Financial Officer

20+ years of finance experience having held several senior roles for listed and multi-national organisations



Renzo
DiCarlo
Head of
Transformation

25 years
experience and led the R&D
of TheraSphere.
Established the first PET
production technology
with University of Liege
for Lu-177, Y-90 and Sr-82
isotopes

# OncoSil<sup>™</sup> Device

#### **Overview**

- OncoSil™ is intended for the treatment of **locally advanced unresectable** pancreatic cancer, in combination with gemcitabine-based chemotherapy.
- OncoSil<sup>™</sup> is a single-use brachytherapy device comprised of microparticles and a diluent.
- OncoSil™ is **implanted directly** into a pancreatic tumour via injection under **endoscopic ultrasound** guidance.
- 98% of all radiation is delivered within 81 days of injection causing direct damage to cancer cell DNA, and ultimately shrinking tumour masses when the cells die.



# What we have accomplished







**CE Marking obtained** 



**Innovation Funding** (NUB) approved

German funding of the OncoSil<sup>™</sup> device



**Enabled HDE pathway** for bile duct cancer in the US

Application submitted to FDA



**PanCO Study** completed

and submitted to peerreviewed journal Data presented at leading oncology congresses



**Breakthrough device** designation achieved

in US, EU, UK and Singapore



**Current market approvals** 

Europe (CE Mark) United Kingdom Switzerland Singapore Malaysia

Hong Kong New Zealand Turkey Israel

**FDA:** Food and Drug Administration **HDE:** Humanitarian Device Exemption \*Distal cholangiocarcinoma (DCC or bile duct cancer)

# PanCO results showing compelling evidence of downstaging

OncoSil<sup>™</sup> converted patients with unresectable locally advanced pancreatic cancer (LAPC) to resection, transforming their prognosis and substantially extending survival

What did the PanCO study show?



Adding OncoSil<sup>™</sup> to chemotherapy led to a high proportion of patients having substantial reductions in their tumour volume (range +11% to -90%), with 57% having a >50% reduction<sup>2</sup>



1 in 3 patients with unresectable LAPC receiving OncoSil<sup>™</sup> plus chemotherapy became eligible for curative surgery<sup>2</sup>



Nearly 1 in 4 patients (23.8%) with unresectable LAPC receiving OncoSil™ plus chemotherapy underwent surgery with curative intent<sup>2</sup>



At the end of the PanCO Study with a follow-up of 32 months, 6 of the 10 resected patients remained alive, 5 without any evidence of disease (26.4-35.3 months from enrolment in the study) $^{2,3}$ 

# Sales and training activities to date

During the year, the OncoSil<sup>™</sup> team has progressed on key site start-up activities





# This is where we are today

### Market access and clinical development supporting sales activities

Sales team fully engaged with targeted Key Opinion Leaders to improve knowledge base of OncoSil™ technology.

 Personal Key Opinion Leader (KOL) interaction now possible following lilting of Covid restrictions Detailed health economic and market access analysis.

- Seeking reimbursement in several European jurisdictions
- Achievement of UK reimbursement with two leading private health insurers
- Working with private health insurers to agree reimbursement of the OncoSil<sup>™</sup> device for their clients
- Have had treatments already funded by private health insurers

Identifying programs for fully funded, government sponsored clinical trials including paid patient doses in the EU.

- NUB Status 1 Innovation Funding approved at 36 hospitals in Germany
- GBA fully funded clinical trial in Germany approved with mandatory dose payment by statutory health insurances

# **Clinical Development** pathway

- Preparation for commencement of TRIPP FFX clinical trial – 15 sites enrolled
- Investigating possible expansion of OncoSil device in future indications or in combination with other treatment regimens including checkpoint inhibitors



# Commercial expansation opportunities

Future work required to expand opportunities for the OncoSil<sup>TM</sup> device



Expansion of current label to include FOLFIRINOX chemo



Generate clinical evidence to access public payer markets globally



Alternative device delivery methods (percutaneous application)



Improvements to the OncoSil<sup>™</sup> device to incorporate imaging modalities



Identify possible indication expansion (i.e. liver cancer, Glioblastoma)



# **Nigel Lange**

**CEO & Managing Director** 

E: nigel.lange@oncosil.com

OncoSil Medical Ltd www.oncosil.com

T: +49 30 300 149 3043

