

ASX Announcement

28 April 2023

Quarterly Activities & Cash Flow Report

Quarter ended 31 March 2023

Sydney, Australia – 28 April 2023: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), is pleased to provide an update on activities, for the quarter ending 31 March 2023. 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

- ✓ **Two key treatment centres treat first patients with OncoSil:** with the first patient being treated in Israel at the Wolfson Medical Center in Tel Aviv, and the first patient treatment at the Clínica Universidad de Navarra, located in Pamplona, Spain;
- ✓ **USA HDE for distal cholangiocarcinoma:** Currently in ongoing discussions with FDA;
- ✓ **Cash position:** Cash balance of \$3.07 million as at 31 March 2023; and
- ✓ **Investor Webinar to be held on Tuesday, 2 May 2023 at 2:00pm AEST.**

Subsequent to period-end

- ✓ **Oral presentation at The Mayo Clinic IMPACT Course 2023:** Dr Frank Weilert presented the clinical outcomes of 49 patients implanted with the OncoSil™ device at Royal Adelaide Hospital in Australia and Waikato Hospital, New Zealand; and
- ✓ **Further commercial milestones achieved in Spain:** The first patient treated with the OncoSil™ device at Las Palmas Hospital in the Canary Islands has undergone a success surgical resection, a tender was approved at the same hospital with a value of €220k and the sixth hospital in Spain has commenced patient treatments at Vall d’Hebron Hospital.

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.

Two key treatment centres treat first patients with OncoSil

OncoSil has achieved a significant milestone with the first patient treated with the OncoSil™ device in the Middle East. The first patient treatment in Israel has been performed at the Wolfson Medical Center in Tel Aviv, Israel. We are working with other institutions in Israel to treat patients with the OncoSil™ device.

OncoSil is also pleased to announce the first patient treatment at the Clínica Universidad de Navarra, located in Pamplona, Spain. This hospital is considered a leading private hospital in Spain, as well as being an institution which is highly recognised for being at the forefront of scientific research in oncology.

Oral presentation at The Mayo Clinic IMPACT Course 2023

On Friday 21 April 2023, Dr Frank Weilert from Waikato Hospital presented the clinical outcomes of 49 patients who were implanted with the OncoSil™ device at Royal Adelaide Hospital in Australia and Waikato Hospital, New Zealand. These patients were also treated with either FOLFIRINOX or gemcitabine and nab-paclitaxel chemotherapy. The key data presented included:

- ✓ Local disease control in patients 12 weeks post-implant was 96%
- ✓ 15 patients (31%) had tumour downstaging and were technically resectable; and
- ✓ Technical success of OncoSil™ implantation was 100% with no acute complications.

Further commercial milestones achieved in Spain

The first patient who was commercially treated with the OncoSil™ device at Las Palmas hospital in the Canary Islands, Spain in October 2022 has undergone a successful resection of their primary LAPC tumour this week. Patients who undergo successful resections of their primary tumour show dramatically improved outcomes.

The Ministry of Health has also approved a tender at the Las Palmas hospital in the Canary Islands with a tender valued at €220K (A\$361k). This tender includes a set number of patient doses to be delivered by the hospital which will be subject to renewal once utilised, with standard termination clauses applying.

OncoSil has also expanded the number of sites treating patients with the OncoSil™ device, with the sixth hospital site, Vall d'Hebron treating their first patient.

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 mid- year.

Corporate

As at 31 March 2023, OncoSil had a cash balance of \$3.07 million. During the Quarter, the Company's net cash used in operations was \$2.7 million, with \$0.36 million invested in R&D activities. Item 6.1 of the Appendix 4C relates to director fees and salaries paid in the quarter.

On 17 March 2023, OncoSil announced the launch of an up to \$9.9 million capital raising consisting of a non-renounceable entitlement offer to shareholders. 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, manufacturing and supply chain optimisation projects, clinical trial expenditure for the expansion of the use of the OncoSil™ device in combination with FOLFIRINNOX chemotherapy and general working capital. The company has received binding letters of commitment for \$5 million of any potential shortfall which may occur at the conclusion of the entitlement offer.

The Company is in continuing discussions with several strategic industry partners in respect of a significant investment in the Company and commercial licensing opportunities.

Investor Webinar Tuesday, 2nd May 2023

OncoSil is pleased to invite investors and other interested parties to attend a webinar on Tuesday, 2nd May 2023 at 2:00pm AEST.

CEO & Managing Director, Nigel Lange, will provide an update on the Company's progress to date and the 1 for 1 non-renounceable entitlement offer, where binding commitments have been received for \$5 million.

Following the formal update, attendees will have the opportunity to ask questions of Mr Lange during a moderated Q&A session.

Please register for the webinar at:

https://us02web.zoom.us/webinar/register/WN_92UrawEcQ8SiKYhhNUU5jA#/registration

After registering, you will receive a confirmation email containing information about joining the webinar.

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

89 113 824 141

Quarter ended ("current quarter")

31 March 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	108	310
1.2 Payments for		
(a) research and development	(363)	(1,772)
(b) product manufacturing and operating costs	(344)	(816)
(c) advertising and marketing	(51)	(254)
(d) leased assets	-	-
(e) staff costs	(1,301)	(4,104)
(f) administration and corporate costs	(742)	(2,417)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	821
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(2,692)	(8,231)

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 (9 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)	-	150
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	-	(161)
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	-	(11)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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	5,757	11,280
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,692)	(8,231)
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)	-	(11)
4.5	Effect of movement in exchange rates on cash held	5	32
4.6	Cash and cash equivalents at end of period	3,070	3,070

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	3,070	5,757
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)	3,070	5,757

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**

51

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. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	2,692
8.2 Cash and cash equivalents at quarter end (Item 4.6)	3,070
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	3,070
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	1.14
<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: The entity expects to have the current level of net operating cashflows in the coming quarters.

- 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: The entity has announced a non-renounceable entitlement offer of up to \$9.9m to existing shareholders. The entity has received letters of commitment to subscribe for \$5m from any potential shortfall from the offer. The entity expects that the offer will be fully subscribed.

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: The entity expects to be able to continue its operations and to meet its business objectives on the basis of the expected completion of the non-renounceable pro-rata entitlement offer to existing investors.

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.

28/04/2023

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.