ASX Announcement

26 July 2021

Quarterly Activities & Cash Flow Report
Quarter ended 30 June 2021

Sydney, Australia – 26 July 2021: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 30 June 2021 (the Quarter). OncoSil is a medical device company that is currently commercialising its platform technology for the treatment of patients with locally advanced pancreatic cancer (LAPC) and bile duct cancer or distal cholangiocarcinoma (DCC).

Key Highlights

- **Europe: London Clinic actively patient screening:** Patient screening has begun in the London Clinic despite COVID headwinds which continue to disrupt wider site activation efforts and sales in the region;
- **APAC regulatory and commercial discussions advancing:** Regulatory approval received in Hong Kong and advanced discussions with APAC hospitals to obtain Osprey registry approval despite COVID challenges;
- **USA:** Updating the data package to the FDA is ongoing, with COVID delaying the closing out of the Panco clinical study;
- **Clinical development:** Ongoing consultation with regulatory authorities for support and acceptance of strategic global clinical development initiatives aimed at warranting that the OncoSil™ device in combination with chemotherapy becomes the standard of care for LAPC patients; and
- **Cash position:** Cash balance of $12.2 million as at 30 June 2021.

All financial results are in Australian dollars and are unaudited.

Europe and UK: Patient screening has been activated at the London Clinic

Despite COVID-19 headwinds, patient screening at the London Clinic has commenced. OncoSil continues to progress through the final stages of onboarding and training of the remaining hospitals in the UK that have received ethics approval from the Health Research Authority (HRA) and the Research Ethics Committee (REC), including the receipt of the appropriate radiation licenses.

COVID-19 continues to impact hospitals across the UK whose priorities are temporarily skewed towards combatting the pandemic. The disruptions to UK hospitals continues to impact OncoSil's ability to visit the required sites and processing delays for Osprey registry applications remain. However, with rising vaccination rates and no restrictions from 19 July 2021, sites are starting to prioritise consultations with OncoSil. In Germany, the sales team has commenced face to face meetings with hospital sites after

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extended strict COVID-19 restrictions. The team is focusing initially on opportunities through hospitals where "single patient approvals" can be obtained for reimbursement by statutory German health funds (Krankenkassen), on a case-by-case basis. The team is targeting 15 leading centres involved in the treatment of pancreatic cancer. Phosphorous-32 (^{32}P) Licenses in German hospitals are not an inhibiting factor.

Our sales team in Italy have been in discussions with several public hospitals. The approval for the Osprey registry is currently underway, and in parallel hospital licenses for the use of ^{32}P product is expected in late September 2021. In Spain, the sales team is targeting 6 key hospitals where approval for the Osprey registry is currently underway. In Italy and Spain, funding for the OncoSil device is expected to occur through annual allocations of public hospital budgets at a site level, and through the private payer market in private hospitals.

In Belgium, the team has been working on the preparation of a dossier for potential public reimbursement of the OncoSil device which will be listed on the nominative list of reimbursed Radio-Isotopes by the Technical Council of Radio-Isotopes. Finalisation of the dossier is awaiting the publication of the PanCo manuscript.

In Luxembourg one centre has been identified to adopt the OncoSil device. We anticipate full approval by the end of October 2021, treatments to commence shortly thereafter. Treatments will be funded via the hospital budget.

The company has been in discussions with various distributors in EMEA serving countries which recognise the CE Marking approval for local registration, as well as targeting smaller European countries where it is not economic to have direct staff employed in these regions. The initial targeted countries include Switzerland, Austria, Portugal, Greece, Israel, Turkey and Egypt.

OncoSil will continue discussions with other distributors for countries in both EMEA and APAC to accelerate registration approvals and increase the number of sites for the treatment of the OncoSil device.

Irrespective of the COVID disruptions in the UK and Europe, OncoSil continues to push forward with commercialisation plans and expects that a post-COVID return to normality will see increased site activation and commercial throughput which the Company is ready to capitalise on.

APAC: Regulatory and commercial discussions advancing

During the Quarter, OncoSil received regulatory approval in Hong Kong to market and sell the OncoSil™ device for the treatment of LAPC (announced on 4 May 2021).

Having made the strategic decision to currently withdraw our application with the Therapeutic Goods Administration (TGA) in Australia, OncoSil continues to engage with other 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. As with Europe COVID-19 has presented additional challenges in being able to activate sites.

US: Bile Duct Cancer or Distal Cholangiocarcinoma (DCC)

On 28 July 2020, OncoSil announced that it had filed a Humanitarian Device Exemption (HDE) application with the US Food and Drug Administration (FDA) for its OncoSil™ device in the treatment of distal cholangiocarcinoma (DCC or bile duct cancer).

The FDA requested an updated dataset involving more recent safety and efficacy data from the Panco trial. Covid has impacted the ability for the Company to officially close out study sites and this has impacted the timing on finalising this data package. The company will provide this updated information as soon as final sites can be officially closed out.

Clinical development

Having recruited an experienced clinical team over the past few months, including Chief Medical Officer (Dr. Ralph Peters), Global Head of Medical Affairs (David Turner) and Global Director of Clinical Development (Henk Tissing), the team has been focused on the development and implementation of OncoSil's clinical strategy to achieve regulatory approval and public reimbursement in major markets.

An optimal clinical development pathway to generate additional clinical evidence, which will establish OncoSil™ as the standard of care for treatment of patients with LAPC in combination with chemotherapy is currently being progressed. The Company is also in ongoing discussions with the FDA, as well as other regulatory bodies and key external stakeholders in relation to the design of the clinical development plan to ensure that data generated from clinical trials support regulatory approval and public reimbursement.

Corporate

As at 30 June 2021, OncoSil had a cash balance of $12.2 million. During the Quarter, the Company's net cash used in operations was $3.0 million, with $0.9 million invested in R&D activities. Item 6.1 of the Appendix 4C relates to director fees and salaries paid in the quarter.

Subsequent to the Quarter, on 20 July 2021, OncoSil announced the appointment of Mr Otto Buttula to the Board of Directors. The addition of Mr Buttula provides significant commercial and financial expertise to the OncoSil Board which is expected to facilitate OncoSil's ongoing global expansion. Dr Chris Roberts and Mr Michael Bassett intend to step down from the Board at the time of OncoSil's Annual General Meeting, expected to be held in October 2021. Chris and Michael will work closely with the OncoSil Board to ensure a smooth transition during this period. Upon the departure of Dr Chris Roberts from the Board, it is expected that Mr Buttula will be elected Chairman.

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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
ONCOSIL MEDICAL LIMITED	
ABN	***Quarter ended ("current quarter")***
89 113 824 141	30 June 2021

	Consolidated statement of cash flows	**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	45	200
1.2	Payments for		
	(a) research and development	(889)	(2,990)
	(b) product manufacturing and operating costs	(133)	(286)
	(c) advertising and marketing	(82)	(910)
	(d) leased assets	-	-
	(e) staff costs	(1,419)	(5,307)
	(f) administration and corporate costs	(539)	(2,657)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	82
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	2,897
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,010)**	**(8,971)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(c) property, plant and equipment	(15)	(54)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	-
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(15)**	**(54)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	260
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**260**

	Consolidated statement of cash flows	Current quarter $A'000	Year to date (12 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	15,258	21,000
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,010)	(8,971)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(15)	(54)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	260
4.5	Effect of movement in exchange rates on cash held	7	5
4.6	**Cash and cash equivalents at end of period**	**12,240**	**12,240**

5.	***Reconciliation of cash and cash equivalents*** *at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts*	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	12,240	15,258
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**12,240**	**15,258**

6.	***Payments to related parties of the entity and their associates***	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	80
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

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7.	***Financing facilities*** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	***Estimated cash available for future operating activities***	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	3,010
8.2	Cash and cash equivalents at quarter end (Item 4.6)	12,240
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	12,240
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	4.06

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

26/07/2021

Date: .....

By the Board

Authorised by: .....

(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

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