

ASX Announcement

30 October 2026

Quarterly Activities & Cash Flow Report
Quarter ended 30 September 2026

**OncoSil Medical Achieves Landmark U.S. FDA Approval
and Accelerates Global Commercial Expansion in Q1 FY27**

Key highlights

- Strong revenue growth reflects increasing commercial adoption – Q1 FY27 sales revenue increased 45.8% year-on-year compared with Q1 FY26, demonstrating growing commercial traction.
- U.S. FDA grants HDE approval for the OncoSil™ device for distal cholangiocarcinoma, establishing a pathway to the U.S. market.
- Cyclotek achieves ISO 13485 certification following completed manufacturing validation.
- \$5.6 million raised from the Company's three largest institutional shareholders to support U.S. and Australian commercial launches.
- 100th patient treated with the OncoSil™ device in Spain across 11 active treatment sites.
- Updated TRIPP-FFX results presented at ESMO GI 2026; OSPREY Registry data accepted for oral presentation at EANM 2026.
- OncoSil Medical selected to participate in the PALACROS European academic consortium through the PULSE Phase II study.
- Cash and cash equivalents of \$8.7 million as at 30 September 2026.

Sydney, Australia – 30 October 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 announce its Appendix 4C cash flow report for the quarter ended 30 September 2026 (Q1 FY27), along with the following financial and operational update.

OncoSil Medical CEO & Managing Director Nigel Lange said:

"Q1 FY27 was a landmark quarter for OncoSil Medical, highlighted by FDA approval of OncoSil™ for distal cholangiocarcinoma in the United States, continued progress across our clinical programmes and further expansion of our international commercial footprint. These achievements represent important steps in our ambition to make OncoSil™ available to more patients who may benefit from this innovative treatment.

With a clear pathway towards our planned U.S. commercial launch, progress towards establishing Australian

manufacturing capability and growing adoption in established markets such as Spain, we are increasingly focused on translating our regulatory and clinical achievements into sustainable commercial growth. The encouraging results from our TRIPP-FFX study and OSPREY Registry further strengthen the evidence supporting OncoSil™ and our efforts to broaden its clinical use.

Supported by the recent investment from our major institutional shareholders, we enter the next quarter focused on executing our key regulatory, manufacturing and commercial milestones. We believe these initiatives position OncoSil Medical to build momentum across our priority markets and create long-term value for patients, clinicians and shareholders.”

Strong Q1 FY27 revenue growth reflects increasing commercial adoption

OncoSil Medical delivered strong commercial performance during the quarter, with sales revenue increasing 45.8% year-on-year compared with Q1 FY26, reflecting growing adoption of the OncoSil™ device across established markets.

This growth demonstrates increasing commercial traction and provides a strong foundation for future expansion. Combined with recent regulatory approvals and progress towards Australian manufacturing, the Company is well positioned to accelerate revenue growth as it advances commercialisation in the United States, Australia and Saudi Arabia.

U.S. FDA approval and reimbursement pathway establishes major commercial opportunity

OncoSil Medical achieved a landmark regulatory milestone during the quarter, announcing on 17 August 2026 that the U.S. Food and Drug Administration (FDA) had granted Humanitarian Device Exemption (HDE) approval for the OncoSil™ device for the treatment of distal cholangiocarcinoma (dCCA). The approval provides U.S. marketing authorisation for patients with unresectable, non-metastatic dCCA as an adjunct to systemic therapy, representing a major step forward in the Company's global commercialisation strategy.

The approval makes OncoSil™ the first and only FDA-approved Class III medical device for dCCA. The Company estimates an annual addressable U.S. patient population of approximately 1,000, representing a potential total addressable market of A\$80 million per annum.

Following this achievement, the Company announced on 2 September 2026 that it had applied to the U.S. Centers for Medicare & Medicaid Services (CMS) for Transitional Pass-Through (TPT) Payment status at a proposed price of US\$55,000 per dose. The CMS review process regarding Transitional Pass-Through (TPT) status remains ongoing. While 1 January 2027 had previously been identified as a possible commencement date, the timing of any potential commencement remains subject to the outcome and timing of the CMS process. The Company will provide further updates as appropriate. If approved, TPT status could provide supplemental reimbursement for up to three years, supporting hospital adoption and the Company's U.S. commercialisation strategy.

Under the FDA approval conditions, initial distribution is limited to five academic medical centres participating in a mandatory Post-Approval Study (PAS) involving 30 patients. The Company intends to engage with the FDA regarding broader U.S. distribution following completion of patient enrolment, with the study's follow-up period extending for approximately 24 months.

Together, the FDA approval and reimbursement application represent significant progress towards establishing a sustainable U.S. commercial business. With a planned commercial launch during the second half of FY27, the Company is focused on translating regulatory approval into clinical adoption, expanding patient access and developing a new revenue stream in the world's largest healthcare market.

Saudi FDA approval expands Middle East commercial access

OncoSil Medical announced on 20 July 2026 that the OncoSil™ device had received approval from the Saudi Food and Drug Authority (Saudi FDA), providing access to the Middle East's largest healthcare market. Importantly, eligible Saudi nationals can receive fully reimbursed OncoSil™ treatment, removing a significant financial barrier to patient access.

TRIPP-FFX and OSPREY clinical data strengthen evidence base and supports broader adoption

OncoSil Medical announced encouraging updated results from its Phase II TRIPP-FFX study at ESMO GI 2026, confirming achievement of both co-primary endpoints of safety/tolerability and local disease control at 16 weeks. The intention-to-treat analysis demonstrated a local disease control rate of 82.2% and median overall survival of 18.2 months in patients receiving OncoSil™ plus FOLFIRINOX. The updated per-protocol analysis demonstrated median overall survival of 21.3 months compared with 15.6 months in the chemotherapy-only group, with encouraging surgical resection outcomes and no new safety signals. These results support the Company's planned regulatory submission to expand the OncoSil™ product label to include FOLFIRINOX, subject to approval.

Separately, the Company announced that initial outcomes from its OSPREY real-world registry had been selected for oral presentation at EANM 2026 in October. The analysis included 64 patients across 19 European centres and demonstrated 12-week local disease control rates of 91.4% in first-line patients and 77.8% in second-line patients, with no Grade 3 or higher adverse device effects reported. Seven patients underwent surgical resection, including five R0 resections. Together, the TRIPP-FFX and OSPREY findings strengthen the clinical evidence supporting OncoSil™, reinforce physician confidence and support the Company's regulatory and commercial expansion strategy.

PALACROS Consortium selection strengthens European clinical development

OncoSil Medical announced on 2 July 2026 that its European subsidiary (OncoSil Medical Europe GmbH) had been selected to participate in PALACROS, a major European academic research consortium focused on

improving outcomes for patients with locally advanced pancreatic cancer. The Company will participate through the PULSE Phase II study, a multicentre, randomised trial evaluating repeat OncoSil™ treatment in 120 patients across five European centres.

The consortium is supported by European Union grant funding, with OncoSil Medical contributing device treatments in-kind and incurring no other study-related costs under the announced arrangement. The Company estimates this participation represents approximately A\$9 million in savings compared with an equivalent Company-sponsored study, providing a capital-efficient opportunity to expand clinical evidence and strengthen relationships with leading European treatment centres.

Australian manufacturing capability advances towards commercial production

OncoSil Medical achieved significant manufacturing milestones during the quarter through its strategic partnership with Cyclotek, successfully completing three validation cycles involving more than 50 OncoSil™ device doses. The dedicated manufacturing capability at Cyclotek's Macquarie Park facility in Sydney is supported by approximately A\$2.1 million of Company-owned specialised equipment, establishing a scalable platform for future commercial supply.

Further progress was achieved in September when Cyclotek received ISO 13485 certification, an internationally recognised quality management standard for medical device manufacturing. Subject to the remaining Notified Body approval requirements, commercial production is targeted to commence by the end of 2H FY27. The facility is expected to improve supply chain resilience, manufacturing efficiency and production scalability as global demand increases.

For investors, ISO 13485 certification, together with completed validation, substantially de-risks a key component of the Company's commercial strategy and brings the Company closer to an Australian production capability to support the planned launches in Australia and the United States. Once operational, the facility is expected to support significantly higher annual production capacity with capital intensity of less than 5% at full capacity, provide greater control over product quality and supply chain resilience, and over time support improvements in gross margins as production volumes and efficiencies increase.

Spanish commercial adoption reaches 100-patient milestone

OncoSil Medical announced on 8 September 2026 that the 100th patient in Spain had been treated with the OncoSil™ device, with the milestone procedure performed at Hospital HM Sanchinarro in Madrid. Spain remains the most important European market for the Company, with 11 active treatment sites supporting access to OncoSil™ for eligible patients.

The milestone demonstrates continued clinical adoption and provides a strong foundation for increasing treatment volumes through greater utilisation of existing centres and expansion into additional hospitals. With approximately 9,200 new pancreatic cancer cases diagnosed annually in Spain, the Company remains focused on strengthening physician engagement and expanding patient access to support further commercial growth.

\$5.6 million institutional funding strengthens financial position

OncoSil Medical announced on 7 September 2026 that it had secured A\$5.6 million in capital commitments from its three largest institutional shareholders, Pengana High Conviction Equities Fund, Regal Partners and Australian Ethical Investments. The funding comprised a A\$4.0 million placement at A\$1.00 per share and approximately A\$1.6 million from the early exercise of listed options at A\$0.90 per option, with the placement price representing a 9.9% premium to the Company's last traded share price.

For investors, the participation of the Company's largest institutional shareholders, including the exercise of options well ahead of their June 2027 expiry, reflects confidence in the Company's strategy and outlook. The funds will support the commercial launch of the OncoSil™ device in the United States and Australia following FDA and TGA approvals, and lifted the Company's pro forma cash position to \$12.1 million, based on cash of \$6.5 million at 30 June 2026.

Finance update

The Appendix 4C Quarterly Cash Flow report for the September 2026 quarter is attached to this announcement.

During the quarter ended 30 September 2026, OncoSil Medical continued to maintain disciplined financial management while advancing its regulatory, manufacturing and commercialisation objectives.

The Company had \$8.7 million in cash and cash equivalents as at 30 September 2026, increasing by \$2.2 million from \$6.5 million at 30 June 2026, including proceeds from the \$5.6 million institutional capital raise completed in September 2026.

The Company received customer receipts of \$0.47 million during the quarter, a decrease of 26.6% compared with the prior corresponding period (Q1 FY26: \$0.64 million). While cash receipts were lower than the prior corresponding period, recognised revenue increased by 45.8% when compared to the same period reflecting continued growth in commercial activity.

The difference between cash receipts and recognised revenue is primarily attributable to the timing of customer collections rather than underlying sales performance. Revenue is recognised when performance obligations are satisfied, whereas cash receipts depend on when customers settle their invoices. Collection periods vary depending on the commercial terms agreed with individual customers and, as a result, revenue recognised during the quarter may not be collected until a subsequent reporting period.

Research and development payments increased by \$0.54 million from the prior quarter to \$1.3 million, primarily due to the close out of the TRIPP-FFX study. The Company continues to expect research and development cash outflows to decline from the second quarter of FY27 as trial activities are completed.

The Company continues to carefully manage its cost base while prioritising investment in:

- Preparation for U.S. commercial launch following FDA HDE approval, including treatment centre establishment, clinician training, and reimbursement and market access;

- Commercial launch in Australia following TGA approval;
- Sales growth in key existing markets to include Spain, Germany, Italy, Greece, Israel and Saudi Arabia;
- Regulatory approvals related to label expansion for additional chemotherapy and percutaneous application; and
- Commercial production from the Sydney manufacturing facility with Cyclotek.

Management remains focused on aligning expenditure with strategic milestones and revenue generation opportunities.

Pursuant to Listing Rule 4.7C.3 and as disclosed in Item 6.1 of the attached Appendix 4C, \$179,341 was paid in respect of remuneration of director fees in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

Milestones expected in FY27

1H FY27	2H FY27
<ul style="list-style-type: none"> • G-BA funded study CRO final approval • Finalisation of FDA Post-Approval Study protocol and activation of initial U.S. treatment centres* • EU regulatory submission – percutaneous label change (PANCOSIL) • EU regulatory submission – FOLFIRINOX label change (TRIPP-FFX) 	<ul style="list-style-type: none"> • Commercial sales from OncoSil Cyclotek manufacturing facility in Sydney* • EU regulatory approval – percutaneous label change (PANCOSIL) • EU regulatory approval – FOLFIRINOX label change (TRIPP-FFX) • Launch of OncoSil™ device in Australia • Launch of OncoSil™ device in the United States* • G-BA funded study commencement

* subject to approvals

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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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 (³²P) 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 12th most common cancer in men and the 11th most common cancer in women across the globe, with 500,000 new cases detected every year¹. 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>

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

ONCOSIL MEDICAL LIMITED

ABN

89 113 824 141

Quarter ended ("current quarter")

30 September 2026

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	467	467
1.2 Payments for		
(a) research and development	(1,290)	(1,290)
(b) product manufacturing and operating costs	(723)	(723)
(c) advertising and marketing	(32)	(32)
(d) leased assets	(16)	(16)
(e) staff costs	(1,137)	(1,137)
(f) administration and corporate costs	(465)	(465)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	45	45
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	76	76
1.9 Net cash from / (used in) operating activities	(3,075)	(3,075)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(279)	(279)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5,631	5,631
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	2	2
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4)	(4)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	5,629	5,629

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,476	5,476
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,075)	(3,075)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(279)	(279)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	5,629	5,629
4.5	Effect of movement in exchange rates on cash held	(30)	(30)
4.6	Cash and cash equivalents at end of period	8,721	8,721

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	8,721	6,476
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	8,721	6,476

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	179
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at quarter end		-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,075)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,721
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,721
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.84
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>		
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	Answer: N/A	
8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
	Answer: N/A	
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
	Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>		

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 30 October 2026

Authorised by: By the Board of Directors
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.