# Optiscan

ASX Announcement 28 April 2023

### APPENDIX 4C QUARTERLY ACTIVITIES & CASHFLOW REPORT QUARTER 31 MARCH 2023

**Melbourne, Australia, 28 April 2023**: Optiscan Imaging Limited (ASX: OIL) (Optiscan or the Company), a leader in medical imaging using confocal laser endomicroscopy, is pleased to release its Appendix 4C – Quarterly Cashflow report and business update for the quarter ended 31 March 2023 (Quarter). All financial results are in Australian dollars and are unaudited.

#### Highlights for the Quarter

- Sale of ViewnVivo® research device to a large American pharmaceutical company.
- Cash receipts from customers more than doubled from last quarter to \$670k.
- Net cash outflows for the Quarter of (\$886k) and year to date is overall less compared to last year, with cash outflows from Operating Activities of (\$766k) for the Quarter.
- Breast Cancer Surgical Margin Assessment Study recruitment completed, with image analysis ongoing.
- Oral Cancer Imaging Study shows 100% accuracy for on-the-fly diagnosis of cancer and 88.9% accuracy for cancer/precancer.

# Food and Drug Administration (FDA) review of the InVivage® device in the United States

Following the announcement on the 2nd of March 2023, regarding the feedback from the FDA in relation to its InVivage® product, the Company in close consultation with its US-based Regulatory Consultants, has been carefully reviewing and addressing this feedback, and the additional requirements needed for a De Novo submission. Optiscan is conducting this additional work to satisfy the recommendations and feedback of the FDA, with additional work required to strengthen its De Novo submission, within the shortest commercially realistic timelines as possible. Data from the Melbourne Dental School clinical imaging study are being reanalysed for inclusion in the Company's De Novo submission based on FDA feedback.

#### **Clinical Studies**

#### • Oral Cancer Imaging Studies

Data analysisfrom the Oral Cancer Imaging Study led by Professor Farah, conducted at the Australian Centre for Oral Oncology Research & Education, continued. During the Quarter, the Company announced the interim results of a subset analysis of its acquired data. Diagnostic accuracy was extremely high at 88.9% for the presence of oral precancer/cancer, while other performance metrics were sensitivity (Sn) 86.8%, specificity (Sp) 92%, positive predictive value (PPV) 94.3% and negative predictive value (NPV) 82.1%. 100% of cancer cases were diagnosed correctly using Optiscan's confocal probe with on-the-fly clinical assessment of its images in real-time. These results, which have been subsequently accepted for publication in the Journal of Oral Pathology & Medicine, will be showcased in Dr Farah's plenary lecture at the annual conference of the American Academy of Oral Medicine to be held in Savannah USA in April 2023. Further analysis of a larger dataset is ongoing with results expected in Q2 2023.

#### Breast Cancer Imaging Study

The current phase of the ex vivo Breast Cancer Surgical Margin Assessment Study has been concluded and analysis is underway correlating the digital images with traditional histopathology. An interim readout is planned in Q2 2023 in preparation for approval to undertake a larger in vivo clinical study. The Company has continued to meet with interested parties in the Breast Cancer space as it prepares for its in vivo clinical study in anticipation of early encouraging results to date.

#### **Artificial Intelligence & Telepathology Applications**

Since signing an agreement with Canadian-based software company, Prolucid Technologies, Optiscan has made good progress with its artificial intelligence/machine learning (AI/ML) and telepathology applications. Good progress has been made in re-risking the AI/ML and telepathology applications as results from early iterations of sub-components of the final pipeline solution are explored. Prolucid and Optiscan are working closely through the various development phases of the agreed solutions, with early gains made in oral imaging analysis as the platforms are being built out with other clinical applications in mind.

#### **Business Development**

The Company has increased its customer database significantly this Quarter, culminating in a series of communications to Life Science Researchers. Of note, the company arranged a webinar featuring Dr. Tami Yap from the University of Melbourne and Emma Gill from Swinburne University. The event was well received with global attendance and the company is looking forward to holding further events in future. Further to this, the Company is currently preparing for a series of key international conferences which it will be attending in the next quarter.

#### Marketing, Communications & Public Relations

The current Quarter saw excellent progress in the Company's marketing, communications, and public relations efforts. Of note, the Company implemented a new marketing automation system, which has enabled regular updates for shareholders and customers, ensuring they receive timely and relevant information.

In addition, the Company launched a new eDM campaign for ViewnVivo®, which was initially piloted in APAC. The high level of engagement from the target audience prompted the campaign to be rolled out globally, leading to increased awareness and interest in the product.

The Company also received favourable media coverage during the Quarter, with the announcement of Optiscan's partnership with Canadian-based software company Prolucid Technologies on AI generating significant interest. This resulted in Dr. Camile Farah being invited to a series of interviews on Bulls n Bears, a financial news outlet that covers the market news of ASX-listed small to medium capped companies. The announcement of the Company's interim results of the Oral Imaging Study was also featured in AusBiotech's Biotech Despatch and other entities such as the BioMelbourne Network.

A particular highlight was the Company's feature in the Australian Financial Review. Dr. Farah was featured in the Medical Technology in Innovation section, where he spoke about Optiscan's technology, product portfolio,

and broader long-term strategy. This feature provided valuable exposure for the Company, with the reach and engagement of this news on media channels increasing tenfold compared to the previous year.

#### **Distributor Support & Sales Generation**

During this Quarter, the Company has maintained its commitment to providing sustained sales and marketing support and engagement across the APAC distribution network. The Company's efforts have included a range of cross-promotional activities aimed at strengthening relationships within the network. The Company's active co-promotion of the inaugural See Life Connected webinar attracted a number of attendees from the APAC region, and a number of ViewnVivo® leads within the APAC distribution network continue to be developed.

#### **Production & Operations**

Ongoing production continues as the Company fulfilled committed orders for the Quarter shipping product to both EU and the US. Ongoing production training continues while the Company fulfils customer orders. The Company also continued with its transition to its digital Enterprise Resource Planning system (**ERP**) (M1) as it prepares for its EOFY implementation program.

#### **Engineering, Research & Development**

During the Quarter, Optiscan continued to explore pathways for enhancing the Company's product portfolio. These include inhouse R&D activities, as well as evaluating external partners with whom the Company can partner on projects aligned to the Company's overall strategy. Based on user feedback, the InVivage® user interface is being upgraded to be more user-friendly and intuitive, with work to be completed in Q2 2023 in preparation for the InVivage® FDA De Novo submission.

The Company is adopting a multi-pronged strategy to de-risk its production by enhancing the robustness of its supply chains. On one hand, critical components were procured to cover projected customer demand, particularly from Zeiss Meditec. On the other hand, alternate components were explored, evaluated and approved.. With these steps in place, the Company is well poised to cater to the growing market demand.

#### **Quality Management System Review**

Ongoing ISO 13485:2016 based internal audits help determine the actual status and health of Optiscan's current Quality Management System (QMS) and processes. The purpose of conducting internal quality audits is to verify that manufacturing, development, and related control facilities meet current good manufacturing processes (GMP), as well as conform to the commitments of ISO 13485:2016. The Company continues to examine its processes more closely and identify areas for improvement.

#### **Corporate Update & Outlook**

In the March Quarter, the Company received \$670k from its customers, which is more than double when compared to the previous two quarters. This includes the sale of a ViewnVivo® research device to a large American pharmaceutical company. The outlook in the United States is positive following this sale and the expansion of the Company's operational presence in Minnesota.

Despite increased commercialization activities such as expansion to the United States, net cash outflows for the Quarter of (\$886k) and year to date are overall less compared to last year, due to management's prudent cost control. As management continues to align costs with its strategy, cash spent on administration, staff and research and development decreased by \$272k compared to last quarter. Due to anticipated sales orders in the coming year, cash incurred for product manufacturing and operations increased to \$437k.

P: (61 3) 9538 3333 A: 16 Miles St, Mulgrave VIC 3170, Australia W: www.optiscan.com 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.

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

#### For investor queries, please contact:

Dr. Camile Farah Chief Executive Officer & Managing Director Optiscan Imaging Ltd E: <u>cfarah@optiscan.com</u>

#### 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	Quarter ended ("current quarter")		
81 077 771 987	31 MARCH 2023		

Con	solidated 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	670	1,332
1.2	Payments for		
	(a) research and development	(337)	(1,375)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	(437)	(837)
	(c) advertising and marketing	(28)	(86)
	(d) leased assets	-	-
	(e) staff costs	(571)	(1,782)
	(f) administration and corporate costs	(70)	(315)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	22
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,084
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(766)	(1,957)

2.	Cash flows from investing	activities	
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipme	ent (5)	(127)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Con	solidated 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	(5)	(127)

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	-	34
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(60)	(128)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payments for lease liabilities)	(55)	(172)
3.10	Net cash from / (used in) financing activities	(115)	(266)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,065	4,529
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(766)	(1,957)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(5)	(127)

Con	solidated 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)	(115)	(266)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	2,179	2,179

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	2,179	3,065
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)	2,179	3,065

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	166
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
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.	<b>Financing facilities</b> 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	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at qu	larter end	-
7.6	6 Include in the box below a description of each facility above, including the lender, int 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		

8.	Estimated cash available for future operating activities	\$A'000	
8.1	Net cash from / (used in) operating activities (item 1.9)	(766)	
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,179	
8.3	Unused finance facilities available at quarter end (item 7.5)	-	
8.4	Total available funding (item 8.2 + item 8.3)	2,179	
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.84	
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer ite figure for the estimated quarters of funding available must be included in item 8.5.	em 8.5 as "N/A". Otherwise, a	
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 cash to fund its operations and, if so, what are those steps a believe that they will be successful?		
	8.6.3 Does the entity expect to be able to continue its operations a objectives and, if so, on what basis?	nd to meet its business	
	Answer: N/A		
	Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 ab	ove must be answered.	

#### **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.

#### 28 April 2023

Date: .....

#### The Board of Directors

#### Notes

- 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.