

ASX Announcement

31 July 2019

Quarterly Activities & Cash Flow Report

Quarter ended 30 June 2019

Sydney, Australia, 31 July 2019: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 30 June 2019 (the **Quarter** or **4Q19**). 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

Company submits response to BSI

As announced on 30 July, the Company has submitted a comprehensive response to questions from BSI and its Clinical Oversight Committee regarding the certification of the OncoSil™ device based on the results of the PanCO study.

This response has been developed and prepared with the support of leading, pre-eminent experts in medical oncology, radiation oncology and pancreatic surgery.

The response includes updated and new clinical data, together with a Systematic Literature Review (SLR) on state-of-the-art chemotherapy (CT-only) and induction chemotherapy combined with consolidation chemoradiotherapy (ICT + CCRT) regimens, enabling a treatment comparison that demonstrates the OncoSil™ device provides statistically significant and clinically meaningful benefits over and above the benefit of chemotherapy alone for patients with unresectable, locally advanced pancreatic cancer (LAPC).

The Company will keep the market informed of developments with respect to the COC's review and the progress to the final CE Marking determination.

Positive Overall Survival data from PanCo Study

During the quarter, the Company shared positive Overall Survival data for its PanCo study at the American Society of Clinical Oncology (ASCO) Annual Meeting 2019 in Chicago.

The PanCo study is an international multi-institutional, single arm study conducted across 12 sites in Australia, UK and Belgium. The aim of the study is to further investigate the safety, efficacy, feasibility and performance of the OncoSil device when implanted intra-tumorally in patients with unresectable locally advanced pancreatic cancer (LAPC).

The study shows promising survival estimates with mean overall survival of 16 months. The accepted population median overall survival estimates of patients with LAPC is only 9-11 months¹.

The results are comparable to, and in many cases surpasses, that of the best available published literature in the patient population.

¹ Loehrer PJ et al. J Clin Oncol 211 Nov 1;29 (31) 4105-12

The study data demonstrates an unequivocal and direct clinical benefit for patients and this, alongside other relevant outcome measures, have been included in the package submission and will be discussed with the BSI and COC.

Corporate and Financial

During the Quarter, the Company had cash outflows from operations of \$2.5 million, resulting in a cash balance as at 30 June 2019 of \$7.7 million.

As announced in the previous cashflow report, 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 is continuing with such measures with the aim of maximising long-term shareholder value and strengthening its cashflow position.

– ENDS –

Company	Media
Mr Daniel Kenny CEO & Managing Director E: daniel.kenny@oncosil.com.au T: +61 2 9223 3344	Arthur Chan WE Buchan E: arthurc@we-buchan.com M: +61 404 369 388

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 (Phosphorous-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with 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 with commercial launch, subject to approval.

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 June 2019

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities			
1.1 Receipts from customers	-	-	-
1.2 Payments for			
(a) research and development	(1,268)	(5,765)	
(b) product manufacturing and operating costs	-	-	
(c) advertising and marketing	(17)	(62)	
(d) leased assets	-	-	
(e) staff costs	(919)	(4,466)	
(f) administration and corporate costs	(360)	(1,489)	
1.3 Dividends received (see note 3)	-	-	
1.4 Interest received	48	203	
1.5 Interest and other costs of finance paid	-	-	
1.6 Income taxes paid	-	-	
1.7 Government grants and tax incentives	-	4,209	
1.8 Other (License fee)	-	(141)	
1.9 Net cash from / (used in) operating activities	(2, 516)	(7,511)	
2. Cash flows from investing activities			
2.1 Payments to acquire:			
(a) property, plant and equipment	-	-	
(b) businesses (see item 10)	-	-	
(c) investments	-	-	

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
	(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)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities	-	-
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)	-	-
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 quarter/year to date	10,210	15,205
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,516)	(7,511)
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)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	7,694	7,694

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	7,694	10,210
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)	7,694	10,210

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	80
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	

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

1,000

9.6 Administration and corporate costs

300

9.7 Other (provide details if material)

9.8 Total estimated cash outflows

2,300

**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 July 2019

Print name: Tom Milicevic

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.