

ASX Announcement  
27 July 2016

## Quarterly Activities & Cash flow Report

### Quarter ended 30 June 2016

*Investor Call to discuss Quarterly Results and Outlook at 9.00am AEST, 3 August 2016*

**Sydney, Australia – 27 July 2016:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a late stage medical devices 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 2016 (the **Quarter**). All financial results are in Australian dollars and are unaudited.

### Highlights for the Quarter

- **Filed IDE Amendment with the U.S. FDA**
- **Further submission to the Notified Body for CE mark application responding to all questions**
- **Michael Warrener, appointed Global Head of Sales and Marketing**
- **All 30 June 2016 options exercised for cash, with receipts of \$0.9m**
- **Cash outflow from Operations of \$2.0m for the Quarter - closing cash balance of \$13.4m**

### Key Points – Operational

The Company has continued to make progress with its two key regulatory filings during the Quarter, which remain the primary focus and value enablers for the OncoSil™ technology.

In May 2016, additional material was submitted to BSI, the Company's Notified Body, in support of its CE Mark application for the OncoSil™ product. This submission addressed all questions requested from BSI to date and no additional follow up questions have been received since. The Company is seeking to expedite a response from BSI and remains confident of a successful outcome in its CE Mark, thus enabling commercial sales of OncoSil™ in the European Union and other non U.S. markets.

During the Quarter, the Company and its advisers also had ongoing interactions with the United States Food and Drug Administration (the **FDA**) following the Q-Submissions meeting in March. Following on from this, the Company lodged an Investigational Device Exemption (**IDE**) Amendment with the FDA on 30 June 2016, for the planned global clinical study of the OncoSil™ for the treatment of pancreatic cancer.

The Company remains confident of a successful outcome with the FDA which it believes could be in the near term. The collection of data from the IDE study will be used to support a Premarket Approval application to the FDA and enable OncoSil™ to be commercialised in the United States, one of the world's largest healthcare markets.

As the Company builds towards a planned commercial launch, Michael Warrener commenced in the role of Global Sales and Marketing Director in June. Michael has over 23 years' experience in the pharmaceutical and medical device sector, including eight years with Sirtex Medical Ltd where he helped introduce and then drive adoption of the Sir-Spheres product in the Australian, European Union and Middle East markets. The appointment of Michael Warrener also completed the Company's Leadership Team.

During the Quarter, the Company continued efforts to introduce OncoSil™ and build early awareness among clinicians. As part of this, in July, Michael Warrener and Chief Medical officer, Dr Ash Soman attended the 48th *European Pancreatic Club* meeting in Liverpool, England, a key meeting focused entirely on pancreatic diseases and pancreatic cancer with over 80 speakers. The team met with potential key opinion leaders as well as intended commercial and clinical sites for OncoSil™.

To assist with Regulatory filings, the Company has also completed and presented dosimetry simulation research on the OncoSil™ microparticles at the Inaugural Australian Institute for Nanoscale Science and Technology (AINST) Research Showcase in Sydney. This data developed in collaboration with The School of Physics, The University of Sydney investigated the effect of absorbed radiation dose of different distributions of OncoSil™ Phosphorous-32 microparticles in different tumour shapes and sizes

OncoSil Chief executive Officer, Daniel Kenny commented:

*"This second Quarter has been another period of steady progress towards our immediate regulatory goals. The whole team including our VP of Regulatory, Nicole Wilson, has again put in a huge amount of work with both BSI on the CE mark and the FDA for our IDE, which we expect will result in successful determinations the near term. We remain highly focussed and driven to achieving both of these regulatory outcomes for our shareholders and stakeholders."*

## Key Points – Financial and Corporate

During the Quarter, the Company undertook a number of shareholder engagement initiatives. This included presenting at the *Asia BiotechInvest* conference in Hong Kong in May 2016 and meeting a number of existing and potential new institutional shareholders in Australia and Asia.

Also during the Quarter the Company moved offices to North Sydney to accommodate for future growth.

The Company received \$0.9 million of cash inflows during the Quarter on the exercise of 18.3m unlisted options. This meant that all options due to expire on 30 June 2016 were exercised by the holders for cash.

During the Quarter, cash outflow from operations was \$2.0m and the net cash outflow was \$1.1m, resulting in the Company's cash balance as at 30 June 2016 was \$13.4m.

## Investor Conference Call

The Company will hold a conference call at **9.00 a.m. AEST on Wednesday, 3 August 2016** 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: 457277**

<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>800 616 2288</b>
<b>United Kingdom Toll Free:</b>	<b>0800 051 1453</b>
<b>United States/Canada Toll Free:</b>	<b>1855 624 0077</b>

– ENDS –

Company	Investor Enquiries	Media
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## About OncoSil

OncoSil™ is a clinical-stage 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 trials 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 planned for 2H2016, subject to approval.

An Investigational Device Exemption has also been lodged with the U.S Food and Drug Administration to seek approval to conduct a global 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.

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 materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil 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 admitted on the basis of commitments

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

Name of entity

**OncoSil Medical Limited**

ABN

89 113 824 141

Quarter ended ("current quarter")

**30 June 2016**

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (12 months) \$A'000
1.1 Receipts from customers		
1.2 Payments for (a) staff costs	(892)	(2,485)
(b) advertising and marketing	-	-
(c) research and development	(548)	(2,519)
(d) leased assets	-	-
(e) other working capital	(695)	(1,371)
1.3 Dividends received	40	112
1.4 Interest and other items of a similar nature received	79	158
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes refunded	-	-
1.7 Other (provide details if material)	32	(27)
<b>Net operating cash flows</b>	<b>(1,984)</b>	<b>(4,604)</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	Current quarter \$A'000	Year to date (12 months) \$A'000
1.8 Net operating cash flows (carried forward)		
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	(24)	(48)
(e) other non-current assets	-	-
1.10 Proceeds from disposal of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	-	-
(e) other non-current assets	-	-
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities	-	-
1.13 Other (provide details if material)	-	-
<b>Net investing cash flows</b>	(24)	(48)
<b>1.14 Total operating and investing cash flows</b>	(2,008)	(4,652)
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	927	11,888
1.16 Proceeds from sale of forfeited shares	-	-
1.17 Proceeds from borrowings	-	-
1.18 Repayment of borrowings	-	-
1.19 Dividends paid	-	-
1.20 Other – Share Issue Costs	-	-
<b>Net financing cash flows</b>	927	11,888
<b>Net increase (decrease) in cash held</b>	(1,081)	7,236
1.21 Cash at beginning of quarter/year to date	14,436	6,120
1.22 Exchange rate adjustments	1	-
<b>1.23 Cash at end of quarter</b>	13,356	13,356

+ See chapter 19 for defined terms.

**Payments to directors of the entity and associates of the directors**  
**Payments to related entities of the entity and associates of the related entities**

		Current quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	85
1.25	Aggregate amount of loans to the parties included in item 1.11	-
1.26	Explanation necessary for an understanding of the transactions The amount disclosed is all payments made to directors and related parties in the quarter. The full amount is included in the total at 1.2(a).	

**Non-cash financing and investing activities**

- 2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

NIL

- 2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

NIL

Financing facilities available

Add notes as necessary for an understanding of the position.

	Amount available \$A'000	Amount used \$A'000
3.1 Loan facilities	n/a	n/a
3.2 Credit standby arrangements	n/a	n/a

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

**Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
4.1	Cash on hand and at bank	10,097	10,897
4.2	Deposits at call	3,259	3,539
4.3	Bank overdraft	-	-
4.4	Other (provide details)	-	-
<b>Total: cash at end of quarter (item 1.23)</b>		<b>13,356</b>	<b>14,436</b>

**Acquisitions and disposals of business entities**

		<b>Acquisitions (Item 1.9(a))</b>	<b>Disposals (Item 1.10(a))</b>
5.1	Name of entity	n/a	n/a
5.2	Place of incorporation or registration	n/a	n/a
5.3	Consideration for acquisition or disposal	n/a	n/a
5.4	Total net assets	n/a	n/a
5.5	Nature of business	n/a	n/a

**Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Sign here:  ..... Date: 27/07/2016  
 Chief Financial Officer & Company secretary

Print name: Tom Milicevic

+ See chapter 19 for defined terms.



## **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 wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report except for any additional disclosure requirements requested by AASB 107 that are not already itemised in this report.
3. Accounting Standards. ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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