

ASX Announcement
27 April 2017

Quarterly Activities & Cash flow Report Quarter ended 31 March 2017

Investor Call to discuss Quarterly Results and Outlook at 9.00am AEDT, 4 May 2017

Sydney, Australia – 27 April 2017: 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 31 March 2017 (the **Quarter**). All financial results are in Australian dollars and are unaudited.

Highlights for the Quarter

- **Global Pancreatic Clinical Study programme OncoPac-1 Update**
- **Cash outflow from Operations of \$2.1m for the Quarter - closing cash balance of \$9.4m**

Key Points – Operational

OncoSil™ is an Active Implantable Medical Device (AIMD) and the CE Mark review of the device continues. Many aspects of this lengthy review have now been successfully closed out. During the quarter the Company announced that CE Certification for the pancreatic cancer indication will now be granted subject to the following conditions:

- Provision of supplemental data from 20 locally advanced pancreatic cancer patients supporting the existing safety and clinical performance data already reviewed, and;
- OncoSil Medical agrees to undertake a Post Marketing Clinical Follow-up programme.

The 20 patient supplemental data request from BSI is consistent with the request received from the US FDA prior to granting an Investigational Device Exemption (IDE) in July 2016. The Company is well positioned to provide the supplemental data from its Global Pancreatic Clinical Study programme.

During the Quarter, the Company achieved a number of significant milestones as part of the initial stages of its global pancreatic clinical study programme including:

- **Ethics Approval by Monash Health** - Monash Health is the largest public health service in Melbourne, and has agreed to be the lead Australian study centre.
- **Medicines and Health Care Products Regulatory Agency (MHRA) Approval** - following a rigorous review, MHRA has approved the commencement of our Pancreatic Cancer Clinical Study in the UK.
- **Appointment of Dr Martin Cross as an Independent Non-Executive** – a highly regarded pharmaceutical executive with 30 years' experience in corporate and industry leadership roles directly influencing healthcare policy and government legislation in Australia.
- **Monash Health recruited the first subject for the global clinical study program**
- **St Vincent's Hospital, Sydney received Ethics approval on 16 March**
- **Westmead Hospital, Sydney was granted Ethics approval on 28 March**
- **Royal Adelaide Hospital, Ethics Committee approval granted on 30 March**
- **UK Central Ethics Approval for Pancreatic Clinical Study Programme** - The Central Ethics Approval granted on 31 March initially covering Guys and St Thomas' Hospital, London will facilitate ethics

approval for all 5 participating centres in the UK. This in turn will help expedite the patient recruitment process for the UK arm of the clinical study.

- **MD Anderson Cancer Center, Texas grants Institutional Review Board (IRB) Approval on 19 April** – IRB approval is the final step for US hospitals to agree to participate in a clinical study and recruit and treat patients under the agreed study protocols, and first patient recruitment by MD Anderson is expected to occur in May.
- **Specialised Therapeutics Australia (STA) to support global clinical study programme** – STA to supply subsidised ABRAXANE® to Australian sites to support examination of OncoSil technology in combination with different chemotherapy regimens.
- **First OncoSil TM device implantation procedure completed at Monash Health on April 24th**

The Company can confirm the following centres will participate in the global clinical programme:

USA

- The University of Texas, MD Anderson Cancer Centre in Texas, USA – *joint lead US study centre*
- The Johns Hopkins University Hospital, University Medical School in Maryland, USA – *joint lead US study centre*
- The Moffitt Cancer Centre, Tampa, USA
- Northwestern Memorial Hospital, Chicago, USA
- Cedars-Sinai Hospital, Los Angeles, USA

United Kingdom

- Guy's and St Thomas' Hospital, London – *lead UK study centre*
- The Leicester Cancer Centre (The University of Leicester)
- The Royal Liverpool University Hospital
- Hammersmith Hospital, London
- Addenbrookes Hospital, Cambridge

Belgium

- The Institute Jules Bordet, Brussel, Belgium – *lead Belgian study centre*

Australia

- Monash Health, Melbourne – *lead Australian study centre*
- St Vincent's Hospital, Sydney
- Westmead Hospital Sydney
- Royal North Shore Hospital, Sydney
- Royal Adelaide Hospital

OncoSil Chief Executive Officer, Daniel Kenny commented:

"The Company has made steady progress during the most recent Quarter, particularly with our global study programme as necessary approvals continue to be received, and patient recruitment advances. Our trial site partners are world class, and we remain focused on achieving our CE Mark by working with BSI towards a positive outcome."

Key Points – Financial and Corporate

During the Quarter, the Company announced the appointment of Dr Martin Cross as an Independent Non-Executive – a highly regarded pharmaceutical executive with 30 years' experience in corporate and industry leadership roles directly influencing healthcare policy and government legislation in Australia.

The cash outflow from operations for the quarter was \$2.1m, resulting in a cash balance as at 31 March 2017 of \$9.4m.

Investor Conference Call

The Company will hold a conference call at **9.00am AEDT on 4th May 2017** 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: 228059

Australian Toll Free: 1800 908 299
Australia Local (if dialling from international location): +61 2 9007 8048

New Zealand Toll Free: 0800 452 795
Hong Kong Toll Free: 800 968 273
Singapore Toll Free: 800 101 2702
China Toll Free: 1080 0140 1776
United Kingdom Toll Free: 0800 051 1453
United States/Canada Toll Free: 1855 624 0077

– ENDS –

| Company | Media |
|---|--|
| Mr Daniel Kenny CEO & Managing Director E: daniel.kenny@oncosil.com.au T: +61 2 9223 3344 | Ben Walsh WE Buchan E: bwalsh@buchanwe.com.au M: +61 411 520 012 |

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")

31 March 2017

| Consolidated statement of cash flows | Current quarter \$A'000 | Year to date (9 months) \$A'000 |
|---|----------------------------|---------------------------------------|
| 1. Cash flows from operating activities | | |
| 1.1 Receipts from customers | - | - |
| 1.2 Payments for | | |
| (a) research and development | (798) | (1,769) |
| (b) product manufacturing and operating costs | - | - |
| (c) advertising and marketing | - | - |
| (d) leased assets | - | - |
| (e) staff costs | (1,024) | (3,355) |
| (f) administration and corporate costs | (340) | (1,301) |
| 1.3 Dividends received (see note 3) | 1 | 18 |
| 1.4 Interest received | 55 | 174 |
| 1.5 Interest and other costs of finance paid | - | |
| 1.6 Income taxes paid | - | |
| 1.7 Government grants and tax incentives | - | 2,297 |
| 1.8 Other (provide details if material) | - | 39 |
| 1.9 Net cash from / (used in) operating activities | (2,106) | (3,897) |

| | | |
|--|-----|-----|
| 2. Cash flows from investing activities | | |
| 2.1 Payments to acquire: | | |
| (a) property, plant and equipment | (4) | (9) |
| (b) businesses (see item 10) | | |
| (c) investments | | |

| Consolidated statement of cash flows | Current quarter \$A'000 | Year to date (9 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 | (4) | (9) |

| | | |
|---|----------|----------|
| 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 | 11,553 | 13,356 |
| 4.2 Net cash from / (used in) operating activities (item 1.9 above) | (2,106) | (3,897) |
| 4.3 Net cash from / (used in) investing activities (item 2.6 above) | (4) | (9) |
| 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 (9 months) \$A'000 |
|--------------------------------------|--|----------------------------|---------------------------------------|
| 4.5 | Effect of movement in exchange rates on cash held | (4) | (7) |
| 4.6 | Cash and cash equivalents at end of quarter | 9,443 | 9,443 |

| 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 | 9,318 | 10,737 |
| 5.2 | Call deposits | 125 | 816 |
| 5.3 | Bank overdrafts | 0 | 0 |
| 5.4 | Other (provide details) | 0 | 0 |
| 5.5 | Cash and cash equivalents at end of quarter (should equal item 4.6 above) | 9,443 | 11,553 |

| 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 | 52 |
| 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 <i>Add notes as necessary for an understanding of the position</i> | 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 | 850 |
| 9.2 Product manufacturing and operating costs | - |
| 9.3 Advertising and marketing | - |
| 9.4 Leased assets | - |
| 9.5 Staff costs | 1,050 |
| 9.6 Administration and corporate costs | 400 |
| 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:



(Director/Company secretary)

Date: 27th April 2017

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.