EQUITY RESEARCH | DESK NOTE

OSL: Regulatory Progress Supports a Catalyst-Rich 2H CY2026

ASX: OSL | 3 July 2026

Company Name	Oncosil Medical Ltd
Exchange/Code	ASX: OSL
Share Price	$0.81
Shares on Issue	31m
Market Cap	25m
Cash	9m
Lead Asset	OncoSil device, delivers radiation directly into cancerous tissue
Significant Shareholders	Pengana Capital Ltd. 20% Regal Partners Limited 10% Australian Ethical Investment Limited 8%

Over the past several weeks OncoSil has achieved several milestones that set it up for a catalyst rich back half of the year.

1. FDA Review for Humanitarian Device Exemption Application
2. TRIPP-FFX Clinical Trial Met Its Co-Primary Endpoints
3. OncoSil Selected to Participate in European Research Consortium

FDA Review for Humanitarian Device Exemption Application

OncoSil recently heard from the FDA that its Humanitarian Device Exemption (HDE) application for its device for the treatment of distal cholangiocarcinoma dCCA in the U.S has progressed to the final stage of review.

Humanitarian Device Exemption (HDE)

A humanitarian device exemption is a marketing application for a Humanitarian Use Device (HUD), a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects less than 8,000 people in the United States per year.

It important to note the if the device is granted an HDE there will be a limit on the number of devices that can be sold each year. That number is calculated by taking the number of devices reasonably necessary to treat or diagnose an individual per year and multiplying it by 8000.

Distal Cholangiocarcinoma (dCCA)

Distal cholangiocarcinoma (dCCA) is a type of bile duct cancer that develops in the lower (distal) portion of the common bile duct.

Treatment depends on whether the tumour can be surgically removed.

Surgery offers the best chance of cure, typically a Whipple procedure because of the tumour's location. Chemotherapy may also be given before or after surgery.

Unresectable or tumours that can't be surgically removed are often treated by inserting a biliary stent which relieves the obstruction and restore bile flow. Chemotherapy or radiation therapy are also given but eventually the tumour continues to growing blocking the stent

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Patients with unresectable locally advanced distal cholangiocarcinoma have a poor prognosis. Studies of advanced cholangiocarcinoma report median overall survival of approximately 12-15 months with current first-line therapy.

Next Steps

- OncoSil to submit final labelling for the OncoSil device and any modifications to the Company's proposed post-market study, if any
- Upon receiving the required information, the FDA intends to complete its review and decide whether to grant the HDE within 45 days

If an HDE is granted it will allow OncoSil to market and sell its device to a limited number of patients (for profit) in the US.

TRIPP-FFX Clinical Trial Meets Co-Primary Endpoints

On 9 June, OncoSil announced the results of its TRIPP-FFX clinical study. TRIPP-FFX tested the OncoSil device in addition to the standard-of-care chemotherapy called FOLFIRINOX and compared it with FOLFIRINOX on its own. In total 88 patients took part across 15 sites in Europe and Australia.

The trial had two co-primary endpoints. To show it was safe and tolerable and to demonstrate a meaningful improvement in local disease control rate LDCR at 16 weeks.

Study Design

Trial Characteristic	Details
Study design	Open-label, multi-centre, randomised, non-comparative
Subjects	88 • FOLFIRINOX (n=43) • FOLFIRINOX + OncoSil™ (n=45)
Study sites	15 sites in Europe and Australia
Patient population	Patients with unresectable locally advanced pancreatic cancer (LAPC)
Treatment arms	1. Chemotherapy only 2. Chemotherapy plus OncoSil device
Primary endpoints	1. Safety and tolerability 2. Local disease control rate at 16 weeks
Secondary endpoints	• Overall survival • Tumour response rate • Surgical resection rate • Quality of life • Pain scores

Results

The trial set clear rules before it began for what would count as a successful result. To pass, the results needed to show with a high degree of confidence that the true Local Disease Control Rate (LDCR) was better than 55%, with a target rate of 75%.

The trial reported an LDCR with a 95% confidence interval of 68% to 92%. This means the researchers are 95% confident the true LDCR lies somewhere between 68% and 92%.

Because 68% is well above the minimum success threshold of 55%, and 75% falls within the estimated range, the trial met its primary endpoint.

Measure	FOLFIRINOX	FOLFIRINOX + OncoSIL
Local disease control at 16 weeks (95% CI)	86.0% (72–95%)	82.2% (68–92%)
Median overall survival (months) (95% CI)	15.9 (10.2–nc)	18.3 (12.8–22.2)

CI = confidence interval

The company states the trial was not built to prove one group did better than the other in a strict statistical way. It says the trial was designed to check safety and gather supporting evidence, and that a full head-to-head comparison would need many more patients and more time. As a result, the efficacy results are best read as supportive rather than as proof that adding the OncoSil device improves outcomes.

Next Steps

The company plans to file with an EU & UK Notified Body to expand the current CE Mark for the OncoSil™ device to include FOLFIRINOX as an additional chemotherapy option for patients with unresectable LAPC, in addition to its current approved use with gemcitabine-based chemotherapy.

The results will also be presented at the European Society for Medical Oncology Gastrointestinal Cancers Congress 2026 (ESMO GI 2026),

Selected to Participate in European Research Consortium

OncoSil has also been selected to participate in PALACROS (Prioritising Multimodal Surgical Care for Patients with Locally Advanced Pancreatic Cancer Across Europe) a European research consortium dedicated to improving outcomes for patients with LAPC.

As part of PALACROS OncoSil will participate through a clinical study known as the PULSE Trial. The trial aims to evaluate whether repeat radiation treatment delivered directly into the tumour using the OncoSil™ device can improve outcomes in patients whose pancreatic cancer cannot be removed with surgery, and whose cancer that has not worsened following initial chemotherapy.

Study Design

Trial Characteristic	Details
Study design	Randomised (1:1)
Patients	120
Study sites	5 European centres
Patient population	Patients with unresectable, non-progressive LAPC following at least four months of induction chemotherapy
Treatment arms	1. Single OncoSil™ device implantation; 2. Repeat OncoSil™ device implantation every three months until disease progression
Primary endpoint	Nine-month local progression-free survival
Secondary endpoints	• Overall progression-free survival • Overall survival • Safety and tolerability • Quality of life • Pain • Opioid use • Patients whose cancer becomes removable with surgery after treatment • Biomarker assessment

Significant Savings

As part of the study OncoSil will provide the devices but will bear no other study sots. This allows OncoSil to generate clinical data without bearing the costs of the site, monitoring, regulatory process, data manage or other costs that would be expected if the company were to sponsor the trial itself. The company says this is approximately a $9m saving.

Outcomes of the Study

While OncoSil doesn't have to bear the costs of the trial it still gets to reap the rewards including:

- Clinical data generated from the trial can be used for both regulatory submissions and commercial activities.
- Positive results could strengthen the clinical evidence supporting OncoSil™ across key markets.
- Strong data may support discussions with clinicians, payers and regulators, aiding commercialisation.
- If the trial supports OncoSil™ becoming a standard treatment for LAPC, device utilisation could increase significantly.

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Upcoming Catalysts

Catalyst	Timeline	Significance
US FDA decision on the HDE	Within 45 days of final filing	Granting of an HDE would allow OncoSil to sell its device in the United States.
Federal Joint Committee (G-BA) trial in Germany commencement	2H CY2026	Marks an important step towards securing reimbursement for OncoSil™ in one of Europe's largest healthcare markets.
EU regulatory submission – percutaneous label change (PANCOSIL)	2H CY2026	Could help OncoSil™ reach more patients by allowing interventional radiologists to perform the procedure, not just the current treating specialists.
EU regulatory submission – FOLFIRINOX label change (TRIPP-FFX)	2H CY2026	Would align the device with the current standard chemotherapy used to treat pancreatic cancer.
Launch of OncoSil device in Australia	2H CY2026	Creates a pathway to revenue in Australia.
Launch of OncoSil device in the U.S.	Pending grant of HDE	Potential to treat up to 8,000 patients (for profit) in the U.S.

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