



OncoSil™

Intratumoural placement of ^{32}P for
locally advanced pancreatic cancer

Targeted Approach • Positive Impact

Nigel Lange, 29 November 2023



• Disclaimer

This Presentation has been prepared by OncoSil Medical Ltd (ASX:OSL) (**OncoSil** or the **Company**) to provide a general 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 for further information.

Not an Offer for Securities

Nothing in this Presentation constitutes investment advice or should be construed as either an offer to sell or a solicitation of an offer to buy or sell shares in the Company, in any jurisdiction.

This presentation is not exhaustive of all of the information a potential investor or their professional advisers would require. This presentation does NOT constitute a "Prospectus" or a "Disclosure Document" (as defined in the Corporations Act 2001 (Cth) (Corporations Act)) and has not been, and will not be, lodged with the Australian Securities and Investments Commission or any other regulatory authority. Accordingly, it is not required to contain, and may not necessarily contain, all of the information that a Prospectus or like Disclosure Document would be required to contain pursuant to the Corporations Act.

Forward-Looking Statements

This document contains certain forward-looking statements as at the date of this presentation 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 national and international 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, nor that that any specific objective of the Company will be achieved or that any particular performance of the Company or of its shares will be achieved.

In particular, the Company's expectations regarding the approval and commercialisation of the product candidates could be affected by, amongst other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; changes in legislation or regulatory requirements, 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 Company, products, product candidates, financial results and business prospects. Should one or more of these changes, 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. There is NO guarantee of future performance - actual results and future outcomes will in all likelihood differ from those outlined herein. You are urged to consider all of the above and advice from your own advisers carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The information in this presentation is not financial product advice, is not an offer to invest in the securities of OncoSil and does not take into account your investment position or objectives, financial situation or any particular requirements. For these and other reasons, you are strongly recommended to obtain your own up to date independent legal, financial and investment advice – those acting without such advice do so at their own risk.

Disclaimer

This Presentation and any supplemental materials have been prepared by OncoSil based on available information. Although reasonable care has been taken to ensure the facts stated in this presentation are accurate and that the opinions expressed are fair and reasonable, no representation or warranty, express or implied, is made as to the fairness, accuracy, completeness, or correctness of such information and opinions and no reliance should be placed on such information or opinions. To the maximum extent permitted by law, none of OncoSil or any of its members, directors, officers, employees, or agents or corporate advisors, nor any other person accepts any liability whatsoever for any loss, however arising, from the use of the presentation or its contents or otherwise arising in connection with it, including, without limitation, any liability arising from fault or negligence on the part of OncoSil or any of its directors, officers, employees or agents.

The information contained in this presentation is current as at 22 November 2023.

• 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



Douglas Cubbin
Non-
executive
Chairman

Experienced biopharmaceutical
executive with over 30 years'
experience in senior roles across
varied industries.

Was a key member of Telix
Pharmaceuticals (ASX:TLX) which
completed IPO, raised \$270m
in capital



Gabriel Liberatore
Non-
executive
Director

Dr Liberatore is an experienced
biopharmaceutical executive with
over 25 years' experience. Until
recently, he was the Group Chief
Operating Officer at Telix
Pharmaceuticals (ASX:TLX)



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
and Sanofi Aventis



Christian Dal Cin
Chief
Financial
Officer

Christian has over 20 years'
experience with listed and private
companies includes corporate
secretarial, accounting and general
management through The CFO
Solution and previous roles



Renzo DiCarlo
Head of
Transformation

A proven nuclear medicine executive
Renzo brings over 25 years'
experience in therapeutic drugs and
medical devices



Dr Jon Bell MD
Chief
Medical
Officer

8+ years experience as
an interventional radiologist
and an internationally
recognised expert in
interventional oncology

• Corporate Overview

OncoSil Medical Limited | as at 27 Nov 2023

GICS:	Health Care – Pharmaceuticals, Biotechnology & Life Sciences (Life Sciences Tools & Services)
ASX Code:	OSL
ASX Listing Date:	15 August 2005
Market cap:	\$15.8m
Shares on Issue:	1,975.8m
Share price:	\$0.008
52-week high:	\$0.041
52-week low;	\$0.008
Average volume:	2 million
Free float	74.7%
Cash on Hand (September 2023 quarter)	\$6.1m

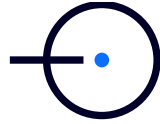
Major Shareholders (% of listed shares, as at 27 Nov 2023)

MRS SARAH CAMERON	6.82%
ALUA CAPITAL PTY LTD	2.53%
BANNABY INVESTMENTS PTY LTD	2.33%



• Executive Summary

OncoSil™ is a commercial-stage breakthrough device delivering targeted radiotherapy for pancreatic cancer



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

Experienced management and sales team in place



- Experienced management and sales 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

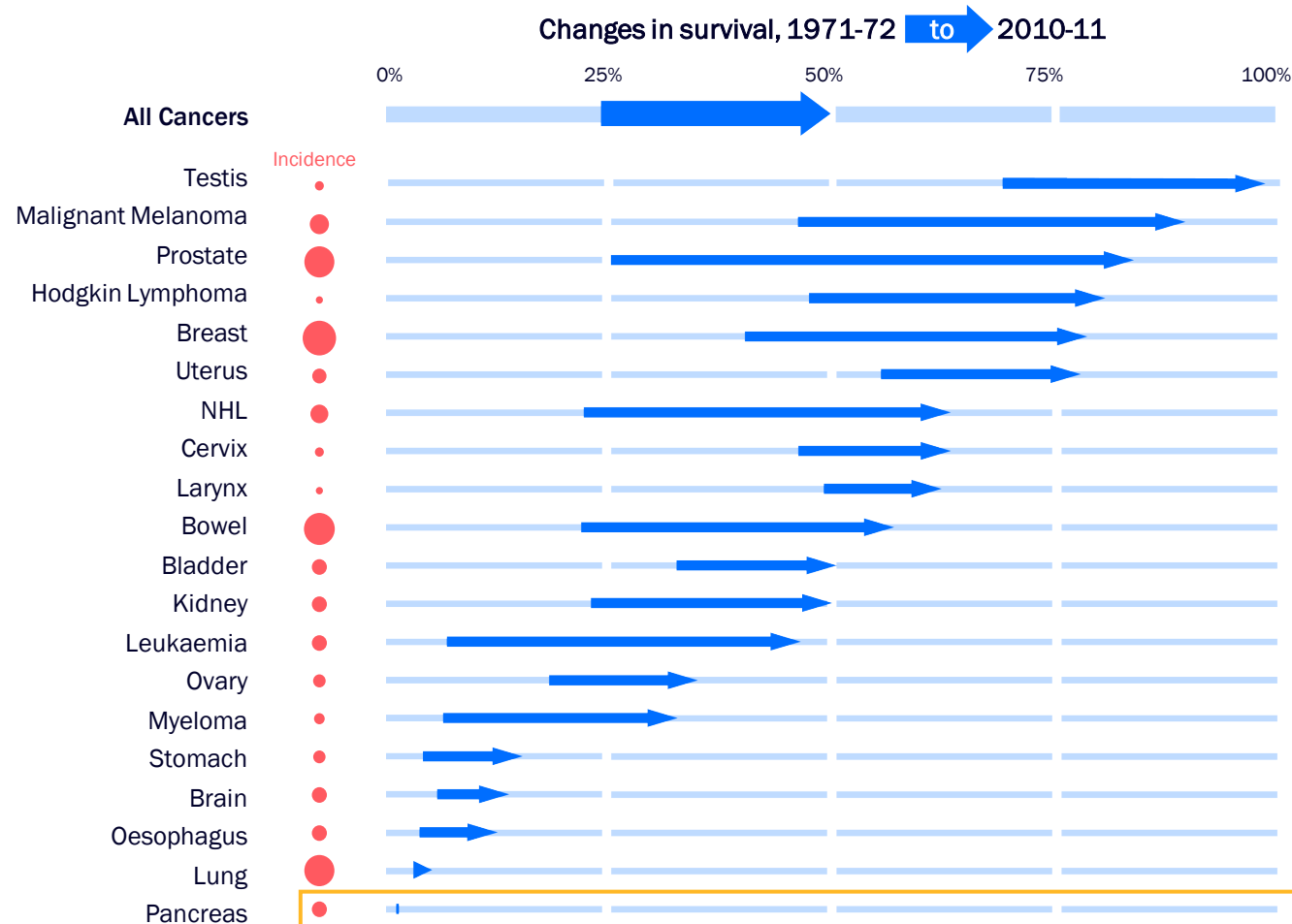
Large global addressable market



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

• Introduction

The prognosis for pancreatic cancer patients has remained almost unchanged for over 40 years¹ with a reported five-year survival rate for the disease of 10%²

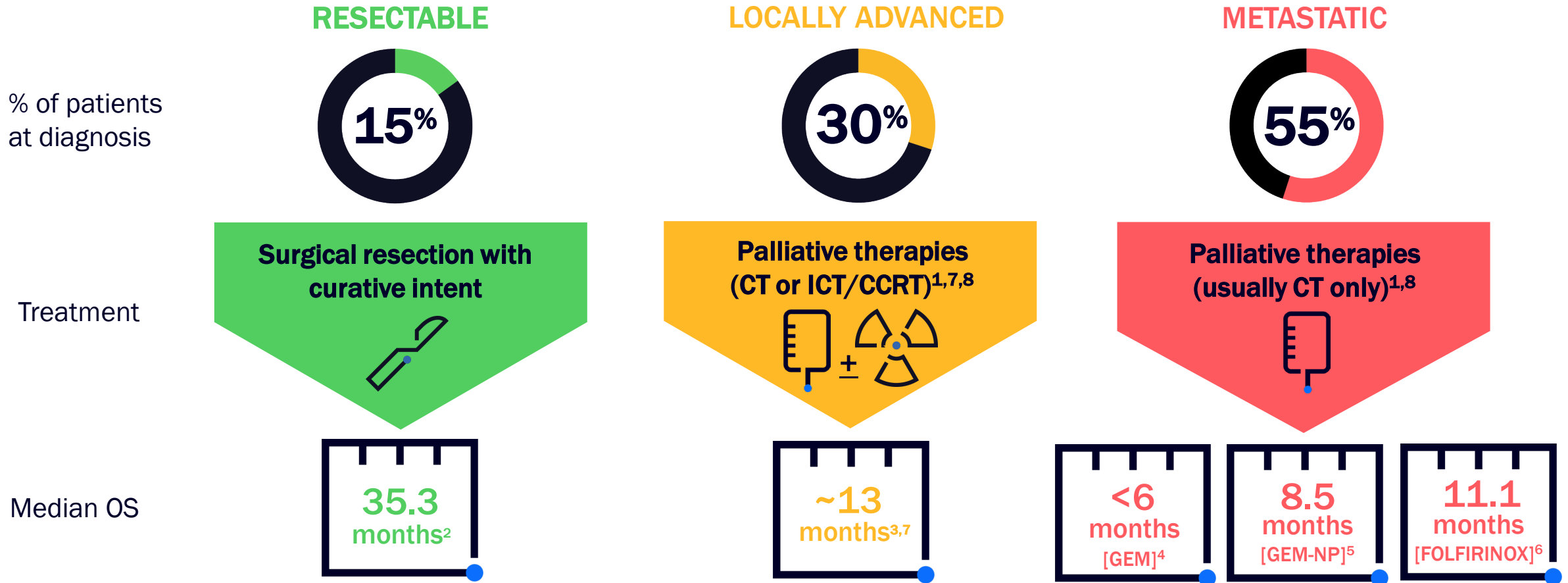


References: 1. Cancer Research UK. www.cancerresearchuk.org/health-professional/cancer-statistics/survival/common-cancers-compared#heading-Three (accessed November 2021)

2. American Cancer Society. Cancer Facts & Figures 2021. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>

• Surgical Resection

The only potentially curative treatment for pancreatic cancer¹



30% of LAPC patients shows metastatic progression with 3-6 months^{9,10}

References: 1. Ducreux M et al. Ann Oncol 2015; 26 (Suppl 5): v56–68. 2. Gemenetzis G et al. Ann Surg 2019; 270: 340–347. 3. Chang JS et al. Cancer Res Treat 2018; 50: 562–574 (suppl data). 4. Burris HA 3rd et al. J Clin Oncol 1997; 15: 2403–2413. 5. Von Hoff DD et al. N Engl J Med 2013; 369: 1691–1703. 6. Conroy T et al. N Engl J Med 2011; 364: 1817–1825. 7. Balaban EP et al. J Clin Oncol 2016; 34: 2654–2668. 8. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Pancreatic adenocarcinoma. Version 1.2020. 9. Huguier et al. J Clin Oncol 2010. 10. Mukherjee et al. Lancet Oncol 2013.

Abbreviations

CT: Chemotherapy
ICT: Induction chemotherapy
CCRT: Concurrent chemoradiation therapy

• OncoSil™ Device

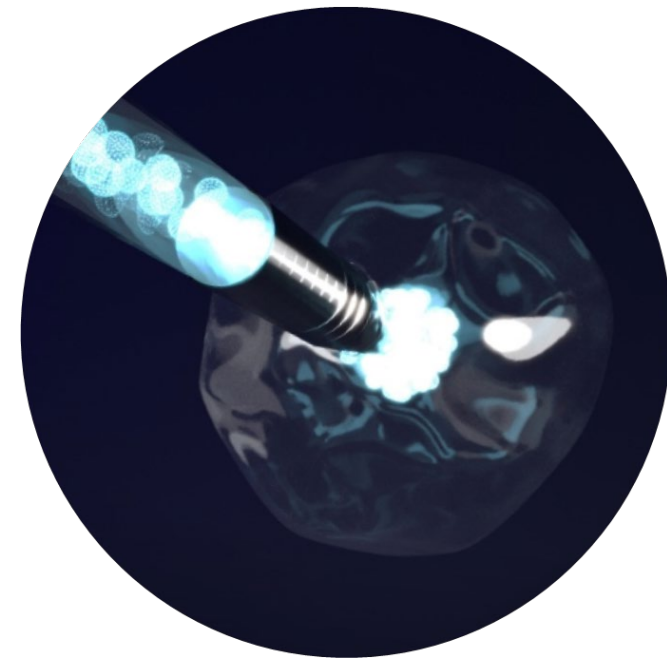
Overview

OncoSil™ is intended for the treatment of **locally advanced unresectable pancreatic cancer**, in combination with gemcitabine-based chemotherapy

OncoSil™ 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 damage to cancer cell DNA and killing malignant cancer cell and no damage to surrounding tissue



• Significant Accomplishments



Experienced team in place



CE Marking obtained



Innovation Funding (NUB) approved

German funding of the OncoSil™ device



Enabled HDE¹ pathway for bile duct cancer³ in US enabled

Application submitted to FDA²



PanCO Study completed

and submitted to peer-reviewed journal



Breakthrough device designation achieved

in US, EU, UK, Singapore



Current market approvals

Europe (CE Mark)
United Kingdom
Switzerland

Hong Kong
New Zealand
Turkey
Israel



PANCOSIL trial

First patient enrolled

1. HDE: Humanitarian Device Exemption

2. FDA: Food and Drug Administration

3. Distal cholangiocarcinoma (DCC or bile duct cancer)

• PanCO study demonstrated positive safety and efficacy signals

Of the many encouraging outcomes from the PanCO study¹, four are particularly important:



Established safety profile:

No evidence suggesting any additional risk from using OncoSil™



90.5% of OncoSil™ treated patients had local disease control at 16 weeks, which was the primary efficacy measure of the study and was statistically significant compared to the pre-set hypothesis



Although all study participants were initially unresectable, 1 in 3 patients (33%) became eligible for resection after receiving OncoSil™, and nearly 1 in 4 patients (23.8%) underwent surgical resection with curative intent



There was a statistically significant reduction in tumour volume for patients who received OncoSil™, with 57% of participants having their tumour volume reduced by at least 50%

• PanCO results showing compelling evidence of downstaging

OncoSil™ converted patients with unresectable locally advanced pancreatic cancer (LAPC) to surgically resectable, transforming their prognosis and substantially extending survival



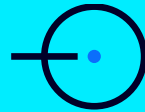
Why is resection important?

Surgical resection remains the only potentially curative treatment for pancreatic cancer, but is limited to ~15% of patients

Patients with LAPC are inoperable due to the size of the tumour and its proximity to major blood vessels

Chemotherapy helps to convert ~7% with unresectable LAPC to surgical resection¹

What did the PanCO study show?



Adding OncoSil™ 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% reduction²



1 in 3 patients with unresectable LAPC receiving OncoSil™ plus chemotherapy became eligible for curative surgery²



Nearly 1 in 4 patients (23.8%) with unresectable LAPC receiving OncoSil™ plus chemotherapy underwent surgery with curative intent²



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}

• OncoSil™ for metastatic pancreatic adenocarcinoma (mPDAC)*



Objective

Assess clinical outcomes following delivery of novel ^{32}P microparticles via EUS-guided brachytherapy in patients with mPDAC



Location

Multicentre (5 centres in Australia and UK) retrospective analysis from Sept 2017-Sept 2020



Results

^{32}P -microparticles implantation is safe and feasible for mPDAC patients

Encouraging outcomes with:

- 100% Local disease control rate at 3 months post-implantation
- 13.9 months overall survival from commencement of chemotherapy

Potential clinical benefits:


- Local tumour control
- Overall survival


* Use of OncoSil TM for metastatic pancreatic adenocarcinoma (mPDAC) is off-label

Reference: 1. Lim A, Singhal N, Bartholomeusz D et al. Outcomes of phosphorus-32 microparticle intratumoural implantation added to chemotherapy in patients with metastatic pancreatic adenocarcinoma. Presented at the European Society of Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer. Annals of Oncology 2023 Jun; 34 (Suppl 1): S138, Abs P-353.


• **TRIPP-FFX**

An open-label, multi-centre, randomized study of **TaRgeted Intratumoural Placement of Phosphorous-32 (OncoSil™)** in addition to **FOLFIRINOX** chemotherapy versus **FOLFIRINOX** chemotherapy alone in patients with unresectable locally advanced pancreatic adenocarcinoma

 **Objective** To assess the safety and efficacy of OncoSil™ when given in addition to standard FOLFIRINOX chemotherapy for treatment of Locally Advanced Pancreatic Cancer


 **Location** 16-18 sites in Spain, UK, Belgium, Australia and Italy with:


- 9 sites open for recruitment
- 12 subjects recruited to date


 **Primary Endpoint** Safety and Tolerability as determined by the Adverse Event profile
Local Disease Control Rate at 16 weeks

• **PANCOSIL** (Investigator Initiated Study)

Safety and feasibility of CT-guided percutaneous radionuclide therapy with the OncoSil™ device in patients with non-progressive locally advanced pancreatic cancer (PANCOSIL): an open-label, single-arm phase 1-2 feasibility study

 **Objective** To assess the safety and feasibility of percutaneous CT-or ultrasound-guided RNT using the OncoSil™ device in patients with non-progressive LAPC after induction chemotherapy treatment.

 **Study Sites** Amsterdam UMC & Antonius Hospital Nieuwegein
1/2 sites initiated
1/20 subjects recruited

 **Primary Endpoint** Safety and feasibility of percutaneous RNT using the OncoSil™ device defined by the percentage of device or procedure related CTCAE grade 3 or higher adverse events, until 90 days post-procedure

• PANCOSIL (Investigator Initiated Study)

First patient enrolled on 28 November 2023



Martijn Meijerink

Professor of interventional radiology,
Amsterdam UMC

“

*I am very excited that today we have been able to treat the first patient with OncoSil™ through a **CT-guided percutaneous** implantation procedure. This novel means of implantation of the OncoSil™ device has a number of potential advantages, such as the ability to **more precisely place the radioactive microparticles** within the pancreatic tumour in a simpler procedure, which can be performed by **interventional radiologists** many of whom are used to working with radionuclide therapies in the treatment of various malignant diseases.*

“

*Today we set the first step in developing a more flexible approach to the OncoSil™ treatment by implanting the first patient using a **percutaneous approach**. Eventually, we aim to give caregivers more **flexibility** to treat their patients with Locally Advanced Pancreatic Cancer with OncoSil™ as they will have the ability to **select the route of administration** of the device based on the tumour location, patient preference and the availability of different specialists within the Multidisciplinary treatment team.*

”



Marc Besselink

Professor of pancreatic and hepatobiliary (HPB)
surgery, Amsterdam UMC

• Innovation Funding (NUB) in Germany

Funding for the use of the OncoSil™ device in Europe's largest market



In February 2022, the Institute for the Hospital Remuneration System (InEK) granted the OncoSil™ device with a “Positive Status 1” classification

Feb
2022

Hospitals who have submitted NUB applications can now negotiate with Statutory Health Insurance providers (“Sickness Funds”) for reimbursement of the OncoSil™ device for a set number of patient treatments for the upcoming year

25 leading university hospital sites in Germany submitted requests for innovation funding (NUB) for the OncoSil™ device; all 25 were approved

The University of Cologne Hospital ethics committee has approved the OSPREY Registry, acting as central ethics approval for all hospital sites within Germany

• G-BA Fully Funded trial in Germany

Fully-funded trial leading to public insurance reimbursement



In March 2022, the Federal Joint Committee (G-BA) recommended a fully-funded trial take place in Germany

Mar
2022

OncoSil will receive revenue payments for the provision of the OncoSil™ device used within the clinical trial

Favourable results from the clinical trial will lead to the OncoSil™ device being fully-funded for patients in Germany through public insurance reimbursement

The 36 leading university sites in Germany who had submitted NUB requests will also be able to participate within the clinical trial

The second round of stakeholder meetings was completed in September 2023. These meetings allows the GBA to gather further information for decision-making of the final coverage with evidence development (CED) study directive.

• Site Training Update

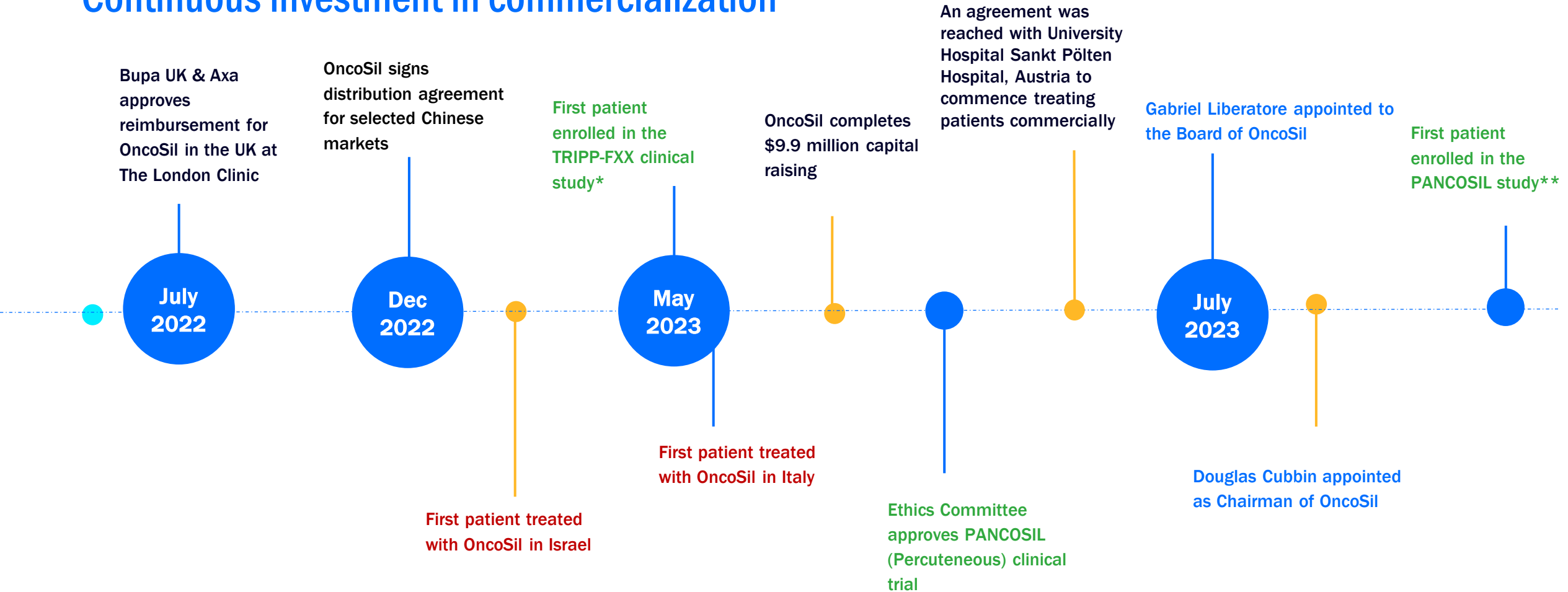
Training New Sites to start
OncoSil™ treatments

- Training Commenced
- Training Completed and ready to start
- Sites using OncoSil



• FY23 Highlights

Continuous investment in commercialization



* 16 patients enrolled in the study as of 29 November 2023

** 1 patient enrolled in the study as of 29 November 2023

• Regulatory Updates



UKCA Renewal – *In progress (deadline 26 May 2024)*



EU MDR Submission – *In progress (deadline 26 May 2024)*



Additional questions from **FDA** – *In progress (deadline 26 July 2024)*



TGA Pre-submission Request – *Q1 2024*

• FY24 MARKETING ACTIVITIES

Reached over 10,000 HCPs



• Transformation Overview

- New State of the Art Facility at the Macquarie Medical Centre in the Sydney, NSW area. Proudly Australian site serving the global market.
- Transformational technology being applied to the new facility:
 - High tech Opening and laminar dispensing system
 - Higher grade cleanroom with terminal sterilization
 - Sustainable enhanced Type A package
- Expanded new Global Technical & Development Team:
 - Medical facility and isolator design
 - Medical transport packages and logistics development
 - Set up of health solutions for end-to-end supply chain
- Results in :
 - Scalability
 - Enhanced risk management
 - Improved per unit gross margin (> 10%)



• Cyclotek Site, MacQuarie University Hospital

- Partnership with Australian based Molecular Imaging company, Cyclotek, a proven supplier of Positron Emission Tomography (PET) radiopharmaceuticals.
- Cyclotek will be a key supplier of our medical device to our global markets.
- Situated at Cyclotek's Macquarie University Medical centre product will be produced and supplied to commercial and clinical sites in Australia, Asia, Europe and North America.
- This state of the art facility will be used to augment supply from our existing site in Germany, E&Z.
- This new Australian site is needed for our growing volume needs, regional requirements and for mutual global back-up to our existing site in Germany.



• Innovation

- Expanded Technology Development Team to provide:

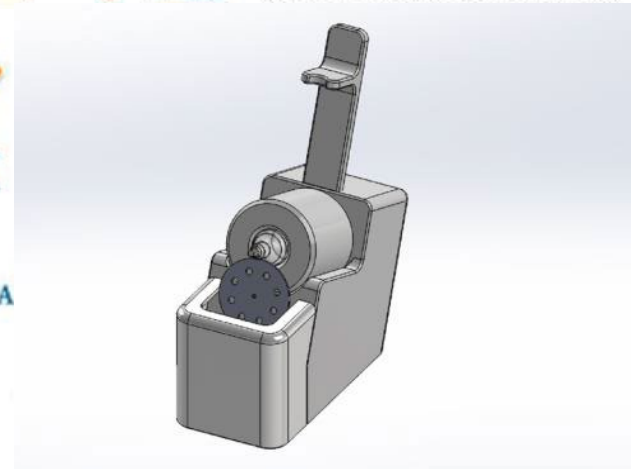
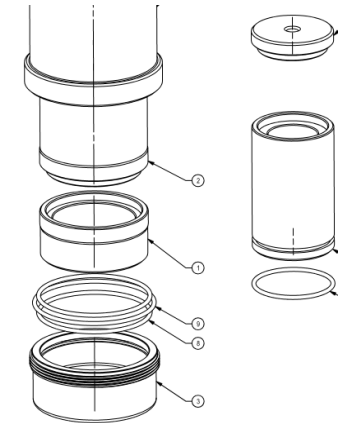
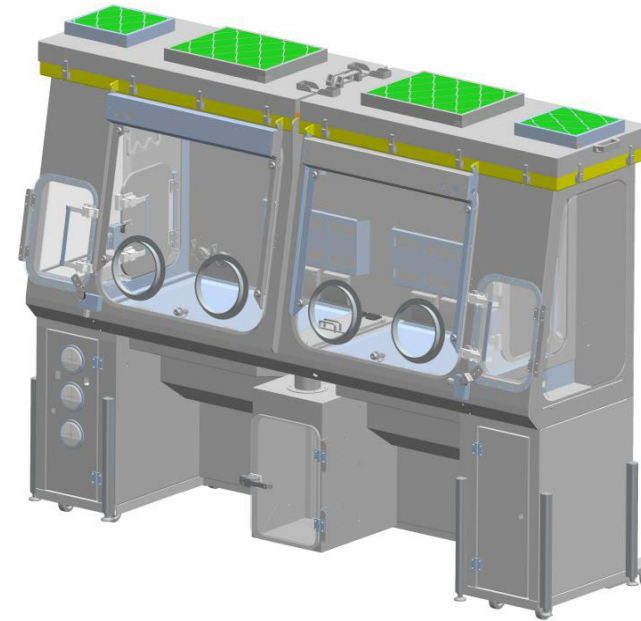
- Clinical and site design support
- Package engineering
- Process and Product Development
- Commercial logistics and supply-chain

- New innovative designs & solutions :

- Target quartz ampoule
- Isolator technologies
- Enhanced dispensing system

- Potential and Existing Partners:

- Nuclear Australia
- Mo-Sci Quartz Solutions
- Isotech Designs





Key Inflection Points

- US HDE approval in distal cholangiocarcinoma (dCCA)
- GBA German fully funded clinical trial approval

✓ PancoSil clinical trial - (percutaneous application under CT guidance administered by Interventional Radiology)

• The OncoSil™ device is now in early stage commercialisation

The OncoSil™ device, an effective treatment for locally advanced pancreatic cancer, is now penetrating its already large and continually growing target addressable markets

- ✓ Many key components of commercialisation strategy are already in place (breakthrough device designation; market approvals in a steadily increasing number of countries/regions)
- ✓ The device is approved for sale in 34 countries
- ✓ A growing network of hospitals located across an expanding geographic footprint are treating patients with the OncoSil™ device
- ✓ OncoSil™ has converted patients with unresectable locally advanced pancreatic cancer to surgically resectable, transforming their prognosis and substantially extending survival
- ✓ The consensus view is that rival treatment options are sub-optimal
- ✓ Working towards innovation funding in Germany
- ✓ Further studies are now being progressed
- ✓ OncoSil's journey to commercialisation is being led by a highly experienced Board and Senior Executive team
- ✓ Market access and clinical development teams are working on multiple activities to expand the addressable market

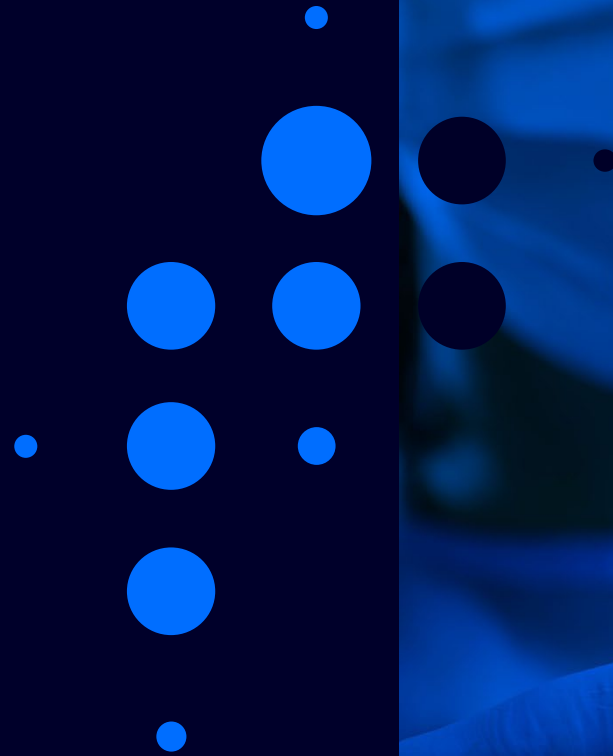


OncoSil™

Intratumoural placement of ^{32}P for
locally advanced pancreatic cancer

Targeted Approach • Positive Impact

Nigel Lange, November 2023



• Transformation Overview

- New State of the Art Facility at the Macquarie Medical Centre in the Sydney, NSW area. Proudly Australian site serving the global market.
- Transformational technology being applied to the new facility:
 - High tech Opening and laminar dispensing system
 - Higher grade cleanroom with terminal sterilization
 - Sustainable enhanced Type A package
- Expanded new Global Technical & Development Team:
 - Medical facility and isolator design,
 - Medical transport packages and logistics development
 - Set-up of health solutions for end-to-end supply chain

Results in :

- **Scalability**
- **Enhanced risk management**
- **Improved per unit gross margin (> 10%)**



• Cyclotek Site, MacQuarie University Hospital

- Partnership with Australian based Molecular Imaging company, Cyclotek, a proven supplier of Positron Emission Tomography (PET) radiopharmaceuticals.
- Cyclotek will be a key supplier of our medical device to our global markets.
- Situated at Cyclotek's Macquarie University Medical centre - product will be produced and supplied to commercial and clinical sites in Australia, Asia , Europe and North America
- This state-of-the-art facility will be used to augment supply from our existing site in Germany, E&Z .
- This new Australian site is needed for our growing volume needs , regional requirements and for mutual global back-up to our existing site in Germany.



• Innovation



Expanded Technology Development Team to provide:

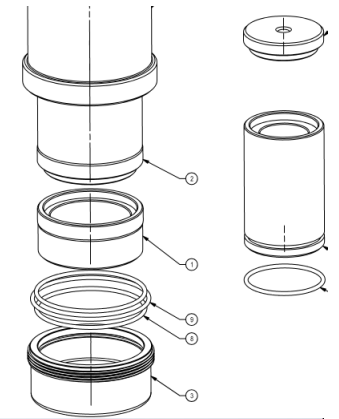
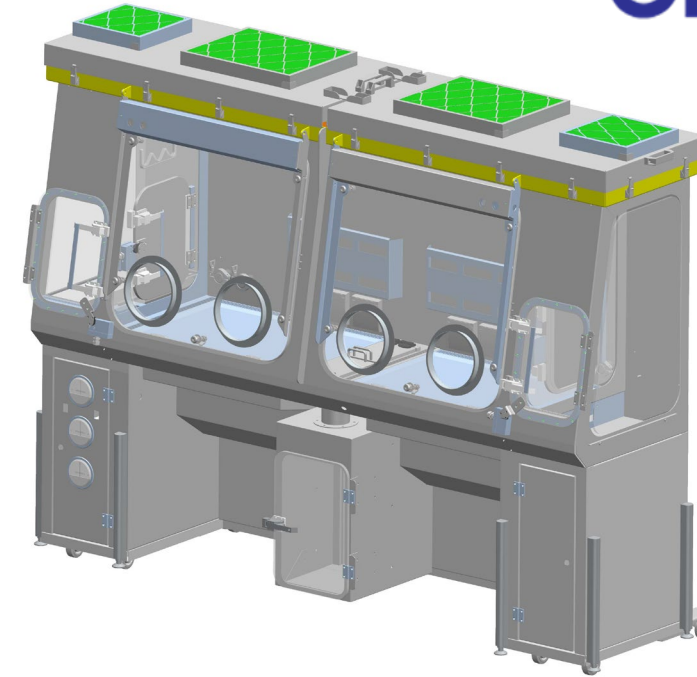
- Clinical and site design support
- Package engineering
- Process and Product Development
- Commercial logistics and supply-chain

New innovative designs & solutions :

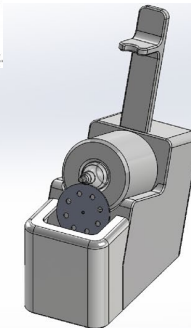
- Target quartz ampoule
- Isolator technologies
- Enhanced dispensing system

Potential and Existing Partners:

- ***Nuclear Australia***
- ***Mo-Sci Quartz Solutions***
- ***Isotech Designs***



PET RADIOPHARMACEUTICALS
Molecular Imaging
AUSTRALIA & NEW ZEALAND





Nigel Lange

CEO & Managing Director

E: nigel.lange@oncosil.com

OncoSil Medical Ltd

www.oncosil.com

Targeted Approach • Positive Impact

