



Investor Presentation

15 July 2026

Targeted Approach • Positive Impact

ASX Code: OSL



Corporate Summary

Focus

A Class III medical device company focused on localised treatments for patients with unresectable locally advanced pancreatic cancer (LAPC) and more recently distal cholangiocarcinoma (dCCA) under a pending HDE in the US

Key Product: OncoSil™ device (approved in 34+ countries)
Breakthrough Device Designation: US, Europe + UK



Corporate Summary^{1,2}

Share price (ASX:OSL) **\$1.40**

Shares on Issue **30.9 million**

Market Capitalisation **\$43.3 million**

Cash (31 March 2026) **\$9.3 million**

Enterprise Value **\$34.0 million**

Options ASX:OSLOE (\$0.90 | 30 Jun-27) **12.1 million**

Options ASX:OSLOD (\$1.20 | 31 Jul-27) **7.7 million**

Top 20 Shareholders **58.4%**

Substantial Shareholders
Pengana Capital (20.2%)
Regal Partners Funds (10.4%)
Australian Ethical (8.4%)

Analyst Coverage Nick Lau | Dr Dennis Hulme: Taylor Collison

1. Share price, investor data as at 13 July 2026
2. Financial data per OncoSil Medical financial reports

Directors / Management

Dr Thomas Duthy

Non-Executive Chairman

Nigel Lange

CEO & Managing Director

Lelde Smits

Non-Executive Director

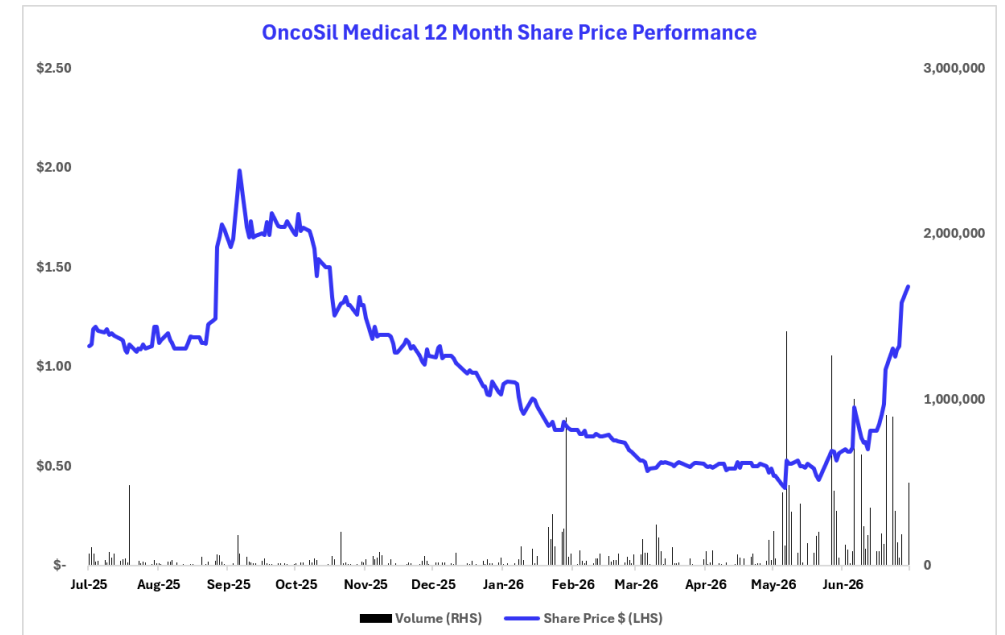
Shelley Steyn

Chief Financial Officer

Renzo DiCarlo

Head of Operations & Development

Share Price Graph



• Executive Summary

Commercialising targeted radiotherapy for pancreatic cancer

- OncoSil Medical is commercialising the OncoSil™ device, an implanted device (brachytherapy) delivering targeted radiation (³²P) to pancreatic tumours
- OncoSil™ device is now **approved for sale in over 34 countries** via CE Mark
- **Commercial ramp-up** has commenced in FY26, driven by significant growth in existing European markets
- TGA approval received in Australia
- Reached **final FDA review stage** for Humanitarian Device Exemption (HDE) application in the United States (US) for distal cholangiocarcinoma (dCCA)
- **Increasing market access** via label expansion combining new delivery methods and new chemotherapy combinations¹
- \$2.1 million investment in new Sydney facility supports a potential \$98 million revenue opportunity at ~70% Gross Margin at scale
- **Platform technology** can be leveraged into other cancer indications (Bile duct cancer, liver, glioblastoma)
- Experienced Board & Management team in the commercialisation of interventional oncology devices

>US\$4.2bn global addressable market³

- 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 2035²**
- Negligible survival improvement in over 20 years with <12% survival rates at 5-years and 8.5 months median overall
- Existing commercial markets have an addressable total market of approximately **\$900 million** annually
- Patient recruitment completed for **PANCOSIL & TRIPP-FFX** trials, targeting:
 - ✓ **Percutaneous** delivery to drive market access and clinical adoption globally
 - ✓ Label expansion in addition to standard-of-care chemotherapy (**FOLFIRINOX**)

• Executive Summary (cont.)

Significant achievements over FY26

- Patient recruitment completed for **PANCOSIL** study and preliminary data presented at CIRSE 2025 Congress (a groundbreaking delivery method for OncoSil™ device)
- **TRIPP-FFX** trial (to expand OncoSil™ device label with additional chemotherapy combination) **meets co-primary endpoints** and initial data presented at ESMO GI 2026 Congress
- **OSPREY** Interim results presented at ESGE Days 2026 Congress
- **TGA** Approval received in Australia
- Second manufacturing facility in **Sydney**, Australia activated, validation has been successfully completed, awaiting regulatory approval
- **US FDA** confirmed all outstanding questions relating to HDE application for the treatment of dCCA have been satisfactorily addressed. Remaining documentation submitted and awaiting the approval
- German Federal Joint Committee (**G-BA**) tender process underway to appoint a CRO
- First patient treatments completed at **Germany, Portugal** and the **UK**

Momentum achieved in late FY26 is expected to continue in FY27, which is anticipated to deliver significant regulatory, manufacturing and commercial milestones for OncoSil Medical:

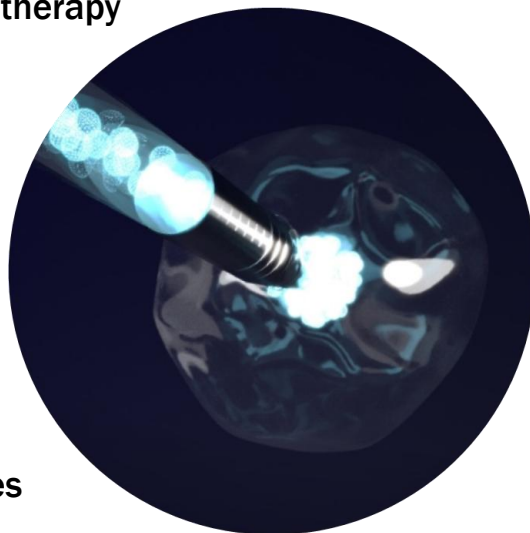
- Expanding market access for **LAPC** and **dCCA** patients
- Facilitating new combinations of the **OncoSil™** Device with standard chemotherapy in first-line **LAPC**
- Facilitating new treatment delivery method for the **OncoSil™** device
- New manufacturing to simplify supply and expand margins

• OncoSil™ Device

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

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



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**

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

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

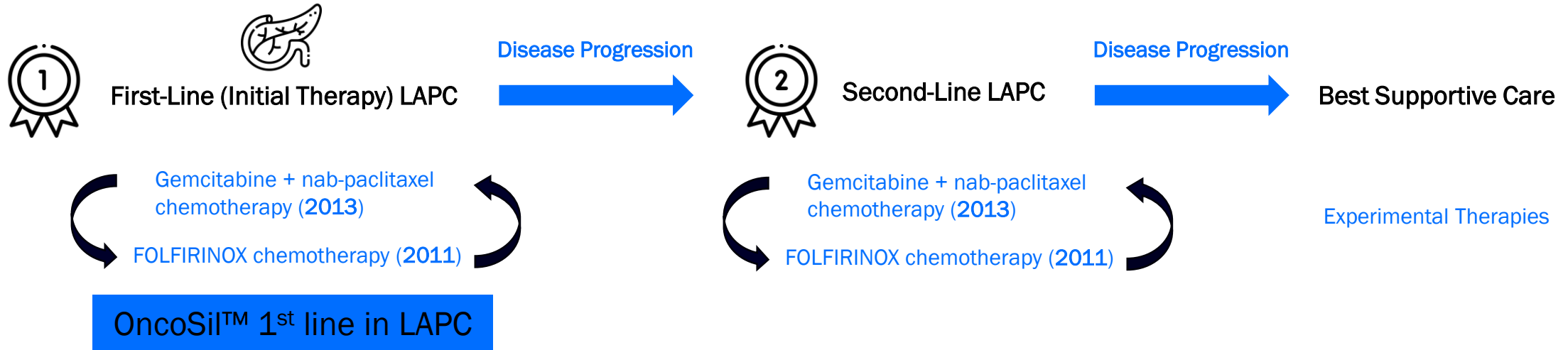
- ✓ Expanding the number of treating clinicians to include **Interventional Radiologists**
- ✓ Broader patient access and points of care
- ✓ Outpatient day procedure
- ✓ Conscious sedation (patient awake)

Label extension with FOLFIRINOX chemotherapy*:

- ✓ Accelerates market penetration with label expansion to include coverage of OncoSil™ device in addition to standard-of-care chemotherapy (FOLFIRINOX)

• Pancreatic Cancer Treatment Has Seen Limited Guideline Evolution

Reinforcing the significant unmet need for new therapeutic approaches



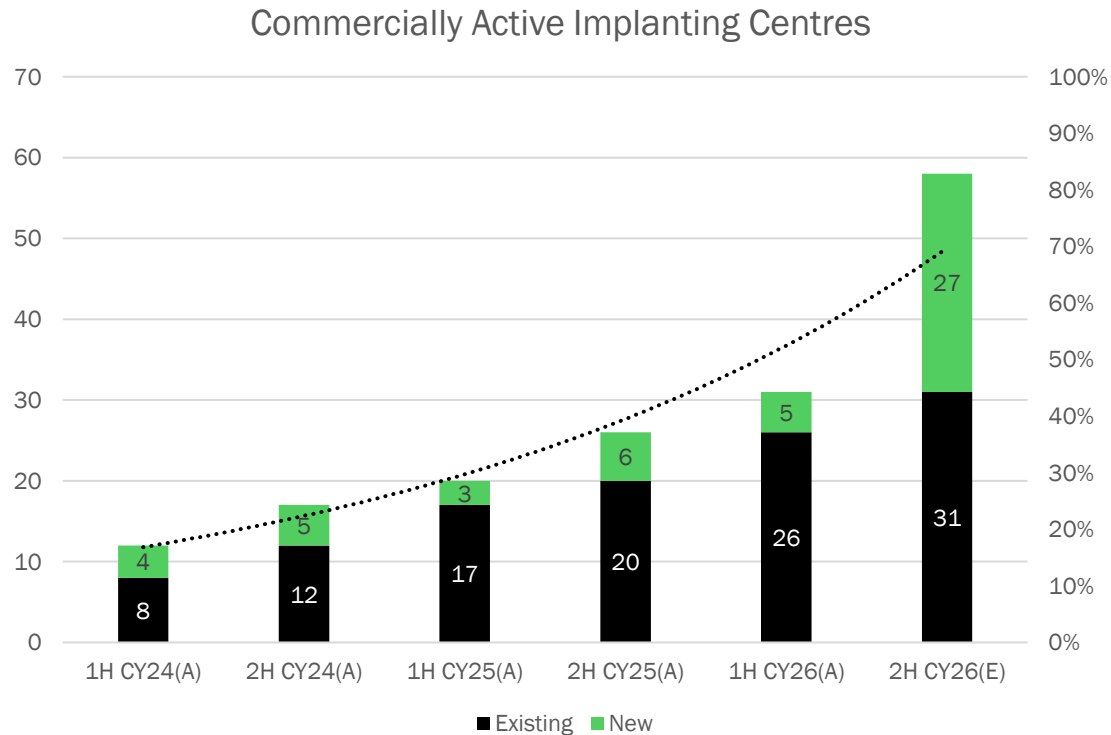
Guideline recommendations have remained largely consistent across multiple annual updates, only change has been NALIRIFOX in 2024 – 10+ years after initial clinical data for other regimens



OncoSil™ device is **chemotherapy agnostic**; immunotherapies (mono therapy / combination therapies) have shown no survival benefit – hence, no incorporation into treatment guidelines (NCCN, ESMO) – significantly lower risk of product obsolescence

Expanding Commercial Footprint Across Key European Markets

Growing number of active implanting centres to drive revenue momentum



Germany



- 2 hospitals already opened before G-BA trial
- 40 new hospitals expected to start by 1H CY27
- Expecting to commence G-BA trial in 2H CY26
- **Patients' ineligible for trial may still be treated commercially** provided they are candidates for OncoSil™ treatment

Spain



- Largest revenue-contributing market
- 9 hospitals routinely ordering and treating with OncoSil™
- 4 new hospitals are expected to start in CY26
- Strong referral acceptance from oncologists and surgeons

Italy



- 5 hospitals routinely ordering and treating with OncoSil™
- 4 new hospitals are expected to start in CY26
- OncoSil™ adopted by two leading hospitals — University of Verona and San Camillo Forlanini Hospital
- Revenue contribution expected to increase significantly in 2H CY26 following finalisation of individual tender agreements

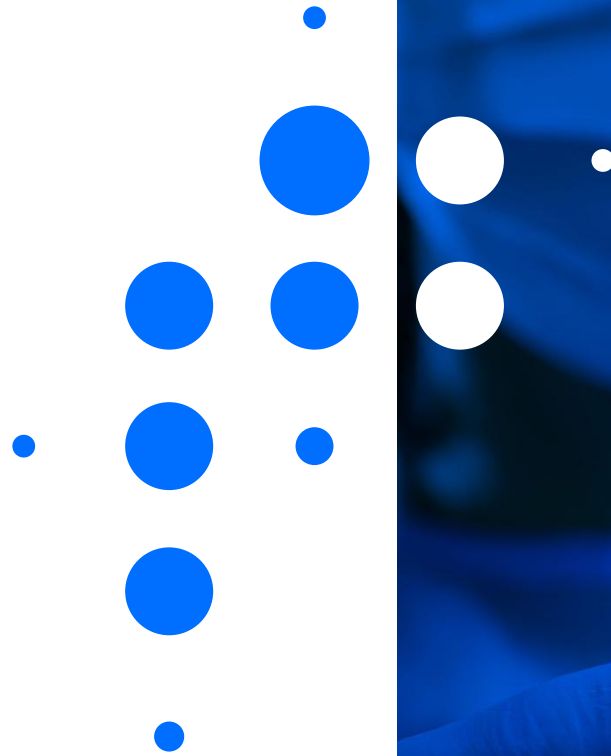
Turkiye



- 5 hospitals routinely ordering and treating with OncoSil™
- 4 new hospitals are expected to start in CY26
- **Cumulatively 45% resection rate in real-world setting**
- One of the largest potential markets in oncology and nuclear medicine treatments
- Ongoing referral education initiatives to increase patient flow

G-BA Funded Study

*German Federal Government Funded
Expected to be announced 1H FY27
~\$47 million in est. value accretion*



Germany: Capital-Efficient Phase III with Commercial Momentum

System-funded clinical evidence generation alongside ongoing commercial use



Population	~ 84 million
Pancreatic Cancer Incidence p.a. ¹	22,587
Locally Advanced Pancreatic Cancer p.a.	6,776
Market Opportunity p.a.	\$264 million



The top 40 German pancreatic cancer centres performed approximately 4,400 complex pancreatic surgeries in 2024², accounting for ~40% of all such procedures nationwide.

These high-volume centres represent our primary targets for commercial adoption, alongside their anticipated participation in the G-BA trial³.

Abbreviation: G-BA: Gemeinsamer Bundesausschuss (Federal Joint Committee).

References: **1.** Globocan 2025 data **2.** <https://www.aok.de/pp/hintergrund/mindestmengen/mindestmengen-transparenzkarte-2026/> **3.** The centres with appropriate nuclear medicine facilities capable of delivering OncoSil™ device

• G-BA Market Opportunity



4,400



Est. LAPC patients within G-BA Centres (n=40)

280



Est. LAPC patients to be recruited into G-BA Trial¹

4,120



Est. pool of patients potentially able to receive OncoSil™ outside of trial within G-BA sites (eligible for reimbursement²)

\$168 million (annually)



Serviceable market opportunity with high sales synergies

• How the G-BA Initiative Accretes Significant Value in OncoSil

\$5.6 million



Direct Sales Revenue Over Trial Period¹

\$6.5 million



Potential ancillary commercial sales at G-BA sites over Trial Period²

\$35.0 million



Est. cost if OncoSil Sponsored Identical G-BA Trial

Additional Actual + Potential Intangible Benefits



- Level 1 evidence trial (gold standard for regulators/clinicians)
- Positive data provides National Reimbursement in Germany
- Incorporation into German consensus treatment guidelines
- Potential for other European consensus treatment guidelines
- Important for Health Technology Assessments (HTAs) re: further reimbursement in additional markets (e.g. NICE UK, HAS France)
- Significantly increases trained clinicians in Germany, driving future adoption patterns

\$47.1 million



Total est. value accretion

1. At the commercial selling price per OncoSil™ treatment
2. Trial recruitment expected to be over a two-year period, commencing 1H CY26

Clinical Trials

Two substantive studies reported both meeting primary endpoints

Total investment (ex COGS) - \$8.1 million

Two major regulatory changes to approved label in FY27



OncoSil
MEDICAL

Preliminary results from the **PANCOSIL** Investigator Initiated Study, presented at the CIRSE 2025, demonstrate that CT-guided percutaneous administration of OncoSil™ is safe and feasible.

- [illegible]

- **Expanded physician access:** Broadens treating base to include Interventional Radiologists (IRs)
- **Compelling healthcare economics:**
 - 10–20-minute procedure time
 - Outpatient setting*
 - Conscious sedation (no general anaesthesia)
- **High procedural familiarity:** IRs experienced in minimally invasive, tumour-directed radiation therapies (e.g. SIR-Spheres[®], TheraSphere[™], QuiremSpheres[®])
- **Portfolio strategy:** Attractive tuck-in product for surgical and interventional offerings

European IR Market Dynamics



> 5,000 Interventional Radiologists



CAGR 7-8% into 2030



~ 2,000 Interventional Radiologists in Germany



Active Tumour Board Participation

• M&A Activity in the Interventional Radiology Space



Significant M&A Activity in IR/Interventional Oncology since 2018

Acquirer

Boston
Scientific

CGE 远大健康
CGE HEALTHCARE

VARIAN
medical systems

TERUMO

SIEMENS
Healthineers



Target

Intera®
Oncology

SIRTeX

endocare
extending life every day®

Quirem

varian
A Siemens Healthineers Company

BSIDIO
Redefining Therapeutic Embolization

BTG

Alicon (China)

Boston
Scientific
[Embolitic Bead Business]

• **TRIPP-FFX: Positive Phase II Results Support FOLFIRINOX Label Expansion**

Preliminary results from the **TRIPP-FFX** Trial, presented at the ESMO GI 2026, demonstrated that the **study met both co-primary endpoints**, supporting the use of OncoSil™ alongside standard-of-care FOLFIRINOX chemotherapy in patients with unresectable LAPC.

- OncoSil will file a change notification with the British Standards Institute (BSI) for its existing regulatory approval (CE Mark) in 1H FY27¹
- Anticipate regulatory acceptance in 2H FY27 & commence on-label marketing of OncoSil™ device in addition to standard-of-care FOLFIRINOX chemotherapy

Study Results

- Study met both co-primary endpoints (Safety and LDCR at 16 weeks)
- **Median OS:** 21.3 months for OncoSil™ + FOLFIRINOX arm; 15.6 months for FOLFIRINOX only arm¹
- **LDCR at 16 weeks:** 85.0% for OncoSil™ + FOLFIRINOX arm¹
- **12.5% resection rate**, with 60% R0 margins¹
- Manageable safety profile

Commercial Implications

Regulatory

- Supports label expansion to include FOLFIRINOX

Clinical

- Validates OncoSil™ device alongside standard-of-care chemotherapy

Market Access

- Accelerates market penetration by aligning with established treatment pathways

Commercial

- Strengthens physician adoption and supports broader uptake of OncoSil™ device

1. Per protocol (PP) Analysis

• TRIPP-FFX: Positive Phase II Results Support FOLFIRINOX Label Expansion

	FOLFIRINOX		OncoSil™ device + FOLFIRINOX	
	ITT (n=43)	PP (n=41)	ITT (n=45)	PP (n=40)
LDCR at 16 weeks * (95% CI)	86.0% (72.1–94.7)	85.4% (70.8–94.4)	82.2% (67.9–92.0)	85.0% (70.2–94.3)
Best Overall Response *				
Partial Response	37.2%	36.6%	55.6%	60.0%
Stable Disease	51.2%	53.7%	31.1%	30.0%
Progressive Disease	9.3%	9.8%	8.9%	10.0%
Missing	2.3%	0	4.4%	0
Surgical Resection	11.6%	7.3%	11.1%	12.5%
R0 margins	16.7%	33%	60%	60%
Tumour Volume, median maximal change	–57.0%	–55.9%	–72.1%	–72.2%
Local PFS,* median months (95% CI)	11.8 (7.8–nc)	9.9 (7.8–nc)	12.8 (7.8–nc)	12.8 (11.2–nc)
PFS,* median months (95% CI)	9.9 (7.8–nc)	9.9 (7.5–nc)	12.1 (7.8–15.1)	12.1 (7.8–15.1)
Overall Survival, median months (95% CI)	15.8 (10.2–nc)	15.6 (10.2–21.0)	18.2 (13.8–nc)	21.3 (13.8–nc)
Follow-Up, median months (95% CI)	12.2 (9.9–17.0)	Not reached	12.4 (11.0–17.0)	Not reached

• PALACROS Participation and PULSE Trial Investment Rationale

Clinical trial insights supporting strategic investment decisions

What the PULSE Study Is

- **Study Purpose and Consortium:** PULSE is a Phase II trial evaluating the OncoSil™ device within the PALACROS European academic consortium focused on LAPC treatment.
- **Study Design and Patient Population:** The trial enrolls 120 patients with unresectable LAPC post-chemotherapy, comparing single versus repeat OncoSil™ device implantations.
- **Primary and Secondary Endpoints:** Primary endpoint is 9 month local progression-free survival (LDCR); secondary endpoints include survival, quality of life, and safety measures.
- **Integration and Significance:** PULSE integrates OncoSil Medical into Europe's largest pancreatic cancer research, building on earlier studies for credible multimodal therapy evidence.



PULSE Phase II Trial as a Value Driver

- **Capital-Efficient Clinical Development:** OncoSil™ device treatments provided in-kind as part of the trial, with no other study related-costs applicable, resulting in estimated cost savings of **\$9 million** versus an OncoSil Medical sponsored study.
- **Regulatory and Payer Engagement:** Academic trial participation enhances evidence credibility, supporting regulatory approval and reimbursement discussions.
- **Commercial Upside Potential:** Positive trial outcomes could increase **patient treatments and revenue** through broader adoption and repeat use.

US FDA Approval

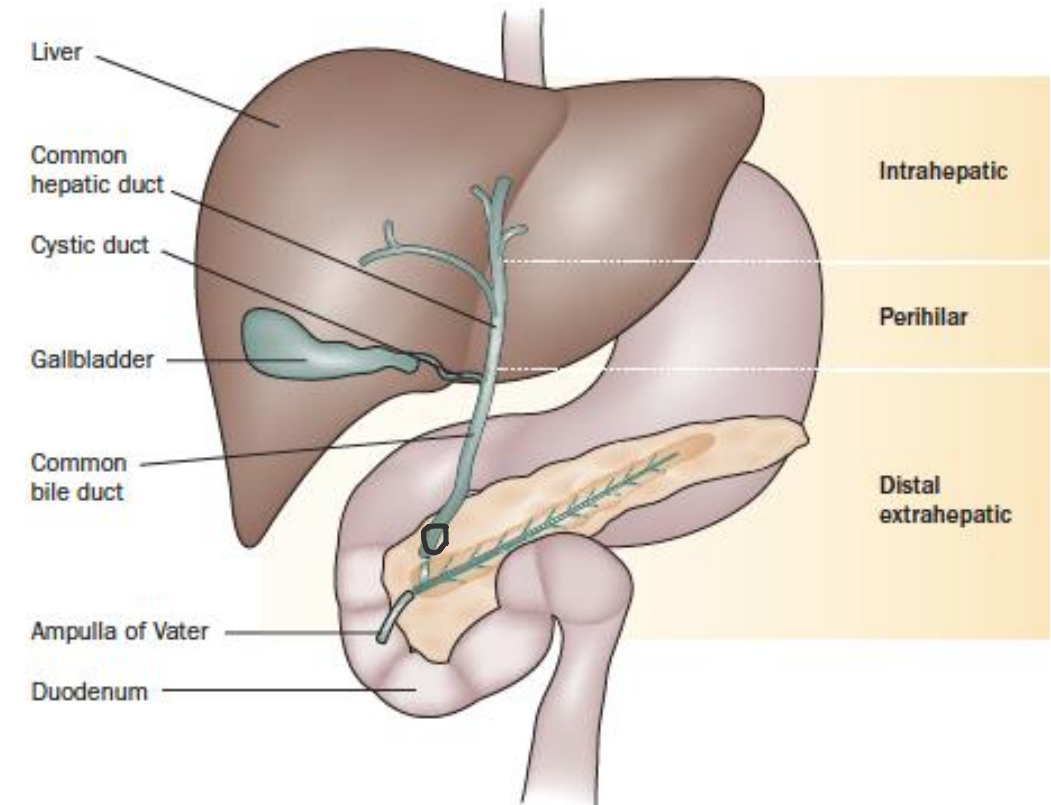
*Humanitarian Device Approval (HDE) expected in August 2026
dCCA a rare, largely untreatable cancer with poor survival*



• Distal Cholangiocarcinoma (dCCA)

Patients with dCCA have a poor prognosis with limited treatment options and survival

- dCCA develops as a cancerous tumour in the common bile duct within the head of the pancreas.
- Clinical symptoms of the disease are not evident until the tumour has developed to a point that it is difficult to remove with surgery.
- More than 50% of patients who develop dCCA cannot have the tumour removed surgically (the tumour is “unresectable”)¹.
- Treatments for unresectable tumours involve the placement of a stent, chemotherapy, external radiation therapy, or a combination of the two.
- Side effects due to chemotherapy and radiation therapy are considerable and have a negative impact on the quality of life for the patient.
- OncoSil™ has shown considerable promise for dCCA² and is the basis for the HDE.
- The advantage of OncoSil™ is the ability to deliver a high radiation dose to the target dCCA tumour with minimal side-effects.



References:

1. Hester CA, Dogeas E, Augustine MM, et al. Incidence and comparative outcomes of periampullary cancer: A population-based analysis demonstrating improved outcomes and increased use of adjuvant therapy from 2004 to 2012. *J Surg Oncol* 2019; 119:303-317. doi: 10.1002/jso.25336
2. 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.

• HDE: Accelerating US Market Access for OncoSil™ in dCCA

What is HDE Pathway?

- Designed for medical devices targeting rare diseases affecting **fewer than 8,000 individuals** annually
- Permits approval based on demonstration of **probable benefit outweighing risk**, rather than requiring the extensive clinical evidence of a costly Phase III randomised clinical trial needed for a Pre-market approval (PMA)
- Provides **shortened market access with a cost-efficient route**

Why HDE is Relevant for OncoSil™ in dCCA

- dCCA is a rare and highly aggressive cancer with limited treatment options and poor prognosis
- OncoSil™ device is being positioned as a **novel, localized radiation treatment** that may address a **significant unmet need** in this patient population
- Under this approval, OncoSil Medical will be authorised to **commercially market and sell** the OncoSil™ device in the US*

Strategic Benefit for OncoSil Medical

- **Reduced** clinical development **burden and cost (no randomised trial)**
- **Earlier US commercial entry** opportunity
- **Homogeneous reimbursement landscape**
- **Shorter regulatory timeline** versus PMA
- Ability to generate **real-world evidence** and physician adoption post-approval
- Establishes US market presence in a high-value oncology indication

HDE Eligibility → FDA Approval → Coding & Reimbursement → Initial Commercialisation → US Adoption

• OncoSil™ Advances to Final Administrative Stage Before Potential FDA HDE Approval



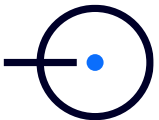
Major Regulatory Milestone Achieved

- On 3 June 2026, the FDA confirmed that all previously raised questions have been [satisfactorily addressed](#).
- Completion of the substantive review process represents the most advanced stage reached in the Company's U.S. regulatory program.



Final FDA Requirements

- The FDA has requested submission of:
 - Final device labelling for the OncoSil™ device – [submitted 2 July](#)
 - Any required updates to the proposed post-market study – [submitted 2 July](#)



Clear Path to Approval

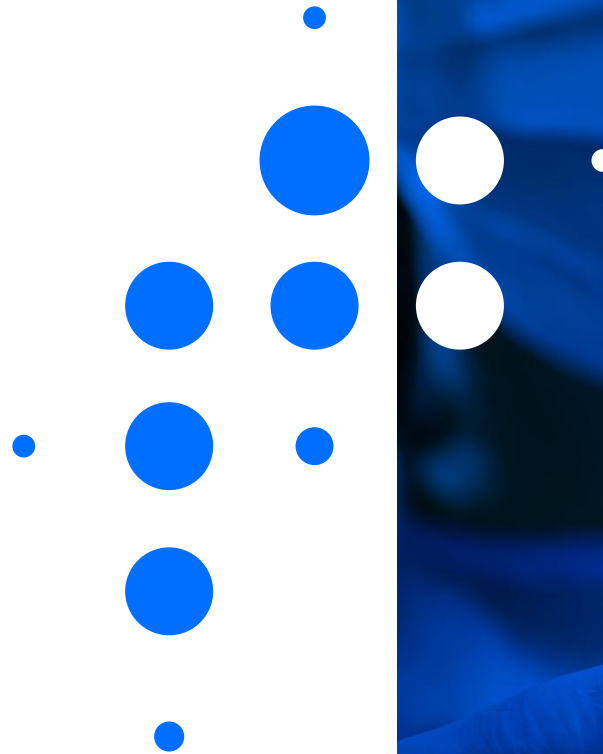
- Following receipt of the requested information, the FDA indicated its intention to [complete the review within 45 days](#) and [grant the HDE](#).
- Potential HDE approval would establish OncoSil's first U.S. regulatory approval pathway.

Manufacturing

Investment largely complete

Strong economics <5% capital intensity

Supports potential sales of ~\$100 million at full capacity



• Technology & Innovation

Macquarie Cyclotek site

Key Milestones

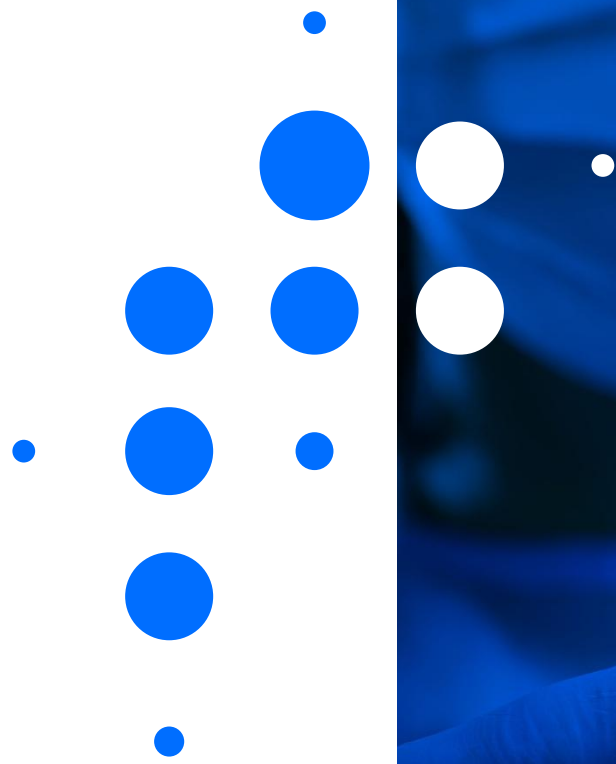
- Established a dedicated Australian manufacturing capability at Macquarie Park through a strategic partnership with Cyclotek.
- Successfully completed three manufacturing validation cycles with Cyclotek, producing more than 50 validation doses of the OncoSil™ device.
- Commercial production expected to commence in **2H CY2026**, subject to final regulatory approval.

Strategic Benefits

- Scalable production platform capable of supporting increasing global commercial demand.
- Capital-efficient manufacturing model combining Cyclotek's infrastructure with OncoSil-owned manufacturing equipment and proprietary process.
- Greater control over product quality, manufacturing capability and supply chain resilience.
- Expected to improve gross margins over time through enhanced manufacturing efficiencies.



Outlook



• Upcoming Milestones in FY27

1H FY27

-  OncoSil™ device US label filing to FDA (HDE)
-  Presentation of TRIPP-FFX Clinical Trial Results at ESMO GI Congress
-  Completion of validation of manufacturing at Cyclotek
-  PALACROS European consortium | PULSE trial
- G-BA funded study commencement
- FDA HDE approval for distal cholangiocarcinoma (dCCA)
- EU regulatory submission – percutaneous label change (PANCOSIL)
- EU regulatory submission – FOLFIRINOX label change (TRIPP-FFX)
- Commercial sales from OncoSil | Cyclotek manufacturing facility in Sydney*

2H FY27

- EU regulatory approval – percutaneous label change (PANCOSIL)
- EU regulatory approval – FOLFIRINOX label change (TRIPP-FFX)
- Launch of OncoSil™ device in Australia
- Launch of OncoSil™ device in the United States*



Learn more about OncoSil Medical:

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

Targeted Approach • Positive Impact

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

