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US Reimbursement Decision Anchors Near-Term Catalysts

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Company Snapshot

Company	OncoSil Medical Ltd (ASX: OSL)
Lead asset	OncoSil device: implant of radioactive (phosphorus-32) particles, injected directly into the tumour
Lead indication	Unresectable locally advanced pancreatic cancer (LAPC) with chemotherapy; distal cholangiocarcinoma (dCCA)
Shares on issue	36.7m
Share Price (27 Oct 2026)	A$0.7
Market Capitalisation	A$25.7m
Net Cash (pro forma)	A$12.1m

Net cash consists of A$6.5m in cash as of 30 June 2026 plus A$5.6m raised announced on 7 September 2026.

OncoSil now holds approval to treat pancreatic cancer in Europe, the UK and Australia (CE Mark and TGA) and distal cholangiocarcinoma (dCCA) in the US (FDA).

Since our 19 August note, OncoSil has lodged its US reimbursement application, had its Sydney manufacturing partner certified, raised A$5.6m from its three largest shareholders and formally launched the European research program that will test repeat treatment. It also treated its 100th patient in Spain and reported full-year results. Still to come are the start of the German government-funded trial, two European label filings and the choice of US study centres.

The next twelve months are about turning approvals into revenue with its first US treatments, an Australian launch and wider European labels.

What OncoSil Delivered

Since the FDA approval of the OncoSil device for distal cholangiocarcinoma, seven developments have followed:

1. Full-year results on 28 August: unit sales up 53% and revenue up 44% to A$1.7m
2. US reimbursement application lodged on 1 September (US time) at US$55,000 a dose
3. A$5.6m raised on 7 September from the three largest shareholders (Pengana, Regal Partners and Australian Ethical)
4. 100th patient treated in Spain on 7 September, at Hospital HM Sanchinarro in Madrid
5. Cyclotek manufacturing site certified to ISO 13485 on 9 September
6. PALACROS European research program launched in Amsterdam on 13 October, with the PULSE trial inside it

7. Real-world results from the OSPREY registry selected for an oral presentation at the EANM congress (announced 30 September), with updated results presented in Vienna on 20 October (announced 21 October)

The US: Reimbursement Filed

On 1 September (US time) OncoSil lodged an application with the US Medicare agency (CMS) for Transitional Pass-Through payment status. It asks Medicare to pay hospitals a separate extra amount for the device on top of the normal procedure payment, so that a new and costly treatment does not land on the hospital's own budget. OncoSil filed at US$55,000 a dose. CMS is targeted to decide, and any approval to start, on 1 January 2027. If granted, the extra payment would run for up to three years from launch.

The first US patients will be treated inside the FDA-required post-approval study: 30 patients at up to five academic centres, followed for about 24 months after the last patient is treated. If each patient receives one reimbursed treatment, that is about US$1.7m of revenue across the study (30 patients at US$55,000 is US$1.65m).

Funding and the Annual Result

On 7 September the three largest shareholders, Pengana, Regal Partners and Australian Ethical, committed A$5.6m in a A$4.0m placement at A$1.00 and about A$1.6m from the early exercise of 1.8m listed options at A$0.90. The company puts pro forma cash at A$12.1m, against $6.5m at 30 June, and says the money is for the US and Australian launches.

Unit sales rose 53% and revenue rose 44% to A$1.7m in FY26. Cash received from customers rose 179% to A$2.1m. The loss after tax narrowed 28% to A$10.9m, helped by A$3.4m of research tax incentive income, up from A$0.4m. Cash used in operations was A$10.5m. Management is targeting annualised cost savings of A$3.4m to A$3.9m, which it expects to realise from FY27. Research cash outflows are expected to start falling from the December 2026 quarter as the TRIPP-FFX and PANCOSIL studies close out.

Manufacturing in Sydney

On 9 September Cyclotek, the contract manufacturer hosting OncoSil's Sydney production line at Macquarie Park, received ISO 13485 certification, the international quality standard for medical device makers. OncoSil must now have the Macquarie Park site added to its existing European certificate through its notified body, and it aims to start production by the end of CY26, subject to that review. The company says capital intensity at the site, meaning the capital it needs relative to sales, would be below 5% at full capacity.

PALACROS and the PULSE Trial

On 13 October OncoSil took part in the official launch in Amsterdam of PALACROS, a European research program backed by the EU's Horizon Europe funding and the EU Mission on Cancer. OncoSil's part is the PULSE trial, which tests whether treating patients every three months until the cancer progresses holds the tumour in check for longer than a single implant. It is a randomised Phase II study in 120 patients at five European centres, in people whose pancreatic cancer cannot be removed and has not progressed after at

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least four months of chemotherapy. The main measure is the share of patients with no growth of the treated tumour at nine months.

The commercial attraction is cost and upside. OncoSil supplies the devices and the trial sponsor carries every other cost, which the company estimates saves about A$9m against running the study itself. If repeat treatment works, each patient could use more than one device, generating additional revenues.

Spain Reaches 100 Patients

OncoSil treated its 100th patient in Spain on 7 September. It now has 11 active treatment sites in a country with about 9,200 new pancreatic cancer cases a year, and management says its focus is turning to getting more use out of that network. Across all markets the company expects about 50 active treatment centres by the end of CY26.

Real-World Results Grow

On 30 September OncoSil announced that results from OSPREY, its registry of patients treated in everyday hospital practice, had been selected for an oral presentation at the European Association of Nuclear Medicine congress in Vienna. Updated results presented on 20 October cover 88 patients at 19 centres in Spain, Italy, Greece and Austria, up from 64 in the original abstract. No serious side effects from the device were reported. Ten patients went on to have their tumour surgically removed, up from seven, and in eight of them no cancer was left at the edges of the removed tissue. Twelve weeks after the implant, the treated tumour had not grown in 88.6% of patients treated within four months of starting chemotherapy.

Median overall survival was 19.8 months for first-line patients who had the device within four months of starting chemotherapy, and 25.1 months for those treated between four and twelve months after starting it. A separate poster from Bilkent City Hospital in Ankara described seven patients treated with the device alongside FOLFIRINOX, the chemotherapy the company wants added to its European label. Five went on to surgery. In the registry itself, 10 of 88 patients (about 11%) had surgery. If the device helps turn some inoperable tumours into operable ones, that could strengthen the case for reimbursement.

Revenue Pipelines

OncoSil has two revenue pipelines. Unresectable locally advanced pancreatic cancer (LAPC) is the volume business and is the one earning revenue today. Distal cholangiocarcinoma (dCCA, a cancer of the lower bile duct) is a smaller, currently US opportunity that is targeted to start in 1H CY27. For each we set out where OncoSil is approved, how many patients there are, how they are treated now and what treatment costs.

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Pipeline 1: Unresectable locally advanced pancreatic cancer (LAPC)

Question	Answer
Where is OncoSil approved?	CE Mark covers the EU and UK, and the TGA approved the device in Australia in May 2026. The company says it is approved for sale in 30+ countries, including Saudi Arabia, Türkiye and Israel, and has treated patients in Spain, Italy, Austria, Germany, Greece, Türkiye, Portugal, Israel and the UK. The approved use is alongside gemcitabine-based chemotherapy. The US approval is for distal cholangiocarcinoma (dCCA) only, so there is no US approval for LAPC.
How many people have it?	Europe has about 147,000 new pancreatic cancer cases a year (a 2024 estimate for the whole continent, including countries where OncoSil is not approved) and Australia has 4,353 (company figure), about 151,500 in total. The company assumes that 30% of pancreatic cancer cases are locally advanced, which gives about 45,500 LAPC patients a year.
How is it treated today?	Standard care is chemotherapy, with or without radiotherapy. Modified FOLFIRINOX (a combination of four chemotherapy drugs) is favoured, with gemcitabine plus nab-paclitaxel as an alternative. Some centres add stereotactic body radiotherapy (SBRT, a tightly focused beam). OncoSil is injected into the tumour in one procedure, using an endoscope with an ultrasound probe, and is given alongside the chemotherapy.
How much does treatment cost?	We use about A$40,000 per treatment, derived from the A$5.6m of device sales the company expects from about 140 OncoSil patients in the German trial. For context, first-line chemotherapy care for pancreatic cancer that has already spread cost roughly US$100,000 to US$140,000 depending on regimen and insurer per patient (on average in 2023).

At our estimate of about A$40,000 per treatment, one treatment for each of the 45,500 LAPC patients would be about A$1.8bn a year (about A$1.77bn in Europe and A$52m in Australia). This is a ceiling and not a forecast. It includes countries where OncoSil is not approved, assumes every patient is suitable and treated once, and applies our European price estimate to Australia.

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Pipeline 2: Distal cholangiocarcinoma (dCCA)

Question	Answer
Where is OncoSil approved?	The United States only. The FDA approved the device on 14 August 2026 under its Humanitarian Device Exemption (a pathway for devices that treat rare conditions) for unresectable dCCA that has not spread, as an addition to drug treatment. Use is limited at first to a 30-patient post-approval study at up to five academic centres.
How many people have it?	About 8,000 Americans are diagnosed with bile duct cancer a year. Of these, the company estimates 30% to 40% are distal and puts the number within the approved label at about 1,000 a year. At US$55,000 per dose that implies a market of about US$55m (~A$80m). The US also has about 67,500 new pancreatic cancer cases a year, but OncoSil is not yet approved for those.
How is it treated today?	Common treatment is gemcitabine and cisplatin chemotherapy together with the immunotherapy durvalumab (Imfinzi), with pembrolizumab (Keytruda) as an alternative. OncoSil is injected into the tumour through an endoscope and is added to the drug treatment.
How much does treatment cost?	OncoSil filed a price of US$55,000 per dose with the US Medicare agency, with a decision targeted for 1 January 2027. Durvalumab alone costs about US$13,000 per three-week cycle in the US, so the eight cycles given with chemotherapy come to about US$105,000. At UK list prices a single durvalumab dose is about £7,400. Durvalumab is given every three weeks for up to eight cycles with chemotherapy, then every four weeks on its own until the cancer progresses. A patient who stays on treatment for a full year would receive about 15 doses, roughly £111,000 at UK list price or US$195,000 at the US price. Many patients stop sooner because the cancer progresses.

The Next 12 Months

Over the next twelve months the story moves from approvals to revenue.

The September-quarter cash flow report is due by the end of October and gives the first look at spending after the raise. By the end of CY26 the company's guidance points to seven things:

1. The first sites in the German G-BA trial (280 patients at 40 hospitals, funded by Germany's G-BA, in a market the company puts at 2,000 to 3,000 patients a year)
2. A European label filing to add FOLFIRINOX, a common chemotherapy combination, to the approved use

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3. A European label filing for percutaneous delivery, meaning injection through the skin by interventional radiologists
4. Sydney production once the notified body approves the site
5. 50 active treatment centres worldwide
6. Italy growing from four to eight authorised hospitals
7. In the US, the company still has to confirm the post-approval study protocol and line up its first centres. CMS is targeted to decide on the pass-through payment on 1 January 2027.

The US and Australian launches are both guided to 1H CY27. In the US the first treatments will be for distal cholangiocarcinoma (dCCA) at up to five academic centres, with the Medicare pass-through payment as the hospital's extra reimbursement if CMS approves. In Australia the company estimates about 1,300 patients a year are addressable once reimbursement is in place. In Europe the company targets approval of both label changes in the same half, which would let OncoSil be used alongside the standard FOLFIRINOX chemotherapy regimen and by interventional radiologists as well as endoscopists. The December-quarter cash flow report, due by the end of January, will show pre-launch spending.

Beyond these near-term catalysts, several longer-term milestones will determine the pace of commercial adoption. These include recruitment into PULSE, the German trial enrolling over about two years, and the US study enrolling its 30 patients, which opens the wider-distribution conversation with the FDA. The company expects higher production volumes to improve gross margin, and volumes at Macquarie Park will show whether that reaches the accounts.

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Future Catalysts

Catalyst	Expected timing	Significance
Quarterly cash flow reports for the September and December quarters	By Oct 2026 and Jan 2027	First read on spending after the raise and on sales momentum
G-BA trial starts in Germany (~280 patients, ~40 hospitals)	By end CY26	Government-funded evidence, paid device supply and a path to German national reimbursement
European label filing: FOLFIRINOX chemotherapy	By end CY26	Begins the regulatory review to add FOLFIRINOX, a common chemotherapy combination to the approved use
European label filing: percutaneous delivery (through the skin)	By end CY26	Begins the regulatory review to let interventional radiologists use the device, widening who can treat
Macquarie Park added to the European certificate; Sydney production starts	By end CY26 (subject to approval)	Supply security and the path to better gross margin
US post-approval study protocol confirmed; first centres activated	Before US launch (no date given)	Gate to the first US treatments
Network growth: about 50 active centres worldwide	By end CY26	Wider footprint drives unit sales
CMS decision on Transitional Pass-Through payment	1 Jan 2027	Extra Medicare payment for up to three years from launch; US$55,000 a dose filed
US launch: first dCCA treatments at up to five centres	1H CY27	First US revenue; we estimate about US$1.7m across the 30-patient study
Australian commercial launch	1H CY27	~1,300 addressable patients a year once reimbursed
European label approval: FOLFIRINOX chemotherapy	1H CY27	Aligns the label with standard chemotherapy and widens the eligible patient population across the EU and UK.
European label approval: percutaneous delivery	1H CY27	Opens the device to interventional radiologists as well as endoscopists
PULSE trial first patient (120 patients, repeat dosing)	To be confirmed	Start of recruitment, the first step towards evidence on repeat treatment

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

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ASX Comparisons

The table below sets out ASX-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	Phase 3 imaging; Phase 1 and 2 therapies; no product revenue	587.6
Cyclopharm (ASX: CYC)	Technegas, a radioactive aerosol the patient breathes in so the lungs can be scanned	Commercial; FDA approved, US rollout under way	46.5
Amplia (ASX: ATX)	Narmafotinib, an oral capsule given alongside chemotherapy for advanced pancreatic cancer	Phase 2b initiated; no product revenue	40.0
OncoSil Medical (ASX: OSL)	**OncoSil phosphorus-32 microparticle brachytherapy; LAPC and dCCA; endoscopic ultrasound delivery**	**Commercial in Europe; approved in Australia (TGA) and the US (HDE/FDA)**	25.7
Radiopharm Theranostics (ASX: RAD)	Portfolio of injected radioactive imaging and treatment agents	Pivotal Phase 3 imaging trial planned; no product revenue	23.6

As of 26 October 2026

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Global Comparisons

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

Assumptions: 1 USD = 1.42 AUD; 1 SEK = 0.14 AUD; 1 EUR = 1.60 AUD

Company (Ticker)	Lead Asset, Indication and Delivery	Annual Revenue (most recent FY; AUD, m)	Market capitalisation (AUD, m)
Elekta (Nasdaq Stockholm: EKTA B)	Radiotherapy machines (including Elekta Evo) that aim radiation at tumours from outside the body, plus internal radiation (brachytherapy) equipment; cancers and some brain disorders	2,340.5	3,081.1
Novocure (Nasdaq: NVCR)	Optune, device worn on the skin that sends electric fields into the tumour to disrupt cancer cell division; glioblastoma, mesothelioma, lung and locally advanced pancreatic cancer	930.6	2,427.4
Eckert & Ziegler (XETRA: EUZ)	Radioactive isotopes and sources; supplies radioactive ingredients, gallium generators and contract manufacturing to makers of radiopharmaceuticals; also makes brachytherapy seeds implanted into the prostate	499.1	1,320.6
AngioDynamics (Nasdaq: ANGO)	NanoKnife, which destroys tumour cells with short electrical pulses through electrodes placed in the tumour; prostate and liver cancer, also studied in pancreatic cancer	454.6	738.4
Profound Medical (Nasdaq: PROF; TSX: PRN)	TULSA-PRO, which uses ultrasound from a probe in the urethra, guided by MRI, to heat and destroy prostate tissue; prostate cancer and benign prostate disease	22.9	288.4

As of 26 October 2026

Sector M&A Landscape

Beyond listed market comparables, M&A activity provides further context for how larger pharmaceutical companies value assets and capabilities in nuclear medicine. A relevant transaction was AstraZeneca's acquisition of Fusion Pharmaceuticals, completed in June 2024, with an upfront payment of about US$2.0bn, potentially rising to US$2.4bn if a regulatory milestone is met by August 2029. Fusion was a clinical-stage company developing radioconjugates (medicines that attach a radioactive isotope to a tumour-seeking molecule), led by an actinium-225 treatment for advanced prostate cancer.

Also in 2024, Novartis agreed to acquire Mariana Oncology for US$1.0bn upfront, plus up to US$750m in milestone payments. Mariana was a preclinical-stage company developing radioligand therapies (medicines that pair a tumour-seeking molecule with a radioactive isotope), led by an actinium-based candidate for small cell lung cancer.

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In January 2025, Lantheus agreed to acquire Evergreen Theragnostics (completed in April 2025) for US$250m upfront, plus up to US$752.5m in development and sales milestones, adding radiopharmaceutical manufacturing infrastructure, including a contract manufacturing business, and an oncology pipeline led by OCTEVY, an imaging agent for neuroendocrine tumours. Together, these transactions demonstrate continued strategic interest in radiopharmaceuticals, including radioactive cancer treatments, and in specialised platforms.

Risks to the Story

Timing: The German trial start has slipped before. In October 2025 and again in April 2026 the company guided to a start in Q4 FY26, which is April to June 2026. On 30 July 2026 it reported a delay in the start and now expects it "later in calendar year 2026", with sites activated in stages.

US scale: US revenue in 1H CY27 is limited to the 30-patient study at up to five centres. Wider distribution depends on FDA discussions after enrolment, and the pass-through status is an application, not an approval.

Licence payments: Under its licence, OncoSil pays the technology licensor, pSiMedica, a royalty of 8% of net sales. A first milestone payment falls due once cumulative net sales reach US$5m. Sales had reached US$2.9m by 30 June 2026, so about US$2.1m more is needed.

Closing Thoughts

OncoSil delivered on near-term items we flagged on 19 August. It has lodged the US reimbursement application, secured funding, had its Sydney manufacturing partner certified, launched the European program that will test repeat treatment, and reached 100 patients in Spain, all while growing FY26 unit sales by 53%.

The next twelve months are about turning approvals into revenue. The events to watch are the US decision on the extra Medicare payment on 1 January 2027, the first US and Australian treatments in 1H CY27, and the European label changes in the same half. Along the way, the German trial, Sydney production and growth in Italy and Spain should show whether sales can grow faster than costs.

The main risk is time. Cash covers about a year at the FY26 spending rate, so delays to the US or Australian launches would bring the next capital raise forward. If the milestones land on schedule, the company reaches 2027 with approvals converting into revenue and a clearer line of sight to breakeven.

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