



**ASX Announcement**  
**29 January 2021**

## **APPENDIX 4C**

### **QUARTERLY ACTIVITIES & CASHFLOW REPORT**

#### **QUARTER ENDED 31 DECEMBER 2020**

**Melbourne, Australia, 29 JANUARY 2021:** Australian medical technology company Optiscan Imaging Limited (ASX:OIL) (**Optiscan** or the Company), a leader in medical technology using confocal laser endomicroscopy, is pleased to release its Appendix 4C – Quarterly Cashflow report and business update for the quarter ended 31 December 2020 (**Quarter**). All financial results are in Australian dollars and are unaudited.

#### **Highlights for the Quarter**

- **Obtained written feedback from the United States Food and Drug Administration (FDA) and held a subsequent follow-up call with the FDA indicating Optiscan's 510(k) pathway remains on track for the use of its InVivage™ device in Oral Cancer Screening and/or Surgery.**
- **Completed Tranche 2 of the Capital raising announced during the September 2020 quarter with receipt of \$7.4m in October 2020. Shareholder ratification of the placement and approval of the granting of options pursuant to the placement took place at the Company's General Meeting in November 2020.**
- **Commenced third party independent testing for the InVivage™ device required for FDA 510(k) clearance.**
- **Received the first payment pursuant to the BioMedTech Horizons Program grant to support the University of Melbourne's Melbourne Dental School trial, including funds of \$180k retained by Optiscan.**
- **Entered into a distribution agreement with J&H Technology Co Ltd for the distribution of the FIVE2 (ViewnVivo) pre-clinical device in Taiwan.**
- **Registration of the CONVIVO® and the Sterile Sheath (which acts as a sterile barrier between the probe of the CONVIVO® and the tissue in the brain) on the Australian Register of Therapeutic Goods enabling those devices to be lawfully supplied for use in Neurosurgery in Australia.**
- **Receipt of ethical approval from the Melbourne Health Human Research Ethics Committee for the Breast Cancer Surgical Margin Assessment Trial to take place at Royal Melbourne Hospital, Frances Perry House and the Epworth Hospital.**
- **Cash Flows from Operating Activities of (\$409k) for the Quarter and (\$176k) for the 6 months to 31 December 2020.**

#### **Developments Post End of Quarter**

- **Receipt of orders from Carl Zeiss Meditec AG (CZM) for approx. \$350k.**
- **Award of Federal Government Entrepreneurs' Programme - Growth Grant with matched funding of \$20k to support the engagement of expert advisers for the development of a United States market entry strategy for InVivage™.**

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## **FDA feedback regarding 510(k) Pathway for InVivage™ device**

During the quarter, Optiscan received written feedback from the Center for Devices and Radiological Health (CDRH) of the FDA in response to specific questions raised by the Company following its meeting with the FDA in January 2020 and subsequent written submissions made in late June 2020.

Following this feedback, Optiscan continued to prepare its submission for 510(k) clearance to market the InVivage™ device for legal sale in the United States in Oral Cancer Screening and/or Surgery. This includes third party validation and verification testing required to be completed for the 510(k) submission commenced during the quarter.

## **Capital Raising**

In September 2020, the Company announced a capital raising of \$9.8m via a placement to sophisticated and professional investors at an issue price of \$0.0825 (8.25 cents) per share (Placement). For every four Placement Shares, one free attaching option was issued, exercisable at \$0.15 (15 cents) per option and with an expiry date of 30 months from the date of issue (Placement Option). Funds from some of these investors were received in September 2020 with the balance of funds (\$7.4m) received in October 2020.

The issue of the Placement Options was approved at the Company's General Meeting in November 2020.

## **Oral Cancer Surgery and Screening Application – InVivage™**

### **BioMedTech Horizons Program grant for 150 patient Oral Cancer Study at Melbourne Dental School**

In the September Quarter, Optiscan was awarded a BioMedTech Horizons Program grant for \$971k to assist the University of Melbourne's Melbourne Dental School to undertake a trial with approximately 150 patients over a 12-month period, to improve screening, diagnosis, and treatment of oral cancer.

During the Quarter, Optiscan received the first payment pursuant to the BioMedTech Horizons Program grant to support the University of Melbourne's Melbourne Dental School trial, including funds of \$180k retained by Optiscan.

In this Quarter, Optiscan and the Melbourne Dental School commenced the dosing study for the topical use of fluorescein indicated by the FDA as one of the requirements for Optiscan's intended 510(k) application.

In December, the Melbourne Dental School and Optiscan presented our collaborative oral cancer in vivo imaging clinical study to leading dental hospitals in Shanghai at The 2nd China Smart Health and Medical Conference 2020.

### **Oral Cancer Trials and Studies**

The Oral Cancer Trials and Studies at Memorial Sloan Kettering Cancer Center (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.

## **NeuroSurgery – CONVIVO® - Carl Zeiss Meditec Collaboration**

Discussions with Carl Zeiss Meditec AG (CZM) continued during the Quarter (and are on-going) in relation to future orders for products and research and development services.

Optiscan was informed by CZM that the CONVIVO® and the Sterile Sheath (which acts as a sterile barrier between the probe of the CONVIVO® and the tissue in the brain) have both been registered on the Australian

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Register of Therapeutic Goods enabling those devices to be lawfully supplied for use in Neurosurgery in Australia. These registrations are in addition to approvals previously received by CZM to market the CONVIVO® in the United States and Europe as CZM continues the full commercialization of the CONVIVO®, developed as part of the co-operation agreement between CZM and Optiscan.

### **Breast Cancer Surgical Margin Assessment Trial (Breast Trial)**

Preparation for a 20 patient breast cancer surgical margin assessment study at a number of leading Melbourne hospitals continued during the Quarter. Ethics approval from the Melbourne Health Human Research Ethics Committee for the study has been received and the Company is completing required site approvals, protocols and research agreements with Royal Melbourne Hospital, Frances Perry House and Epworth Hospital. Funding from the Medical Device Partnering Program (MDPP) is intended to be used for this study and these agreements are being finalised. The Company expects to finalise these arrangements and commence the trial in February 2021.

### **FIVE2(ViewnVivo) Distribution**

During the Quarter, the Company appointed J&H Technology as its exclusive distributor in Taiwan for the FIVE2(ViewnVivo) in the pre-clinical research market. This appointment follows the appointment of two (2) China distributors in Shanghai and Guangzhou in 2019 and a new distributor in North America in 2020. Taiwan represents an attractive market for the FIVE2(ViewnVivo), being consistently ranked as the top knowledge economy in Asia and with its biomedical sector identified as one of the five pillar industries for its national development.

The Company continued to develop its sales pipeline with multiple current prospects in China and North America developed during the Quarter.

### **COVID-19**

The Company maintained its COVID-19 working arrangements during the Quarter with Optiscan staff working both remotely and from the Company premises. The layout of the Company premises is well-suited to the continuation of production as production staff can be isolated from other staff.

### **Corporate Update and Outlook**

The Company received funds of \$2.4m pursuant to the Placement prior to the end of the September 2020 Quarter, with the balance of the proceeds of approximately \$7.4m (before capital raising costs) received following the end of the quarter.

Receipts from customers for the quarter of \$407k comprised the balance of payments for the 2 FIVE2(ViewnVivo) sales to China based customers and payments from Carl Zeiss Meditec. The Company received \$250k plus GST pursuant to the BioMedTech Horizons Program grant with \$180k plus GST to be retained by Optiscan. Additional funds from Federal and State Government COVID funding programs of \$89k were received.

Research and development costs during the quarter amounted to \$307k and the Company incurred \$145k in manufacturing and operating costs.

The Company recruited 2 additional production staff during the Quarter who have commenced in January 2021 and also engaged an additional person in Quality Management during the Quarter. The further recruitment of additional staff is currently underway.

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Optiscan has been awarded a Federal Government grant of \$20k to be matched by Optiscan to support the engagement of expert advisers for the development of a United States market entry strategy for InVivage™. Optiscan is currently engaged in discussions with a number of potential experts.

All related party payments noted in Section 6 of the accompanying Appendix 4C during the Quarter relate to payment of executive and non-executive director's fees and salaries, including payment of \$150k made to CEO and Executive Chairman, Darren Lurie upon the execution of an Executive Services Agreement with Mr Lurie.

- Ends -

This announcement has been authorised for release by the Board of OIL.

**For investor queries, please contact:**

Darren Lurie  
Executive Chairman – Optiscan Imaging  
E: [dlurie@OptiScan.com](mailto: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 LIMITED

**ABN**

81 077 771 987

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

31 DECEMBER 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	407	517
1.2 Payments for		
(a) research and development	(307)	(654)
(b) product manufacturing and operating costs	(145)	(270)
(c) advertising and marketing	(25)	(35)
(d) leased assets	-	-
(e) staff costs	(586)	(700)
(f) administration and corporate costs	(95)	(196)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	3	3
1.5 Interest and other costs of finance paid	-	(34)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	250	951
1.8 Other (COVID-19 grants)	89	242
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(409)</b>	<b>(176)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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)	-	-
<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)	7,383	9,814
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	(406)	(406)
3.5	Proceeds from borrowings	-	185
3.6	Repayment of borrowings	-	(545)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Payment of lease liabilities	(47)	(93)
3.9	Other	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>6,930</b>	<b>8,955</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	2,784	526
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(409)	(176)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,930	8,955
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>9,305</b>	<b>9,305</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	9,305	2,784
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>9,305</b>	<b>2,784</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	355
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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</i>		

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>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.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
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.		
N/A		

<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)	(409)
8.2 Cash and cash equivalents at quarter end (item 4.6)	9,305
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	9,305
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	22.75
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 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: N/A	
8.6.2 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: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	



## 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.

29 January 2021

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.