

ASX Announcement  
30 July 2021

## APPENDIX 4C QUARTERLY ACTIVITIES & CASHFLOW REPORTS QUARTER ENDED 30 JUNE 2021

**Melbourne, Australia, 30 July 2021:** 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 30 June 2021 (**Quarter**). All financial results are in Australian dollars and are unaudited.

### Highlights for the Quarter

- Continued imaging patients as part of the University of Melbourne's Melbourne Dental School (MDS) trial to improve screening, diagnosis and treatment of oral cancer, with 58 imaging sets completed by the end of the Quarter.
- Substantial progress in preparing for the application for FDA approval for the InVivage™ device's use in oral cancer screening and surgery in the United States:
  - Continued third party independent testing and conducted validation and verification activities with further testing requirements being met;
  - Successfully completed the required fluorescein dosing study.
- Completed imaging of 20 patients for stage three of the Breast Cancer Surgical Margin Assessment Trial.
- Orders from Carl Zeiss Meditec AG (CZM) for the CONVIVO device of approximately \$200k for use in neurosurgery.
- OptiScan's quality management system was independently audited and certified as in accordance with international standard ISO13485. Certification is for 3 years.
- Appointment of Mr Robert Cooke as Non-executive Chair and Professor Camile Farah as a Non-executive Director.
- Total Cash outflows and operating outflows for the quarter were (\$1.02m). Total Cash inflows for the financial year were \$7.92m and Cash outflows from Operating Activities were (\$2.1m) for the 12 months to 30 June 2021.

### Developments Post End of Quarter

- Due to success in patient recruitment, the Breast Trial has been expanded to 40 patients and OptiScan has imaged 27 patients.
- OptiScan recorded its first Australian sale of the FIVE2 (ViewnVivo) system to a leading Australian University as part of a Victorian Government medical technology initiative.
- The University of Adelaide Dental School received ethics approval for its "Proof of Concept Study: A diagnostic tool to detect Oral Squamous Cell Carcinoma" which will utilise OptiScan's FIVE2 (ViewnVivo) system. OptiScan is now working with Australia's two highest ranked dental schools (University of Melbourne ranked #14 in the world and University of Adelaide ranked #25 in the world).
- OptiScan continues to strengthen its distribution network for its FIVE2 (ViewnVivo) system, with the recent addition of South Korea to its existing distribution network which encompasses North America, Eastern and Southern China and Taiwan.
- OptiScan has appointed Ms Karen Borg as a non-executive Director with recent appointments to the Board comprising Directors with diverse experience across healthcare, marketing, strategy and finance.

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

### **Oral Cancer Trial at Melbourne Dental School**

In the September 2020 Quarter, OptiScan was awarded a BioMedTech Horizons Program grant for \$971,000 to assist the University of Melbourne's Melbourne Dental School (MDS) to undertake a trial with approximately 150 patients, to improve screening, diagnosis, and treatment of oral cancer.

By the end of the Quarter, the MDS had completed 59 imaging sets and had successfully completed the fluorescein dosing study required to support OptiScan's intended 510(k) application to market the InVivage™ in the United States.

Following the end of the Quarter, Dr Tami Yap from the MDS presented a webinar lecture to the European Association of Oral Medicine titled "In vivo microscopy of OPMDs (Oral Potentially Malignant Disorders) in clinical practice" describing the work being undertaken as part of this trial.

### **Other 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.

Following the end of the Quarter, the University of Adelaide Dental School received ethics approval for its "Proof of Concept Study: A diagnostic tool to detect Oral Squamous Cell Carcinoma" which will utilise OptiScan's FIVE2 (ViewnVivo) system for a 30 patient ex vivo study. The University of Adelaide, is Australia's 2nd highest ranked dental school, ranked #25 in the world.

### **Preparations for seeking United States Food and Drug Administration (FDA) approval for the InVivage™ device in the United States**

During the June Quarter, OptiScan continued to prepare its application for 510(k) clearance in order to market the InVivage™ clinical device for use in human oral cancer screening and surgery in the United States. OptiScan is working with a leading United States based independent contract testing laboratory for Medical Devices and Pharmaceuticals to conduct various cleaning, disinfection and sterilisation tests.

Separately, OptiScan carried out and undertook preparations for various other storage, transportation, aging, life, electromagnetic compatibility (EMC) and electrical safety tests (to be conducted either internally or via independent contract testing providers). During and following the end of the Quarter, OptiScan successfully passed a number of these internal and external tests.

The Company continues to work with a former leading medical executive and Oral surgeon to assist in the development of a United States market entry strategy for InVivage™ supported by funding from Federal Government Entrepreneurs' Programme - Growth Grant. Marketing agencies are being interviewed in both Australia and the United States as part of this process.

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

OptiScan completed imaging of 20 patients for Stage 3 of its Breast Trial at Royal Melbourne Hospital, Frances Perry House and Epworth Hospital, led by Professor Bruce Mann, Director of Breast Cancer Services for the Royal Melbourne Hospital and Royal Women's Hospital and Professor of Surgery at The University of Melbourne ("Breast Trial").

Funding for these 20 patients was supported by the Medical Device Partnering Program (MDPP), following a successful MDPP workshop last year with breast surgeons from five leading Melbourne hospitals. Subsequent

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to the end of the Quarter and due to success in patient recruitment, the Breast Trial has been extended to 40 patients, with 27 patients having been imaged.

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

OptiScan has received purchase orders from Carl Zeiss Meditec AG (CZM) for approximately \$200k.

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

The Company continued to develop its sales pipeline and distribution arrangements for FIVE2 (ViewnVivo) both in Australia and offshore.

The first Australian sale was recorded after the end of the Quarter to a leading Australian University as part of a Victorian Government medical technology initiative; and encouraging demonstrations were made to a number of highly regarded Melbourne based medical research institutions.

Significant progress was also made offshore, with multiple current prospects in China and North America. Marketing initiatives increased including publications and presentations. After the end of the Quarter, South Korea was added to Optiscan's growing distribution network across North America, Asia and Australia.

### **COVID-19 update**

The Company continues to maintain a COVID-19 safe working environment. Optiscan has adjusted well to conducting presentations and demonstrations remotely and is closely managing its customers and suppliers throughout the COVID-19 pandemic.

### **Corporate Update and Outlook**

The Company has appointed Ms Karen Borg as a non-executive Director of the Company. Ms Borg is a highly regarded senior private and public sector organisation leader and non-executive director, with significant experience in medical devices and technology, consumer products and government services. Over the past 30 years, Karen has held senior roles across regional management, global marketing and government relations.

The Company received funds of \$72k pursuant to the exercise of options during the Quarter.

Research and development costs during the quarter amounted to \$493k, including \$111k paid to the MDS received from the BioMedtech Horizons grant. The Company incurred \$495k in manufacturing and operating costs with significant purchases of inventory during the period.

The Company recruited additional staff in corporate development and production during the Quarter.

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.

- ends -

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

### **For investor queries, please contact:**

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## 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 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")**

30 JUNE 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	138	657
1.2 Payments for		
(a) research and development	(493)	(1,654)
(b) product manufacturing and operating costs	(495)	(911)
(c) advertising and marketing	(32)	(106)
(d) leased assets	-	-
(e) staff costs	(182)	(1,137)
(f) administration and corporate costs	(89)	(415)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	7	17
1.5 Interest and other costs of finance paid	-	(34)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	131	1,213
1.8 Other (provide details if material)	-	276
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,015)</b>	<b>(2,094)</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	(20)	(34)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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	<b>Net cash from / (used in) investing activities</b>	<b>(20)</b>	<b>(34)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	9,814
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	72	1,193
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(406)
3.5	Proceeds from borrowings	-	185
3.6	Repayment of borrowings	-	(545)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payments for lease liabilities)	(54)	(197)
3.10	<b>Net cash from / (used in) financing activities</b>	<b>18</b>	<b>10,044</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	9,459	526
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,015)	(2,094)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(20)	(34)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	18	10,044
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	<b>Cash and cash equivalents at end of period</b>	<b>8,442</b>	<b>8,442</b>

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	8,442	9,459
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>8,442</b>	<b>9,459</b>

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	162
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>		

<b>7. Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
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)	(1,015)
8.2 Cash and cash equivalents at quarter end (item 4.6)	8,442
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	8,442
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	8.32
<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.

30 July 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.