EQUITY RESEARCH | DESK NOTE

OSL – Delivers on Milestones as Stock Re-Rates, Catalysts Still Ahead

ASX: OSL | 15 July 2026 | Analyst: Nathan Graves | nathan@prenzlergoup.com.au

Company Snapshot

Company Name	Oncosil Medical Ltd
Exchange/Code	ASX: OSL
Lead Asset	OncoSil device, delivers radiation directly into cancerous tissue
Shares on Issue	30.9m
Share Price (14 July 2026)	$1.375
Market Cap (14 July 2026)	$42.5m
Cash (31 March 2026)	$9.3m
Significant Shareholders	Pengana Capital Ltd. 20.2% Regal Partners Limited 10.4% Australian Ethical Investment Limited 8.4%

OncoSil has rerated sharply since our last note, +70% as of close yesterday and reaching a high of A$1.575 (+94%) off the back of three milestones.

1. FDA Humanitarian Device Exemption (HDE) application submission completed
2. Updated TRIPP-FFX results presented at ESMO GI 2026 in Munich
3. Manufacturing validation completed with Cyclotek

FDA HDE Application Submission

OncoSil completed submission of its Humanitarian Device Exemption (HDE) application to the FDA for the OncoSil device in distal cholangiocarcinoma (dCCA, a cancer of the lower portion of the common bile duct). The application has now entered the FDA's review phase, and the FDA has advised the company it expects to complete its review within approximately 45 days.

If granted, the device would be the first and only FDA-approved Class III medical device specifically indicated for dCCA, and it would be OncoSil's first US regulatory approval. HDE is the FDA pathway for devices intended to treat diseases affecting fewer than 8,000 US patients per year, and marketing under HDE is subject to a unit cap tied to that population.

TRIPP-FFX Results Presented at ESMO GI 2026

Updated TRIPP-FFX results were presented as at the European Society for Medical Oncology Gastrointestinal Cancers Congress 2026 (ESMO GI 2026) in Munich by co-principal investigator Professor Michele Milella of the University of Verona. The presentation confirmed the previously reported Intent-to-Treat outcomes (the study met both co-primary endpoints of safety and Local Disease Control Rate at 16 weeks) and, for the first time, reported a Per Protocol (PP) analysis (the subset of patients who actually received the device to the target tumour).

The PP readout showed median overall survival of 21.3 months in the OncoSil plus FOLFIRINOX arm versus 15.6 months in FOLFIRINOX alone, a 12.5% surgical resection rate (60% with R0 or complete-removal margins) versus 7.3% (33% R0), and median tumour volume reduction of 72.2% versus 55.9%. Local Disease Control Rate at 16 weeks

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Suite 1 Level 12/25 Bligh St, Sydney NSW 2000, Australia
www.prenzlergroup.com.au

was effectively identical between arms in PP (85.0% vs 85.4%). Safety was consistent with prior reports with no new signals identified.

OncoSil remains on track to submit a Change Notification to its EU and UK Notified Body in late 2H CY26 to expand the label to include FOLFIRINOX alongside the existing gemcitabine-based indication.

Manufacturing Validation Completed with Cyclotek

OncoSil announced completion of manufacturing validation with its Australian partner Cyclotek, comprising three validation cycles and more than 50 validation doses of the OncoSil device. The capability has been established inside Cyclotek's existing Macquarie Park facility at Macquarie University Hospital in Sydney, with OncoSil retaining ownership of the specialised production equipment and proprietary manufacturing process, and Cyclotek providing the facility and operational manufacturing services.

Total capital investment is stated at approximately A$2.1 million. The platform is designed against ISO 13485 (the medical device quality management standard), TGA and FDA expectations. Subject to regulatory inspection and approval, commercial production is expected to commence in 2H CY2026.

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.
Australian commercial production commencement	2H CY2026	Would enable OSL to supply commercial demand.
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/UK 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.

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

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