ASX Announcement

30 October 2023

Quarterly Activities & Cash Flow Report

Quarter ended 30 September 2023

Sydney, Australia – 30 October 2023: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), is pleased to provide an update on activities, for the quarter ending 30 September 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

- ✓ **Appointment of Mr Douglas Cubbin and Dr Gabriel Liberatore to OncoSil Board:** With the retirement of Mr Otto Buttula, Mr Douglas Cubbin was appointed as the Non-Executive Chairman of the OncoSil Board. Dr Gabriel Liberatore was also appointed to the Board as a Non-Executive Director.
- ✓ **G-BA Fully Funded Trial in Germany:** The second round of stakeholder meetings occurred in September, and subsequently, the committee is poised to commence the development of the study design.
- ✓ **36th Annual Congress of the European Association of Nuclear Medicine (EANM):** OncoSil team attended EANM Congress at Vienna, Austria on 19-23 October 2023. Several meetings were held with HCPs and potential distributors from different countries. OncoSil™ treatment was also presented by Dr. Zarni Win from Hammersmith Hospital / Imperial College, London, UK during the scientific program.
- ✓ **Update on Commercial activities in Spain:** 8 centres are now actively treating patients with OncoSil™ in Spain. In total 18 patients were treated until now in both commercial setting and for clinical trials.
- ✓ **Update on OSPREY post-marketing registry patient numbers:** 16 patients were treated with OncoSil™ device under the OSPREY registry.
- ✓ **Commercial activities in Italy:** After the announcement of the first patient treated with the OncoSil™ device in Q4 FY23, 2 more patients were treated at the San Camillo-Forlanini Hospital in Rome, Italy in Q1 FY24.
- ✓ **OncoSil™ treatments in Israel:** Hadassah Hospital, one of the key oncology centers in Israel, successfully completed the treatment of their 4th patient in August 2023.
- ✓ **Update on patient numbers at TRIPP-FFX Clinical Study:** Following the announcement of the first patient treatment at TRIPP-FXX study in May, in total of 12 patients were randomised by the end of September 2023.
- ✓ **USA HDE for distal cholangiocarcinoma:** Currently engaged in ongoing dialogue with the FDA to progress the application.
- ✓ **Cash position:** Cash balance of $6.08 million as at 30 September 2023.

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. OSPREY is a post marketing registry that forms part of the approval labelling for the OncoSil device. Each hospital in the EU and UK are required to obtain ethics approval for OSPREY in order to allow OncoSil to ship the dose.

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

Appointment of Mr Douglas Cubbin and Dr Gabriel Liberatore to OncoSil Board - Announced 7 August 2023 and 14 July 2023

Mr Douglas Cubbin joined the Board on 7 August 2023 and with the retirement of Mr Otto Buttula on 31 August 2023, Mr Cubbin was appointed as the Non-Executive Chairman of the OncoSil Board. Mr Cubbin is an experienced biopharmaceutical executive with over 30 years' experience in senior executive, CFO, Director and Chair roles, across varied industries. He was a key member of the Telix Pharmaceuticals Limited (ASX:TLX) team which successfully completed the IPO, raised $270 million in capital and grew the business to a multi-billion dollar market capitalization.

Dr Gabriel Liberatore was also appointed to the Board as a Non-Executive Director on 14 July 2023. Dr Liberatore is an experienced biopharmaceutical executive with over 25 years' experience in senior Business Development, R&D and strategic operational management positions. Until recently, he was the Group Chief Operating Officer at Telix Pharmaceuticals (ASX:TLX).

Mr. Brian Leedman has informed the Board of Directors of his intention to retire as a Non-Executive Director at the Annual General Meeting on November 29, 2023. The Board wishes Brian well and thanks him for his contribution.

G-BA Fully Funded Trial in Germany

In March 2022, the Federal Joint Committee (G-BA) recommended a fully funded trial take place in Germany for OncoSil™ device. Possible favourable results from the clinical trial will lead to the OncoSil™ device being fully funded for patients in Germany through public insurance reimbursement. OncoSil will receive revenue payments for the provision of the OncoSil™ device used within the clinical trial. The 36 leading university sites in Germany who had submitted NUB requests will also be able to participate within the clinical trial.

The second round of stakeholder meetings was completed on 28 September 2023. This meeting allows the GBA to gather further information for decision-making of the final coverage with evidence development (CED) study directive.

36th Annual Congress of the European Association of Nuclear Medicine (EANM)

The biggest Nuclear Medicine meeting of Europe, EANM'23, took place between 19-23 October 2023 at Vienna, Austria. Over 7,000 participants attend the event from all around the world and more than 150 companies were present at the exhibition including OncoSil.

OncoSil sales & marketing teams attend the congress to promote OncoSil™ device to the HCPs and make connections with potential distributors from different countries.

On Sunday September 10, 2023; Dr. Zarni Win from Hammersmith Hospital/ Imperial College, London, UK presented OncoSil treatment during the scientific program.

Update on Commercial activities in Spain

Since commencing treatment in Spain as announced on 13 April 2022, a total of eight medical centres within Spain are now actively engaged in the treatment of patients utilizing OncoSil™ device. This strategic expansion represents a significant milestone in the ongoing implementation of this cutting-edge technology within Spain. To date, a combined total of 18 patients have received treatment, encompassing both clinical trial settings and commercial applications.

Update on OSPREY post-marketing registry patient numbers

The OSPREY patient registry has been developed to collect and assess the performance and safety data related to the use of the OncoSil™ device when used within the approved indication of unresectable, locally advanced pancreatic cancer, in combination with gemcitabine-based chemotherapy, within a real-world observational registry in European Union and UK.

Until now; 16 patients were successfully treated with OncoSil™ device under the OSPREY registry.

Commercial activities in Italy

Following the declaration of the initial patient's treatment with the OncoSil™ device during the fourth quarter of fiscal year 2023, two additional patients received treatment at the San Camillo-Forlanini Hospital in Rome, Italy. Additional centres are expected to be opened in near future.

OncoSil™ treatments in Israel

Hadassah Hospital, a renowned oncology institution based in Jerusalem, Israel, initiated OncoSil™ treatments in April 2023. Through the unwavering commitment and expertise of their multidisciplinary team, the successful completion of treatment for the fourth patient was achieved by August 2023.

Update on patient numbers at TRIPP-FFX Clinical Study

The TRIPP-FFX Clinical Study is an open-label, multi-centre, randomized study of **T**a**R**geted **I**ntratumoural **P**lacement of **P**hosphorous-32 (OncoSil™) in addition to **F**OL**F**IRINO**X** chemotherapy versus FOLFIRINOX chemotherapy alone in patients with unresectable locally advanced pancreatic cancer. The aim of this Clinical Study is to expand the CE Marking approved use of the OncoSilTM device in the UK and the

European Union for patients being treated either with gemcitabine-based chemotherapy or FOLFIRINOX chemotherapy.

Subsequent to the initial patient treatment announcement within the TRIPP-FXX study in May 2023, a total of 12 patients are now randomized to participate.

USA Humanitarian Device Exemption (HDE) for distal cholangiocarcinoma

OncoSil maintains an ongoing and proactive communication with the United States Food and Drug Administration (FDA) as part of its endeavors to progress the submitted HDE application for the OncoSilTM device intended for the treatment of distal cholangiocarcinoma (dCCA or bile duct cancer).

Finance Update

An Appendix 4C Quarterly Cash Flow report is attached to this announcement.

As detailed in the attached ASX Appendix 4C, the Company had $6.08 million in cash and equivalents as at 30 September 2023, decreasing from $9.39 million at 30 June 2023.

The Net Cash used in Operating Activities during the quarter was $3.29 million, with Staff costs and direct Research and Development expenditures accounting for over 69% of the $3.29 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 non-executive 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.

Strategic Discussions

Further to comments made on 24 May 2023, the Company is identifying potential opportunities for new strategic industry partners in respect of investment in the Company and other forms of collaboration in conjunction with its strategic adviser, Kidder Williams. There is no certainty at this time that a strategic proposal will progress. The Company will keep shareholders updated with developments.

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 September 2023

	Consolidated statement of cash flows	**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	66	66
1.2	Payments for		
	(a) research and development	(1,165)	(1,165)
	(b) product manufacturing and operating costs	(173)	(173)
	(c) advertising and marketing	(93)	(93)
	(d) leased assets	-	-
	(e) staff costs	(1,124)	(1,124)
	(f) administration and corporate costs	(950)	(950)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	51	51
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	88	88
1.9	**Net cash from / (used in) operating activities**	**(3,300)**	**(3,300)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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 (3 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	9,394	9,394
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,300)	(3,300)
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	(13)	(13)
4.6	**Cash and cash equivalents at end of period**	**6,081**	**6,081**

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	6,081	9,394
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)**	**6,081**	**9,394**

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	166
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)	(3,300)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	6,081
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	6,081
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	1.84
	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: The Company does not expect to maintain the current net operating cash outflow level as there were multiple one-off large payments this quarter. The board will continue to monitor the cash position closely.

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 Board believes that the Company can raise sufficient capital on the basis of past success and current interest in the company and its projects. The Board continues to evaluate alternative sources of capital.

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: Yes, the Board expects to be able to continue its operations and to meet its business objectives. The Board believe that the Company can raise sufficient capital on the basis of past success and current interest in the company and its projects. The Board continues to evaluate alternative sources of capital.

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: 30 October 2023

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.