



# Capital Raise Presentation

October 2024

Nigel Lange, CEO & Managing Director

Targeted Approach • Positive Impact

ASX Code: OSL



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The information contained in this presentation is current as at 24 October 2024.

# • Executive Summary

## Commercialising targeted radiotherapy for pancreatic cancer

- OncoSil Medical is commercialising the OncoSil™ device, an implanted device (brachytherapy) delivering targeted radiation (<sup>32</sup>P) to pancreatic tumours – In Oct-24, OncoSil Medical treated its **200<sup>th</sup> patient**
- OncoSil™ device is now **approved for sale in over 34 countries** via CE Mark
- **Commercial ramp-up expected in FY25** and beyond following newly added markets and near-term market entry expectations
- **Increasing market access** via label expansion combining new delivery methods and new chemotherapy combinations<sup>1</sup>
- **Accelerating market penetration** with a shortened sales cycle and an increase in addressable hospital sites in the EU and UK
- **Platform technology** can be leveraged into other cancer indications (Bile duct cancer, liver, glioblastoma)
- Experienced Board & Management team in the commercialisation of radiotherapies

## >US\$4.2bn global addressable market with no competition<sup>4</sup>

- Granted **Breakthrough designation** in the EU, UK and US with extensive **patent coverage** across all key geographies
- Large global pancreatic cancer patient population of ~510k p.a and targeting locally unresectable population of ~153k (~30%) with the **market expected to increase by 37% by 2035<sup>2</sup>**
- Negligible survival improvement in over 20 years with <12% survival rates at 5-years and 8.5 months Median Overall
- **First ever Comparative analysis released in Sep-24 indicates significant benefit in combination with Chemotherapy:<sup>3</sup>**
  - ✓ **Overall Survival benefit of 7 months** – 20.0 months survival of OncoSil™ + chemotherapy vs. 13.0 months in chemotherapy alone
  - ✓ **More than doubled surgical resection rate** – 28.6% in OncoSil™ + chemotherapy vs. 12.1% in chemotherapy alone
  - ✓ **More than doubled patients downstaged** – 31.4% in OncoSil™ + chemotherapy vs. 13.6% in chemotherapy alone

## Attractive unit economics

- Indicative ~US\$24k per device with Gross Margin expansion expected to increase from 50% to 65% in FY25 and target of >75% expected at scale
- **Operating cost base now largely fixed** (~\$13m) with significant opportunity for operating leverage over the medium term
- Development expenses now largely completed with **negligible additional capex** required

# • Executive Summary

## Significant achievements over CY24

- Received UKCA Certificate which includes the removal of all existing post-market restrictions in the UK (OSPREY registry)
- 50% Recruitment achieved in landmark PANCOSIL study (a groundbreaking delivery method for OncoSil™ device)
- 50% Recruitment achieved in TRIPP-FFX study (to expand OncoSil™ device label with additional chemotherapy combinations)
- Second manufacturing facility in Sydney, Australia activated and ready to undergo validation.
- New distribution agreements in UAE, Qatar, Oman, Bahrain, Saudi Arabia and Turkey
- Constructive discussions with US FDA regarding the approval pathway for OncoSil™ device in Bile Duct Cancer (dCCA)
- Received German Federal Joint Committee (G-BA) approval and conditional reimbursement across 84 hospitals in Germany

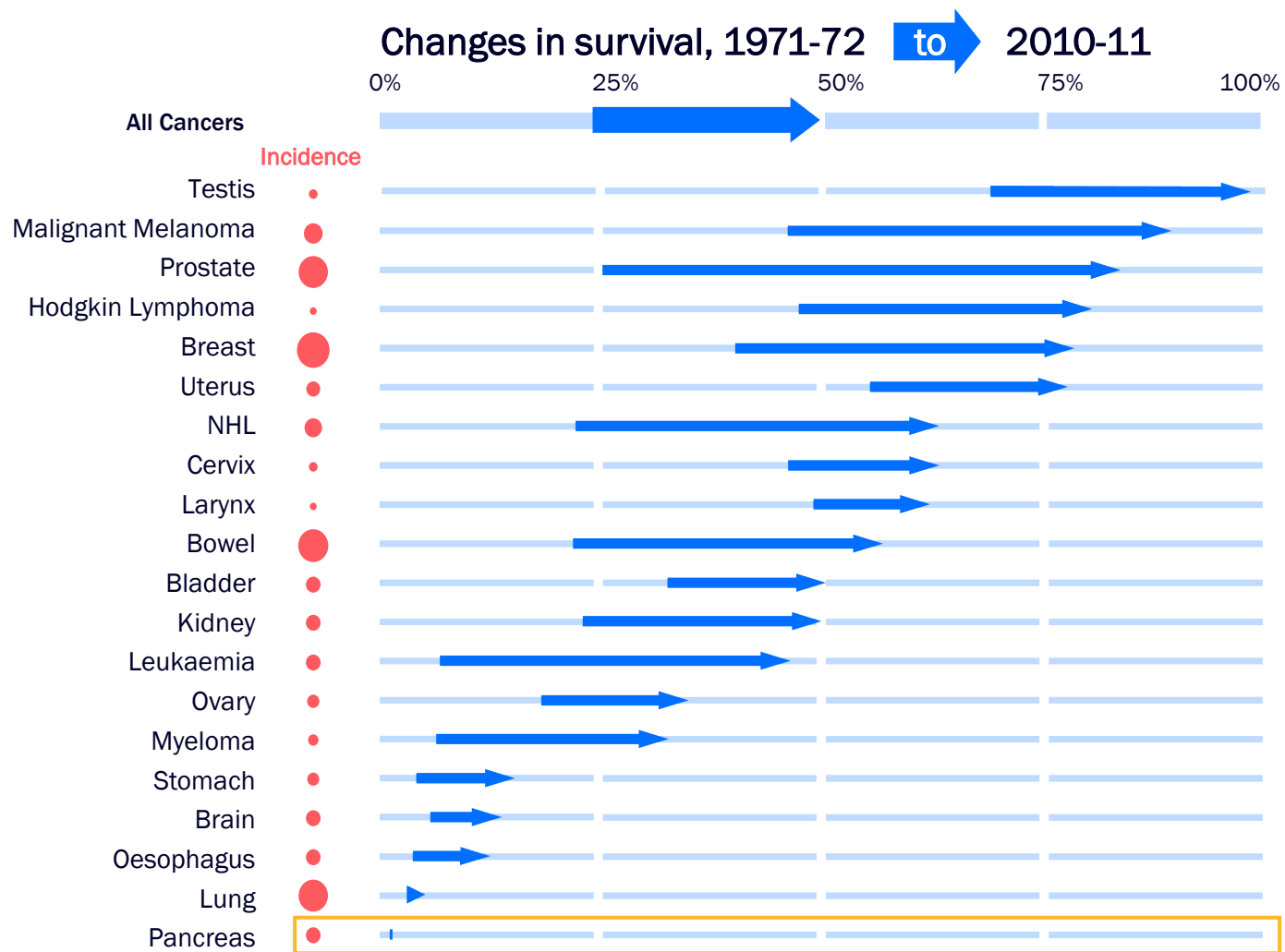
## Catalyst rich CY25/26

- At commercial ramp up in existing markets including Austria, Greece, Israel, Italy, Spain, Turkey, UK
- Medical Device Regulation (MDR) approval anticipated in Q4 2024 expected to accelerate market penetration in EU regions
- Accelerating commercial activities via expanded market access and geographical opportunities including:
  - *Distribution agreements or direct representation in key markets including Argentina, Brazil, Chile, France, Nordic countries, South Korea, Switzerland<sup>1</sup>*
  - *Label expansion to include delivery method for a new medical speciality, Interventional Radiology (PANCOSIL study) – submission expected Q2 CY25*
- Therapeutic Goods Administration (TGA) filing in (Q1 CY25)
- First Commercial production in Sydney Manufacturing facility (Q2 CY25)
- Regulatory filings in Argentina and Brazil (2Q CY25)

## Offer details

- Equity Raising of up to ~A\$8m comprised of an institutional placement (“**Placement**”) to raise up to ~A\$7m and a share purchase plan (“**SPP**”) of up to A\$1m
- Equity raising is at a fixed issue price of \$0.010 per New Share, representing a:
  - 23.1% discount to the last close price on Wednesday 23 October 2024 of \$0.0130; and
  - 19.8% discount to 5-day VWAP of \$0.0125.
- Shares will be offered under the Placement and the SPP with one (1) free attaching Options for every one (1) New Shares issued. The attaching options are intended to be listed on the ASX with an exercise price of \$0.0150 and expire 3 years from their issue date
- Bell Potter Securities Limited is acting as Sole Lead Manager and Bookrunner to the Offer.

# • Pancreatic Cancer Prognosis has Remained Unchanged for 40 Years<sup>1</sup>



## Survival rates are very poor:

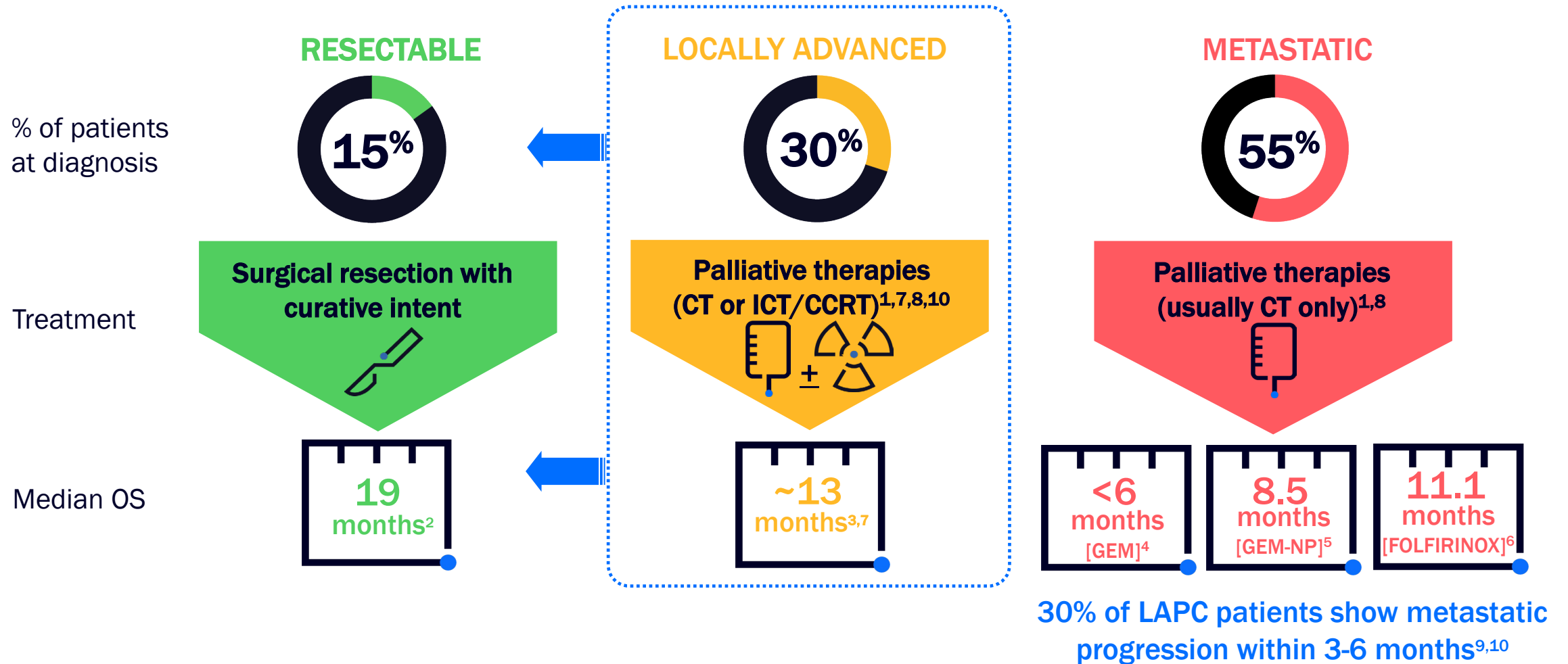
- 8.5 months overall median survival
- <12% reach 5-year survival<sup>2</sup>
- Lower survival rate than any other cancer<sup>3</sup>
- The number of cases and deaths both estimated to increase by 40% before 2035<sup>3</sup>



New therapeutic options urgently needed

# • Pancreatic Cancer Stage at Diagnosis

**Surgical resection remains the only potentially curative treatment for pancreatic cancer<sup>1</sup>**



**Abbreviations:** CT: Chemotherapy; ICT: Induction chemotherapy; CCRT: Concurrent chemoradiation therapy.

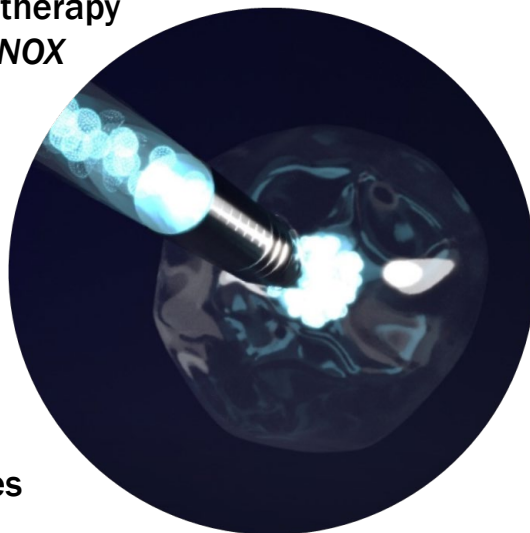
**References:** <sup>1</sup>. Ducreux M et al. Ann Oncol 2015; 26 (Suppl 5): v56–68. <sup>2</sup>. van Dam JL et al. Eur J Cancer. 2022; 160: 140–149. <sup>3</sup>. Chang JS et al. Cancer Res Treat 2018; 50: 562–574 (suppl data). <sup>4</sup>. Burris HA 3rd et al. J Clin Oncol 1997; 15: 2403–2413. <sup>5</sup>. Von Hoff DD et al. N Engl J Med 2013; 369: 1691–1703. <sup>6</sup>. Conroy T et al. N Engl J Med 2011; 364: 1817–1825. <sup>7</sup>. Balaban EP et al. J Clin Oncol 2016; 34: 2654–2668. <sup>8</sup>. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Pancreatic adenocarcinoma. Version 1.2020. <sup>9</sup>. Huguier et al. J Clin Oncol 2010. <sup>10</sup>. Mukherjee et al, Lancet Oncol 2013.



## Driving increased resection rates, downstaging, survival benefits and quality of life

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

OncoSil™ is a **single-use** brachytherapy device comprised of microparticles and a diluent



**Requires only one supervised procedure given simplicity and familiarity with standard, everyday, biopsy procedures**

OncoSil™ is currently 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 cells with no damage to surrounding tissue**



**Percutaneous delivery is transformational and anticipated to significantly accelerate market penetration:**

- ✓ Expanding the number of treating clinicians to include Interventional Radiologists
- ✓ Broader patient access and points of care
- ✓ Outpatient day procedure – complete within 20 minutes
- ✓ Conscious sedation (patient awake)

PANCOSIL study anticipated to complete in Q4 CY24 – **topline readout in Q2 CY25**

**Targeting Q3 CY25 to make OncoSil™ commercially available to Interventional Radiologists**

# • How the OncoSil™ Device Works

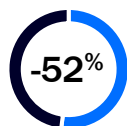


[Video Link](#)



# OncoSil™ plus Standard-of-Care Chemotherapy

## Landmark analysis supports evidence of transforming prognosis and extending survival



Adding OncoSil™ to chemotherapy led to a high proportion of patients having **substantial reductions in their tumour volume** (median 51.9%; range +11% to -90%), **with 60% having a >50% reduction<sup>2</sup>**



**Local disease control at 16 weeks in 90.5% of treated patients** – meeting the primary efficacy measure and statistically significant compared to the pre-set hypothesis



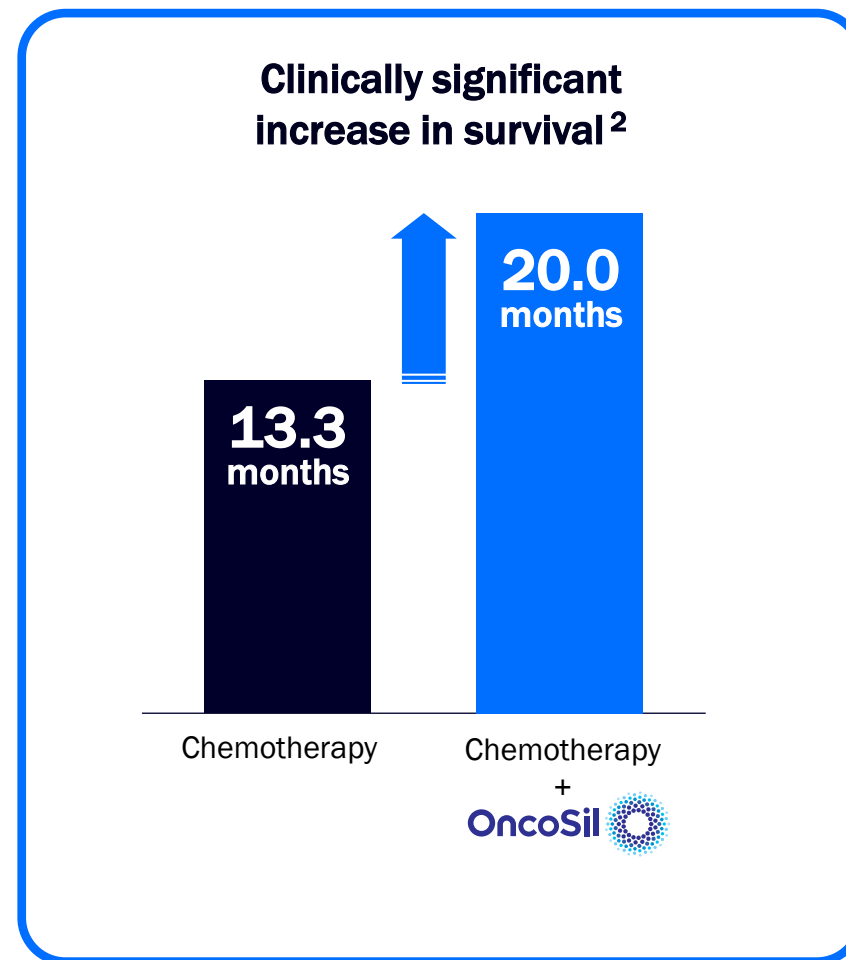
**Significantly increased survival** in those receiving OncoSil™ compared to chemotherapy alone in a propensity score analysis: median overall survival 20.0 vs. 13.3 months ( $p=0.001$ ), with 3.7 months (+32.3%) longer restricted mean survival time (RMST) at 24 months from starting treatment<sup>2</sup>



OncoSil™ also **significantly increased both local and distant Progression-Free Survival (PFS)** compared to chemotherapy alone in a propensity score analysis: median local PFS was 14.7 vs. 10.0 months ( $p<0.01$ ), with 3.7 months (+41.3%) longer RMST at 24 months from starting treatment<sup>2</sup>



Established safety profile with no evidence of additional risk from adding OncoSil™ to standard-of-care chemotherapy



**Abbreviations:** PFS: Progression-free survival; RMST: Restricted mean survival time.

**References:** 1. Ross PJ et al. Results of a single-arm pilot study of 32P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/ nab-paclitaxel or FOLFIRINOX chemotherapy. ESMO Open February 2022; 7 (1): 100356. 2.

Lim A et al. Combined phosphorus-32 implantation and chemotherapy: A comparison with standard therapy using a propensity-score weighted landmark analysis and an assessment of its impact on vascularity in locally advanced pancreatic cancer.

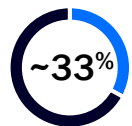
Presented at the Gastroenterological Society of Australia's Australian Gastroenterology Week (AGW 24) Meeting; 14–16 September 2024. Journal of Gastroenterology and Hepatology 2024; 39 (Suppl. 1): 39 Abs, 337.

# • OncoSil™ plus Standard-of-Care Chemotherapy

At least doubling the number achieving surgical resection or downstaging compared to chemotherapy alone<sup>1,2</sup>



Around 1 in 4 patients (23.8% in PanCO; 28.6% in the Propensity Score analysis) with unresectable LAPC receiving OncoSil™ plus chemotherapy **underwent surgery with curative intent, compared with resection rates of 12.1% of patients receiving chemotherapy alone in the Propensity Score analysis** <sup>1,2</sup>

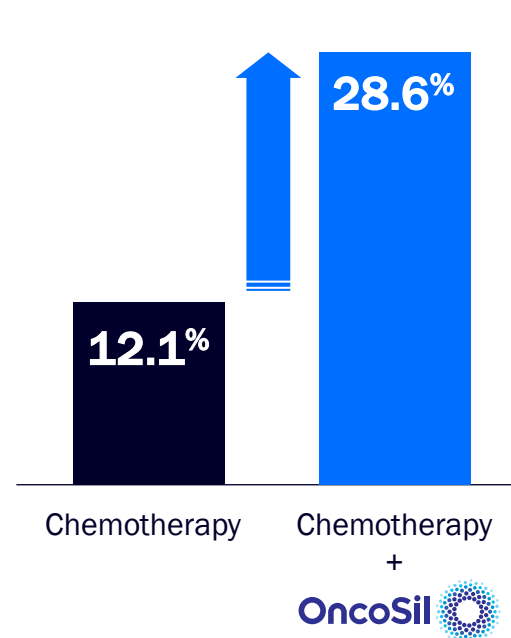


Nearly 1 in 3 patients (33.3% in PanCO; 31.4% in the Propensity Score analysis) **were downstaged** (tumour size reduced sufficiently to allow surgical resection, independent of whether the patient is fit for surgery), **compared 13.6% of patients receiving chemotherapy alone in the Propensity Score analysis** <sup>1,2</sup>

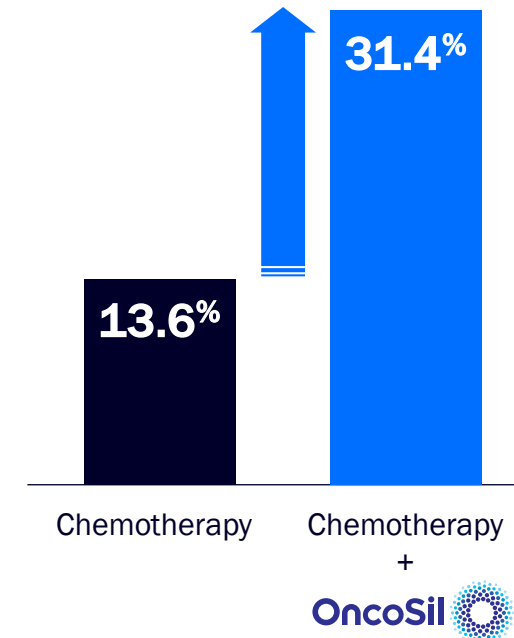


6 of the 10 resected patients in the PanCO study **remained alive, 5 having no evidence of disease, at 32.0 months median follow-up from enrolment in the study** <sup>1</sup>

More than doubled the number surgically resected<sup>2</sup>



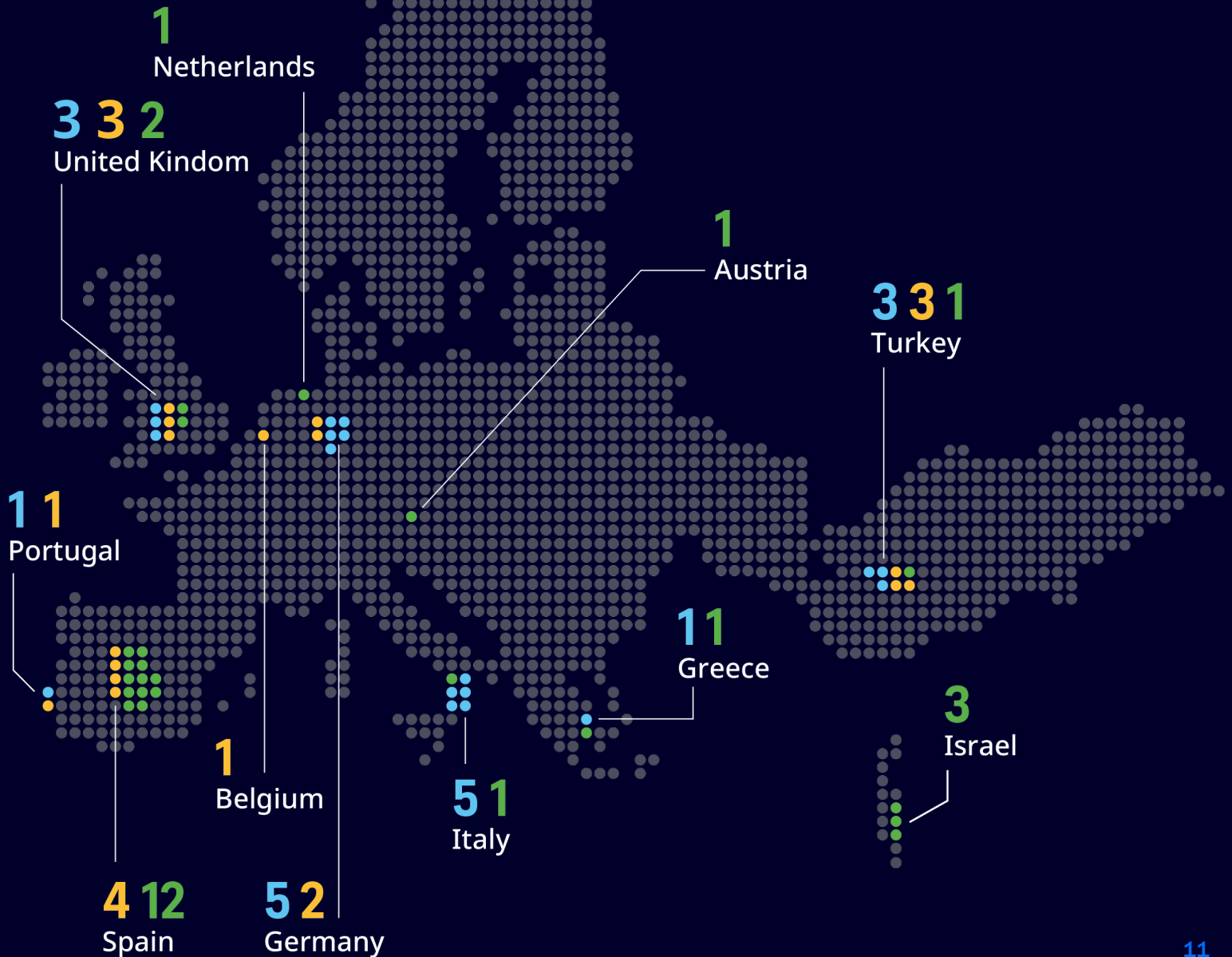
More than doubled the number downstaged<sup>2</sup>



# • Growing Global Adoption

Sites undertaking  
OncoSil™ Device  
treatments continue  
to grow

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



# • Significant Commercial Opportunity

## Existing Priority Markets

Target Market	Pancreatic Cancer Incidence p.a. <sup>1</sup>	Locally Advanced Pancreatic Cancer <sup>2</sup>	Market Opportunity (\$USm)
UK	12,710	3,813	~98
Spain	8,946	2,684	~66
Italy	15,181	4,554	~112
Germany	22,727	6,818	~175
Greece	2,422	727	~18
Austria	2,181	654	~17
Turkey	9,888	2,966	~66
Portugal	1,920	576	~14
Israel	1,336	401	~10
Saudi Arabia	745	224	~6
Hong Kong	1,116	335	~8
<b>Total (Existing)</b>	<b>79,172</b>	<b>23,752</b>	<b>~588</b>

## Near-Term Target Markets

South Korea	8,891	2,667	~65
France	15,596	1,114	~27
Switzerland	1,958	4,679	~115
Brazil	14,670	701	~17
Argentina	5,554	587	~14
Chile	1,899	4,401	~108
Netherlands	3,714	1,666	~41
Belgium	2,338	570	~14
<b>Total (New)</b>	<b>54,620</b>	<b>16,386</b>	<b>~401</b>



OncoSil™ device remains **at the early-stage of commercialization** in existing geographies with ~US\$588m market size

Expanding to ~US\$990m addressable market over next **18 –24 months**

**Market Penetration** expected to now accelerate over the near-term driven by:

- Full MDR approval to replace existing post-market restrictions in UK/EU; and
- Percutaneous Delivery following a target Q3 CY2025 label expansion

# • Attractive Commercial Model

## Compelling cost-benefit proposition with no direct competition

### Attractive Unit Economics



- Average list price of ~€22k/~US\$24k
- Gross Margin of 50% expected to increase to 65% driven by manufacturing productivity and **targeting >75%** at device margins at scale

### No direct Competition



- Granted **Breakthrough Designation** in the US, EU, UK
- The **only commercially available, or in development, targeted Radiotherapy for LAPC**
- Patented technology that is difficult to reverse engineer

### Capital light operating model



- **Concentrated industry structure** with high volumes undertaken at 'centres of excellence'
- High Return on Capital with relatively **small sales force required** in direct markets to drive adoption
- High operating leverage anticipated through economies of scale in the long-term

### Commercial scale manufacturing capability



- **End-to-end manufacturing capabilities** and logistics already in place and able to meet commercial quantities
- Second manufacturing facility (Sydney, Australia) expected to be accretive to Gross Margin and producing first commercial doses in Q2 CY25

### Multiple high value initiatives to broaden market access & accelerate commercialisation



- Label expansion to include **additional method of delivery** (PANCOSIL study – expected completion Q1 CY25)
- Label expansion to include **additional chemotherapy combination** (TRIPP-FFX study – expected completion Q3 CY25)
- **Expansion into new markets** (Argentina, Brazil, Chile, France, Hong Kong, South Korea, Switzerland)

# • Eliminating Barriers to Hospital Adoption

MDR approval anticipated to increase market penetration across EU and UK markets

## Current Status

OSPREY Post Market Registry in EU and UK adds multiple layers of administration and complexity for approving and onboarding clinical sites

Increased time to onboard hospitals with up to six months to clear hospital ethics committee

Company incurs costs for ethics committee applications and Clinical Research Organisations (CROs) related to patient recruitment



## Incoming changes

- OncoSil has now received the UK Conformity Assessment Certificate removing all post-market restrictions in the UK market, including OSPREY
- OncoSil is expecting to receive full Medical Device Regulation (MDR) approval in the near-term given confidence by the regulatory authorities in the clinical safety data for the OncoSil™ device
- Implementation of the MDR is to replace the requirement for OSPREY Registry in EU in addition to the UK and results in:
  - ✓ Removal of administrative burden and requirement for ethics committee approval with six months saved to onboard new hospital accounts
  - ✓ Only isotope (<sup>32</sup>P) license required at new hospital accounts (all current hospital sites have required license)
  - ✓ Company to save €2 million over three years in ethics approval and patient recruitment related costs



# • Accelerating Commercialisation

## Enhancing market access in existing and new geographies

Program	Description	Key Milestones	Commercial Impact
PANCOSIL	Feasibility and safety of CT-guided percutaneous radionuclide therapy with OncoSil™ device + Chemotherapy in non-progressive locally advanced pancreatic cancer	<ul style="list-style-type: none"> <li>&gt;50% recruitment achieved (11/20)</li> <li>Target Study completion Q1 2025</li> <li>Regulatory submission target of Q2 2025               <ul style="list-style-type: none"> <li>Added to Label and targeted commercial launch in EU and UK markets in 2H25</li> </ul> </li> </ul>	Accelerates market penetration with lower barriers to adoption via a new method of delivery for a new medical speciality (Interventional Radiology)
TRIPP-FFX	Efficacy and Safety of OncoSil combined with standard Folfirinox chemotherapy vs. FOLFIRINOX chemotherapy alone	<ul style="list-style-type: none"> <li>50% recruitment achieved (40/80)</li> <li>Target completion Q3 CY25</li> <li>Target Regulatory submission Q3/4 CY25</li> <li>Added to Label in all approved jurisdictions H1 CY26</li> </ul>	Accelerates market penetration with label expansion to include coverage of OncoSil™ device with all typical LPAC chemotherapy regimens (EU region)
Bile Duct Cancer	Bile Duct Cancer (Distal Cholangiocarcinoma - dCCA) For approval by US FDA under Human Device Exemption (HDE)	<ul style="list-style-type: none"> <li>Discussions remain ongoing and constructive with US FDA</li> <li>OncoSil is preparing additional data to support HDE application</li> </ul>	Small addressable market however a supportive pathway to US market entry for LAPC
G-BA Trial	84 German Hospitals to negotiate reimbursement of the OncoSil™ device under the innovation funding program (NUB). Currently awaiting confirmation from German Public Health Agencies Federal Joint Committee (G-BA)	<ul style="list-style-type: none"> <li>G-BA approval received Oct-24</li> <li>Procedural finalisation from Ministry of Health Q1 2025</li> <li>Expected completion date Q4 CY27</li> </ul>	Public insurance reimbursement for OncoSil™ device in Germany for trial participants Opportunity to participating hospitals to receive reimbursement for patients not participating in trial

# • PANCOSIL: Expanding Market Access – Novel Delivery Method

Greater market access for OncoSil™ with the adoption of Interventional Radiology/Oncology medical specialty

**Trial in  
progress**



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

**50%  
recruited**



Amsterdam UMC & Antonius Hospital Nieuwegein – (11/20 subjects)

**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

**Objective**



Expanded Commercial use of OncoSil™ device by Interventional Radiologists/Oncologists

## Commercial ramp up with upside expected from new market access initiatives

Unit volumes are expected to ramp up materially following onboarding activities in existing initial markets in CY24

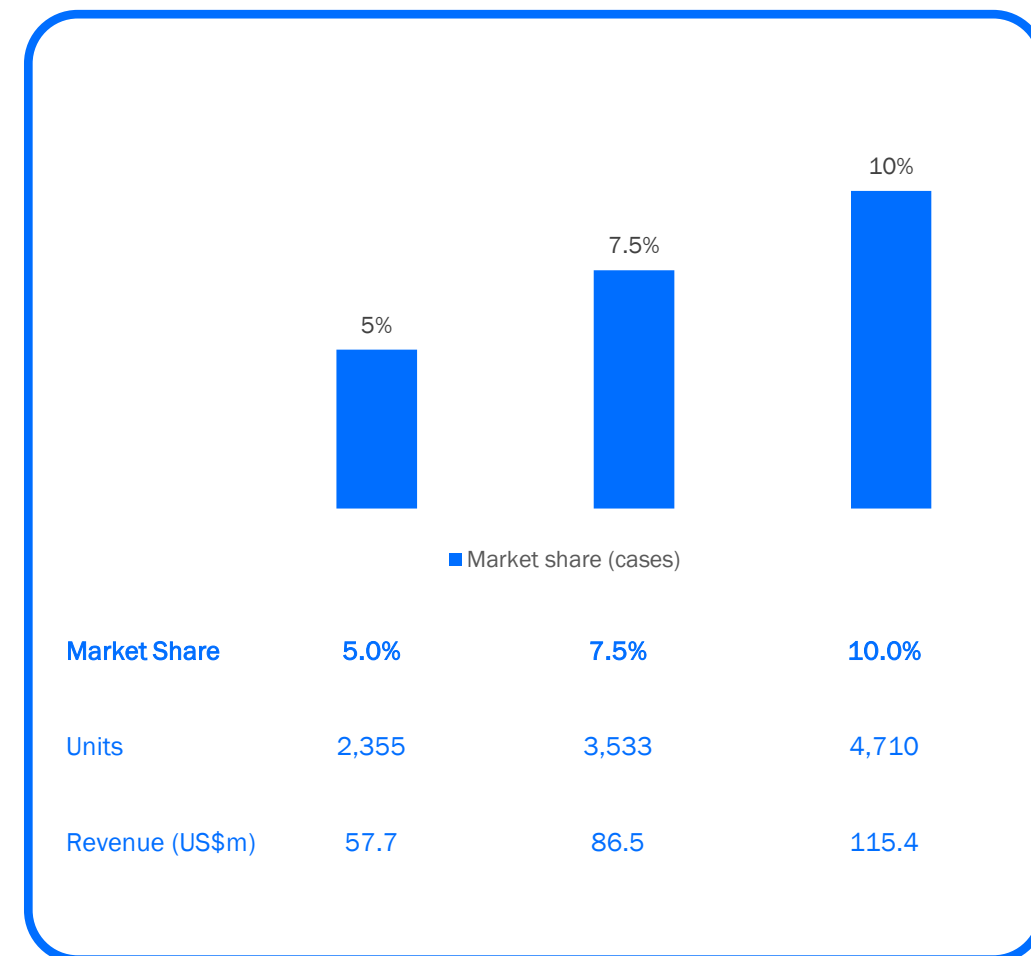
Volumes in existing markets are expected to underpin growth from market entry expectations over the near-term

OncoSil™ has an aspirational target of 5–10% market share by CY29 in existing and near-term target markets implying up to 4,710 units p.a.

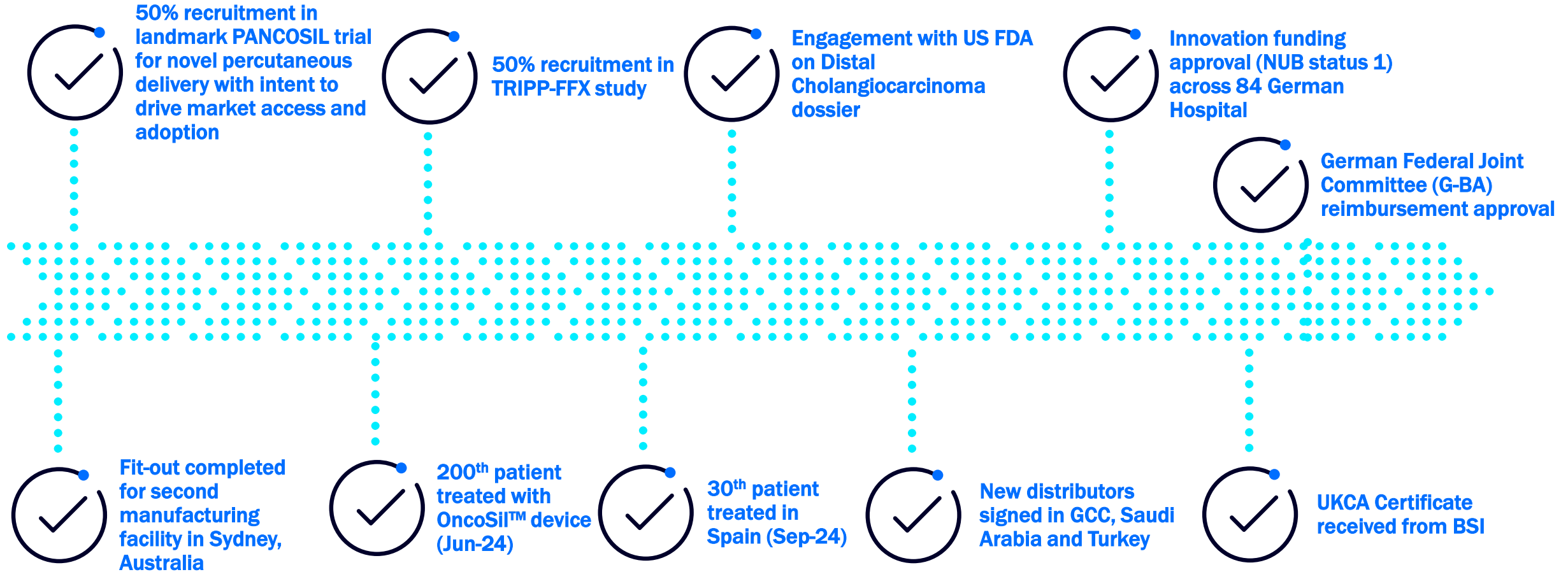
Label expansion activities enhancing market access including:

- Percutaneous delivery method for new clinician group (Interventional Radiologists); and
- Combination with FOLFIRINOX chemotherapy

 Is expected to significantly accelerate current aspirational volume targets

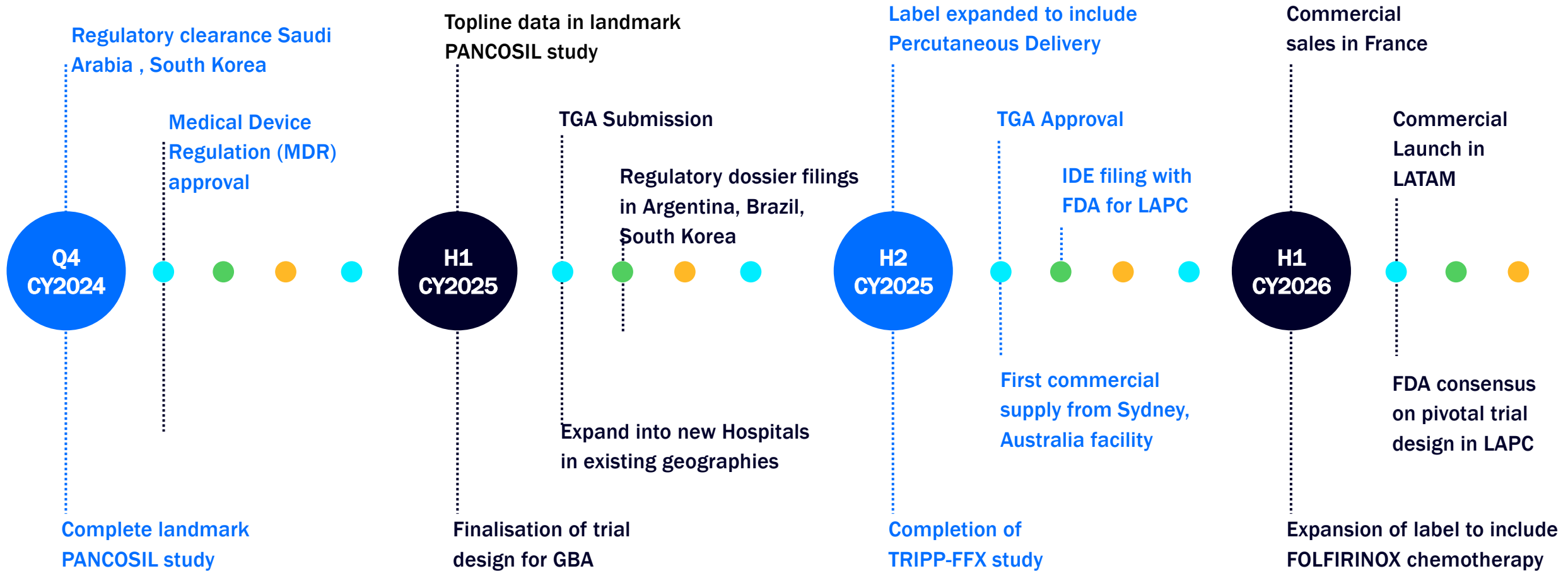


# Recent Achievements



# • Upcoming Milestones

## Significant catalysts over the next 24 months



# **Corporate Overview and Leadership Team**





# • Experienced Board and Management

## Depth in Nuclear Medicine Commercialisation



**Nigel Lange**  
Managing  
Director & CEO

30+ years' experience in medical device industry  
Served as Group COO and Interim Group CEO of Sirtex Medical



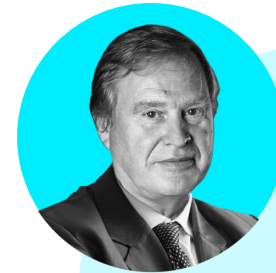
**Douglas Cubbin**  
Non-executive  
Chairman

30+ years' biopharmaceutical experience in senior roles across varied industries.  
Was a key member of Telix Pharmaceuticals (ASX:TLX) which completed IPO, raising \$270



**Gabriel Liberatore**  
Non-executive  
Director

Dr Liberatore is an experienced biopharmaceutical executive with >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

>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)

# Offer Details



# • Offer Details

## Capital Raising of up to ~A\$8m via a ~A\$7m Placement and an up to A\$1m SPP

### Placement

- An institutional placement (“**Placement**”) to raise up to approximately A\$7m via the issuance of approximately 700 million new fully paid shares in the Company (“**New Shares**”) to Professional and Sophisticated investors under Listing Rule 7.1 and 7.1A
- The New Shares to be issued under the Placement represent approximately 18.5% of OSL current shares on issue
- The Company reserves the right to increase the size of the Placement if there is additional demand.

### Share Purchase Plan

- Eligible Shareholders the opportunity to participate in a non-underwritten SPP to raise up to A\$1.0 million.
- Eligible Shareholders on the register at 7:00pm (AEDT) on Friday, 25 October 2024 in Australia and New Zealand will be invited to subscribe for up to \$30,000 of new shares free of any brokerage and transactions costs at the same price as the Placement
- OSL reserves the right to increase the size of the SPP or to scale back applications in its absolute discretion.
- New Shares issued under the SPP will rank equally with existing OSL shares.
- Further details in relation to the SPP including the timetable will be provided to eligible shareholders in an SPP booklet expected to be released following the Placement.

### Offer Price

- The Offer is at a fixed price of \$0.010 per New Share, which represents:
  - A 23.1% discount to the last close price on Wednesday 23 October 2024 of \$0.01300;
  - A 19.8% discount to a 5-day VWAP of \$0.01247; and
  - A 23.3% discount to a 15-day VWAP of \$0.01304

### Attaching Options

- New Shares will be offered under the institutional placement with one (1) free attaching option for every one (1) New Share issued (“Attaching Options”)
- The Attaching Options are intended to be listed on the ASX (subject to the Company satisfying ASX quotation requirements) with an exercise price of \$0.0150 and will expire 3 years from their issue date.
- The Attaching Options will be offered under a transaction-specific prospectus and the issue of the Options will be conditional on shareholder approval at the AGM and the Options meeting the ASX’s quotation condition

### Ranking

- New Shares issued under the Offer will rank equally with existing shares on issue.

### Lead Manager and Bookrunner

- Bell Potter Securities Limited (“**Bell Potter**”) is acting as Sole Lead Manager and Bookrunner to the Offer.

# • Use of Funds & Timetable

## Sources (A\$m)

Institutional Placement	\$8.0
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<b>Total Sources</b>	<b>A\$8.0</b>
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## Uses (A\$m)

Macquarie Park manufacturing facility	\$0.3
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Clinical trials	\$3.0
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Working Capital & Costs of the offer	\$4.7
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<b>Total</b>	<b>\$8.0</b>
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## Indicative Timetable

### Event

Trading Halt	Thursday, 24 October 2024
Bookbuild opens	10:00am (Sydney time), Thursday, 24 October 2024
Bookbuild closes for receipt of firm and irrevocable Bids	2:00pm (Sydney time), Friday, 25 October 2024
Record Date for SPP	7:00pm (Sydney time), Friday 25 October 2024
Trading resumes, Announcement of Capital Raising	Monday, 28 October 2024
Settlement of Placement	Thursday, 31 October 2024
Allotment of Placement Shares	Friday, 1 November 2024
SPP Opens	Wednesday, 6 November 2024
SPP Closes	5:00pm (Sydney time), Thursday 21 November 2024
Announcement of SPP results (subject to shareholder approval)	Thursday, 28 November 2024
Shareholder Approval of Options issued under the Offer	Wednesday, 11 December 2024
Quotation of Listed Options issued under the Offer	Wednesday, 18 December 2024

All dates are subject to change and are indicative only. OncoSil, in consultation with the Lead Manager, reserves the right to vary these dates without prior notice, all references are to AEST

The above table is a statement of current intentions as at the date of this Presentation. Investors should note that, as with any budget, the allocation of funds set out in the above table may change depending on a number of factors, including the outcome of sales performance, operational and development activities, regulatory developments, and market and general economic conditions. In light of this, OncoSil reserves its right to alter the way the funds are applied.



## Nigel Lange

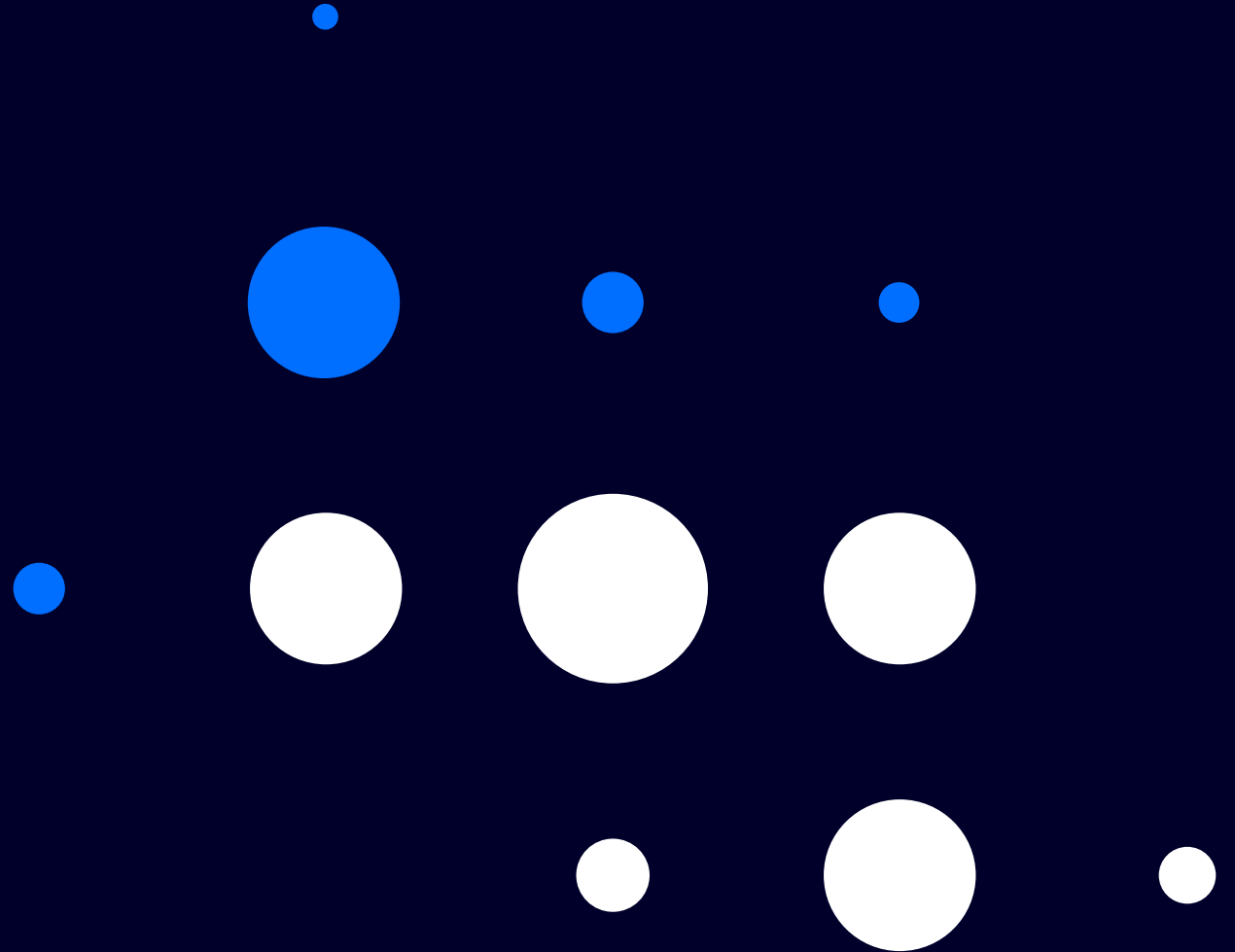
CEO & Managing Director

E: [nigel.lange@oncosil.com](mailto:nigel.lange@oncosil.com)

### Learn more about OncoSil Medical:

- [Website](#)
- [ASX announcements](#)
- [LinkedIn](#)

Targeted Approach • Positive Impact



# Appendices





# • Growing Body of Evidence

## 3 clinical studies supporting commercialisation demonstrate efficacy, safety and tolerability in LAPC

	Locally Advanced Pancreatic Cancer						Metastatic PDAC
Study	PanCO Study <sup>1</sup>	OncoPaC-1 Study <sup>2</sup>	Propensity Score Weighted Landmark Analysis <sup>3</sup>		TRIPP-FFX Study	PANCOSIL Study	Metastatic Study <sup>4</sup>
Treatment	OncoSil™ + Chemotherapy <sup>a</sup>	OncoSil™ + gemcitabine/ nab-paclitaxel	OncoSil™ + Chemotherapy <sup>b</sup>	vs. Chemotherapy <sup>b</sup> (± Chemoradiotherapy)	OncoSil™ + FOLFIRINOX vs. FOLFIRINOX	OncoSil™ + Chemotherapy <sup>a</sup>	OncoSil™ + Chemotherapy <sup>a</sup>
Sample Size	42 (50 ITT)	9	50 35 at landmark	54 66 at landmark	40 recruited of 80	10 recruited of 20	14
Local Disease Control Rate at 16 weeks	90.5%	77.8%	not reported	not reported	Ongoing Study	Ongoing Study	100%
Objective Response Rate	31.0%	22.2%	not reported	not reported			57.1%
Disease Control Rate	100%	100%	not reported	not reported			100%
Surgical Resection with Curative Intent	23.8%	0	28.6%	12.1%			7.1%
Downstaging	33.3%	not reported	31.4%	13.6%			7.1%
Local PFS, median	9.8 months	27.3 months	14.7 months	10.0 months			12.2 months
Distant PFS (dPFS), or PFS, median	9.3 months <sup>PFS</sup>	12.2 months <sup>PFS</sup>	14.2 months <sup>dPFS</sup>	11.1 months <sup>dPFS</sup>			9.2 months
Overall Survival, median	15.5 months	27.3 months	20.0 months	13.3 months			13.8 months

<sup>a</sup> Gemcitabine/nab-paclitaxel or FOLFIRINOX chemotherapy; <sup>b</sup> gemcitabine/nab-paclitaxel, gemcitabine or FOLFIRINOX chemotherapy; LAPC, locally advanced pancreatic cancer; PDAC, pancreatic ductal adenocarcinoma; PFS, progression-free survival.  
Use of OncoSil™ for metastatic pancreatic ductal adenocarcinoma (mPDAC) is off-label

**References:** **1.** Ross PJ et al. Results of a single-arm pilot study of <sup>32</sup>P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/ nab-paclitaxel or FOLFIRINOX chemotherapy. ESMO Open February 2022; 7 (1): 100356.  
**2.** OncoSil Medical Ltd. Data on file. **3.** Lim A et al. Combined phosphorus-32 implantation and chemotherapy: A comparison with standard therapy using a propensity-score weighted landmark analysis and an assessment of its impact on vascularity in locally advanced pancreatic cancer. Presented at the Gastroenterological Society of Australia's Australian Gastroenterology Week (AGW 24) Meeting; 14–16 September 2024. Journal of Gastroenterology and Hepatology 2024; 39 (Suppl. 1): 39 Abs, 337.  
**4.** Lim A et al. Outcomes of phosphorus-32 microparticle intratumoral implantation added to chemotherapy in patients with metastatic pancreatic adenocarcinoma. iGIE 2024 July 2; ePub 1–9. doi.org/10.1016/j.igie.2024.06.005.

# • Comparative analysis shows OncoSil™ increases survival and resection



Propensity Score Weighted Landmark Analysis demonstrated substantial increases in survival, local and distant progression-free survival, downstaging and resection



## Why is this analysis important?

This is the first comparative study of treatment using OncoSil™ plus chemotherapy compared with standard therapy comprising chemotherapy (± chemoradiotherapy) in patients with LAPC, and the analysis was conducted carefully in order to avoid potential bias.<sup>1</sup>

The analysis showed adding OncoSil™ to chemotherapy significantly increased survival, disease control and down-staging/resection.<sup>1</sup>

## What did the vascular study show?



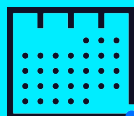
Patients with LAPC receiving OncoSil™ plus chemotherapy were compared with those receiving chemotherapy (± chemoradiotherapy) only (35 vs. 66, respectively at the landmark analysis) for a retrospective cohort study.<sup>1</sup>

20  
months

vs.

13.3  
months

Significantly increased survival in those receiving OncoSil™: median overall survival 20.0 vs. 13.3 months (p=0.001), with 3.7 months (+32.3%) longer restricted mean survival time (RMST) at 24 months from starting treatment.<sup>1</sup>



OncoSil™ also significantly increased both local and distant PFS: median local PFS was 14.7 vs. 10.0 months (p<0.01), with 3.7 months (+41.3%) longer RMST; median distant PFS was 14.2 vs. 11.1 months (p=0.02), with 2.5 months (+29.2%) longer RMST.<sup>1</sup>



Downstaging (31.4% vs. 13.6%) and resection rates (28.6% vs. 12.1%) were significantly higher following OncoSil™.<sup>1</sup>

**Footnotes:** PFS, progression-free survival; RMST, restricted mean survival time at 24 months from starting treatment.

**References:** 1. Lim A et al. Combined phosphorus-32 implantation and chemotherapy: A comparison with standard therapy using a propensity-score weighted landmark analysis and an assessment of its impact on vascularity in locally advanced pancreatic cancer. Presented at the Gastroenterological Society of Australia's Australian Gastroenterology Week (AGW 24) Meeting; 14–16 September 2024. Journal of Gastroenterology and Hepatology 2024; 39 (Suppl. 1): 39 Abs, 337.

# • Royal Adelaide Study Shows OncoSil™ Increases Tumour Vascularity

Results helps understand further the potential benefits of chemoradiotherapy using OncoSil™ over chemotherapy alone in patients with pancreatic cancer



## Why is this study important?

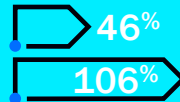
Vascularity increased in response to OncoSil™ implantation in addition to FOLFIRINOX chemotherapy.<sup>1</sup> Historical data has not supported vascularity changes in response to chemotherapy alone. Results suggest chemotherapy concentration in the tumour increases following OncoSil™ implantation.<sup>1</sup>

This is the first study in man to show vascularity of pancreatic tumours can be increased. This may increase chemotherapy concentration and further explains OncoSil™ mode of action.<sup>1</sup>

## What did the vascularity study show?



The vascularity of target tumour in 20 patients with LAPC receiving OncoSil™ plus FOLFIRINOX chemotherapy were assessed using contrast-enhanced harmonic EUS before plus 4 and 12 weeks after implantation.<sup>1,2</sup>



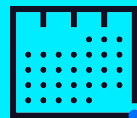
At baseline, all tumours demonstrated lower intensity of enhancement relative to surrounding normal pancreatic tissue suggestive of lower vascularity, but increased by 46% and 106% at 4 weeks ( $p=0.007$ ) and 12 weeks ( $p=0.002$ ) respectively after OncoSil™ implantation.<sup>1,2</sup>



In parallel, the median longest tumour diameter at baseline decreased by 25% at 12 weeks ( $p<0.001$ ).<sup>1,2</sup>



5 patients were downstaged and 4 patients resected following OncoSil™ (1 refused surgery).<sup>1,2</sup>



After a median follow-up of 11.2 months, 75% of patients remained alive; 15% had distant and local progression, 15% had distant progression only.<sup>1,2</sup>

**Footnotes:** EUS, endoscopic ultrasound; LAPC, locally advanced pancreatic cancer.

**References:** <sup>1</sup>. Lim AH, Zobel J, Bills M et al. The impact of combined chemotherapy and intra-tumoral injection of Phosphorus-32 microparticles on vascularity in locally advanced pancreatic carcinoma. Presented at the 54th Annual Scientific Meeting of the Australian and New Zealand Society of Nuclear Medicine (ANZSNM) in Christchurch, New Zealand. <sup>2</sup>. Lim A et al. Combined phosphorus-32 implantation and chemotherapy: A comparison with standard therapy using a propensity-score weighted landmark analysis and an assessment of its impact on vascularity in locally advanced pancreatic cancer. Presented at the Gastroenterological Society of Australia's Australian Gastroenterology Week (AGW 24) Meeting; 14–16 September 2024. Journal of Gastroenterology and Hepatology 2024; 39 (Suppl. 1): 39 Abs, 337.

# • PanCO Results Show Compelling Evidence of Downstaging

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



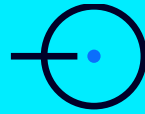
## Why is resection important?

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 resection.<sup>1</sup>

## 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% reduction.<sup>2</sup>



1 in 3 patients with unresectable LAPC receiving OncoSil™ 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 median 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).<sup>2,3</sup>

# • OncoSil™ for Metastatic Pancreatic Adenocarcinoma (mPDAC)<sup>1</sup>



## Objective



Assess clinical outcomes following delivery of novel <sup>32</sup>P microparticles via EUS-guided brachytherapy in patients with mPDAC – represents significant upside opportunity as 55% of all patients have metastases at time of diagnosis

## Location



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

## Results



- <sup>32</sup>P-microparticles implantation is safe and feasible for mPDAC patients
- Encouraging outcomes<sup>2</sup> with:
  - 100% Local disease control rate at 3 months post-implantation
  - Median local progression-free survival (LPFS) was 12.2 months from commencement of chemotherapy
  - 13.8 months median overall survival from commencement of chemotherapy
- Potential clinical benefits:
  - Local tumour control
  - Overall survival

# • Key Risks

Shareholders should consider the investment in the context of their individual risk profile for speculative investments, investment objectives and individual financial circumstances. Each Shareholder should consult their own stockbroker, solicitor, accountant or other professional adviser before deciding whether or not to invest in the Offer Securities. This is not an exhaustive list of the relevant risks and the risks set out below are not in order of importance.

## **Speculative nature of investment**

Any potential investor should be aware that subscribing for Offer Securities involves various risks. The New Shares to be issued carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those shares. The Company's business is in the commercialisation and continued development of the OncoSil™ device. An investment in the Company should therefore be considered very speculative.

## **Business risks associated with the Company**

### **Sufficiency of funding / requirement for additional capital in the future**

The Company has limited financial resources and will need to raise additional funds from time to time to finance the continued development and commercialisation of its technology / products and its other longer-term objectives. The Company's technology / product development activities may never generate revenues and the Company may never achieve profitability. The Company's ability to raise additional funds will be subject to, among other things, factors beyond the control of the Company and its Directors, including cyclical factors affecting the economy and share markets generally. The Directors can give no assurance that future funds can be raised by the Company on favourable terms, if at all. If for any reason the Company was unable to raise future its ability to achieve the milestones under this Prospectus or continue future development / commercialisation of its technology would be significantly affected.

### **Regulatory risk**

The Company and the development / commercialisation of its proposed products/technologies are subject to extensive laws and regulations including but not limited to the regulation of human medical device products. Additionally, human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. A risk exists that the Company's technology may not satisfy regulatory requirements in markets in which we are seeking approval and ultimately may not gain approval, or that the approval process may take much longer than expected. As a result, the Company may fail to commercialise or out-license any products. If the Company fails to remain compliant with these various regulatory requirements, there is a risk that the Company's financial performance could be adversely affected.

### **Research and Development**

The Company's future success is dependent on the performance of the Company's product in clinical trials and whether it proves to be a safe and effective treatment. The Company's lead product continues in clinical development and product commercialisation in markets for which it is unapproved. It requires additional research and development, including ongoing clinical evaluation of safety and efficacy in clinical trials and regulatory approval prior to marketing authorisation. Medical device development generally is often associated with a high failure rate and until the Company is able to provide further clinical evidence of the ability of the Company's product to improve outcomes in patients, the future success of the product in development remains speculative. Research and development risks include uncertainty of the outcome of results, difficulties or delays in development and the uncertainty around that surrounds scientific development of novel medical devices generally.

### **Future potential sales**

There is a risk that even after obtaining regulatory approvals, the Company's products/technologies may not gain market acceptance among physicians, patients and the medical community, even if they are approved by regulatory authorities. Physicians, patients, payers or the medical community may be unwilling to accept, use or recommend the Company's products which would adversely affect its potential reviews and future profitability.

### **Manufacturing**

Scale-up of the Company's manufacture to support commercialisation and clinical studies is substantially underway but not complete. As such, there is a risk that scale-up may present technical difficulties. Technical difficulties could include the inability to produce medical devices that meet regulatory specifications for human administration or the production from manufacturing batches may be insufficient to conduct the clinical studies as currently planned. Any unforeseen difficulty relating to manufacturing may negatively impact the Company's ability to generate profit in future.

### **Innovative and clinical stage technological development**

The Company's technology is at a clinical stage of development in unapproved markets and further development is necessary. If the Company's proposed products are shown to be toxic, unsafe for human application or ineffective for therapeutic purposes or the cost of commercial scale manufacture becomes too expensive, the value of the Company's technology and resulting value of its Shares may be materially harmed.

### **Commercial risk**

The Company may, from time to time, consider acquisition, licensing, partnership or other corporate opportunities for the Company's product development programs. There can be no assurance that any such acquisition, licensing, partnership or corporate opportunities can be concluded on terms that are, or are believed by the Company to be, commercially acceptable. In the case of licensing and partnership opportunities, even if such terms are agreed there is a risk that the performance of distributors and the delivery of contracted outcomes by collaborators will not occur due to a range of unforeseen factors relating to environment, technology and market conditions.



# • Key Risks (continued)

## **Intellectual property**

Securing rights in technology and patents is an integral part of securing potential product value in the outcomes of medical device research and development. Competition in retaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes. The Company's success depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties.

Because the patent position of medical device companies can be highly uncertain and frequently involves complex legal and factual questions, neither the breadth of claims allowed in medical device patents nor their enforceability can be predicted.

There can be no assurance that any patents which the Company may own, access or control will afford the Company commercially significant protection of its technology or its products or have commercial application, or that access to these patents will mean that the Company will be free to commercialise its product candidates.

## **Infringement of third-party IP**

If a third party accuses the Company of infringing its IP rights or if a third party commences litigation against the Company for the infringement of patent or other IP rights, the Company may incur significant costs in defending such action, whether or not it ultimately prevails. Costs that the Company incurs in defending third party infringement actions would also include diversion of management's and technical personnel's time. In addition, parties making claims against the Company may be able to obtain injunctive or other equitable relief that could prevent the Company from further developing discoveries or commercialising its products / technology. In the event of a successful claim of infringement against the Company, it may be required to pay damages and obtain one or more licenses from the prevailing third party. If it is not able to obtain these licenses at a reasonable cost, if at all, it could encounter delays in product introductions and loss of substantial resources while it attempts to develop alternative products / technology. Defence of any lawsuit or failure to obtain any of these licenses could prevent the Company or its partners from commercialising available products / technology and could cause it to incur substantial expenditure.

## **Product liability**

As with all new products, even after the granting of regulatory approval, there is no assurance that unforeseen adverse events or defects will not arise. Adverse events could expose the Company to product liability claims or litigation, resulting in the removal of the regulatory approval for the relevant products and/or monetary damages being awarded against the Company. In such event, the Company's liability may exceed the Company's insurance coverage.

## **Reliance on key personnel**

The Company currently employs a number of key management and scientific personnel. The Company's future depends on retaining and attracting suitably qualified personnel. The Company has included in its employment with key personnel, terms aimed at providing incentives attractive for the recruitment and retention of such personnel. It has also, as far as legally possible, established contractual mechanisms through employment and consultancy contracts to limit the ability of key personnel to join a competitor or compete directly with the Company. Despite these measures, however, there is no guarantee that the Company will be able to attract and retain suitably qualified personnel, and a failure to do so could materially and adversely affect the value of the Company's technology and resulting value of its Shares may be materially harmed.

## **Dependence on service providers**

The Company intends to operate a significant amount of its key activities through a series of contractual relationships with licensees, independent contractors, manufacturers, suppliers and distributors. All of the Company's contracts carry a risk that the third parties do not adequately or fully comply with its or their respective contractual rights and obligations. Such failure can lead to termination and/or significant damage to the Company's research, development and commercialisation efforts that may add time and additional costs.

## **Stock Market Volatility**

The price of Shares may rise or fall depending upon a range of factors beyond the Company's control and which are unrelated to the Company's operational performance. No assurances can be made that the Company's market performance will not be adversely affected by any such market fluctuations or factors. Investors who decide to sell their Shares after the Company's capital raising may not receive the entire amount of their original investment. The price of Shares listed on ASX may also be affected by multiple factors including the Company's financial performance and by changes in the business environment.

The Shares carry no guarantee in respect of profitability, dividends, return on capital, or the price at which they may trade on the ASX. No guarantee can be given that the Company's share price will be greater than the issue price.

## **Value of the New Options**

The New Options that are being issued as part of the Offers are issued for no additional consideration but require the exercise price for each Option to be paid at the time of exercise. If the prevailing trading price of the Company's shares during the Option's exercise period is lower than the exercise price for the New Options, then it is likely that the New Options will not be exercised. In this case, for investors, the unexercised New Options will not have a value and will lapse on the respective expiry dates of the New Options. If the New Options are not exercised, or only some are exercised, then the Company may not receive the proceeds that would otherwise be generated if Option holders pay the Option exercise price. This possibility may reduce the amount of capital that the Company would receive if all of the New Options are exercised on or before the respective Option expiry dates.

# • International Offer Restrictions

This document does not constitute an offer of new ordinary shares (“New Shares”) of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

## **Hong Kong**

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the “SFO”). Accordingly, this document may not be distributed, and the New Shares may not be offered or sold, in Hong Kong other than to “professional investors” (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

## **New Zealand**

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the “FMC Act”).

The New Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

## **Singapore**

This document and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the “SFA”) or another exemption under the SFA.

This document has been given to you on the basis that you are an “institutional investor” or an “accredited investor” (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.