



ASX Announcement  
31 October 2023

## APPENDIX 4C QUARTERLY ACTIVITIES & CASHFLOW REPORT QUARTER 30 SEPTEMBER 2023

Optiscan Imaging Limited (ASX: OIL) (Optiscan or the Company), a leader in medical imaging using confocal laser endomicroscopy, herewith releases its Appendix 4C Quarterly Cashflow report and business update for the quarter ended 30 September 2023 (Quarter). All financial results are in Australian dollars and are unaudited.

### Highlights for the Quarter:

- The capital raise of \$16.7m received during the Quarter will enable the Company to strategically expand its portfolio and accelerate commercialization.
- In line with projections, this Quarter's focus on increased R&D and commercial activities both locally and in the US, have resulted in a net cash outflow from Operating activities for the Quarter of (\$1.6m).
- Significant progress was made towards the FDA De Novo application for the InVivage® with submission of a research dossier based on FDA feedback undertaken during the Quarter, and a planned meeting with the FDA early next quarter.

### Capital Raise

During the Quarter, the Company concluded a partially underwritten renounceable entitlement offer to raise \$16.7M to fund its strategic portfolio expansion. The Offer was structured to raise up to \$16,698,816 by the issue of up to 208,735,201 Shares in the capital of the Company at an issue price of \$0.08 per Share. The Company engaged substantial shareholders, Peters Investments Pty Ltd (Peters) and Orchid Capital Investments Pte. Ltd (Orchid) to partially underwrite the Offer. On the close of Offer on 7 July 2023, the Company received applications totalling \$8,784,700.80 for 109,808,760 shares.

The Company allocated the remaining 98,926,441 Shares according to the Joint Underwriters Agreement and raised a further \$5,050,382.21 for 63,129,778 Shares from Peters, and \$2,863,733.04 for 35,796,663 Shares from Orchid.

The funds have been received by the Company and will be used to accelerate the Company's research and development (R&D) projects and commercialisation plans as articulated in the prospectus and previous reports.

### Product Development

During the Quarter, work commenced to implement the Company's telepathology platform following the passing of the proof-of-concept stage announced in August 2023. Optiscan engineers continued to work with

our partner, Prolucid Technologies, to develop cloud infrastructure as well as to update device software. Regulatory requirements are being pursued from the outset, to streamline future submissions. At the same time, work continued on the Company's oral imaging Artificial Intelligence (AI) algorithm, with ongoing work on data curation and cell segmentation.

Work commenced to enhance the Company's core technology, starting with feasibility studies, considering not only technology but also manufacturability and regulatory aspects. Pathways identified in these studies will feed future product development activities. A new-look InVivage® device with enhanced software interface was completed in the Quarter.

Concurrently, work commenced on the Company's new surgical device to be used for open breast surgery in the first instance, but which can be adapted to other surgical applications with distinct probe designs to come. This approach is part of the Company's planned technology roadmap where hardware and software product development will occur in parallel to accelerate the Company's product development, clinical testing and regulatory submissions allowing for earlier future commercialisation.

Subset data analysis from the breast surgery ex vivo imaging of lumpectomies was concluded utilising samples with known presence of cancer as controls. This showed that the Optiscan platform could provide images comparable to conventional histopathology for determination of presence of cancer and for determination of tumour involvement in surgical margins. Additional analysis of more scans from earlier resections continued during the Quarter, once again demonstrating excellent concordance between presence of tumour at excision margins and that noted on histopathology. This analysis will continue in the next Quarter while preparations are finalised for an in vivo intraoperative study of Breast Cancer Surgery at the Royal Melbourne Hospital.

### **Food and Drug Administration (FDA) submission for the InVivage® device in the United States**

The Company continued to work closely with its US based regulatory consultants and the FDA, and has completed several key components on its planned De Novo submission. Significant progress was made in the Quarter, with the objective to complete this within the shortest timeline possible.

The Company contracted a US-based manufacturer to assist with the design, manufacture and testing of a sterile sheath for the new InVivage® probe on an accelerated timeline. Completion of design changes to support the updated InVivage® have also been completed, leading to a significantly more user-friendly system. Enhanced changes to the InVivage® probe, its sheath and the software interface take into account the feedback received from the FDA earlier in 2023, to significantly de-risk its De Novo submission. These learnings have been integrated into the Company's other device development, such as those underway for the new surgical device to be rolled out for breast surgery in the first instance.

Extensive testing of an alternate fluorescein contrast agent to support Oral Imaging with the InVivage® system was completed, again based on FDA feedback. This alternate fluorescein contrast agent provides significant benefits to the end user in a commercially more competitive format, whilst providing images of equivalent quality.

New qualitative studies and analyses have been completed using the existing clinical dataset produced from the Melbourne Dental School study, in addition to new data obtained from the Australian Centre for Oral Oncology Research & Education. These data points help to demonstrate the utility and effectiveness of the InVivage® in

acquiring interpretable digital images of oral tissues linked to currently accepted clinical and histological guidelines such as those of the World Health Organisation.

This extensive research dossier was lodged with the FDA during the Quarter, following which the Company has been granted a Q-Sub meeting with the Agency early in the next quarter to discuss the results of these studies for inclusion into the Company's InVivage® De Novo submission.

### **Manufacturing & Production**

End of financial year 22/23 and its associated financial audit activities were successfully finalised, with significant efficiencies derived from the Company's Enterprise Resource Planning software (M1). In addition, all customer orders for Q1 FY24 were completed and shipped on time. The next phase of implementation has commenced, which will enable better visibility of prototype builds for new product developments.

The Company continues to de-risk its manufacturing processes and has doubled its technical capacity to deal with increased orders, while proactively managing succession planning.

Optiscan has once again demonstrated its capability to consistently meet customer and regulatory requirements in the field of medical devices, as evidenced by the Company's successful completion of another external audit related to ISO 13485:2016 standard, initiated by Carl Zeiss Meditec. As the Company ramps up future product development, assessment of electronic Quality Management Software has commenced and will be implemented in subsequent quarters in parallel with the rollout of the Company's new devices.

### **Distributor Support and Sales Generation**

Following previous announcements regarding the establishment of a US commercial operation, the Company continued its search for highly skilled staff in the US to broaden its sales team there. The Company appointed two Business Development Managers (BDM) in the United States, aimed at spearheading an ambitious expansion effort. Their strategic knowledge and expertise are poised to solidify the Company's presence in the competitive preclinical and biomedical market and increase its revenue over the coming year.

The consolidation of the APAC distributor base at the end of FY23 has resulted in focus and progression of ViewnVivo® leads in China as the Company pursues revenue generation in the region by the end of this year.

### **Marketing, Communications & Public Relations**

The Company featured prominently at several key conferences throughout the Quarter. Internationally, Dr Farah was invited to present at the 11th International Conference of the American Head and Neck Society (AHNS) in Montreal, Canada, and the 48th Brazilian Congress of Stomatology and Oral Pathology (SOBEP) in Curitiba, Brazil. At AHNS 2023, Dr Farah's presentation, titled "Image Guided Oral Diagnosis Using Confocal Laser Endomicroscopy," was delivered to 1,500 leading head and neck surgeons. As keynote speaker at SOBEP 2023, Dr Farah presented on "Real-Time Optical Microscopy of Oral Mucosal Lesions using Confocal Laser Endomicroscopy" to more than 1,000 dentists, oral physicians, and pathologists, primarily from South America. Both showcased the advancements offered by Optiscan's groundbreaking oral imaging technology.

The Company was invited to attend the BioMedTech Horizons (BMTH) Finale Conference by MTP Connect, and present on the outcomes of its Oral Imaging Study undertaken in collaboration with the Melbourne Dental School to an audience of investors, medical device leaders and industry partners. Published in *Frontiers in Oncology*, a journal that ranks in the top 5% globally, the presentation was well received, and Optiscan were well represented amongst the MedTech community.

The Company has consistently provided regular ASX updates and received coverage across a variety of media networks. Specifically, the Company was featured 5 times in the West Australian's breaking news email to 22k subscribers, and across The West Australian and Bulls N' Bears media channels encompassing more than 600,000 followers with the following stories: "Optiscan gets speaking gig at key healthcare conferences", "Optiscan secures \$16.7m research and development funding", "Optiscan clears key telepathology project milestone", "Nod of approval: Optiscan deal boosts revenue by 66%" and "Optiscan on the cusp of real-time cancer breakthrough". Coverage was also received in the Australian Manufacturing Forum, Market Screener, BioMelbourne Network, AusBiotech, The Sentiment and Mirage News.

Providing regular updates to shareholders, customers and stakeholders throughout this Quarter, the Company will continue to build on its coverage and brand awareness efforts over the coming months with additional activities and media channels planned.

## **People & Culture**

In addition to appointment of two experienced BDMs during the Quarter, the Company also led a search for a Chief Operating Officer to oversee operations at its Melbourne manufacturing headquarters, and has since appointed Brendan Fafiani to the role. In parallel with this effort, and as part of succession planning, the Company has appointed a new Mechanical Engineer.

The Company continues to search for additional hires in engineering, clinical applications and corporate development, as it intensifies its portfolio development with additional device and software offerings, and looks to capitalize on increased interest in the Company's technology.

Throughout the Quarter, members of Optiscan's management team participated in the ANDHealth Activate program, leveraging valuable insights for immediate implementation, and in preparation for AI and Telepathology software due for completion by the end of 2024.

As part of its Environmental, Social and Governance (ESG) credentials, the Company participated in the "Stepping Up to the Breast Cancer Challenge" in August raising awareness and support for breast cancer research and demonstrating its dedication to making a meaningful impact in the community.

## **Corporate Update and Outlook**

In the September Quarter, the Company received the full proceeds of \$16,698,816 from its recent entitlement offer that was partially underwritten by the Company's substantial shareholders, Peters Investments Pty Ltd and Orchid Capital Investments Pte. Ltd. With increased resources, the Company can further its strategic portfolio expansion and accelerate commercialization.

As the Company executes on its commercialization plan into the US, there has been increased business operational activities which will continue throughout the year to maintain the strong momentum the Company is building to enhance its presence in the US market. The Company also continues to make progress with its various R&D projects and product development that will ensure innovative solutions are brought to market. With all these increased activities, it has resulted in a net cash outflow from Operating activities for the Quarter of (\$1.6m), which is in line with management's strategic projections.

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, salaries and superannuation payments.

– ends –

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

**For investor queries, contact:**

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Optiscan Imaging Ltd

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**About Optiscan**

Optiscan Imaging Ltd (ASX:OIL) is a global leader in the development, manufacturing, and commercialisation of confocal endomicroscopic imaging technologies for medical, translational and pre-clinical applications. Our technology enables real-time, non-destructive, 3D, *in-vivo* imaging at the single-cell level.

We are driven by developing technology and its use to give healthcare providers and researchers the highest quality real-time microscopic imaging tools to enable the early detection and management of disease, improve patient outcomes, and reduce the high cost of curative medicine and associated procedures.

Our patent-protected proprietary technology, using specially miniaturised componentry, has created a pen-sized digital microscope, which can be used on any tissue it contacts to produce high resolution digital pathology images for cancer diagnosis and surgical margin detection in real-time. The aim of our technology development is for earlier diagnosis and subsequent treatment of cancerous tumours with expected associated improved patient outcomes.

**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.*

## 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 SEPTEMBER 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	190	190
1.2 Payments for		
(a) research and development	(635)	(635)
(b) product manufacturing and operating costs	(386)	(386)
(c) advertising and marketing	(8)	(8)
(d) leased assets	-	-
(e) staff costs	(710)	(710)
(f) administration and corporate costs	(181)	(181)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	112	112
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,618)</b>	<b>(1,618)</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)	(20)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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>(20)</b>	<b>(20)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	16,699	16,699
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	(105)	(105)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(40)	(40)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payments for lease liabilities)	(56)	(56)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>16,498</b>	<b>16,498</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	875	875
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,618)	(1,618)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(20)	(20)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	16,498	16,498
4.5	Effect of movement in exchange rates on cash held	1	1
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>15,736</b>	<b>15,736</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	15,736	875
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>15,736</b>	<b>875</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	281
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.</i>		
<i>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)	(1,618)
8.2 Cash and cash equivalents at quarter end (item 4.6)	15,736
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	15,736
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	9.73
<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.

31 October 2023

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.