ASX Announcement

18 January 2021

OncoSil FY21 Half Yearly Review

Sydney, Australia – 18 January 2021: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) would like to provide a review of the Company's operating activities over the first half of financial year 2021 (1H FY21).

Building Organisational Capability

OncoSil Medical employed Nigel Lange as President EMEA to head up the activities in the EMEA region. Nigel Lange has deep experience in interventional oncology (including his time with Sirtex Medical) and has assembled a team of 7 experienced people in Europe.

In December 2020, the Board determined that it was necessary for a change in the leadership at OncoSil, and as a result terminated Daniel Kenny as CEO. Chris Roberts has stepped in as Executive Chairman whilst the Board currently undertakes a recruitment process for a new CEO. The Company expects the new CEO to be announced shortly.

Establishing Post-Marking Observational Study (OSPREY Registry)

A requirement for CE Marking approval requires the company to undertake a post-marketing observational study of 500 patients implanted with commercial doses to further document performance and safety of the OncoSil™ device, (recorded within the "OSPREY" registry) when used within the approved indication (unresectable, locally advanced pancreatic cancer, in combination with gemcitabine-based chemotherapy) and this registry will be a global registry in approved markets, not just for Europe.

The post-marketing surveillance study requires a range of approvals which differs by country. For example, in the United Kingdom, review and approval of the registry and associated protocol by a Notified Body, (BSI), Competent Authority, (MHRA) and Radiation Authority (ARSAC) was completed in the second quarter. Ethics approval is also required by the UK's Research Ethics Committee (REC) and this is in the final stages of approval. Final approval from the UK's Health Research Authority (HRA) will be needed after REC approval. There are 9 sites in greater London that have been submitted to REC, and each of these sites will need licensing approval for using radioactive phosphorous (^{32}P).

Each country differs in the approval mechanisms for the observational study, for example ethics committee approval is required, which might be by country, region, or hospital site. Similarly, each country has its own radiation licensing system, which might be by country (such as the UK) or by state (such as in Germany). We are progressing with these approvals during 2021, and at the same time, the Company has started seeking reimbursement approvals from the respective authorities and territories.

During the half year, 5 sites and 25 medical professionals were trained in using the OncoSil™ device, primarily in the United Kingdom.

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

COVID-19 slowing approvals and constraining access to hospitals

COVID-19 has impacted on the timelines for approvals from many of the authorities for the post-market observational study as the number of applications reviewed monthly has been reduced.

In addition, lockdowns have constrained activities, particularly the ability to visit hospitals.

Progressing regulatory approvals in ASEAN countries

In Singapore, Malaysia and New Zealand OncoSil is continuing to seek further approvals for the post-marketing observational study and training of sites. Whilst OncoSil has obtain first patient revenues in New Zealand, the Company is working with additional New Zealand sites to expand acceptance in the New Zealand market.

In Australia, an application was made to the Therapeutic Goods Administration (TGA) in July 2020. The TGA has requested further data which was submitted on 11 January 2021.

Applying for an HDE in the USA for distal cholangiocarcinoma

A Humanitarian Device Exemption (HDE), for OncoSil™, was submitted to the FDA in July 2020 for the treatment of distal cholangiocarcinoma. An HDE is a marketing application for a Humanitarian Use Device (HUD) particularly targeting the treatment of rare diseases or conditions in patient populations with an incidence of fewer than 8,000 patients per year. The HDE provides companies with the opportunity to bring to market a device, secure reimbursement while at the same time conducting further research to prove efficacy and subsequently apply for a PMA (pre-market approval).

An HDE is exempt from the effectiveness requirements and is subject to certain profit and use restrictions. FDA has requested an update of the clinical data from the PANCO trial based on an updated data cut-off point and the company is continuing to finalise this data package to the FDA.

Financial

During the half, OncoSil Medical shipped 9 doses comprising of commercial and non-commercial doses. Unaudited sales revenue for the half was $93k and unaudited cash assets of approximately $18m as of 31 December 2020.

Authorisation & Additional Information

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

Company	Investor Relations
Mr Karl Pechmann CFO & Company Secretary E: karl.pechmann@oncosil.com T: +61 2 9223 3344	Leijie Li Vesparum Capital E: oncosil@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 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.