



ASX Announcement
30 April 2020

APPENDIX 4C

QUARTERLY ACTIVITIES & CASHFLOW REPORT

QUARTER ENDED 31 MARCH 2020

Melbourne, Australia, 30 April 2020: Australian medical technology company, OptiScan Imaging Limited (ASX:OIL) ('OptiScan' or 'the Company'), is pleased to release its Appendix 4C – Quarterly Cashflow Report and business update for the quarter ended 31 March 2020 (Quarter). All financial results are in Australian dollars and are unaudited.

Highlights for the Quarter

- **Met with the United States Food and Drug Administration seeking feedback for a 510(k) submission in Oral Cancer Surgery and/or Oral Cancer Screening.**
- **Progress in Oral Cancer Trials and Studies being led by Memorial Sloan Kettering Cancer Centre, Melbourne Dental School and Australian Centre for Oral Oncology Research and Education.**
- **Leading medical journal, Nature Biomedical Engineering, published study confirming potential of OptiScan technology.**
- **Revenue from Carl Zeiss Meditec of approximately \$500k.**
- **Delivery of a FIVE2 (ViewnVivo) system to a university in Shanghai –OptiScan's first China sale with new distribution arrangements.**
- **Receipt of \$211k from financing of Research and Development Tax Credit.**

Oral Cancer Surgery and Screening Application - InVivage®

FDA 510(k) Submission

In January 2020, OptiScan met with the Center for Devices and Radiological Health of the U.S. Food and Drug Administration (FDA) in Washington D.C., and obtained feedback on the proposed content and format to support a 510(k) submission in Oral Cancer Surgery and/or Oral Cancer Screening in humans.

A 510(k) submission is a pre-market submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective – that is, substantially equivalent – to a legally marketed device. Following the meeting, and during the Quarter, OptiScan prepared supplementary information for the FDA in relation to the proposed content to further support a 510(k) submission.

OptiScan commenced building a number of InVivage® systems – its clinical device for use in Oral Cancer and other applications – to support validation and verification activities, including electrical and laser safety testing, required prior to the formal 510(k) submission.

These tests are similar to those previously performed and met by the FDA approved CONVIVO® system, developed in collaboration with Carl Zeiss Meditec, albeit OptiScan's InVivage® system focuses on Oral Cancer rather than Brain Cancer in humans.

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Oral Cancer Trials and Studies

The Oral Cancer Trials and Studies at Memorial Sloan Kettering Cancer Centre (MSKCC), one of the leading cancer centres in the United States, and at the Australian Centre for Oral Oncology Research and Education (ACOORE), continued during the period, with positive feedback received from investigators of both trials and studies.

The Ethics Committee application for the Oral Cancer Screening Trial at the Melbourne Dental School (with collaborators the Royal Melbourne Hospital, Peter MacCallum Cancer Centre, MSKCC, and ACOORE) also progressed during the Quarter.

Publication in leading medical journal, Nature Biomedical Engineering

The use of OptiScan technology in pre-clinical and clinical trials at MSKCC was included in a paper titled: “Validation of the use of a fluorescent PARP1 inhibitor for the detection of oral, oropharyngeal and oesophageal epithelial cancers”, which was published in the March 2020 issue of leading medical journal, Nature Biomedical Engineering.

In the paper, the authors stated that they “validated an in vivo imaging device, the ViewnVivo (OptiScan), a miniaturized handheld confocal endomicroscope”, and that: “The ViewnVivo has the potential to be used for intraoperative, PARPi-FL-based in vivo imaging without tissue excision”.

The authors also noted the importance of early diagnosis and the opportunities for OptiScan’s InVivage® system in both screening and surgically – “Novel methods for early detection, surveillance, and surgical guidance are also urgently needed in oral and oropharyngeal cancer. The incidence of both malignancies is increasing, whereas survival has shown only modest improvement over the last three decades. Although the oral cavity is easily accessible for regular inspection, about two-thirds of all patients in the US present with advanced-stage disease”; and “the global situation is now more dire than ever, with respect to both incidence and number of associated deaths (300,000 and 145,000, respectively)”.

Neurosurgery – CONVIVO® – Carl Zeiss Meditec Collaboration

A number of systems were delivered to Carl Zeiss Meditech (CZM) during the Quarter, with revenue of approximately \$500k.

Discussions also took place during the Quarter in relation to future orders for products, research and development services, and the final milestone payment pursuant to the cooperation agreement. These discussions were ongoing at the end of the Quarter.

Breast Cancer Surgical Margin Assessment Trial

OptiScan commenced preparing the report of Stages 1 and 2 of its four-stage breast cancer surgical margin assessment trial, and, as part of preparing for Stage 3 of the trial, participated in a Medical Device Partnering Program Workshop during the Quarter.

The Medical Device Partnering Program fosters collaborations between researchers, industry, end-users and government to develop medical technologies with global market potential.

The Workshop was attended by six breast surgeons and a pathologist from five leading Melbourne hospitals. There was strong interest to arrange Stage 3 of the trial in Melbourne, which would involve imaging (in the operating theatre) breast tumour and other tissue once it has been removed from the patient before it is sent to pathology. The results of the imaging with OptiScan technology would then be compared with the traditional pathology images.

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FIVE2 (ViewnVivo) Distribution

During the Quarter, OptiScan and its distributors engaged with prospective customers in Australia, China, Europe and the United States. Quotations were provided for potential customers in Australia, China and Europe with on-going discussions with potential customers in the United States where quotations were provided prior to the commencement of the Quarter.

In China, OptiScan delivered a FIVE2 (ViewnVivo) system to a Shanghai-based university – its first sale in China with its new distribution arrangements. The Company's distributors in Eastern China (Biotimes Technology Ltd) and Southern and Western China (Gunagzhou Yunxing Scientific Equipment) pursued multiple sales opportunities during the Quarter, although the conduct of on-site demonstrations and visits was prevented by COVID-19.

A planned visit by OptiScan representatives to China to support distributors with demonstrations and visits was also unable to proceed due to COVID-19. To address this, OptiScan has enhanced its online support for distributors, and as described in the Business Outlook section, following the end of the Quarter successfully delivered a webinar with approximately 40 participants for its Chinese distributors and prospective customers.

Visits and demonstrations also ceased during the Quarter in North America and Australia due to COVID-19; in North America, there are a number of sales prospects with institutions seeking funding to purchase the FIVE2 (ViewnVivo) system.

COVID-19

In response to COVID-19, OptiScan implemented new working arrangements during the Quarter, including staff working remotely, and limitations on staff at the company's premises at any one time.

Many activities, particularly in relation to preparations for the FDA 510(k) submission, were able to continue uninterrupted during the Quarter.

The layout of the office premises is well-suited to the continuation of production during COVID-19, as production staff can be isolated and/or can meet social distancing requirements.

Corporate Update and Outlook

Cash receipts during the Quarter included payments from CZM, Biotimes, rental payments for FIVE2 (ViewnVivo) systems, and reimbursement of jointly owned patent costs.

During the Quarter, the Company received funds of \$211k pursuant to the financing of its anticipated Research and Development Tax Credit for the first half of the financial year ending 30 June 2020, arranged by Radium Capital. Interest of 15% per annum is payable on the funds advanced, and OptiScan has provided collateral over its Research and Development Tax Credit and any claims and books and records in respect of it.

The Company received funds of \$592k in April, including \$476k from CZM and \$83k from Federal and State Government COVID-19 programs. A further approximately \$165k was expected to be paid by CZM in April, but is now likely to be received in early May 2020.

Total cash receipts for the 60-day period from the end of February is \$872k (not including the aforementioned \$165k from CZM). As at 30 April 2020, the Company has a Cash Balance of \$768k.

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OptiScan has also been advised that its application to finance its 3rd quarter Research and Development Tax Credit has been approved, which will provide a further \$149k. This is expected in early May 2020.

All related party payments noted in Section 6 of the accompanying Appendix 4C during the quarter relate to settlement of directors' fees and salaries.

Business Outlook

While some of OptiScan's activities have been affected due to travel and other restrictions in light of COVID-19, preparations continue to progress for its FDA 510(k) submission, as well as fielding direct interest and via our distributors for FIVE2 (ViewnVivo) sales.

If the impact of COVID-19 continues for an extended period, some future activities may be impacted, such as the conduct of testing by US laboratories, US-based trials for InVivage®, US and European trials for CONVIVO® and demonstrations of FIVE2 (ViewnVivo). These challenges would not be unique to OptiScan, and it's anticipated that alternative arrangements and/or innovative solutions may be able to be coordinated, such as the webinar conducted for Chinese based distributors and prospective customers in late April. This webinar was primarily focused on the use of OptiScan technology for both clinical and pre-clinical in vivo studies in Oral Cancer.

During April, the Company participated in a Medical Device Partnering Program Workshop focused on Oral cancer surgery with 5 leading Oral Cancer Clinicians, Surgeons and Pathologists. The Company has also lodged a grant application with a Federal Government funding program which would support the trial at the Melbourne Dental School.

Finally, work has begun developing machine learning algorithms for image analysis for use as part of the breast cancer trial.

For and on behalf of the Board:

Darren Lurie

Executive Chairman – OptiScan Imaging

E: dlurie@OptiScan.com

About OptiScan

OptiScan is a global leader in the development of microscopic imaging and related technologies for surgery and medical research. Based in Victoria, Australia, OptiScan was established in 1994, and listed on the ASX in 1997 (ASX:OIL). OptiScan has developed and patented endomicroscopic technology which enables real-time, 3D, 'in vivo' imaging of human tissue at the cellular level – instant "virtual biopsies" for cancer screening, diagnoses and in surgery.

Disclaimer

All statements other than statements of historical fact included on this announcement including, without limitation, statements regarding future plans and objectives of OptiScan or any of the other parties referred to herein, are forward-looking statements. Forward-looking statements can be identified by words such as 'anticipate', 'believe', 'could', 'estimate', 'expect', 'future', 'intend', 'may', 'opportunity', 'plan', 'potential', 'project', 'seek', 'will' and other similar words that involve risks and uncertainties. These statements are based on an assessment of present economic and operating conditions, and on assumptions regarding future events and actions that are expected to take place. Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of the Company, its directors and management of OptiScan that could cause actual results to differ from the results expressed or anticipated in these statements.

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Appendix 4C

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

Name of entity

OPTISCAN IMAGING LTD

ABN

81 077 771 987

Quarter ended ("current quarter")

31 MARCH 2020

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	342	574
1.2 Payments for		
(a) research and development	(356)	(998)
(b) product manufacturing and operating costs	(102)	(448)
(c) advertising and marketing	(29)	(80)
(d) leased assets	-	-
(e) staff costs	(86)	(399)
(f) administration and corporate costs	(58)	(178)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	4
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	227
1.8 Other (GST)	-	-
1.9 Net cash from / (used in) operating activities	(288)	(1,298)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(20)	(20)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
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	(20)	(20)

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	-	(4)
3.5	Proceeds from borrowings	211	211
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Payment of lease liabilities	(44)	(140)
3.9	Other (interest costs for office lease liabilities)	(11)	(38)
3.10	Net cash from / (used in) financing activities	156	29

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	614	1,752
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(288)	(1,298)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(20)	(20)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	156	29
4.5	Effect of movement in exchange rates on cash held	-	(1)
4.6	Cash and cash equivalents at end of period	462	462

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	462	614
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)	462	614

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
114
-

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

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

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.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	211	211
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 Total financing facilities	211	211

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.

The Company has received approval for the financing of its anticipated Research and Development tax credit for H1FY20 by Radium Capital for \$211k. Interest of 15% per annum is payable on the funds advanced and the Company has provided collateral over its Research and Development tax credit ("R&D Credit") and any claims and books and records in respect of the R&D Credit.

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	288
8.2 Cash and cash equivalents at quarter end (Item 4.6)	462
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	462
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	1.60

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

- 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: The entity expects its net operating cash position will improve. Cash collected from customers was approximately \$507,000 in April with a further \$82,653 received from Federal and State Government funding. A further \$165,000 has been invoiced and is expected to be collected from Carl Zeiss Meditec shortly. The Company has a number of sales prospects for its Five2 (ViewnVivo) product which may be successful during the next 2 quarters and is also in discussions with Carl Zeiss Meditec regarding the sale of further systems and the provision of further services.

- 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: The entity has received approval for additional funding of \$149k secured against its entitlement to the Research and Development tax credit for expenditure incurred in the 3rd quarter of the 2020 financial year.

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: The entity expects to be able to continue its operations and meet its business objectives on the basis of cash collections, prospective sales opportunities and additional funding noted in (1) and (2) above.

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:

The Board of Directors

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.