

ASX Announcement

13 July 2026

OncoSil Medical Completes Manufacturing Validation Establishing Scalable Australian Production Capability

Key Highlights

- Three manufacturing validation cycles successfully completed with manufacturing partner Cyclotek confirming production of more than 50 validation doses of the OncoSil™ device
- Dedicated Australian manufacturing capability established, supported by OncoSil Medical-owned manufacturing equipment
- Total capital investment of approximately \$2.1 million, supporting significantly higher annual production capacity with capital intensity of <5% at full capacity
- Capital efficient manufacturing model expected to improve gross margins over time while providing greater control over manufacturing capability, product quality and supply chain operations
- Subject to regulatory inspection and approval, commercial production is expected to commence this calendar year (2H CY2026)

Sydney, Australia – 13 July 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), is pleased to announce the successful completion of three manufacturing validation cycles, representing more than 50 validation doses with its strategic manufacturing partner, Cyclotek.

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

"The successful completion of our manufacturing validation program is a significant operational milestone for OncoSil Medical. Through our strategic partnership with Cyclotek, we have established a scalable Australian manufacturing capability that combines the efficiency of an experienced manufacturing partner with ownership of our specialised production equipment and proprietary manufacturing process. This model strengthens our control over quality, supply and manufacturing capability while supporting improved margins and positioning the Company to meet growing global commercial demand."

Importantly, completing manufacturing validation substantially de-risks a key component of our commercial strategy by demonstrating that we have a validated production capability ready to support future market demand, subject to regulatory approval. We look forward to commencing commercial production during the second half of calendar 2026 following the completion of the regulatory approval process."

Australian manufacturing capability established

OncoSil Medical established a dedicated Australian manufacturing capability through a strategic manufacturing partnership with Cyclotek during FY26. As part of this initiative, OncoSil Medical invested approximately \$2.1 million in specialised production equipment and implemented its proprietary manufacturing process within Cyclotek's existing Macquarie Park facility at Macquarie University Hospital in Sydney, Australia.

Capital-efficient manufacturing model

This capital-efficient manufacturing model is designed to support future commercial growth, strengthen supply chain resilience and improve production economics, while enabling OncoSil Medical to retain ownership and control of its critical manufacturing assets, proprietary manufacturing process and production know-how.

Cyclotek provides the manufacturing facility and operational manufacturing services, while OncoSil Medical retains ownership of the specialised production equipment and proprietary manufacturing process used to manufacture the OncoSil™ device. This structure provides OncoSil Medical with strategic control over manufacturing capability and product quality while leveraging Cyclotek's established manufacturing infrastructure and operational expertise.

Validated manufacturing platform

The manufacturing capability incorporates validated production processes and specialised equipment designed to manufacture the OncoSil™ device efficiently, safely and in accordance with applicable quality and regulatory requirements, including ISO 13485, Therapeutic Goods Administration (TGA) and U.S. Food and Drug Administration (FDA) expectations. Cyclotek is currently completing ISO 13485 certification.

To support future commercial demand, OncoSil Medical has also introduced proprietary Type A finished packaging, ampoules and POTs, together with an expanded network of specialist logistics partners, creating a scalable manufacturing and distribution platform capable of supporting global commercial supply.

Manufacturing validation and regulatory progress

Manufacturing validation has now been successfully completed with Cyclotek with confirmed production of more than 50 doses of the OncoSil™ device, and the Company is progressing through the final regulatory inspection and approval process.

Subject to receiving the necessary approvals, OncoSil Medical expects to commence commercial production in the second half of calendar 2026, representing a significant milestone in the Company's commercialisation strategy.

Enhanced economics and commercial scalability

OncoSil Medical's investment in specialised manufacturing equipment and validated production processes is expected to improve gross margins over time through enhanced manufacturing efficiencies while providing greater control over manufacturing capability, product quality and supply chain management as commercial volumes increase.

By combining ownership of its critical manufacturing assets, proprietary manufacturing process and intellectual property with Cyclotek's manufacturing expertise and infrastructure, OncoSil Medical has established a scalable and capital-efficient manufacturing platform designed to support future global commercial growth.

The establishment of this validated manufacturing capability is expected to support the Company's planned commercial expansion across existing and new markets as regulatory approvals and market adoption continue to progress.

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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:OSL) is a global medical device company focused on Interventional Oncology. OncoSil Medical's mission is to improve the outcomes for people living with cancer by utilizing the selected and targeted intratumoural placement of Phosphorous-32 (³²P) Microparticles in addition to chemotherapy.

OncoSil Medical has developed OncoSil™ device for the treatment of unresectable locally advanced pancreatic cancer. Its targeted approach enables healthcare professionals to deliver a greater radiation dose directly into the tumour compared to external beam radiotherapy, while sparing surrounding critical organs.

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.

OncoSil™ has received CE Marking approval, providing marketing authorisation in both the EU and the UK. OncoSil™ is designated as a breakthrough device in both Europe and the United States. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Australia, 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>