

## ASX Announcement

30 January 2020

### Quarterly Activities & Cash Flow Report

Quarter ended 31 December 2019

#### Operational Highlights

- Positive regulatory progress with CE Mark review in final phase following two successful meetings with British Standards Institute (BSI) during the last quarter:
  - Positive status report received on 30 October after meeting with BSI's Clinical Oversight Committee (COC) on 3 October
  - Post meeting with BSI on 14 November, OncoSil submitted its Post-Market Surveillance (PMS) Plan and Post-Market Clinical Follow-Up (PMCF) programme for the OncoSil™ device
- Positive regulatory progress in US - during the quarter the Company confirmed that in December 2018 FDA granted OncoSil Medical a Humanitarian Use Designation (HUD) for both intrahepatic (ICC) and distal cholangiocarcinoma (dCCA)
- Cash balance of \$6.8 million as of 31 December 2019
- \$3.8M R&D tax incentive refund received in October 2019

**Sydney, Australia – 30 January 2020:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 31 December 2019 (the **Quarter**). OncoSil is a medical device company focused on localized treatments for patients with pancreatic and liver cancer.

All financial results are in Australian dollars and are unaudited.

#### CE Mark Update

During the quarter, OncoSil met with BSI and its COC on 3 October in London. In the meeting, the Company made a comprehensive and detailed presentation addressing concerns and issues raised in the previous assessment by the regulatory authorities.

Post the COC meeting, OncoSil submitted an updated Clinical Evaluation Report (CER) as requested by BSI and received a positive CE Mark Status report on 30 October. The report confirmed that BSI has completed the analysis of the data presented to the COC and **closed out concerns with the external clinical and bio-statistical experts.**

In a subsequent meeting with BSI held on 14 November, the Company presented its Post-Market Surveillance (PMS) Plan and Post-Market Clinical Follow-Up (PMCF) programme for the OncoSil™ device. The plans outline how the device would be rolled out by OncoSil **into the European Market post CE Mark approval.** OncoSil has since formally submitted both plans to the BSI, with the CE Mark review now in its final phase. The Company would expect the final determination in the coming weeks.

## US Regulatory Update

OncoSil has been exploring various US regulatory pathways for its device. During the quarter, the Company confirmed that in December 2018 the FDA granted OncoSil Medical a Humanitarian Use Designation (HUD) for both intrahepatic (ICC) and distal cholangiocarcinoma (dCCA) (variants of biliary duct cancer) for the OncoSil™ device.

The HUD program creates an alternative pathway for obtaining market approval for medical devices that may help patients with rare diseases or conditions. As previously announced, the Company is currently preparing an application for Humanitarian Device Exemption (HDE) in dCCA. OncoSil is expecting to file the application in CY Q2 and will update the market upon submission of the HDE.

## Corporate and Financial

During the quarter, the Company had cash flows from operations of positive \$1.32 million, resulting in a cash balance of \$6.8 million as at 31 December 2019. This includes the receipt of \$3.8 million from the R&D Tax Incentive refund.

As previously announced, OncoSil continues to operate under a revised business plan as it awaits the outcome of the CE Mark decision. The Company has continued with these measures with the aim of maximising long-term shareholder value and strengthening its cashflow position.

-ENDS-

## Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil 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 four clinical studies with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil™ in the European Union (EU) is under review.

The U.S Food and Drug Administration granted an Investigational Device Exemption (IDE) in July 2016 with approval to conduct a clinical study of the OncoSil™ device. The aim of the study will be to collect safety

and effectiveness data required to support a Premarket Approval (PMA) application.

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. 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 \$1b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6th most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.

### **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 report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

#### Name of entity

**ONCOSIL MEDICAL LIMITED**

#### ABN

89 113 824 141

#### Quarter ended ("current quarter")

31 December 2019

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,261)	(2,245)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(658)	(1,581)
(f) administration and corporate costs	(566)	(965)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	26	54
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	3,782	3,782
1.8 Other (License fee)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>1,323</b>	<b>(955)</b>

#### **2. Cash flows from investing activities**

##### 2.1 Payments to acquire:

(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.2 Proceeds from disposal of:</b>	-	-
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.3 Cash flows from loans to other entities</b>	-	-
<b>2.4 Dividends received (see note 3)</b>	-	-
<b>2.5 Other (provide details if material)</b>	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares	60	60
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	-	-
3.4 Transaction costs related to issues of shares, convertible notes or options	-	-
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 Net cash from / (used in) financing activities</b>	<b>60</b>	<b>60</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	5,416	7,694
4.2 Net cash from / (used in) operating activities (item 1.9 above)	1,323	(955)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	60	60
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>6,798</b>	<b>6,798</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	6,798	5,416
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>6,798</b>	<b>5,416</b>

**6. Payments to directors of the entity and their associates**

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

<b>Current quarter \$A'000</b>
40

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<b>7. Payments to related entities of the entity and their associates</b>	<b>Current quarter \$A'000</b>
7.1 Aggregate amount of payments to these parties included in item 1.2	
7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3	
7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

<b>8. Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
8.1 Loan facilities		
8.2 Credit standby arrangements		
8.3 Other (please specify)		
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

<b>9. Estimated cash outflows for next quarter</b>	<b>\$A'000</b>
9.1 Research and development	1,300
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	-
9.4 Leased assets	-
9.5 Staff costs	700
9.6 Administration and corporate costs	600
9.7 Other (provide details if material)	
<b>9.8 Total estimated cash outflows</b>	<b>2,600</b>

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity		
10.2	Place of incorporation or registration		
10.3	Consideration for acquisition or disposal		
10.4	Total net assets		
10.5	Nature of business		

#### 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.



Sign here:  
(Company Secretary)

Date: 30 January 2020

Print name: Nicholas Falzon

#### Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.