Nathan Graves
Investment Analyst
nathan@prenzlergroup.com.au

Joel Fishlock
Director – Equity Capital Markets
joel@prenzlergroup.com.au

OncoSil Breaks Into the US

19 August 2026

Company Snapshot

Company	OncoSil Medical Ltd (ASX: OSL)
Lead asset	OncoSil device: a single-use brachytherapy implant of phosphorus-32 microparticles injected directly into the tumour under endoscopic ultrasound guidance
Lead indication	Unresectable locally advanced pancreatic cancer (LAPC) with chemotherapy; distal cholangiocarcinoma (dCCA)
Shares on issue	30.9m
Share Price (Close 18 Aug 2026)	$1.15
Market Cap	$35.5m
Cash (30 Jun 2026)	$6.5m

Sources: Iress, company filings

Some tumours are hard to treat not because they are aggressive, but because they are inconveniently placed. OncoSil's device delivers radiation directly into the tumour of patients suffering from pancreatic cancer. Microscopic particles carrying a radioactive isotope are injected into the tumour using an endoscope fitted with an ultrasound probe. About 98% of the radiation is delivered within 81 days, so the tumour receives a high dose while surrounding organs are largely spared. It is used alongside chemotherapy in patients whose pancreatic cancer cannot be surgically removed but has not spread to distant organs (locally advanced pancreatic cancer, or LAPC). It's estimated that 30% of the roughly 500,000 people diagnosed with pancreatic cancer each year suffer from LAPC.

On 17 August 2026 the FDA approved the OncoSil device for patients aged over 21 with distal cholangiocarcinoma (dCCA), a cancer of the lower bile duct, where the tumour cannot be removed by surgery but has not spread beyond it. Approval came through the Humanitarian Device Exemption (HDE) pathway, which the FDA reserves for devices treating rare conditions. The device is used alongside drug treatment and is injected into the tumour through a tube passed down the throat, guided by ultrasound. It is the first and only FDA-approved Class III device for this cancer.

This is OncoSil's first US authorisation and It lands as three other pieces fall into place. A German government-funded trial across about 40 hospitals, two European label changes that would broaden who can deliver and receive the device, and an in-house manufacturing line intended to move gross margin from negative to roughly 70% at scale.

The Approval

About 8,000 Americans are diagnosed with bile duct cancer each year, 30% to 40% of cases are distal, and roughly 1,000 a year fall within the approved unresectable, non-metastatic label. The company puts the annual addressable market at about A$80m. Median overall survival for these patients has been reported at about 6.7 months, and incidence is rising about 1.4% a year.

Use and distribution will initially be restricted to a maximum of five treatment centres as part of an FDA-required post-approval study, a multicentre prospective study expected to enrol 30 patients followed for up to 24 months. The company expects each study patient to be a reimbursed treatment, worth about US$1.7m of revenue. A second limit applies once for-profit sale is authorised. An HDE device can be sold at a profit only up to an annual distribution

number, set by the FDA as the number of devices needed to treat one patient for a year multiplied by 8,000, and sales beyond that number may continue but not at a profit. The final protocol is still to be confirmed with the FDA.

US launch is expected in the first half of CY27.

This is the fourth milestone since May.

1. TGA approval for LAPC with gemcitabine chemotherapy came on 20 May
2. TRIPP-FFX met its co-primary endpoints on 9 June
3. The Sydney manufacturing line completed three validation cycles and more than 50 doses on 13 July
4. FDA approval of the OncoSil device for patients with distal cholangiocarcinoma (dCCA) on 17 August

The Bigger Reset Behind the Milestones

Under CEO Nigel Lange (who ran Sirtex's European business and later served as its group chief commercial officer) and Chair Dr Thomas Duthy (formerly head of corporate development at Sirtex), the company has spent two years removing the structural barriers to adoption. EU Medical Device Regulation certification in January 2025 lifted the post-market restrictions attached to the original CE Mark; Germany's InEK authorised 120 hospitals to negotiate innovation reimbursement for the device in February 2025; and the G-BA approved a fully funded trial.

G-BA Trial in Germany

The G-BA is Germany's highest health decision-making body. It decides which treatments the country's public insurers pay for. It agreed to fund a trial of OncoSil, a route Germany reserves for promising treatments whose evidence is not yet conclusive. The study will enrol about 280 patients with locally advanced pancreatic cancer across roughly 40 hospitals over about two years, with half receiving OncoSil alongside chemotherapy and half receiving chemotherapy alone. Germany pays for the trial and OncoSil supplies the devices at its commercial price, which the company puts at about A$5.6m, with a further A$6.5m of sales expected to patients at those hospitals who do not qualify for the trial. A positive result would support national reimbursement in Europe's largest pancreatic cancer market.

Next Steps

United States: confirm the post-approval study protocol with the FDA; select and activate up to five academic centres and obtain their ethics-board approvals; apply for Transitional Pass-Through Payment status; obtain FDA authorisation for for-profit sale and the annual distribution number; first commercial treatments in 1H CY27, with about US$1.7m of reimbursed study treatments expected.

Germany: commence the G-BA trial later in calendar 2026 once a contract research organisation is appointed.

Europe more broadly: File change notifications with the notified body BSI to add FOLFIRINOX chemotherapy to the label (late 2H CY26) and to add CT-guided percutaneous delivery through the skin by interventional radiologists (2H CY26), with approvals targeted for 1H CY27; publish TRIPP-FFX in a peer-reviewed journal after its ESMO GI oral presentation on 4 July.

Manufacturing: complete ISO 13485 certification and the final regulatory inspection of the Cyclotek Macquarie Park facility and begin commercial production in 2H CY26.

Australia: Launch in 1H CY27; the company estimates about 1,300 locally advanced patients a year would be addressable once reimbursement is in place.

Evidence: start the PULSE trial within the EU-funded PALACROS consortium, a 120-patient randomised Phase II study of single versus repeat OncoSil treatment across five European centres, with devices supplied in kind and other study costs borne by the consortium (an estimated A$9m saving versus a company-sponsored trial); progress the OSPREY real-world registry publication.

Future Catalysts

Catalyst	Expected timing	Significance
Post-approval study protocol confirmed with FDA; first US centres selected and ethics-board approvals sought	2H CY26	Sets the pace of the US roll-out; up to five centres and 30 patients initially
Transitional Pass-Through Payment application and FDA for-profit authorisation for the HDE device	2H CY26	Reimbursement and pricing certainty for US hospitals
Commercial production sign-off at the Cyclotek Macquarie Park facility (ISO 13485 and regulatory inspection)	2H CY26	Supply security and the path from negative to positive gross margin
G-BA trial commencement in Germany (about 40 hospitals, and 280 patients)	2H CY26	Government-funded Level 1 evidence; about 140 paid OncoSil doses; commercial access to trial sites
EU/UK change notifications: FOLFIRINOX combination (TRIPP-FFX) and percutaneous delivery (PANCOSIL)	2H CY26	Aligns the label with standard chemotherapy and opens the device to interventional radiologists
Italy: target authorised hospital increase from four to eight	2H CY26	Faster onboarding in one of Europe's largest pancreatic cancer markets (16,000 cases a year)
EU/UK label approvals for FOLFIRINOX and percutaneous delivery	1H CY27 (company target)	Broadens patient eligibility and prescriber base across existing markets
Australian commercial launch	1H CY27	First home-market sales; about 1,300 addressable patients a year once reimbursed
US commercial launch: first dCCA treatments at up to five centres	1H CY27	First US revenue; each post-approval study patient expected to be reimbursed
PULSE trial start within the PALACROS consortium (120 patients, repeat dosing)	To be confirmed	Evidence for repeat treatment at minimal cost to the company

Indicative timing only. Events may be delayed, modified or may not occur.

Peer Comparisons

The table below sets out listed companies in cancer treatment and nuclear medicine.

Company (Ticker)	Lead Asset, Indication and Delivery	Clinical Stage	Market capitalisation (AUD, m)
Clarity Pharmaceuticals (ASX: CU6)	Copper-64 and copper-67 SAR-bisPSMA for prostate cancer imaging and treatment; injected into the bloodstream to seek out the tumour	Phase 3 imaging; Phase 1 and 2 therapy; no product revenue	958.8
Amplia (ASX: ATX)	Narmafotinib, an oral capsule given alongside chemotherapy for advanced pancreatic cancer	Phase 2b initiated; no product revenue	79.6
Cyclopharm (ASX: CYC)	Technegas, a radioactive aerosol the patient breathes in so the lungs can be scanned; used mainly to detect blood clots	Commercial; FDA approved, US rollout under way	62.9
Radiopharm (ASX: RAD)	Portfolio of injected radioactive imaging and treatment agents, including RAD101 for cancer that has spread to the brain and RAD301 for pancreatic and other solid tumours	Pivotal Phase 3 imaging trial is planned for Q4 2026; no product revenue	52.1
OncoSil Medical (ASX: OSL)	OncoSil phosphorus-32 microparticle brachytherapy; LAPC and dCCA; endoscopic ultrasound-guided injection, percutaneous expansion planned	Commercial (CE Mark, TGA, FDA HDE)	35.5

Source: Iress, 18 Aug 2026
LAPC = locally advanced pancreatic cancer
dCCA = distal cholangiocarcinoma

General Advice Warning

Please note that any advice given by Prenzler Group Pty Ltd or authorised representatives (Prenzler Group) is GENERAL advice, as the information or advice given does not take into account your particular objectives, financial situation or needs. You should, before acting on the advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument. Prenzler Group Pty Ltd | ABN 77 621 100 730 | Authorised Representative of AFSL 456663.

Disclaimers

Prenzler Group does not warrant the accuracy of any information it sources from others. Prenzler Group provides a report as an opinion held at a point in time about an investment or sector. Prenzler Group has no obligation to update the opinion unless you are a client of Prenzler Group. Assessment of risk can be subjective. Historical information may not translate into future performance. Portfolios of investments need to be well diversified and the risk appropriate for the investor. Prenzler Group does not stand behind the capital value or performance of any investment. To the fullest extent permitted by the law, Prenzler Group disclaim any liability for any loss or damage arising from the use of, or the reliance on, any information within the advice whether or not caused by any negligent act or omission of Prenzler Group. Overseas investors acknowledge that Prenzler Group has not solicited their business.