ASX Announcement

19 August 2020

Annual Report – Year ended 30 June 2021
Preliminary Final Report - Appendix 4E

Sydney, Australia – 19 August 2021: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its financial results for the financial year ended 30 June 2021 (the **Annual Report**) and its Appendix 4E. OncoSil is a medical device company that is currently focused on commercialising its platform technology for the treatment of patients with locally advanced pancreatic cancer (LAPC) and bile duct cancer.

All financial results are in Australian dollars and are audited.

Regulatory and Operating Highlights

During FY21, the Company achieved several key regulatory and operational milestones as the business continues to work towards bringing the OncoSil™ device to market.

Highlights over the period include:

- Strong leadership team in place with the appointment of Nigel Lange as CEO and other key hires consisting of Chief Medical Officer (Dr. Ralph Peters), Head of Medical Affairs (David Turner), Director of Access Reimbursement, Economics and Assessment (Olaf Michaelsen) and Director of Clinical Development (Henk Tissing).
- First revenues achieved when the first commercially treated patient from New Zealand was implanted with the OncoSil™ device, marking the initial step towards becoming a revenue-generating medical devices company.
- Additional regulatory clearance achieved in several geographies despite significant COVID-19 disruptions.
- Patient screening commenced at The London Clinic in the UK, and ethics approval from the Health Research Authority (HRA) and Research Ethics Committee (REC) granted for a further eight sites. OncoSil is progressing through the final stages of onboarding and training these sites.
- Progress made on OncoSil's Humanitarian Device Exemption (HDE) application to the US Food and Drug Administration (FDA) with respect to the treatment of distal cholangiocarcinoma (bile duct cancer). The Company is working on providing the FDA with additional data involving a more recent cut-off point. The HDE will mark an important milestone in the Company's commercialisation strategy if successful.
- Further positive results generated from the PanCO trial, where it was found that treatment with the OncoSil™ device has the potential to 'convert' some patients from an initially inoperable to a surgically operable state thus offers a potentially curative outcome with prolonged survival.

ONCOSIL MEDICAL LIMITED ABN 89 113 824 141 ASX | OSL
Suite 503, Level 5, 15 Blue Street, North Sydney, NSW 2060 AUSTRALIA
TELEPHONE +61 2 9223 3344 FACSIMILE +61 2 9252 3988
WEB www.oncosil.com

COVID-19 Update

COVID-19 continues to impact hospitals across the UK whose priorities are temporarily skewed towards combatting the pandemic. Disruptions in UK hospitals are impacting OncoSil's ability to visit the required sites and is causing processing delays for Osprey registry applications. However, with rising vaccination rates, sites are starting to prioritise consultations with the OncoSil team.

Outside of Europe, OncoSil continues to engage hospitals in the APAC regions where the OncoSil™ device is approved. OncoSil is in discussions with hospitals in Singapore, Hong Kong and New Zealand to obtain Osprey registry approvals that lead to patient revenues. COVID-19 has presented additional challenges in being able to activate sites, given sales engagement are led out of Australia.

Regardless of the disruptions, OncoSil continues to push forward with commercialisation plans and expects that a post-COVID return to normality will see increased site activation and throughput.

Financial highlights

As at the end of 30 June 2021, the Company reported cash and cash equivalents of approximately A$12.2 million. Over the year, the Company's net cash used in operations was $8.8 million, with $2.9 million invested in R&D activities.

The Company continues to manage its finances with the aim of achieving long-term shareholder value and maintaining a positive cash position.

Authorisation & Additional Information

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

Company	Company
Mr Nigel Lange CEO & Managing Director E: nigel.lange@oncosil.com T: +49 30 300 149 3043	Mr Karl Pechmann CFO & Company Secretary E: karl.pechmann@oncosil.com T: +61 2 9223 3344

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.

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