ASX Announcement

31 January 2022

Quarterly Activities & Cash Flow Report

Quarter ended 31 December 2021

Sydney, Australia – 31 January 2022: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 31 December 2021 (the Quarter). OncoSil is a medical device company that is 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

- **Growing Revenues**: Whilst modest, revenue growth is expected to continue accelerating;
- **PanCo clinical study:** Publication of the final results occurred in December 2021 in a high impact international oncology journal;
- **USA HDE data package re-submitted to the FDA:** Following the close out of the PanCo clinical study. Currently in ongoing discussions with FDA;
- **European Union and the United Kingdom:** With CE approval, breakthrough designation and gradual return to normal clinical activities at cancer hospitals after the COVID disruption, the Commercial Team are active in assisting targeted sites with local regulatory and Osprey Registry ethics approvals. Thirteen new hospital sites are now active;
- **APAC regulatory and commercial discussions continuing:** Advanced discussions with APAC hospitals to obtain Osprey Registry approvals; and
- **Cash position:** Cash balance of $6.66 million as at 31 December 2021.

All financial results are in Australian dollars and are unaudited.

PanCO Clinical Study on OncoSil™ Published in ESMO Open

On 24 December 2021, OncoSil announced the publication of the final results of the PanCO clinical study. The results demonstrate the safety and efficacy benefits of the OncoSil™ device in combination with standard-of-care chemotherapy for the treatment of patients with unresectable locally advanced pancreatic cancer (LAPC).

The primary endpoint of the PanCO study was safety and tolerability, and the results demonstrated that OncoSil™ had an acceptable safety profile when added to standard-of-care chemotherapy comprising either gemcitabine plus nab-paclitaxel or FOLFIRINOX, the two most widely used regimens for treating patients with advanced pancreatic cancer. No radiation-related Serious Adverse Events (SAEs) were reported in the PanCO study and there was no evidence that the incidence of severe SAEs changed after OncoSil™ implantation.

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Compared to baseline, there were statistically significant reductions in the volume of the target tumour for study participants (median reduction was 51.9%), as well as in blood biomarkers of the cancer (CA 19-9 decreased by 82.3% on average).

Although the study recruited patients whose cancers were defined as unresectable by highly experienced pancreatic cancer experts, nearly one-in-four of the PanCO study participants (10 of 42; 23.8%) proceeded to surgical resection with curative intent following treatment with chemotherapy plus OncoSil™.

USA HDE data package re-submitted to the FDA

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. The disruption to hospitals caused by the COVID pandemic had impacted the ability for the Company to officially close out study sites and this negatively impacted the timing on finalising this data package. The data package involved the submission of hundreds of supporting documents consisting of updated data and reports. The data has been submitted to the FDA and we are currently answering questions which have been raised during this process.

European Union and the United Kingdom

Although COVID-19 has adversely impacted our ability in achieving first revenues in the European Union and the United Kingdom, our team has actively re-engaged with targeted sites, since limited face-to-face meetings have been allowed in the EU. In the UK, our commercial team continue to be unable to visit hospital sites in person as a result of the Omicron outbreak.

Activities continue to concentrate on assisting with local regulatory approvals and ethics approvals for the OSPREY patient registry. During the quarter, the OncoSil team engaged in site training of 13 hospital sites across Spain, Turkey, Israel and Portugal with 13 sites now fully trained to administer the treatment of the OncoSil device.

OSPREY registry approval achieved in the first Italian site, which will enable national approvals for other sites within Italy, together with receiving registry approvals in Spain and Israel. Ethics submissions continue in several European countries in preparation for commercial sales.

The Company continues to secure agreements with various distributors in EMEA serving countries which recognise the CE Marking approval for local distribution, as well as targeting countries where it is not economically viable to have direct staff employed in these regions. OncoSil has commenced negotiations with a distributor for distribution rights in Norway, Sweden, Denmark and Finland.

The Company has continued to work on several initiatives in preparation for market access, health insurance coverage and reimbursement applications in various European countries.

APAC: Regulatory and commercial discussions continuing

OncoSil continues to engage with hospitals in the APAC region where the OncoSil™ device is approved. OncoSil continues to be in discussions with hospitals in Singapore, Hong Kong and New Zealand to obtain Osprey registry approvals that should lead to patient treatments and revenue growth. OncoSil is in discussions with distributors for South Korea and Taiwan. In Australia we continue to use the Special Access Scheme which enables Australian physicians to treat patients with our device provided OncoSil does not engage in promotional activity.

Board renewal

Prof Ricky Sharma joined the OncoSil Medical board as a non-executive director on 1st November 2021. Prof Sharma is an international authority on the translation of radiobiology from the laboratory to the clinic and on the treatment of cancer with precision radiotherapy. Prof Sharma is Vice President, Clinical Affairs at Varian, a Siemens Healthineers Company, and is an honorary Clinical Professor at University College London where he maintains a clinical practice in radiotherapy and chemotherapy.

Corporate

As at 31 December 2021, OncoSil had a cash balance of $6.66 million. During the Quarter, the Company's net cash used in operations was $2.9 million, with $0.75 million invested in R&D activities. Item 6.1 of the Appendix 4C relates to director fees and salaries paid in the quarter.

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.

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	31 December 2021

	Consolidated statement of cash flows	**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	132	183
1.2	Payments for		
	(a) research and development	(745)	(1,573)
	(b) product manufacturing and operating costs	(180)	(468)
	(c) advertising and marketing	(105)	(266)
	(d) leased assets	-	-
	(e) staff costs	(1,323)	(3,157)
	(f) administration and corporate costs	(679)	(1,385)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	7
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,077
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,898)**	**(5,582)**

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 (6 months) $A'000
	(c) property, plant and equipment	-	-
	(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**	**-**	**-**

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	-	-
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**	**-**	**-**

	Consolidated statement of cash flows	Current quarter $A'000	Year to date (6 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	9,560	12,240
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,898)	(5,582)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(1)	3
4.6	**Cash and cash equivalents at end of period**	**6,661**	**6,661**

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	6,661	9,560
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)**	**6,661**	**9,560**

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	65
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

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)	2,898
8.2	Cash and cash equivalents at quarter end (Item 4.6)	6,661
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	6,661
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	2.30

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.

31/01/2022

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 – e.g., 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.