ASX Announcement

2 November 2026

OncoSil Medical Submits Regulatory Application for Australian Manufacturing Facility

Key highlights

- **OncoSil Medical has submitted its regulatory application to its Notified Body to include Cyclotek's Macquarie Park manufacturing facility under the Company's existing certification.**
- **The submission represents a significant milestone towards commencing commercial production of the OncoSil™ device in Australia, targeted for 2H FY27, subject to regulatory approval.**
- **The Macquarie Park facility is a key component of OncoSil Medical's growth strategy, designed to significantly increase production capacity, strengthen supply chain resilience and support expanding global commercial activities.**
- **Once operational, the facility is expected to deliver greater manufacturing efficiencies and improved gross margins as production volumes increase, while maintaining capital intensity of less than 5% at full capacity.**

Sydney, Australia – 2 November 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 the submission of a regulatory application to its Notified Body for the inclusion of Cyclotek's Macquarie Park manufacturing facility in Sydney as a critical subcontractor under OncoSil Medical's existing certification.

The submission represents an important milestone in the Company's strategy to establish a scalable, capital-efficient manufacturing platform capable of supporting the increasing commercialisation of the OncoSil™ device across international markets.

It follows the achievement of ISO 13485 certification by Cyclotek in September 2026[1], which confirmed that Cyclotek's Quality Management System meets the internationally recognised standard for medical device manufacturing.

The regulatory submission is the next key step towards enabling commercial production of the OncoSil™ device at Macquarie Park, subject to the successful completion of the Notified Body's review and applicable approval processes.

A strategically important manufacturing platform for OncoSil Medical

The establishment of the Macquarie Park facility is a central component of OncoSil Medical's long-term commercialisation and growth strategy.

As the Company expands its international commercial activities, the ability to manufacture the OncoSil™ device at significantly greater scale, efficiently and reliably, will be increasingly important.

The facility has been designed to provide a substantial increase in annual production capacity, creating the manufacturing infrastructure necessary to support growing demand across existing markets and future commercial expansion.

Importantly, the facility combines Cyclotek's established infrastructure with OncoSil-owned manufacturing equipment and the Company's proprietary manufacturing process. This approach enables OncoSil Medical to establish significant manufacturing capability without the capital investment typically associated with developing a standalone production facility.

At full capacity, the manufacturing model is expected to operate with capital intensity of less than 5%, providing an attractive platform for scaling production as commercial demand increases.

The facility is also expected to deliver important financial and operational benefits, including:

- **Improved gross margins:** Greater production volumes and manufacturing efficiencies are expected to reduce unit manufacturing costs and support significant improvements in gross margins over time.
- **Scalable manufacturing capacity:** The facility is designed to accommodate increasing global demand without requiring a proportionate increase in capital investment.
- **Enhanced supply chain resilience:** Establishing Australian manufacturing capability is expected to strengthen the reliability and flexibility of OncoSil Medical's global product supply.
- **Greater operational control:** The manufacturing model is expected to provide improved oversight of product quality, manufacturing processes and production planning.
- **Support for global commercial expansion:** Increased production capability will provide a foundation for supporting broader adoption of the OncoSil™ device across approved markets.

Collectively, these benefits are expected to position Macquarie Park as a strategically important manufacturing platform underpinning the Company's long-term growth and commercial objectives.

Nigel Lange, CEO & Managing Director of OncoSil Medical, said:

"The regulatory submission represents another important milestone towards commencing commercial production at our Macquarie Park facility. This facility is a critical part of our strategy to build a scalable and capital-efficient manufacturing platform to support our growing global commercial activities. We expect it to significantly increase production capacity, strengthen supply chain resilience and deliver manufacturing efficiencies that have the potential to materially improve gross margins over time.

We remain focused on completing the regulatory process and bringing this strategically important facility into commercial operation."

Next steps towards production

Following submission of the regulatory application, the next stage involves review by OncoSil Medical's Notified Body and the completion of any associated regulatory requirements necessary to incorporate the

Macquarie Park facility into the Company's existing certification.

Subject to the applicable regulatory review and approval processes, OncoSil Medical is targeting commencement of commercial production at the Macquarie Park facility in 2H FY27.

The Company will provide further updates as material milestones are achieved.

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.

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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 (^{32}P) 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 year[2]. 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] Company announcement on 9 September 2026

[2] https://gco.iarc.fr/en