

ASX Announcement

29 July 2022

Quarterly Activities & Cash Flow Report

Quarter ended 30 June 2022

Sydney, Australia – 29 July 2022: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), is pleased to provide an update on activities, for the quarter ending 30 June 2022. OncoSil is a medical device company that is commercialising its platform technology for the treatment of patients with locally advanced pancreatic cancer (LAPC) and seeking FDA approval for the OncoSil™ device to treat patients with bile duct cancer or distal cholangiocarcinoma (DCC).

Key Highlights

- ✓ **European Union and the United Kingdom:** The Commercial Team continue to be actively assisting targeted sites with local regulatory and Osprey Registry ethics approvals;
- ✓ **First commercial treatment of the OncoSil™ device in Spain:** Procedure performed at The Hospital Universitario de Fuenlabrada, located in Madrid, Spain;
- ✓ **Commercial Agreement with The Hospital Universitario de Fuenlabrada in Madrid worth €374k (~A\$553k):** Enables the treatment of patients with LAPC to be treated with the OncoSil™ device;
- ✓ **USA HDE for distal cholangiocarcinoma:** Currently in ongoing discussions with FDA; and
- ✓ **Cash position:** Cash balance of \$11.28 million as at 30 June 2022.

Subsequent to period-end

- ✓ **Bupa UK Approves Reimbursement for OncoSil in the UK at The London Clinic;** and
- ✓ **Second Patient commercially treated in Spain successfully resected:** Another important achievement, given the OncoSil™ device is normally administered only to unresectable patients suffering LAPC.

All financial results in the attached 4C are in Australian dollars and are unaudited.

European Union and the United Kingdom

The team have continued to concentrate on assisting with local regulatory and ethics approvals for the OSPREY patient registry.

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



Subsequent to period end, the Company announced that that Bupa UK Insurance had become the first health insurance company to provide reimbursement for the breakthrough OncoSil™ device in the private payer market in the UK.

The London Clinic has worked with OncoSil to obtain this approval to cover Bupa UK's health insurance customers for implantation of the OncoSil™ device in the treatment of LAPC.

The OncoSil team will be working with other insurers to expand reimbursement for patient access to treatments at The London Clinic and other private institutions.

First Commercial Treatment of the OncoSil™ device in Spain

In April 2022, the Company achieved the first commercial treatment of the OncoSil™ device in Europe, with the procedure being performed at The Hospital Universitario de Fuenlabrada, located in Madrid, Spain. In July 2022, the second patient treated in Spain was successfully resected, underlining the success the OncoSil™ device has had in resection of patients considered unresectable (23.8% of patients treated in the PanCO trial were successfully resected).

Commercial Agreement with The Hospital Universitario de Fuenlabrada in Madrid worth €374k (~A\$553k)

Following the first commercial treatment, in April 2022 OncoSil signed a commercial agreement with The Hospital Universitario de Fuenlabrada in Madrid to treat additional patients who suffer from LAPC. The legally binding agreement worth €374k (A\$553k) has been awarded to OncoSil to ensure an ongoing commitment by the Hospital Universitario de Fuenlabrada to further their program with the OncoSil™ device. The agreement is on-going and includes a set number of doses to be delivered to the hospital and is subject to renewal once utilised.

The OncoSil team have fully trained 10 hospital sites in Spain for the implantation of the OncoSil™ device. Hospitals in Spain are permitted to negotiate a departmental budget for a specified number of treatments annually.

Procurement of the OncoSil™ device is done via a formal tender process for each hospital. The sales team in Spain is currently working with other trained hospitals to facilitate the tender process to enable greater patient access to the OncoSil™ device treatment in various regions throughout Spain.

USA Humanitarian Device Exemption for distal cholangiocarcinoma

OncoSil continues to have an ongoing dialogue with the US Food and Drug Administration (FDA) in regard to its filed Humanitarian Device Exemption (HDE) application for its OncoSil™ device in the treatment of distal cholangiocarcinoma (DCC or bile duct cancer). A further meeting is scheduled before the end of this calendar year.

Corporate

As at 30 June 2022, OncoSil had a cash balance of \$11.28 million. During the Quarter, the Company's net cash used in operations was \$2.5 million, with \$0.3 million invested in R&D activities. Item 6.1 of the Appendix 4C relates to director fees and salaries paid in the quarter.

On 29 April 2022, OncoSil announced the launch of a \$10m capital raising consisting of a placement of \$4m to existing and new sophisticated and professional investors, and a non-renounceable entitlement offer to shareholders to raise approximately \$6m. The \$4m placement was issued on 9 May 2022 and on 9 June 2022 it was announced that approximately \$3.2m was raised from the non-renounceable entitlement offer, and that the shortfall was placed with various sophisticated and professional investors, raising approximately \$2.7m. The funds from the capital raising will be used to fund sales and marketing resources to support the EU and UK commercialisation activities for the OncoSil™ device, clinical trial expenditure for the expansion of the use of the OncoSil™ device in combination with FOLFIRINOX chemotherapy and general working capital.

The Company would like to thank Forrest Capital Pty Ltd for their assistance in coordinating the placements.

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

89 113 824 141

Quarter ended ("current quarter")

30 June 2022

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	41	279
1.2 Payments for		
(a) research and development	(326)	(2,376)
(b) product manufacturing and operating costs	(350)	(1,110)
(c) advertising and marketing	(79)	(461)
(d) leased assets	-	-
(e) staff costs	(1,160)	(5,527)
(f) administration and corporate costs	(607)	(2,544)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	9
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	(2,481)	(10,653)

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	(7)	(7)
	(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	(7)	(7)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	9,945	9,945
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	(240)	(240)
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	9,705	9,705

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	4,065	12,240
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,481)	(10,653)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(7)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	9,705	9,705
4.5	Effect of movement in exchange rates on cash held	(2)	(5)
4.6	Cash and cash equivalents at end of period	11,280	11,280

5.	Reconciliation of cash and cash equivalents <i>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts</i>	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	11,280	4,065
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)	11,280	4,065

6. Payments to related parties of the entity and their associates

6.1 Aggregate amount of payments to related parties and their associates included in item 1

6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

65

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.

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000

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.	<i>Estimated cash available for future operating activities</i>	\$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	2,481
8.2	Cash and cash equivalents at quarter end (Item 4.6)	11,280
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	11,280
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	4.55
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>		

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

8.6.1 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:

8.6.2 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:

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

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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.

29/07/2022

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.