

## ASX Announcement

28 January 2021

### Quarterly Activities & Cash Flow Report Quarter ended 31 December 2020

**Sydney, Australia – 28 January 2021:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 31 December 2020 (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

- **Appointment of Chief Executive Officer:** Subsequent to the Quarter, Nigel Lange was appointed as Chief Executive Officer and Managing Director of OncoSil Medical
- **Final stages of establishing post-marketing study in Europe:** OncoSil continues to advance critical launch preparation activities including setting up the OSPREY registry
- **First commercial sale achieved:** OncoSil recorded its first commercial sale, with a patient implanted with the OncoSil™ device in New Zealand
- **Cash position:** Cash balance of \$18.0 million as at 31 December 2020

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

#### Appointment of Chief Executive Officer

Subsequent to the Quarter, on 21 January 2021, OncoSil announced the appointment of Mr Nigel Lange as Chief Executive Officer and Managing Director of the Company. Nigel joined OncoSil as EMEA President in May 2020, bringing with him over 30 years of experience in the medical devices industry and expertise in the field of interventional oncology. Nigel previously served as the Chief Commercial Officer of ASX-listed medical device company Sirtex Medical (formerly ASX:SRX) and as the Chief Executive Officer of Sirtex's European business from 2003 to 2016, where he was responsible for the establishment of the Sirtex brachytherapy device SIR-Spheres in over 300 centres across the EMEA region.

The Company is confident in Nigel's leadership and his experience at Sirtex will be highly valuable as OncoSil transitions towards being a commercial-stage medical device company.

#### Europe and UK update

As previously announced in the OncoSil FY21 Half Yearly review on 18 January 2021, OncoSil is required to undertake a post-marketing observational study of 500 patients to assess the performance and safety of the OncoSil™ device, as part of the requirements associated with its CE Marking. Results are required to be documented within the "OSPREY" registry, which will be a global registry in all approved markets, not just in Europe.

Depending on the region, country or state, the steps in establishing the post-marketing observational study varies and different approvals may be required at varying stages. For instance, in the UK, several different bodies/parties will be required to separately review and approve the registry and its associated protocol. OncoSil is progressing with all necessary approvals, including 9 sites across greater London which have been submitted to UK's Research Ethics Committee.

Outside of establishing the OSPREY registry, the Company continues to progress with its European commercialisation plans. As announced on 5 November 2020, the Company received regulatory clearance to market and sell its device in Switzerland. In addition, as detailed in the announcement on 18 January 2021, the Company continues to focus on its reimbursement strategy and has commenced seeking approvals in certain authorities and territories.

### **ASEAN / APAC update**

As announced on 22 October 2020, OncoSil recorded its first commercial sale of the OncoSil™ device, with a patient treated in New Zealand. This is a milestone achievement for the Company as it transitions toward being a revenue-generating medical device company. OncoSil continues to actively engage with additional New Zealand sites while also advancing its efforts towards obtaining further approvals for the post-marketing observational study 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.

### **HDE submission for bile duct cancer treatment in US**

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). 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.

### **Financials**

As at 31 December 2020, OncoSil had a cash balance of \$18.0 million. During the Quarter, the Company's net cash used in operations was \$2.7 million, which includes R&D investments (A\$0.5 million), staff costs (A\$1.4 million) and administration and corporate costs (A\$0.7 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
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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 December 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	90	90
1.2 Payments for		
(a) research and development	(503)	(1,472)
(b) product manufacturing and operating costs	(77)	(77)
(c) advertising and marketing	(189)	(534)
(d) leased assets	-	-
(e) staff costs	(1,369)	(2,638)
(f) administration and corporate costs	(724)	(1,584)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	24	62
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	27	2,897
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,721)</b>	<b>(3,256)</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 (6 months) \$A'000</b>
	(c) property, plant and equipment	(20)	(28)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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	<b>Net cash from / (used in) investing activities</b>	<b>(20)</b>	<b>(28)</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	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)	-	-
3.10	<b>Net cash from / (used in) financing activities</b>	<b>260</b>	<b>260</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 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	20,457	21,000
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,721)	(3,256)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(20)	(28)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	260	260
4.5	Effect of movement in exchange rates on cash held	(2)	(2)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>17,974</b>	<b>17,974</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	17,974	20,457
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>17,974</b>	<b>20,457</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)	2,721
8.2 Cash and cash equivalents at quarter end (Item 4.6)	17,974
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	17,974
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	6.61

- 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.

28/01/2021

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.