ASX Announcement

9 September 2026

Australian Manufacturing Facility Achieves ISO 13485 Certification

A major milestone towards full commercial production before the end of 2Q FY27

Key points

- **OncoSil Medical's contract manufacturer Cyclotek has received ISO 13485 certification, an internationally recognised quality management standard for the medical device industry.**
- **The certification represents an important step in the regulatory and quality pathway for establishing manufacturing of the OncoSil™ device at the Macquarie Park facility in Sydney.**
- **The next regulatory step is to add the Macquarie Park site as a critical subcontractor to OncoSil Medical's Notified Body (NB), allowing the NB to add Cyclotek to OncoSil Medical's existing certificate.**
- **OncoSil Medical is aiming to complete the certification process and commence production of the OncoSil™ device at Macquarie Park by the end of 2Q FY27, subject to the applicable regulatory review and approval processes.**
- **Once operational, the facility will support significantly higher annual production capacity with capital intensity of <5% at full capacity.**

Sydney, Australia – 9 September 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 that its contract-manufacturer, Cyclotek, has received ISO 13485 certification. Achieving ISO 13485 means that Cyclotek has demonstrated that their Quality Management System (QMS) meets this international standard. This is an important milestone in the establishment of OncoSil Medical's Macquarie Park manufacturing facility in Sydney.

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

"ISO 13485 certification is an important achievement in establishing our Macquarie Park manufacturing capability and brings us another step closer to commencing production. Our focus now moves to adding the Macquarie Park site to OncoSil Medical's existing certification, with the aim of completing this process and commencing production of the OncoSil™ device by the end of 2Q FY27.

Macquarie Park is an important part of our strategy to build a scalable and capital-efficient manufacturing platform to support our growing global commercial activities. As we scale, we expect the facility to provide greater control over product quality and our supply chain, while driving manufacturing efficiencies that have

the potential to significantly improve gross margins over time."

Achieving ISO 13485 certification

ISO 13485 is an internationally recognised standard specifying quality management system requirements for organisations involved in the design, production and manufacture of medical devices. The achievement of ISO 13485 certification represents an important step towards bringing the Macquarie Park facility into production. The next regulatory step is to add the Macquarie Park manufacturing site to OncoSil Medical's existing certification.

Progressing towards production

OncoSil Medical is aiming to complete this certification process and commence production of the OncoSil™ device at the Macquarie Park facility by the end of 2Q FY27, subject to the applicable regulatory review and approval processes.

Building scalable manufacturing capability

The Macquarie Park facility is expected to provide significant strategic benefits to OncoSil Medical as the Company scales its global commercial activities. The facility has been designed to provide a scalable production platform capable of supporting increasing global demand for the OncoSil™ device, while maintaining a capital-efficient manufacturing model that combines Cyclotek's existing infrastructure with OncoSil-owned manufacturing equipment and the Company's proprietary manufacturing process. The model is also expected to provide OncoSil Medical with greater control over product quality and manufacturing capability, while strengthening supply chain resilience. Over time, increased production volumes and enhanced manufacturing efficiencies are expected to support improvements in the Company's gross margins.

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[1]. 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