

ASX Announcement / Media Release

22 February 2022

Financial Report – Half-Year ended 31 December 2021 Half-Yearly Report – Appendix 4D

Sydney, Australia – 22 February 2022: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on localised treatments for patients with pancreatic cancer, is pleased to report its financial results for the half year ended 31 December 2021 (the **Half-Year**) (the **Financial Report**) and its Appendix 4D. All financial results are in Australian dollars and are unaudited.

Operational Highlights

Throughout the six-month period to December 2021, OncoSil continued to progress its commercialisation activities across Europe, the US and Asia Pacific.

The key developments and highlights for the first half of the 2022 financial year are as follows:

- ✓ Publication of the PanCO clinical study in ESMO Open;
- ✓ HDE data package re-submitted to the US Food and Drug Administration (FDA) for the use of the OncoSil™ device in the treatment of distal cholangiocarcinoma (DCC or bile duct cancer);
- ✓ Continuing local regulatory approvals and ethics approvals for the OSPREY patient registry within Europe;
- ✓ Training of various hospital sites throughout Europe and the Middle East for implantation of the OncoSil™ device;
- ✓ Further work undertaken on several initiatives in preparation for market access, health insurance coverage and reimbursement applications in various European countries;
- ✓ Identification of distributors in certain countries throughout EMEA and APAC to accelerate registration approvals for the OncoSil™ device;
- ✓ Continued use of the Special Access Scheme in Australia which enables physicians to treat patients with the OncoSil™ device. The company is strictly prohibited to engage in promotional activity around such usage; and
- ✓ Board renewal with the appointment of Mr Otto Buttula as Non-Executive Chairman of the Company, as well as the appointment of Prof. Ricky Sharma as Non-Executive Director. As part of the board renewal, Dr Chris Roberts, Mr Mike Bassett and Dr Roger Aston have stepped down from the Board.

Subsequent to period end

- ✓ In February 2022, the German institute for the Hospital Remuneration System (InEK) granted the OncoSil™ device with a “Positive Status 1” classification under the innovation funding (NUB) program.

COVID-19 Impact

COVID-19 has adversely impacted the Company’s ability in achieving first revenues in the European Union and the United Kingdom. OncoSil has endured limited access to hospitals, which has delayed the Company’s launch, including onboarding, training and marketing activities at these sites. The impact of the COVID-19 pandemic is ongoing and OncoSil continues to monitor and adjust to the situation.

Financial Highlights

- Revenue from commercial sales of approximately \$112k
- Cash, cash equivalents and financial assets balance as of 31 December 2021 of \$6.6M
- R&D tax incentive refund of \$1.077M received during the half-year period

Commenting on the activities during the period, OncoSil Chief Executive Officer Nigel Lange said,

“Notwithstanding the ongoing difficulties posed with the COVID-19 pandemic, the team have been working diligently with various stakeholders to continue license applications and ethics approvals for various hospital sites throughout Europe and the Middle East. Building on the publication of the PanCO study results in a peer-reviewed scientific journal in late December, significant work has and is being undertaken in the area of market access, health insurance coverage and reimbursement applications. The reimbursement applications have been submitted in several markets and we expect these will assist us greatly as country and hospital access restrictions due to COVID-19 begin to be lifted and we are increasingly able to meet with key decision makers in person.”

-ENDS-

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

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About OncoSil

OncoSil Medical is a medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil™ is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with the OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted six clinical studies with positive results on tolerability, safety and efficacy. CE Marking has been granted for the OncoSil™ device which can be marketed in the European Union and the United Kingdom. The OncoSil™ device has also been classified a Breakthrough Device in the European Union and the United Kingdom.

An Investigational Device Exemption (IDE) has been granted by the United States Food and Drug Administration (FDA) to conduct a clinical study of the OncoSil™ device aimed at supporting a PMA approval.

In December 2018, the FDA granted Humanitarian Use Designation (HUD) for the OncoSil™ device for the treatment of unresectable bile duct cancer. In March 2020, the FDA granted Breakthrough Device Designation for the OncoSil™ for unresectable pancreatic cancer in conjunction with systemic chemotherapy.

Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil™ in pancreatic cancer exceeds \$3b.

Forward Looking Statements

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil Medical is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.