

## ASX Announcement

30 April 2020

### Quarterly Activities & Cash Flow Report Quarter ended 31 March 2020

**Sydney, Australia – 30 April 2020:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 31 March 2020 (the Quarter). OncoSil is a medical device company focused on localised treatments for patients with pancreatic cancer.

#### Key Highlights

- Milestone CE Marking approval and Breakthrough Device designation granted, allowing for OncoSil™ device to be marketed and sold within the European Union and the United Kingdom
- Separate Breakthrough Device designation received from the FDA, which will help expedite development and approval of the device in the US
- Cash balance of A\$4.8 million as at 31 March 2020
- At time of release, Company is in a trading halt for a capital raising that will materially increase its cash balance

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

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

*“The start of 2020 has been a truly significant period for us, marked by several key milestones. Firstly, the achievement of CE Marking, the first regulatory approval of its type for the OncoSil™ device, means OncoSil can now market and sell this product in Europe. In addition, OncoSil has also been granted Breakthrough Device designation in both the EU and US, which provides further validation for the technology and provides a fast track development and approval pathway to the US market.”*

#### CE Mark Approval and Breakthrough Device designation granted by the BSI

During the quarter, OncoSil announced that it had received CE Marking approval for the treatment of locally advanced pancreatic cancer (LAPC) in combination with chemotherapy, from the British Standards Institute (BSI).

This approval marks a significant milestone, as it allows for the OncoSil™ device to be marketed and sold within the European Union and the United Kingdom. This key milestone also paves the way for further regulatory approvals in other key markets whereby the CE Mark authority is recognised.

In addition to CE Marking approval, the OncoSil™ device has been officially classified as a Breakthrough Device, which is defined as one that delivers clinical benefit to patients for unmet medical needs which

are life threatening, and for which current medical alternatives are insufficient or carry significant risks. This designation is a strong endorsement of the OncoSil™ device and further validates the device's efficacy and safety.

Given the recent CE Marking approvals, the Company will turn its focus to registration filings in jurisdictions which recognise CE Marking certification. This activity is not expected to be impacted by the recent COVID-19 situation.

### **Breakthrough Device designation granted by the FDA**

On 18 March 2020, OncoSil announced that it had been granted Breakthrough Device designation by the US Food and Drug Administration (FDA) for the treatment of unresectable locally advanced pancreatic cancer in combination with systemic chemotherapy.

The designation is an important achievement for the Company as it has the potential to expedite the FDA review and approval process, ultimately leading to a faster route to the US market with lower R&D costs. The Company is currently working with the FDA as regards guidance on clinical trial design, in order to generate data in line with the post market setting requirements for pre-market approval (PMA) approval.

As with the EU designation, the FDA breakthrough designation provides further validation of the OncoSil™ device, particularly as regards the advantages and efficacy of the device and also recognising the absence of alternative therapeutic devices.

The OncoSil™ device is now officially designated as a Breakthrough Device in the EU, the UK and the US.

### **Appointment of new Chief Financial Officer / Company Secretary**

On 31 March 2020, OncoSil announced the appointment of Mr Karl Pechmann as Chief Financial Officer and Company Secretary. Prior to joining OncoSil, Karl was Chief Financial Officer and Company Secretary of an ASX-listed regulatory technology company, Kyckr Limited (ASX: KYK). Prior to that, he held a number of senior roles including Finance Director of ASX listed biotech company, Immutep Limited (ASX: IMM).

Karl's relevant financial expertise in biotechnology companies and scale up businesses makes him the ideal person to lead the finance and company secretarial functions as OncoSil transitions towards the commercialisation phase.

### **Financials**

During the quarter, the Company's net cash flows used in operations was A\$2.0 million, resulting in a cash balance of A\$4.8 million as at 31 March 2020. The cash used in operations includes R&D investments (A\$0.8 million), staff costs (A\$0.6 million), administration and corporate costs (A\$0.5 million) and Item 6.1 of Appendix 4C relates to director fees and salaries paid in the quarter.

## Impact of COVID-19

The current COVID-19 pandemic has not impacted OncoSil's regulatory activities and pathways. Given the recent achievement of the CE Marking approval, the Company will focus on registration filings in jurisdictions which recognise CE Marking certification. Given the recent FDA Breakthrough Device designation, the Company is currently working closely with the FDA to optimise the Pre Market Approval (PMA) clinical trial design.

The pandemic is expected to impact the Company's original launch plan for its OncoSil™ device in Europe. However, this has not prevented OncoSil from doing the background work and training necessary to prepare for a launch later this year, subject to limitations from the COVID-19 pandemic.

## 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.

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.

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.

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

**Name of entity**

**ONCOSIL MEDICAL LIMITED**

**ABN**

89 113 824 141

**Quarter ended ("current quarter")**

31 March 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(838)	(3,083)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(620)	(2,201)
(f) administration and corporate costs	(538)	(1,503)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	20	74
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,782
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,976)</b>	<b>(2,931)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	60
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	-	-
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>-</b>	<b>60</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</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 period	6,798	7,694
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,976)	(2,931)
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)	-	60
4.5	Effect of movement in exchange rates on cash held	1	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>4,823</b>	<b>4,823</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> <i>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts</i>	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	4,823	6,798
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>4,823</b>	<b>6,798</b>

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

80

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

**7. Financing facilities**

*Note: the term "facility" includes all forms of financing arrangements available to the entity.*

*Add notes as necessary for an understanding of the sources of finance available to the entity.*

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000

**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.

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	1,976
8.2 Cash and cash equivalents at quarter end (Item 4.6)	4,823
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	4,823
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	2.44

- 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 April 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.