

ASX Announcement  
25 July 2018

## Quarterly Activities & Cash Flow Report Quarter ended 30 June 2018

*Investor Call to discuss Quarterly Results and Outlook at 9:00 am AEDT, 31 July 2018*

**Sydney, Australia, 25 July 2018:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on localised treatments for patients with pancreatic and liver cancer, today released its Appendix 4C – Quarterly Cashflow report for the quarter ended 30 June 2018 (the **Quarter** or **4Q 18**). All financial results are in Australian dollars and are unaudited.

### Key highlights:

- **PanCO study now closed for recruitment globally with 50 patients enrolled** per study protocol
- **41 patients in PanCO study now successfully implanted with OncoSil™ device**
- **6 patients so far have successfully undergone surgical resection with curative intent**
- OncoPaC-1 study (US) remains open for recruitment across all activated trial sites, **with 6 patients now recruited; 4 of these patients successfully implanted with OncoSil™ device**
- Detailed report submitted to the British Standards Institute (BSI) outlining emerging performance and safety data for the OncoSil™ device, further progressing CE Mark application
- **Cash balance as at 30 June 2018 of \$15.2m**

OncoSil Chief Executive Director Daniel Kenny commented:

*“We have had another productive quarter and are excited to have reached a major milestone in our Global Clinical Study Programme, having now closed recruitment for the PanCO study following the successful enrolment of 50 patients.*

*“Early trial data from these patients has been excellent, and in May we were pleased to submit a detailed clinical report on 16-week data for the first 25 patients to the EU Notified Body, BSI in support of our CE Mark application.*

*“In addition to our data submission, we remain highly encouraged by the surgical resection outcomes achieved thus far with patients enrolled in our study. These are important clinical milestones, as they demonstrate the potential of the OncoSil™ device, in combination with chemotherapy, to take patients from an inoperable to operable state.”*

### **Global Pancreatic Clinical Study Programme Update**

#### **PanCO Clinical Study**

OncoSil has successfully completed patient recruitment for its PanCO study across all participating sites in Australia, UK and Belgium, with 50 patients now enrolled.

Of these 50 patients:

- 41 patients have been successfully implanted with the OncoSil™ device
- **Excellent Local Disease Control Rate (DCR) of 100% (Week 8) and 87% (Week 16)**
- **6 patients so far have undergone surgical resection with curative intent**

- **9 patients so far have achieved a Partial Response (defined as a reduction in tumour longest diameter of at least 30% from the baseline)**
- **Reassuring safety profile - No evidence of radiation toxicities, or other safety concerns**
- **OncoSil™ device delivery via EUS considered straightforward for implantation**

### **OncoPaC-1 Clinical Study**

Recruitment and screening efforts continue for the OncoPaC-1 study in the US, with 6 patients now recruited, and 4 of these patients successfully implanted with the OncoSil™ device. OncoSil looks forward to continuing to update the market on progress with this study across all participating sites.

### ***CE Mark application***

As previously announced to the market on 14 May 2018, , OncoSil submitted a detailed clinical report outlining emerging performance and safety data for the OncoSil™ device to the British Standards Institute (BSI), the regulatory body overseeing the Company's CE Mark application, on 11 May 2018. This submission fulfilled the BSI's previous request to provide 20 patient supplemental data to support the previously submitted safety and clinical performance data.

BSI is currently undertaking the detailed review necessary for granting the CE Mark as is required by the relevant EU laws and regulations. As the OncoSil™ device is an implanted radioactive medical device, BSI requires time to undertake the necessary due diligence of the detailed report submitted by the Company.

The report provided to BSI sets out comprehensive safety data relating to both the device and the implantation procedure for all study participants enrolled at that date (N=46), as well as performance data for 25 patients who had been implanted with the OncoSil™ device and had reached the 8 and 16 week Radiological (CT) assessments.

The Company will continue to keep the market informed of progress towards CE Mark certification during this progress.

### **Corporate and Financial**

During the Quarter, the Company had cash outflows from operations of \$2.9m, resulting in a cash balance as at 30 June 2018 of \$15.2m.

### **Investor Conference Call**

The Company will hold a conference call at **9:00 am AEDT on 31 July 2018** to discuss the Company's financial results for the Quarter and the business outlook. The Company's Chief Executive Officer and Managing Director Daniel Kenny, will host the call.

**To access the call please use the following details: Conference ID: 652412**

<b>Australian Toll Free:</b>	<b>1800 908 299</b>
Australia Local (if dialling from international location):	+61 2 9007 8048
<b>New Zealand Toll Free:</b>	<b>0800 452 795</b>
<b>Hong Kong Toll Free:</b>	<b>800 968 273</b>
<b>Singapore Toll Free:</b>	<b>800 101 2702</b>
<b>China Toll Free:</b>	<b>1080 0140 1776</b>

**United Kingdom Toll Free:**  
**United States/Canada Toll Free:**

**0800 051 1453**  
**1855 624 0077**

– 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 (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 6<sup>th</sup> 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 2018

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
<b>1. Cash flows from operating activities</b>			
1.1 Receipts from customers	-	-	-
1.2 Payments for			
(a) research and development	(1,601)	(5,777)	
(b) product manufacturing and operating costs	-	-	
(c) advertising and marketing	-	-	
(d) leased assets	-	-	
(e) staff costs	(965)	(4,830)	
(f) administration and corporate costs	(369)	(1,256)	
1.3 Dividends received (see note 3)	-	-	
1.4 Interest received	50	141	
1.5 Interest and other costs of finance paid	-	-	
1.6 Income taxes paid	-	-	
1.7 Government grants and tax incentives	-	3,449	
1.8 Other (License fee)	-	(135)	
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,885)</b>	<b>(8,408)</b>	
<b>2. Cash flows from investing activities</b>			
2.1 Payments to acquire:			
(a) property, plant and equipment	(5)	(5)	
(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(5)</b>	<b>(5)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>	-	-
3.1	Proceeds from issues of shares	7,994	16,709
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	(615)	(1,093)
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>7,379</b>	<b>15,616</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 quarter/year to date	10,717	8,001
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,885)	(8,408)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(5)	(5)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,379	15,616

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	-1	1
4.6	<b>Cash and cash equivalents at end of quarter</b>	<b>15,205</b>	<b>15,205</b>

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	15,205	10,717
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>15,205</b>	<b>10,717</b>

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	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	

**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

1,500

9.2 Product manufacturing and operating costs

-

9.3 Advertising and marketing

-

9.4 Leased assets

-

9.5 Staff costs

1,400

9.6 Administration and corporate costs

300

9.7 Other (provide details if material)

-

**9.8 Total estimated cash outflows**

**3,200**

**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: 25 July 2018

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.