

## ASX Announcement

31 October 2019

### Quarterly Activities & Cash Flow Report

#### Quarter ended 30 September 2019

- OncoSil submits updated Clinical Evaluation Report after follow up meeting with the British Standards Institute (BSI) and Clinical Oversight Committee (COC)
- Positive regulatory progress in US – OncoSil to apply for Humanitarian Device Exemption (HDE) in distal cholangiocarcinoma (dCCA) from the US Food and Drug Administration (FDA)
- Company continues cost-containment initiatives in line with revised business plan
- Cash balance of \$5.4 million as of 30 September
- \$3.8 million R&D Tax Incentive refund received in October

**Sydney, Australia, 31 October 2019:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 30 September 2019 (the **Quarter**). OncoSil is a medical device company focused on localised 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 prepared for its follow up meeting with the British Standards Institute (BSI) and Clinical Oversight Committee (COC) which was held on 3 October. In the meeting, the Company prepared a comprehensive and detailed presentation which addressed the concerns and issues raised in the previous assessment by the regulatory authorities.

The Company was encouraged with the meeting and the hearing that BSI and the COC provided to the Company. At the conclusion of the meeting, BSI requested OncoSil submit an updated Clinical Evaluation Report (CER) which includes the clinical data and analysis of the PanCO study results. As noted on 29 October, the Company has submitted the updated CER.

The Company will keep the market informed of developments with respect to progress on the final CE Marking determination.

#### Other Regulatory Update

While awaiting the outcome of its CE Mark application in Europe, during the quarter, OncoSil explored various US regulatory pathways for its device. In particular, the Company explored a new indication for the OncoSil device in the treatment of cholangiocarcinoma (bile duct cancer) and made significant progress.

The Company's device has since been granted Humanitarian Use Designation (HUD) by the US FDA for both intrahepatic (ICC) and distal cholangiocarcinoma (dCCA). The HUD program creates an alternative

pathway for obtaining market approval for medical devices that may help patients with rare disease and conditions.

In July, OncoSil held a successful Pre-Submission meeting with the FDA seeking guidance from the FDA on a potential Humanitarian Device Exemption (HDE) submission in dCCA. The FDA has confirmed the acceptance of a predicate approach whereby clinical data obtained in locally advanced pancreatic cancer could be applied to the treatment of dCCA.

OncoSil will now apply for a HDE in dCCA for the OncoSil device from the US FDA. The HDE submission will apply the predicate approach utilising the clinical safety and performance data obtained from the PanCO study. The Company expects to file this submission within the coming months and will update the market upon submission.

### Corporate and Financial

During the quarter, the Company had cash outflows from operations of \$2.2 million, resulting in a cash balance of \$5.4 million as at 30 September 2019. This excludes the recent receipt of \$3.8 million from the R&D Tax Incentive refund.

As previously announced, OncoSil has taken precautionary measures to reduce costs under a revised business plan while it awaits the outcome of the CE Marking decision. The Company has continued with these measures with the aim of maximising long-term shareholder value and strengthening its cashflow position.

**-ENDS-**

Company	Media
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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")

30 Sep 2019

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(984)	(984)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(923)	(923)
(f) administration and corporate costs	(399)	(399)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	28	28
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (License fee)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2, 278)</b>	<b>(2,278)</b>

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
<b>2.</b>	<b>Cash flows from investing activities</b>		
2.1	Payments to acquire:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:	-	-
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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>3.</b>	<b>Cash flows from financing activities</b>	-	-
3.1	Proceeds from issues of shares	-	-
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</b>	<b>Net cash from / (used in) financing activities</b>	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
<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 quarter/year to date	7,694	7,694
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,278)	(2,278)
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	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>5,416</b>	<b>5,416</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	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	5,416	7,694
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>5,416</b>	<b>7,694</b>

<b>6.</b>	<b>Payments to directors of the entity and their associates</b>	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	60
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	

**7. Payments to related entities of the entity and their associates**

**Current quarter  
\$A'000**

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

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**8. Financing facilities available**

*Add notes as necessary for an understanding of the position*

**Total facility amount  
at quarter end  
\$A'000**

**Amount drawn at  
quarter end  
\$A'000**

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.

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**9. Estimated cash outflows for next quarter**

**\$A'000**

9.1 Research and development

1,000

9.2 Product manufacturing and operating costs

-

9.3 Advertising and marketing

-

9.4 Leased assets

-

9.5 Staff costs

800

9.6 Administration and corporate costs

400

9.7 Other (provide details if material)

**9.8 Total estimated cash outflows**

**2,200**

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: 31 October 2019

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.