**ASX Announcement**

**18 November 2026**

# Chairman's Address to 2026 Annual General Meeting

**Sydney, Australia – 18 November 2026:** OncoSil Medical Limited (ASX: OSL) ("OncoSil Medical" or "the Company"), a medical device company focused on localised treatments for patients with unresectable locally advanced pancreatic cancer (LAPC) and distal cholangiocarcinoma (dCCA), is pleased to provide the Chairman's address to today's Annual General Meeting to be held virtually.

## Chairman's Address

Good morning, and welcome.

On behalf of the Board of OncoSil Medical Limited, it is my pleasure to welcome you to the Company's 2026 Annual General Meeting, covering the financial year ended 30 June 2026 (FY26). I would like to begin by thanking our shareholders for their continued support during a year of significant achievement and important transition for the Company.

This is my second Chairman's Address. I joined the Board in July 2025 and became your Chairman on 1 October 2025. Our mission remains unchanged: to expand access to a differentiated, targeted radiation option for patients with pancreatic cancer, a disease with one of the lowest survival rates of any major cancer, and more recently, following a pivotal US regulatory approval, for a rare bile duct cancer called distal cholangiocarcinoma.

FY26 was a transformative year, moving OncoSil Medical from a development-stage company to one positioned for commercial expansion across multiple major markets. The year was marked by landmark regulatory approvals, a growing body of clinical evidence, accelerating commercial adoption and disciplined capital management.

In May 2026, the Therapeutic Goods Administration approved the OncoSil™ device, the first and only TGA-approved Class III device that targets tumours directly within the pancreas. On 17 August 2026, the US Food and Drug Administration approved our Humanitarian Device Exemption application for distal cholangiocarcinoma. These approvals represent significant milestones in our journey and position the Company to launch in both Australia and the United States during the first half of calendar year 2027.

Our clinical evidence continued to deepen throughout the year. TRIPP-FFX met both co-primary endpoints, delivering an 82.2% local disease control rate at 16 weeks and median overall survival of 18.3 months when OncoSil™ was combined with FOLFIRINOX. Although the study was non-comparative, the results support

expanding our label to better align with current standards of care.

PANCOSIL demonstrated that percutaneous delivery is both safe and feasible, while interim data from the OSPREY registry showed median overall survival of 20.6 and 22.0 months in first-line patients. The Company is working towards submitting regulatory applications to extend the device's CE Mark to include use in combination with FOLFIRINOX and percutaneous delivery before the end of calendar year 2026.

In Germany, which remains central to our European strategy, we expect to announce the outcome of the G-BA process prior to the end of this calendar year, with this fully funded trial is expected to commence in the first half of calendar year 2027. As investors will recall, OncoSil will receive a full commercial price for each patient who is randomised to the OncoSil™ device arm in the trial. While the commencement timeline has moved beyond our original expectations, we remain encouraged by the continued support for this important study and its potential to support future reimbursement and adoption throughout Europe. We appreciate the patience and ongoing support of shareholders as we work through this process.

Commercially, unit sales grew 53% and revenue increased 44% to $1.68 million, while customer receipts increased 179% to $2.1 million. During the year, we treated our first commercial patients in Portugal, Germany and the United Kingdom.

We also achieved important manufacturing milestones. Cyclotek obtained ISO 13485 certification and, earlier this month, the Company submitted an application to its Notified Body to include Cyclotek's Macquarie Park facility in Sydney as a critical subcontractor under OncoSil Medical's existing certification. This represents another important step towards supporting future commercial demand from a local manufacturing base.

During FY26, we undertook a comprehensive review of the cost base and identified annualised savings of between $3.4 million and $3.9 million from FY27. We also expect research and development expenditure to reduce as major clinical trials move towards completion. These initiatives are designed to extend our cash runway while maintaining focus on the commercial and regulatory milestones most critical to the creation of long-term shareholder value.

In September, OncoSil Medical secured commitments of $5.6 million from its three largest institutional shareholders, Pengana High Conviction Equities Fund, Regal Partners and Australian Ethical Investments. Raising capital from our existing major holders and without dilution to other shareholders through a large discount, is a strong endorsement of the Company’s strategy and outlook.

Looking ahead, our priorities for FY27 are clear. We intend to launch in the United States and Australia, commence the G-BA trial, progress our CE Mark extensions, expand adoption across Europe and begin selling commercial doses from our new Macquarie Park facility.

There are risks associated with any growth strategy, including regulatory timing, market adoption, reimbursement and funding requirements. However, the Board believes the Company enters FY27 with greater regulatory momentum, stronger clinical support and a clearer pathway to commercial growth than at any point in its history. We have approved products, a strengthening evidence base, an improving commercial platform and a dedicated team focused on execution.

On behalf of the Board, I would like to thank our shareholders for their continued support and confidence, our employees for their dedication and commitment, our clinicians and investigators for advancing the clinical evidence supporting our technology, and our partners for their collaboration throughout the year.

Most importantly, we thank the patients who place their trust in our technology. Their outcomes remain at the centre of everything we do.

Dr Thomas Duthy

Chairman

**Ends.**

Click **here** to view this announcement on Investor Hub.

**Authorisation & Additional Information**

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

**For further information, please contact:**

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|---|---|
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**About OncoSil Medical**

OncoSil Medical (ASX) is a global medical device company focused on Interventional Oncology, with a mission to improve outcomes for people living with cancer. The company has developed OncoSil™, a single-use brachytherapy (internal radiation) device that delivers a pre-determined dose of beta radiation directly into cancerous tissue using targeted intratumoural placement of Phosphorous-32 ($^{32}$P) Microparticles. Its targeted approach enables a greater radiation dose to be delivered directly to the tumour while limiting exposure to surrounding critical organs.

In the United States, OncoSil™ is indicated for the treatment of patients with distal cholangiocarcinoma (dCCA) that is both unresectable (locally advanced and/or unfit for surgery) and non-metastatic, as an adjunct to systemic therapy. In markets outside the United States where OncoSil™ has received regulatory approval, OncoSil™ is indicated for the treatment of patients with unresectable locally advanced pancreatic cancer, in addition to gemcitabine-based chemotherapy.

Pancreatic cancer is the 12$^{th}$ most common cancer in men and the 11$^{th}$ most common cancer in women across the globe, with 500,000 new cases detected every year[1]. Since pancreatic cancer is generally diagnosed at a later stage, it has a poor prognosis for long-term survival. Distal cholangiocarcinoma (dCCA) is a rare form of bile duct cancer. It is often diagnosed at an advanced stage, when surgical treatment may no longer be possible, and is associated with a poor prognosis.

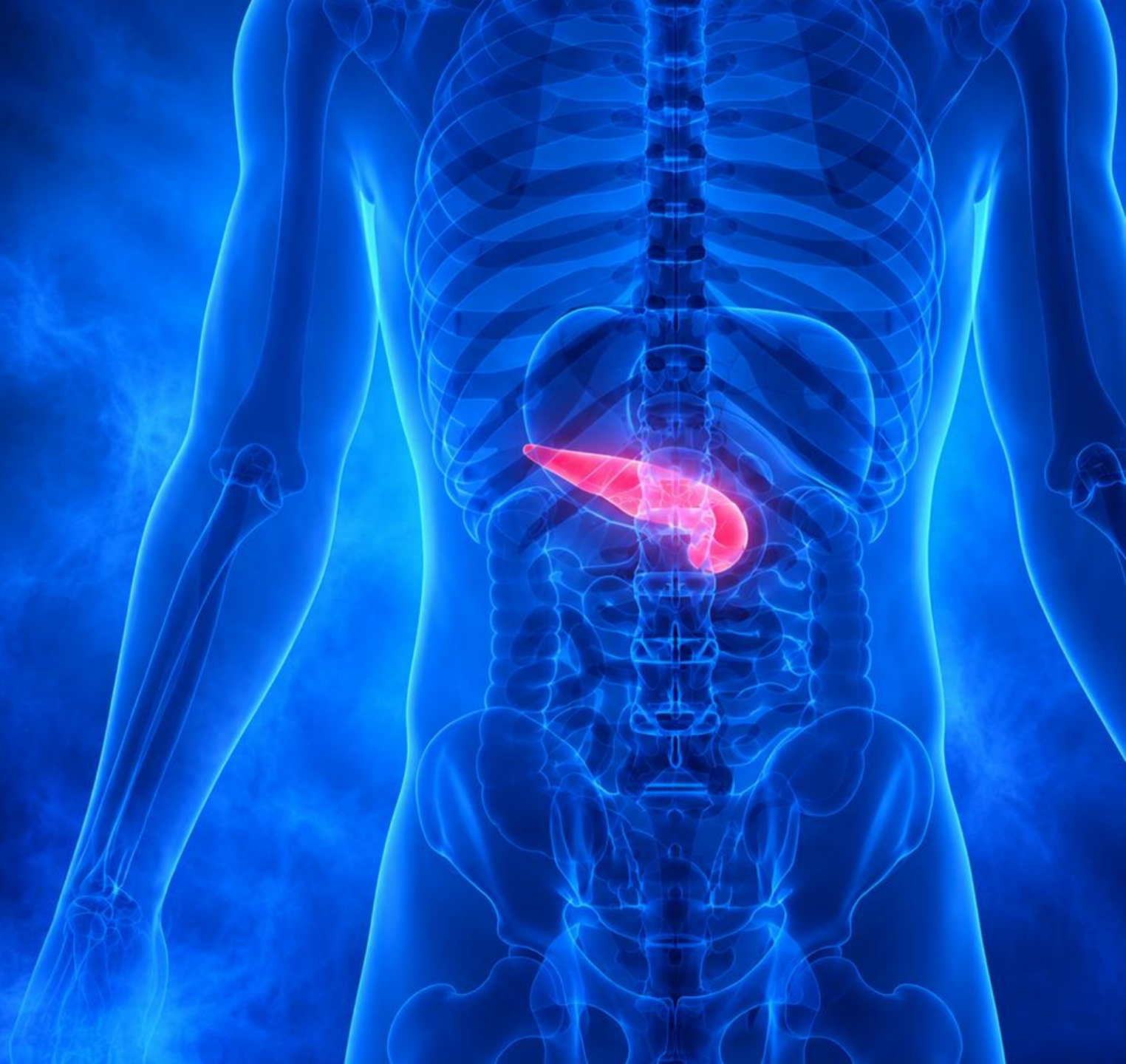
OncoSil™ has received CE Marking approval, providing marketing authorisation in the European Union and the United Kingdom. OncoSil™ has also received approval from the U.S. Food and Drug Administration (FDA) under a Humanitarian Device Exemption (HDE) for the treatment of patients with unresectable, non-metastatic distal cholangiocarcinoma (dCCA), as an adjunct to systemic therapy. OncoSil™ has been designated as a Breakthrough Device in Europe and the United States. It is currently approved for sale in 30+ countries, including the European Union, United Kingdom, United States, Australia, Saudi Arabia, Türkiye and Israel, with commercial treatments using the device already undertaken in Spain, Italy, Austria, Germany, Greece, Türkiye, Portugal, Israel and the UK.

To learn more, please visit: www.oncosil.com/

[1] https://gco.iarc.fr/en

# AGM Presentation

**Commercial Inflection:**
Capitalising on global regulatory approvals and high-margin scalability



**OncoSil Medical Limited (ASX:OSL)**
**18** November 2026

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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 in relation to the underwritten accelerated non-renounceable rights issue and placement to institutional investors of new fully paid ordinary shares in the Company (New Shares) and attaching options. 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.

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All dollar values are in Australian dollar ($A) terms unless otherwise stated. Figures in this presentation are subject to rounding. The information contained in this presentation is current as of 10 November 2026.

# Corporate Summary

## Focus

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



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

## Corporate Summary[1,2]

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|---|---|
| **Share price (ASX:OSL)** | **$0.69** |
| **Shares on Issue** | **36.5 million** |
| **Market Capitalisation** | **$25.2 million** |
| **Cash (30 September 2026)[2]** | **$8.7 million** |
| **Enterprise Value** | **$16.5 million** |
| **Options ASX:OSLOE ($0.90 \| 30 Jun-27)** | **10.3 million** |
| **Options ASX:OSLOD ($1.20 \| 31 Jul-27)** | **7.7 million** |
| **Top 20 Shareholders** | **63.4%** |
| **Substantial Shareholders** | Pengana Capital **(20.2%)**<br>Regal Partners Funds **(13.8%)**<br>Australian Ethical **(10.8%)** |
| **Analyst Coverage** | **Nick Lau \| Dr Dennis Hulme**: Taylor Collison |

## Directors / Management

| | |
|---|---|
| **Dr Thomas Duthy** | Non-Executive Chairman |
| **Nigel Lange** | CEO & Managing Director |
| **Lel Smits** | Non-Executive Director |
| **Shelley Steyn** | Chief Financial Officer |
| **Renzo DiCarlo** | Head of Operations & Development |

## Share Price Graph




1. Share price, investor data as at 10 November 2026
2. Per Q1 FY27 Appendix 4C

# Unlocking scalable execution in endoscopy and interventional oncology

**Targeting unresectable Locally Advanced Pancreatic Cancer (uLAPC) and Distal Cholangiocarcinoma (dCCA)**



**OncoSil Medical (ASX:OSL)** is an advanced, early commercial-stage global medical technology innovator that has transitioned from a high-risk clinical trial entity into a globally approved medical device across multiple regulatory jurisdictions.

**The problem:** Legacy cancer treatments struggle to safely control aggressive, localised gastrointestinal tumours because external radiation hits critical blood vessels and healthy surrounding tissue. Chemotherapy has shown limited effectiveness as much of it can't be taken up by the tumour due to dense scar like stromal tissue.

**The solution:** The OncoSil™ device injects targeted Phosphorous-32 (P-32) microparticles directly into the tumour, safely delivering a localised tumourcidal radiation dose via endoscopy or interventional radiology while sparing adjacent healthy structures.

# Unlocking a A$6.4 billion[1] global market

## From regulatory milestones to commercial scalability

### Key strategic pillars:

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| ***The transition point*** | OncoSil Medical has successfully advanced past the high-risk R&D and clinical trial phase into a fully approved, commercially executing medical technology asset in multiple jurisdictions. |
| ***Severe unmet need*** | Pancreatic and dCCA (distal cholangiocarcinoma) cancers represents a significant unmet need with historically poor patient survival rates. |
| ***Immediate addressable scalability*** | Single-use device targets an immediate, near-term Total Addressable Market (TAM) of **A$1.20 billion[1] in the US, EU, UK** and **Australia**. |

**The Clinical Transformation Thesis: By delivering radiation straight into pancreatic tumours, the OncoSil™ device protects healthy tissue and adjacent organs, shortens hospital stays and makes lifesaving surgery possible for more patients.**

**1** Company estimate. TAM = annual pancreatic cancer incidence (GLOBOCAN 2022, IARC Global Cancer Observatory, gco.iarc.fr, accessed Nov 2026) × estimated proportion of patients eligible for OncoSil™ treatment × average selling price per patient.
**2** Company estimate for markets with existing regulatory approval: EU, UK and Australia (locally advanced pancreatic cancer) and US (distal cholangiocarcinoma, Humanitarian Device Exemption). TAM = annual pancreatic cancer incidence (GLOBOCAN 2022, IARC Global Cancer Observatory, gco.iarc.fr, accessed Nov 2026) × estimated proportion of patients eligible for OncoSil™ treatment × average selling price per patient.

# The US strategy: High-margin asset execution

## Maximising value via the US FDA Humanitarian Device Exemption (HDE) pathway

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|---|---|
| **The strategic reality** | US FDA HDE approval grants **immediate marketing authorisation** for distal cholangiocarcinoma (dCCA) bypassing years of traditional clinical trials to unlock a rapid commercial runway. The approval addresses an underserved patient population of ~ 1,000 patients annually, capturing a commercial opportunity with a TAM of A$80 million[1]. |

***Core execution pillars:***

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| ***Low-capex, targeted institutional rollout:*** | OncoSil Medical is required to complete **a 30 patient, 5 centre post approval study** with patients to be recruited in 24 months. This short-term US strategy focuses entirely on a lean team, activating high-volume, elite academic cancer centres with a focus on treating dCCA. |
| ***Fast tracked reimbursement & market access*** | The company is advancing immediate market-access pathways having submitted an application for **Transitional Pass-Through Payment (TPT)** to secure dedicated codes, ensuring US hospitals are reimbursed for the OncoSil™ device and related procedures. |
| ***Defensible margin profile*** | Every OncoSil™ device sold in the US plugs directly into OncoSil Medical's new manufacturing infrastructure with a projected **gross margin** of **~70%.** |

1. Company estimate. TAM = annual cholangiocarcinoma incidence (GLOBOCAN 2022, IARC Global Cancer Observatory, gco.iarc.fr, accessed Nov 2026) × estimated proportion of patients eligible for OncoSil™ treatment × average selling price per patient.

# De-risked pathway to global execution

## Our message to Shareholders

*OncoSil Medical is no longer a story about clinical trials and regulatory checkboxes - that risk is behind us. With global approvals secured, a de-risked pathway to the US market, and highly favourable 75%+ gross margin economics, our sole focus is strategic commercial execution. We are transforming the standard of care for the underserved patient population while creating a highly efficient, revenue-generating engine for our Shareholders.*

***Shareholder takeaway***

**With clinical and regulatory hurdles 100% cleared in major markets, OncoSil Medical is now fully positioned for commercial scale, hospital site activation, and revenue generation.**



# Established funding channels & expanding the clinical label

## Driving commercial adoption via peer-reviewed evidence in uLAPC

### Deepening reimbursed access & public funding

*German G-BA Approval:* Formally approved by Federal Joint Committee (Gemeinsammer Bundesausschuss), this legal framework establishes a Coverage with Evidence Development (CED) program, allowing OncoSil to be **fully reimbursed** during active clinical data generation in a fully funded 280 patient randomised clinical study.

*EU sponsored European Research Consortium:* OncoSil Medical leveraging a non-dilutive grant to conduct a **120-patient European** study evaluating repeat device treatments, aiming to unlock a **3X expansion of its Total Addressable Market (TAM)** upon successful completion

### Expanding the clinical label & delivery channels

*Percutaneous Delivery Channel (The PANCOSIL Study):* Successfully evaluated feasibility and safety of **CT-guided percutaneous administration**, demonstrating an outstanding **90% technical success rate** and **20.6 months median overall survival (OS)**[1]. Regulatory submission by end of CY2026 seeking formal label expansion. This opens the treatment to Interventional Radiology/Oncology, substantially increasing the number of medical specialists who are able to perform the procedure.

*Global Standard Chemotherapy Integration* (*The TRIPP-FFX Study*): Confirms Oncosil™ acts as a **chemo-agnostic**, additive solution that **integrates into existing hospital protocols without replacing baseline drugs**. Having established a robust clinical and regulatory foundation, our immediate focus is now on commercial execution: activating hospital sites and driving revenue.

1. Vos D et al. Presented at CIRSE Congress, 13-17 September 2025; Presentation 466.2

# A consistent survival signal

## Exceptional survival profiles validated across multiple tiers of clinical evidence

**Clinical performance**

The OncoSil™ device demonstrates highly consistent performance metrics across all trial frameworks, geographies and delivery methodologies:

### Randomised control framework (TRIPP-FFX Phase II Trial: per protocol population, n=81)[1]

- *Survival Signal:* **21.3 Months Median Overall Survival (OS)** when combined with first-line chemotherapy, compared to just 15.6 months for chemotherapy alone.
- ***Clinical Advantage:*** Demonstrated an **85.0% local disease control rate** at 16 weeks while meeting both co-primary safety and efficacy endpoints.

### Real-world commercial evidence (OSPREY Registry, n=88)[2]

- *Survival Signal:* **25.1 Months Median Overall Survival (OS)** from the commencement of first-line chemotherapy (19.8 months for patients implanted within 4 months into chemo).
- ***Clinical Advantage:*** Outstanding safety profile with **zero Grade ≥3 Adverse Device Effects (ADEs)**, converting challenging cases into 10 successful surgical resections (8 R0 surgical margins).

### Alternative delivery methodology (PANCOSIL Percutaneous Study, n=20)[3]

- *Survival Signal:* **20.6 Months Median Overall Survival (OS)** from the date of initial LAPC diagnosis.
- ***Clinical Advantage:*** Demonstrated a **90% technical success rate** utilising standard CT-guidance with zero procedure-related deaths.

### Royal Adelaide Hospital – OncoSil vs SBRT, n=101[4]

- *Survival Signal:* **22.0 Months Median Overall Survival (OS)**, vastly outperforming legacy Stereotactic Body Radiotherapy **(SBRT), which sits at 14.0 months**.
- ***Clinical Advantage:*** Unlocked profoundly higher clinical downstaging and surgical resection conversion rates of **23.8% vs. a negligible 3.4%** for standard radiotherapy.


1. Milella M et al. Presented at ESMO Gastrointestinal Cancers Congress, 1–4 July 2026; Abstract LBA4
2. Prado Wohlwend S et al. EANM 2026: 4 (Suppl): S229-S230. OP-619
3. Vos D et al. Presented at CIRSE Congress, 13-17 September 2025; Presentation 466.2
4. Lim AHW et al. Presented at the Digestive Disease Week (DDW2025) scientific meeting, 3–6 May 2025; Abs Tu1372.

# Asset scalability & core value drivers

## Premium recurring economics (All figures in A$)

**OncoSil Medical (ASX:OSL)** presents a highly efficient, high-margin commercial investment case with a market capitalisation of **A$25.2M**. Backed by a **44% YoY increase in FY26[1] reported product revenue.** OncoSil Medical's financial blueprint is built on highly predictable asset execution.

**The three pillars of our standalone financial moat:**

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| *High-value single-use model* | By eliminating the need for expensive equipment, the OncoSil™ device ensures frictionless hospital adoption. |
| *Industry-standard gross margins (75%+)* | The manufacturing, supply chain, and global logistics infrastructure for the proprietary microparticles are in place, pending regulatory approval of the Macquarie Park facility. Top-line revenue growth is expected to rapidly outpace fixed corporate expenses as global adoption scales. |
| *Commercial-stage valuation inflection* | With the current CE MARK/EU-MDR, FDA HDE and TGA market approvals, the market capitalisation represents a highly attractive entry point for shareholders as the company transitions into commercial stage across three major global healthcare regions. |

1. Financial data per OncoSil Medical FY26 Annual Financial Statements

# A Natural Fit for Interventional Oncology, with Near-Term Catalysts

## CT-guided Percutaneous Delivery

### Broader Physician Access

Expands the treating base to include Interventional Radiologists

### Simplified Procedure

15–20 minutes procedure, local analgesia and outpatient setting

### Established Workflow

Leverages familiar CT-guided biopsy and tumour-directed procedures (e.g. SIR-Spheres®, TheraSphere™)

### Broader Points of Care

Potential to increase the number of hospitals and clinicians able to offer OncoSil™

## Near-Term Catalysts

### US dCCA launch - 1H CY27

Up to five centres within a 30-patient FDA post-approval study

### EU regulatory approval – percutaneous delivery

Change Notification submission planned for Q4 CY26, based on PANCOSIL

### EU regulatory approval – FOLFIRINOX label change

Change Notification submission planned for Q4 CY26, based on TRIPP-FFX

### Second manufacturing site - Sydney

Regulatory filing with BSI in Q4 CY26: added capacity and supply resilience

Commercial sales expected to start in 1H CY27*

### Germany: G-BA Phase III RCT – final approval in Q4 CY26

280 patients (1:1 randomisation), reimbursed by statutory health insurers

### PALACROS: PULSE study

EU-funded; compares 1 *vs*. 3 treatments per patient; launched October 2026

* Subject to approval

# The 12-month shareholder catalyst runway

## Execution-driven milestones driving top-line revenue growth

### Key strategic catalysts:

**US Site Activation & Revenue (1H CY27)**

Launching targeted clinician training and operational setup at elite, high-volume academic cancer centres across the United States, leading to formal commercial launch and **first US commercial revenues** in 1H CY27.

**G-BA Trial Commencement (1H CY27)**

**Fully funded Phase III** randomised trial by Federal Joint Committee in Germany. **uLAPC annual incidence of 6,776, TAM A$264M[1].** Successful completion ensures inclusion in S3 German guidelines paving the way for full market access.

**Australian Commercial Launch (1H CY27)**

Activating strategic hospitals under the TGA approval to initiate the treatment of patients in the company's home market. This represents a **TAM opportunity of A$28M[1]** per annum.

**European Label Expansion regulatory submission (2H CY26)**

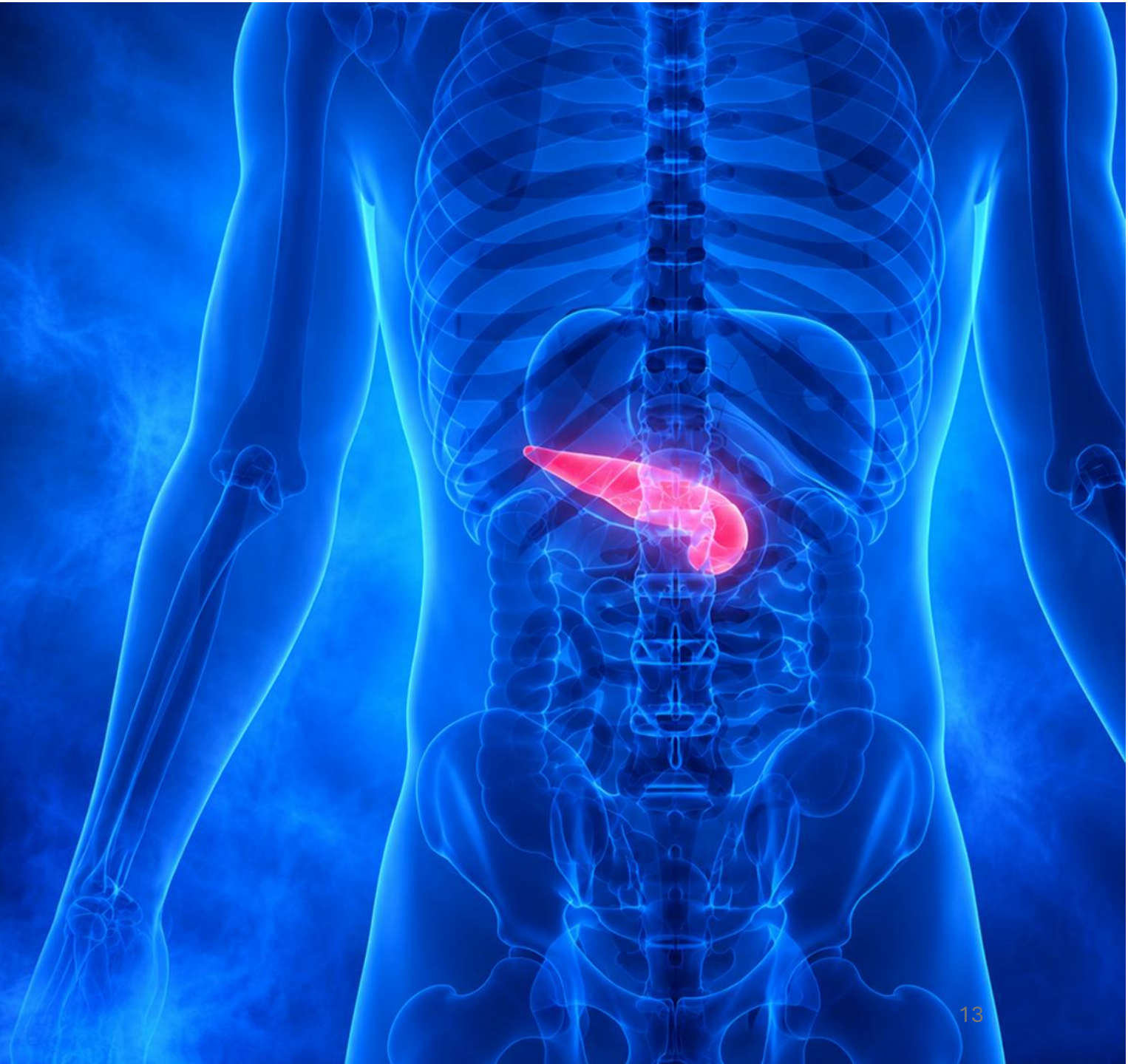
Securing formal regulatory clearance for **CT-guided percutaneous injection**, immediately opening the device to the Interventional Oncology/Radiology sales channel.

**The bottom line for ASX investors:** Every milestone is focused on **top-line commercial revenue generation and market access expansion on a global scale**. Holding a highly defensible global regulatory moat and **~70% gross margin economics**, the company is positioned to drive compounded long-term capital value for Australian shareholders.

1. Company estimate. TAM = annual pancreatic cancer incidence (GLOBOCAN 2022, IARC Global Cancer Observatory, gco.iarc.fr, accessed Nov 2026) × estimated proportion of patients eligible for OncoSil™ treatment × average selling price per patient.

OncoSil MEDICAL

**Targeted approach • Positive impact**



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