**ASX Announcement**

**30 July 2020**

# Quarterly Activities & Cash Flow Report
# Quarter ended 30 June 2020

**Sydney, Australia – 30 July 2020:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 30 June 2020 (the Quarter). OncoSil is a medical device company that is currently focused on commercialising its platform technology for the treatment of patients with locally advanced pancreatic cancer (LAPC) and bile duct cancer.

**Key Highlights**

- **Europe (LAPC):** Achieved CE Mark in April 2020 and progressed critical launch preparation activities including the appointment of Mr Nigel Lange (ex Sirtex CCO) as EMEA president
- **ASEAN / APAC (LAPC):** Received regulatory approvals in Singapore and New Zealand; awaiting outcomes of registrations filed in Australia, Malaysia and Hong Kong
- **US (bile duct cancer):** Filed the Humanitarian Device Exemption (HDE) application with the FDA in July 2020 for the treatment of bile duct cancer; part of OncoSil's dual entry pathway into the US market
- **Cash position:** Cash balance of A$21 million as at 30 June 2020, following a successful A$19m capital raising in May 2020

*All financial results are in Australian dollars and are unaudited.*

**OncoSil Medical CEO, Mr Daniel Kenny commented:**

*"Following CE Marking in April, OncoSil continues to make significant progress on all commercialisation fronts. In Europe, OncoSil continues to make strong headway in all necessary launch activities. In Asia, we have moved quickly to leverage the CE Mark and pleasingly, we received regulatory clearance in New Zealand and Singapore and are awaiting approvals in Australia, Malaysia and Hong Kong.*

*Following the quarter, we also submitted the HDE application for the treatment of bile duct cancer in US. If successful, it will be a significant first step in our US market entry strategy as it will likely supplement our LAPC US pathway and further support the scalability of our platform technology."*

**Impact of COVID-19**

As flagged previously, the COVID-19 pandemic has caused a delay in the Company's initial European launch plans primarily due to limited hospital and site access. Despite these disruptions, OncoSil continues to adjust to the varying restrictions and progress the necessary launch activities where permitted. Outside

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of Europe, commercialisation activities were not materially impacted as OncoSil completed registration filings for Australia and the HDE in US.

**CE Mark and European progress**

On 1 April 2020, the Company announced it had received CE Mark for the treatment of LAPC in combination with chemotherapy. Following this approval, OncoSil has progressed the necessary launch preparation activities while continually adjusting to restrictions arising from the COVID-19 pandemic.

In addition to the above, as announced on 4 May 2020, OncoSil appointed Mr Nigel Lange as its EMEA President. Nigel is responsible for driving the Company's development and commercialisation goals in the European market and further building the Company's commercial infrastructure on the ground. Prior to joining OncoSil, Nigel was Chief Commercial Officer of ASX-listed medical device company, Sirtex Medical (ASX: SRX) and also served as Chief Executive Officer of Sirtex's European business from 2003 to 2016, where he was responsible for establishing the Sirtex brachytherapy device SIR-Spheres in over 300 centres across Europe and the Middle East.

**ASEAN / APAC regulatory approvals**

During the Quarter, the Company received regulatory clearance in New Zealand and Singapore, thus allowing the OncoSil™ device to be marketed and sold in these countries. Following these approvals, OncoSil is undertaking all the necessary launch preparation activities. In addition, OncoSil is currently awaiting outcomes on registrations filed in Australia, Malaysia and Hong Kong.

**HDE submission for bile duct cancer treatment in US**

Following the Quarter, on 28 July 2020, OncoSil announced that it had submitted a Humanitarian Device Exemption (HDE) application to the US Food and Drug Administration (FDA) for its OncoSil™ device in the treatment of cholangiocarcinoma (bile duct cancer)**.**

The submission represents an important milestone in the Company's commercialisation strategy to explore various US regulatory pathways and leverage its platform technology into other cancer indications. If successful, the Humanitarian Device Exemption (HDE) will formally allow OncoSil to market and sell its device in the US for the treatment of bile duct cancer

**Financials**

As at 30 June 2020, OncoSil had a cash balance of A$21 million supported by its A$19m capital raising which was announced in 04 May 2020 involving a A$14m institutional placement and A$5m fully underwritten entitlement offer. The funds from the capital raising enables OncoSil to accelerate commercialisation activities across Europe, UK, ASEAN and APAC for LAPC and in US for bile duct cancer.

During the Quarter, the Company's net cash flows used in operations was A$1.8 million, which includes R&D investments (A$0.6 million), staff costs (A$1.0 million) and administration and corporate costs (A$0.3 million).

## Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

| Company | Investor enquiries |
|---|---|
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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 six clinical studies with positive results on tolerability, safety and efficacy. CE Marking has been granted for the OncoSil™ device which can be marketed in the European Union and the United Kingdom. The OncoSil™ device has also been classified a Breakthrough Device in the European Union and the United Kingdom.

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.

In December 2018, the FDA granted Humanitarian Use Designation (HUD) for the OncoSil™ device for the treatment of unresectable intrahepatic and distal cholangiocarcinoma. In March 2020, the FDA granted Breakthrough Device Designation for the OncoSil™ for unresectable pancreatic cancer in conjunction with systemic chemotherapy. On 28 July 2020 the Company filed for HDE approval in distal cholangiocarcinoma with the US FDA.

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 $3b.

**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.

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# Appendix 4C

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

| *Name of entity* | |
|---|---|
| **ONCOSIL MEDICAL LIMITED** | |
| ***ABN*** | ***Quarter ended ("current quarter")*** |
| 89 113 824 141 | 30 June 2020 |

| | ***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 | (590) | (3,673) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | - | - |
| | (d) leased assets | - | - |
| | (e) staff costs | (969) | (3,170) |
| | (f) administration and corporate costs | (343) | (1,846) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 28 | 102 |
| 1.5 | Interest and other costs of finance paid | - | - |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 89 | 3,871 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,785)** | **(4,716)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |

| *Consolidated statement of cash flows* | | Current quarter $A'000 | Year to date (12 months) $A'000 |
|---|---|---|---|
| | (c) property, plant and equipment | - | - |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | - | - |
| 2.2 | Proceeds from disposal of: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | - | - |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) 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 equity securities (excluding convertible debt securities) | 19,040 | 19,100 |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of options | - | - |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | (1,070) | (1,070) |
| 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** | **17,970** | **18,030** |

| | *Consolidated statement of cash flows* | Current quarter $A'000 | Year to date (12 months) $A'000 |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 4,823 | 7,694 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,785) | (4,716) |
| 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) | 17,970 | 18,030 |
| 4.5 | Effect of movement in exchange rates on cash held | (8) | (8) |
| **4.6** | **Cash and cash equivalents at end of period** | **21,000** | **21,000** |

| **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 | 21,000 | 4,823 |
| 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)** | **21,000** | **4,823** |

| **6.** | ***Payments to related parties of the entity and their associates*** | Current quarter $A'000 |
|---|---|---|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 80 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | |

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

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| 7. | ***Financing facilities***<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **Total facility amount at quarter end $A'000** | **Amount drawn at quarter end $A'000** |
|---|---|---|---|
| 7.1 | Loan facilities | | |
| 7.2 | Credit standby arrangements | | |
| 7.3 | Other (please specify) | | |
| 7.4 | **Total financing facilities** | | |

| | | |
|---|---|---|
| 7.5 | **Unused financing facilities available at quarter end** | |

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

| |
|---|
| |

| **8.** | ***Estimated cash available for future operating activities*** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (Item 1.9) | 1,785 |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6) | 21,000 |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5) | - |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 21,000 |
| 8.5 | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | 11.76 |

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

## *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.

30/07/2020

Date: .....

By the Board

Authorised by: .....

(Name of body or officer authorising release – see note 4)

***Notes***

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow 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 cash flow 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.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

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