ASX Announcement

19 August 2020

Annual Report – Year ended 30 June 2020
Preliminary Final Report - Appendix 4E

Sydney, Australia – 19 August 2020: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its financial results for the year financial year ended 30 June 2020 (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 FY20, the Company has achieved several key clinical and operational milestones as the business continues to work towards commercialisation of the OncoSil™ device.

Highlights over the period include:

- Successfully achieved CE Marking and Breakthrough Device classification for the treatment of locally advanced pancreatic cancer (LAPC) in combination with chemotherapy from the British Standards Institute (BSI) paving the way for OncoSil to sell and market the OncoSil™ device across the United Kingdom and European Union
- Appointment of Nigel Lange, who will drive commercialisation across Europe. Nigel was formerly Group Chief Commercial Officer of Sirtex Medical and his appointment will help the Company establish its commercial presence in the European market
- Leveraged our CE Marking approvals and filed for regulatory approvals with respective authorities in New Zealand, Singapore, Malaysia, Hong Kong and in Australia. As of August 2020, OncoSil has received clearance in New Zealand and Singapore; and are awaiting outcomes on all other applications.
- FDA grants Breakthrough Device Designation for the OncoSil™ device for the treatment of unresectable pancreatic cancer. Breakthrough Device Designation will expedite development and approval of the OncoSil™ device in the US
- Submitted a Humanitarian Device Exemption (HDE) application to the US Food and Drug Administration (FDA) for its OncoSil™ device with respect to the treatment of cholangiocarcinoma (bile duct cancer). The submission represents an important milestone in the Company's commercialisation strategy to explore various US regulatory pathways and leverage its platform technology into other cancer indications. If successful, the Humanitarian Device Exemption (HDE) will formally allow OncoSil to market and sell its device in the US for the treatment of bile duct cancer in the near term

ONCOSIL MEDICAL LIMITED ABN 89 113 824 141 ASX | OSL
Suite 402, Level 4, 50 Berry Street, North Sydney, NSW 2060 AUSTRALIA
TELEPHONE +61 2 9223 3344 FACSIMILE +61 2 9252 3988
WEB www.oncosil.com.au

COVID-19 Update

The impact of the COVID-19 pandemic is ongoing and OncoSil will continue to adjust to the varying restrictions and progress commercialisation accordingly. The COVID-19 pandemic has caused a delay in the Company's initial European launch plans, planned for FY21, primarily due to limited hospital and site access. Outside of Europe, activities were not materially impacted as OncoSil completed registration filings in parts of Asia, Australia and the HDE in the US.

Financial highlights

As at the end of 30 June 2020, the Company reported cash and cash equivalents of approximately A$21 million supported by its A$19m capital raising which was announced in 4 May 2020 involving a A$14m institutional placement and A$5m fully underwritten entitlement offer. The funds from the capital raising enables OncoSil to commence commercialisation activities across Europe, UK, ASEAN and APAC for LAPC and in the US for bile duct cancer assuming HDE approval.

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	**Investor enquiries**
Mr Daniel Kenny CEO & Managing Director E: daniel.kenny@oncosil.com.au T: +61 2 9223 3344	Leijie Li Vesparum Capital E: oncosiil@vesparum.com T: +61 3 8582 4800

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 or bile duct cancer 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 in locally advanced pancreatic cancer 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 intrahepatic and distal cholangiocarcinoma (bile duct cancer). In March 2020, the FDA granted Breakthrough Device Designation for the OncoSil™ for unresectable pancreatic cancer in conjunction with systemic chemotherapy. On 28 July 2020 the Company filed for HDE approval in bile duct cancer with the US FDA.

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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