

ASX Announcement

21 October 2020

Quarterly Activities & Cash Flow Report Quarter ended 30 September 2020

Sydney, Australia – 21 October 2020: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), has released its Appendix 4C – Quarterly Cashflow report for the quarter ended 30 September 2020 (the Quarter). OncoSil is a medical device company that is currently commercialising its platform technology for the treatment of patients with locally advanced pancreatic cancer (LAPC) and bile duct cancer.

Key Highlights

- **Europe (LAPC):** Progressing critical launch preparation activities – OncoSil remains on track for first sales in 2020
- **ASEAN / APAC (LAPC):** Targeting first sales in the region in 2020 - approved in New Zealand, Singapore and Malaysia; awaiting outcomes of registrations filed in Australia and Hong Kong
- **US (bile duct cancer):** Humanitarian Device Exemption (HDE) application filed with the FDA in July 2020 for the treatment of bile duct cancer; building on OncoSil's dual pronged US market strategy
- **PanCO update:** Compelling results highlighting OncoSil's significant downstaging of tumours, with 60% of patients that underwent surgery alive today, with a survival range of 26-35 months post-treatment
- **Cash position:** Cash balance of A\$20.5 million as at 30 September 2020, following the receipt of a R&D Tax Incentive Refund of A\$2.8 million

All financial results are in Australian dollars and are unaudited.

OncoSil Medical CEO, Mr Daniel Kenny commented:

"OncoSil continues to progress its commercialisation activities this quarter. In Europe, OncoSil made strong headway across all necessary launch activities and continues to target first sales by the end of the year. We are currently focused around activating sales in top tier hospitals and developing a repeatable sales model that can be scaled across Europe and beyond. In Asia, we continue to gain significant traction on regulatory clearance with regulatory approvals now being granted in Singapore, Malaysia and New Zealand. In addition to the above, 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 facilitate our LAPC US pathway and further support the scalability of our platform technology."

European and UK update

The Company continues to target first sales in Europe this year as it progresses its critical preparation activities while adjusting to restrictions arising from the COVID-19 pandemic.

As part of these activities, the Company is in advanced discussions with several hospital groups across UK and Europe and remains focused on recruiting and activating large key hospital accounts that will help drive a scalable and repeatable sales model. In addition, the Company continues to progress its customer onboarding efforts across numerous hospitals as it prepares for the first commercial launch later this year.

ASEAN / APAC update

During the Quarter, OncoSil received regulatory clearance from the Medical Device Authority of Malaysia for its OncoSil™ device. The successful registration means OncoSil is now able to market and sell the OncoSil™ device in Malaysia for the treatment of locally advanced pancreatic cancer. Following this approval, the Company has now achieved regulatory clearance in Europe, UK, New Zealand, Singapore and Malaysia. Further to the progress in Europe, OncoSil has made strong headway in Asia with critical activities including onboarding hospitals. OncoSil continues to target first sales in the region this year. In addition, the Company is awaiting the outcomes of its regulatory filings in Australia and Hong Kong.

HDE submission for bile duct cancer treatment in US

On 28 July 2020, OncoSil announced that it had filed 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).

This submission represents a significant milestone in the Company's commercialisation strategy to explore various US regulatory pathways and leverage the OncoSil™ platform technology into other cancer indications. The HDE application follows OncoSil's dual pronged US market strategy, whereby the company was awarded FDA breakthrough device designation with respect to pancreatic cancer treatment in March this year. 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.

PanCO trial update – resected cohort analysis

Subsequent to the Quarter on 20 October 2020, the Company provided an update regarding the PanCO trial, which involved 42 patients with unresectable, locally advanced pancreatic cancer who were all initially deemed to be inoperable or medically unfit for surgery. After being treated with the OncoSil™ device, 10 out of the 42 patients (23.8%) had their tumours sufficiently reduced to enable them to undergo surgical resection with curative intent and a better prognosis. In July 2020, OncoSil conducted an updated analysis on the resected cohort which produced some positive results:

- Median follow-up of 31.1 months for the 10 patients
- 4 deaths have been reported to date (at 18.8, 20.9, 21.0 and 22.1 months)
- 6 patients remain alive with a survival range of 26.4-35.3 months post-treatment

These results demonstrate a remarkable positive outcome and compare very favourably to the typical survival periods for such patients. According to published literature¹, the median survival for unresectable, locally advanced pancreatic cancer patients is only ~8.5 months. Furthermore, with 6 of the 10 resected patients still alive, OncoSil is not able to calculate an exact median overall survival rate at this point in

time. This is a positive outcome and it highlights the significance of the device’s capability to prolong survival outcomes through shrinking the tumours allowing removal of the tumour on patients that were previously deemed inoperable.

Financials

As at 30 September 2020, OncoSil had a cash balance of A\$20.5 million. During the Quarter, the Company’s net cash flows used in operations was A\$0.5 million, which includes R&D investments (A\$1.0 million), marketing costs (A\$0.3 million), staff costs (A\$1.3 million), administration and corporate costs (A\$0.9 million) and the receipt of a R&D Tax Incentive Refund of A\$2.8 million. Item 6.1 of the Appendix 4C relates to director fees and salaries paid in the quarter.

¹ Loehrer PJ et al. J Clin Oncol 2011 Nov 1;29 (31) 4105-12

Authorisation & Additional Information

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

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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 bile duct cancer. 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 \$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.

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")

30 September 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(969)	(969)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(345)	(345)
(d) leased assets	-	-
(e) staff costs	(1,269)	(1,269)
(f) administration and corporate costs	(860)	(860)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	38	38
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,870	2,870
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(535)	(535)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(8)	(8)
(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	(8)	(8)

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
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 period	21,000	21,000
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(535)	(535)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(8)	(8)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	20,457	20,457

5.	Reconciliation of cash and cash equivalents <i>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts</i>	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	20,457	21,000
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)	20,457	21,000

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

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- 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.

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8. Estimated cash available for future operating activities

	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	535
8.2 Cash and cash equivalents at quarter end (Item 4.6)	20,457
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	20,457
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	38.23

- 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.

21/10/2020

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.