

ASX Announcement

31 August 2022

Annual Report – Year ended 30 June 2022 Preliminary Final Report - Appendix 4E

Sydney, Australia – 31 August 2022: OncoSil Medical Ltd (ASX: OSL) (OncoSil or the Company), has released its financial results for the financial year ended 30 June 2022 (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 distal cholangiocarcinoma (dCCA).

All financial results are in Australian dollars and are audited.

In 2022, OncoSil Medical Limited continued with commercialisation plans for our lead product, the OncoSil[™] device. Our progress was marked by several key milestones that has enabled your Company to continue to build upon the commercialisation of the OncoSil[™] device.

The COVID-19 pandemic has resulted in a delay of full commercial launch this financial year ended 30 June 2022. It is difficult to estimate the precise impact that the pandemic will have on the business moving forward, nevertheless positive progress has been evident over more recent months.

Commercialisation

Face-to-face meetings were enabled as COVID-19 restrictions were relaxed in the second half of the financial year ended 30 June 2022 and accordingly, our team were able to re-engage with targeted sites. The team continued to concentrate on assisting with local regulatory approvals and ethics approvals for the OSPREY patient registry. The OncoSil team continued to engage in site training, with 17 hospital sites across Europe and 22 sites globally now fully trained to administer the treatment of the OncoSil™ device.

During the year OncoSil achieved the first commercial treatment with the OncoSil[™] device in Europe. The procedure was performed at The Hospital Universitario de Fuenlabrada, in Madrid, Spain. A commercial agreement for €374,000 (~A\$553,000) was signed with the same hospital to treat further patients afflicted with locally advanced pancreatic cancer (LAPC). The sales team continues to work with other trained hospitals in Spain to facilitate commercial uptake and further agreements to facilitate greater patient access to OncoSil[™] treatments in the various regions throughout the country.

In Germany, the German Institute for the Hospital Remuneration System (InEK) granted the OncoSil[™] device with a "Positive Status 1" status under the Innovation Funding (NUB) program. This provides hospitals with additional funding for a new device which is not covered through the existing Federal hospital DRG system.

Following the NUB status, the Federal Joint Committee (G-BA) approved a fully funded clinical trial in Germany. The Company will receive sales revenue for the provision of the OncoSil™ device over the



course of the clinical trial. A successful outcome of this trial would enable the Company to receive public funding from statutory health insurers under the German DRG system for the treatment of patients within this market.

Clinical and Regulatory Affairs

During the year the team has continued to develop and execute on its strategic objectives related to the further clinical development of the technology.

Additional data was submitted for 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 currently in discussions with the FDA regarding the application and further progress will be made in the FY 2023 financial year. The HDE would mark an important milestone in the Company's commercialisation strategy if approved.

The PanCO Clinical Study was published in European Society for Medical Oncology ('ESMO') Open. This publication stated that the addition of OncoSil[™] to standard-of-care chemotherapy is safe and effective and that 23.8% of patients proceeded to surgical resection with curative intent.

The PanCO Clinical Trial data was presented at the ESMO World Congress on Gastrointestinal Cancer, comparing the resected vs non-resected patients who received the OncoSil™ device. This showed that resected patients had a substantial response to treatment compared to non-resected patients, particularly a decrease in tumour volume.

Financial highlights

As at the end of 30 June 2022, the Company reported cash and cash equivalents of approximately A\$11.3 million. Over the year, the Company's net cash used in operations was \$10.1 million, with \$2.3 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	Mr Karl Pechmann
CEO & Managing Director	CFO & Company Secretary
E: nigel.lange@oncosil.com	E: karl.pechmann@oncosil.com
T: +49 30 300 149 3043	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.