

ASX Announcement

31 January 2024

Quarterly Activities & Cash Flow Report

Quarter ended 31 December 2023

**OncoSil™ device's penetration of the Greek and Israeli markets continues;
1st patient treated in AMC/VUA Dutch PANCOSIL Investigator-Initiated Clinical Trial**

Melbourne, Australia – 31 January 2024: OncoSil Medical Ltd (ASX: OSL) (OncoSil or the Company), a medical device company focused on localised treatments for patients with locally advanced pancreatic cancer (LAPC), is pleased to provide an update on activities and Appendix 4C cash flow report for the quarter ended 31 December 2023 (Q2 FY24).

Key Highlights

- First commercial treatments in Greece involving application of the OncoSil™ device commenced in early December 2023.
- The first patient treated in the PANCOSIL Investigator-Initiated Clinical Trial at the Amsterdam Medical Centre/Vrije Universiteit Amsterdam in late November 2023.
- Major Israeli health insurer Clalit General Health Services approved the OncoSil™ device as an appropriate treatment for locally advanced pancreatic cancer.
- OncoSil received a research and development tax refund of around A\$1.1m under the Australian Government's R&D tax incentive program.
- Cash balance of \$4.9 million as at 31 December 2023.

First Greek commercial treatments using the OncoSil™ device get underway

OncoSil continued to successfully penetrate key European markets over the final part of calendar year 2023.

On 8 December 2023, the Company announced that initial Greece-domiciled commercial treatments involving the OncoSil™ device had commenced on Thursday, 7 December 2023, with the assistance of Greek partner, Mediray. These treatments, which involved two patients, were undertaken at the renowned Agios Savvas Hospital, located in Athens. This medical facility specialises in the treatment of all solid tumors, with a primary emphasis on breast, lung, digestive, pancreatic and melanoma cancers.

This achievement means that Greece has now become the third European country – after Italy and Spain – where commercial treatments utilising the OncoSil™ device have been completed.

First patient onboarded in the PANCOSIL clinical trial

The first patient has been treated in the PANCOSIL Investigator-Initiated Clinical Trial on 28 November 2023 in Amsterdam (see OncoSil Medical ASX announcement, dated 29 November 2023).

PANCOSIL is an Investigator Initiated Clinical Trial looking at the safety and feasibility of CT-guided percutaneous radionuclide therapy with the OncoSil™ device in patients with non-progressive locally advanced pancreatic cancer. Ethics approval for the trial was earlier granted back in mid calendar year 2023 (see OncoSil Medical ASX announcement, dated 5 June 2023).

In all, up to 50 patients may be treated with the OncoSil™ device via percutaneous application over the course of the trial. This will, in turn, expand the available users who can deliver the OncoSil™ device. Importantly from a cash flow perspective, most of the funding contribution by OncoSil for this trial has already booked in previous quarters.

OncoSil™ device gains further traction in the Israeli healthcare market

In late November 2023, major Israeli health insurer Clalit General Health Services (“Clalit”) approved the OncoSil™ device, which is already registered and used in Israel, as an appropriate treatment for unresectable locally advanced pancreatic cancer.

This approval is a necessary first step ahead of Clalit potentially creating any reimbursement schedule for patients using the OncoSil™ device.

OncoSil receives A\$1.1m R&D tax incentive

On 15 December 2023, OncoSil announced that it had received a research and development (R&D) tax refund of around A\$1.1m under the Australian Government’s R&D tax incentive program. This program provides companies engaging in eligible activities with a refundable tax offset of up to 43.5%.

The refund, which was received in recognition of OncoSil’s R&D activities during its 2023 financial year, will provide important funding for the Company’s now well-progressed commercialisation strategy.

After adding back the R&D tax refund, the Company’s net cash / (used in) operating activities was \$2.3 million, which indicates an estimated 2.1 quarters of funding available.

Finance Update

The Appendix 4C Quarterly Cash Flow report for the December 2023 quarter is attached to this announcement.

As detailed in the latter report, the Company had \$4.9 million in cash and equivalents as at 31 December 2023, decreasing from \$6.1 million at 30 September 2023.

The Net Cash used in Operating Activities during the quarter was \$2.3 million (excluding the \$1.1 million Research and Development Grant), with Staff costs and direct Research and Development expenditures accounting for over 62% of the \$2.3 million. This quarters' costs included the annual payment of Insurance, costs associated with closing the office at North Sydney and substantial trial pass through costs.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C include payments for remuneration of director fees to executive and nonexecutive directors in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

As discussed in the prior quarterly update, a rationalisation of the Company's operating expenditure structure was, and continues, to be undertaken, resulting in a reduction in headcount and other operational expenditure. Management will continue its review of the operating structure to ensure that costs are further aligned with Company growth initiatives and managed in a sustainable way to extend the future cash runway.

OncoSil Medical CEO & Managing Director Nigel Lange, said: *"The first Greek commercial treatments involving the OncoSil™ device are an unambiguous positive development for the Company. They demonstrate that we are steadily penetrating our target European markets. And importantly from a financial viability angle, they also represent another step to OncoSil's journey towards long-term sustainability, and proof the Company's commercialisation strategy is continuing to build momentum.*

"I am also very proud of our team's efforts to progress other parts of our commercialisation strategy for the OncoSil™ device over the December 2023 quarter. The period saw the first patient treated in the PANCOSIL study, the results from which could help us to develop an alternative technique for OncoSil™ implantation and provide flexibility for users. In the Middle East region, the move by major Israeli health insurer Clalit General Health Services' to approve the OncoSil™ device as an appropriate treatment for unresectable locally advanced pancreatic cancer is another important step in our efforts to penetrate that country's market.

We now look forward to announcing further milestones in the OncoSil™ device's commercialisation strategy over coming months that will open the way for an increased number of medical professionals to deliver our unique technology to patients with unresectable locally advanced pancreatic cancer."



Authorisation & Additional Information

This announcement was authorised by the Chairman of OncoSil Medical Limited.

For further information, please contact:

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About OncoSil

OncoSil Medical Limited (ASX:OSL) has developed a cancer treatment device, the OncoSil™ brachytherapy device, which is a critical component of a revolutionary brachytherapy treatment for locally advanced unresectable pancreatic cancer. This type of cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with some 500,000 new cases of pancreatic cancer detected every year. With pancreatic cancer typically diagnosed at a later stage, it has a poor prognosis for long-term survival¹.

The OncoSil™ device delivers a targeted intratumoural placement of Phosphorous-32 (32P) in the treatment of locally advanced unresectable pancreatic cancer. This occurs via injection directly into a patient's pancreatic tumours under endoscopic ultrasound guidance and takes place in combination with gemcitabine-based chemotherapy.

The OncoSil™ device that has already received breakthrough device designation in the European Union, United Kingdom and United States for the treatment of locally advanced unresectable pancreatic cancer in combination with chemotherapy. CE Marking has additionally been granted for the OncoSil™ device, which can be marketed in the European Union, United Kingdom.

While clinical trials involving the OncoSil™ device continue to occur, the Company is simultaneously moving to commercialise this unique medical technology. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Turkey and Israel, with initial commercial pancreatic cancer treatments using the device already undertaken in Spain, Italy and Israel.

To learn more, please visit: www.oncosil.com/

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 December 2023

<i>Consolidated statement of cash flows</i>	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	40	106
1.2 Payments for		
(a) research and development	(392)	(1,557)
(b) product manufacturing and operating costs	(219)	(392)
(c) advertising and marketing	(131)	(224)
(d) leased assets	-	-
(e) staff costs	(1,030)	(2,154)
(f) administration and corporate costs	(592)	(1,542)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	5	56
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,100	1,100
1.8 Other (provide details if material)	42	130
1.9 Net cash from / (used in) operating activities	(1,177)	(4,477)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(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	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
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	-	-

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,081	9,394
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,177)	(4,477)
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	(6)	(19)
4.6	Cash and cash equivalents at end of period	4,898	4,898

5.	<i>Reconciliation of cash and cash equivalents</i> <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	4,898	6,081
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)	4,898	6,081

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
139

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
7.1	-	-
7.2	-	-
7.3	-	-
7.4	-	-

7.5 Unused financing facilities available at quarter end

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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)	(1,177)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	4,898
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	4,898
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	4.16

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.

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: N/A

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: N/A

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: N/A

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.

Date: 31 January 2024

Authorised by: By the Board

(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.