

## ASX Announcement

29 April 2021

### Quarterly Activities & Cash Flow Report Quarter ended 31 March 2021

**Sydney, Australia – 29 April 2021:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 31 March 2021 (the Quarter). OncoSil is a medical device company that is currently commercialising its platform technology for the treatment of patients with locally advanced pancreatic cancer (LAPC) and bile duct cancer.

#### Key Highlights

- **Leadership team in place:** Following appointment as Nigel Lange as CEO, key recent hires include a Chief Medical Officer, Head of Medical Affairs, Director of Access Reimbursement, Economics and Assessment and Director of Clinical development
- **Finalising data package for HDE submission:** Currently finalising an updated dataset which involves a more recent data cut-off point, to support its HDE application to the FDA
- **Targeting hospitals in Greater London in the near-term:** Pushing forward with launch preparation activities throughout Europe including establishing the Osprey registry
- **Additional sales in New Zealand:** Following OncoSil's first ever commercial sale, OncoSil has achieved further sales in New Zealand
- **Cash position:** Cash balance of \$15.3 million as at 31 March 2021

*All financial results are in Australian dollars and are unaudited.*

#### Team update: Organisational and commercial capability built

During the Quarter, OncoSil announced the appointment of Mr Nigel Lange as Chief Executive Officer and Managing Director of the Company (refer to ASX announcement on 21 Jan 2021 and quarterly activities report on 28 January 2021). In addition, OncoSil has continued to build out its in-house organisational capability alongside the appointment of Nigel Lange as CEO. This includes a Chief Medical Officer (Dr. Ralph Peters), Head of Medical Affairs (David Turner), Director of Access Reimbursement, Economics and Assessment (Olaf Michaelsen) and Director of Clinical Development (Henk Tissing). The many years of commercial and clinical experience in the medical devices industry shared between these key hires (i.e., ex Sirtex and BTG/Boston Scientific) will be invaluable to OncoSil as the Company embarks on its global commercialisation strategy.

## **US: Finalising data package to support the HDE application for the treatment of bile duct cancer**

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 (bile duct cancer).

The HDE is focussed on mass-forming distal cholangiocarcinoma (dCCA), which is a solid tumour similar in form to pancreatic tumours that develop from the common bile duct within the pancreas. A dCCA mass can be treated using the same endoscopic-guided approach as locally advanced pancreatic cancer (LAPC) and the FDA have agreed that the safety data from the PanCO study in patients with unresectable LAPC are an appropriate surrogate for the treatment of the dCCA using the OncoSil™ device.

During the Quarter, OncoSil has been working on a request from the FDA for an updated dataset involving a more recent data cut-off point. The Company is finalising this data package and will provide it to the FDA once ready.

## **Europe and UK: 9 hospitals in UK have received ethics approval**

During the Quarter, OncoSil continued to progress launch preparation activities throughout Europe and UK. OncoSil anticipates first Europe revenues to come from Greater London, where there are currently 9 hospitals which have received ethics approval from the Health Research Authority (HRA) and the Research Ethics Committee (REC), including the receipt of the appropriate licenses to use radioactive phosphorous (i.e. the OncoSil™ device). For these 9 hospitals, OncoSil continues to progress the final stages of activities and approvals, with a strong focus on ensuring the relevant private payer hospitals are ready-to-order in the near-term. One of these hospitals, The London Clinic, are actively screening for patients at their bi-weekly Multi-Disciplinary meetings.

Outside of these hospitals, OncoSil continues to push forward with the necessary workstreams, including the Osprey registry and obtaining the relevant approvals in different jurisdictions. OncoSil continues to work through and overcome the many disruptions caused by the COVID-19 pandemic, including access and hospital restrictions which have caused delays in OncoSil's Europe and UK commercialisation plans. In addition, the Company continues to work on developing the optimal clinical pathway to support reimbursement, which is critical to OncoSil's long-term growth plans.

## **ASEAN and APAC: Further sales in New Zealand**

Following first sale in New Zealand (announced on 22 October 2020), OncoSil has pleasingly achieved further sales in the region, which is a strong validation of the device. OncoSil continues to actively engage with additional New Zealand sites while also advancing its efforts towards obtaining further necessary approvals for the Osprey registry in New Zealand, Singapore and Malaysia.

In July 2020, the Company filed an application with the Therapeutic Goods Administration (TGA) in Australia. On 11 January 2021, OncoSil submitted additional data in response to the TGA's request.

## Financials

As at 31 March 2021, OncoSil had a cash balance of \$15.3 million. During the Quarter, the Company's net cash used in operations was \$2.7 million, which includes R&D investments (\$0.6 million), staff costs (\$1.3 million) and administration and corporate costs (\$0.5 million). 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	Investor enquiries
<b>Mr Nigel Lange</b> CEO & Managing Director E: <a href="mailto:nigel.lange@oncosil.com">nigel.lange@oncosil.com</a> T: +49 30 300 149 3043	<b>Mr Karl Pechmann</b> CFO & Company Secretary E: <a href="mailto:karl.pechmann@oncosil.com">karl.pechmann@oncosil.com</a> T: +61 2 9223 3344	<b>Ivan Lee</b> Vesparum Capital E: <a href="mailto:oncosil@vesparum.com">oncosil@vesparum.com</a> T: +61 3 8582 4800

## 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 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	65	155
1.2 Payments for		
(a) research and development	(629)	(2,101)
(b) product manufacturing and operating costs	(76)	(153)
(c) advertising and marketing	(294)	(828)
(d) leased assets	-	-
(e) staff costs	(1,250)	(3,888)
(f) administration and corporate costs	(534)	(2,118)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	13	75
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	2,897
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,705)</b>	<b>(5,961)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
	(c) property, plant and equipment	(11)	(39)
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(11)</b>	<b>(39)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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	-	260
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>260</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	17,974	21,000
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,705)	(5,961)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(11)	(39)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	260
4.5	Effect of movement in exchange rates on cash held	-	(2)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>15,258</b>	<b>15,258</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> <i>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts</i>	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	15,258	17,974
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>15,258</b>	<b>17,974</b>

**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**

80

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)	2,705
8.2 Cash and cash equivalents at quarter end (Item 4.6)	15,258
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	15,258
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	5.64

- 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.

29/04/2021

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 – eg 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.