ASX Announcement 30 April 2024
Optiscan Imaging Ltd (ASX:OIL)

APPENDIX 4C
QUARTERLY ACTIVITIES & CASHFLOW REPORT
QUARTER ENDED 31 MARCH 2024

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 31 March 2024 (Quarter). All financial results are in Australian dollars and are unaudited.

Highlights for the Quarter

- Optiscan receives $3 million CRC-P grant from the Australian Government to develop its Edge-AI-enabled gastrointestinal flexible endomicroscope.
- Appointment of two US-based executives to lead the Clinical Affairs and Regulatory functions to strengthen dealings with the FDA.
- Establishment of a US Regional Office in Rochester Minnesota aimed to position the Company at the centre of the US medtech hub.
- Good progress has been made in relation to alternatives to the topical fluorescein approach for oral imaging based on feedback and advice provided by the US FDA.
- The R&D tax incentive rebate of $672k was received during the Quarter, enabling further investment in its multi-product portfolio development that continues to progress successfully.

Product Development

The Company is progressing well with its research and development projects as set out in the scope of work to be undertaken in last year's capital raising initiative.

The Company's second clinical device is designed for intraoperative surgical use and is nearing completion. This includes a new user interface and probes customised for open surgical applications. This device is planned for use in open breast cancer surgery in the first instance, while the Company explores other viable surgical use cases with potential clinical partners. In line with recent appointments of US-based staff in clinical and regulatory affairs, the completion of the surgical device brings the Company one step closer to commencement of clinical studies required for future FDA submissions.

During the Quarter, work progressed at an accelerated pace on developing the Company's third clinical device designed specifically for diagnostic pathology use, as a digital replacement to the frozen section, opening up another use case for the Company's platform technology. Delivery of this device is expected in Q4FY24.

As recently announced, the Company has commenced development of its second generation flexible confocal endomicroscope for gastroenterology that can fit the biopsy channels of commonly used colonoscopes, unlocking commercial opportunities across the full spectrum of the gastrointestinal endoscopy market with its scope-agnostic approach. The development activities of the Company's fourth clinical device will run until Q4FY26, and are coupled with deliverables set out in the Company's successful $3 million Cooperative Research Centres - Projects (CRCP) grant awarded by the Federal Government. The CRC-P project includes research and development focussed on further optical enhancements and miniaturisation required for gastrointestinal endoscopy, prototyping of the flexible endomicroscope, clinical feasibility testing with the Company's clinical collaborator, Professor Ralf Kiesslich based in Germany, and data gathering and Edge-AI generation.

In addition to significant advancements in hardware development, the Company has progressed with its cloud-based telepathology platform with its beta phase progressing to schedule. Real-time image streaming to the cloud, and storage, have been demonstrated by our partner Prolucid Technologies. Optiscan engineers commenced work on updating InVivage® software to interface with the web portal. The next phase of the project - development of a minimum viable product - is expected to commence in June 2024. The Company's other clinical products are designed for future integration with the telepathology portal.

Finally, the updated InVivage® received safety certification in January 2024, and is ready for deployment in clinical trials awaiting advice from the US FDA on the most appropriate path to regulatory approval.

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

Due to the complexity of the FDA regulatory pathway required for the Company's combination (device/drug) suite of products including its future software as a medical device (SaMD), the Company has appointed two US-based executives; Ken Lock as Head of Clinical Affairs and Nicole Williams as Head of Regulatory Affairs. These appointments provide the Company with deep knowledge of the FDA regulatory space, and allow it to deploy clinical studies locally with increased avenues for successful completion. In addition, the Company has engaged a US-based combination products consultancy firm to further assist it in dealing with the FDA for clearance of its various products including the InVivage®.

The Company continues to work with the FDA on the suitability of its topical fluorescein approach for oral tissue imaging following feedback received from the Agency late in 2023. Given the requirement for a contrast agent for successful deployment of the Optiscan devices, coupled with the new regulatory changes around contrast agents being classified as drugs, and the feedback and advice received from the FDA, the Company has commenced discussions with drug manufacturers to find appropriate alternate pathways to resolve the issues raised by the Agency in relation to the novel topical use of fluorescein.

The Company is also concurrently exploring alternative approaches for non-topical fluorescein use, which may facilitate the progress of the InVivage® submission through alternative means, and simultaneously streamline discussions around the Company's other devices with the Agency. The FDA have granted the Company additional time to explore these alternatives before finalising its latest Q-submission guidance. It is anticipated that these dealings will take place by end of Q4FY24, after which a decision will be made on the

most appropriate path forward and the relevant clinical studies required to demonstrate utility and efficacy for oral imaging.

In the meantime, the human factors usability validation, with our US based partner TE Connectivity, has been paused, but work on the Company's Sterile Disposable Sheath and Drape, and the AI applications continue. Good progress has been made with our US partners on an injection molding tool that has been used to produce prototype sheath samples. Performance testing of the sheaths will occur during the next quarter, followed by other regulatory based testing.

Business Development and Sales Generation

The Company continues to make significant progress with its sales pipeline of its ViewnVivo® life sciences product, especially in the US with intensification of activities of the US-based business development team.

USA: In the Quarter, the US business development team have been actively engaged in the market with a number of promising leads generated from outbound sales activities, and industry engagement at several key research conferences including the Spatial Biology for Immuno-Oncology Summit, the Human Proteome Organisation Conference, and the American Association of Cancer Research annual meeting which further enhanced our outreach.

China: The Company's distributor-led sales efforts in China are advancing steadily, with new opportunities being actively pursued by partners, supported by the broader Optiscan sales and marketing team. As the sales pipeline strengthens, it is anticipated that additional sales will materialise in the coming quarters.

Europe: Targeted sales pilots and market entry assessments in Europe, with a specific focus initially on Germany and Switzerland, continue to show encouraging results and additional activities are planned in the next financial year.

Marketing, Communications & Public Relations

The Company's visibility and engagement was elevated with increased media activity including a visit by Hon. Clare O'Neil MP, Minister for Home Affairs and Cybersecurity to the Company's Melbourne Headquarters following announcement of the Company's success in securing $3 million from the CRC-P program.

Digital campaigns have shown impressive results with an increase in unique website visitors and a notable increase in social media interactions through the Company's multiple platforms.

During the Quarter the Company was featured favourably by several media outlets including:

- Stockhead (Optiscan cash receipts more than double)
- Stockhead (Optiscan optimises AI in its fight against GI baddies)
- The West Australian (Optiscan looks to AI future with $3m grant)
- The West Australian (Optiscan to power innovative imaging research with tax cash)

People & Culture

The Company continues to strengthen its team to support its ambitious growth plans with the recruitment of Melbourne-based Systems and Firmware Engineers, and US-based Heads of Clinical and Regulatory Affairs. Recruitment efforts are ongoing for additional strategic roles to bolster the Company's capabilities in marketing, media and communications and digital content.

During the Quarter, the Company established a US Regional Office at the Minnesota BioBusiness Center in Rochester MN which will serve as its clinical and regulatory hub. The office is strategically located amongst other biotechnology research and development companies and large healthcare providers operating in the wider Rochester area, with easy access to large strategics in the Minneapolis/St Paul region.

Corporate Update and Outlook

R&D activities to develop the Company's multi-product portfolio has significantly increased over the Quarter. With the successful CRC-P grant application that will result in $3m contribution from the Federal Government over the next 3 years, the Company can accelerate its product development. In particular, integrating AI into various areas of the Company's product offerings will further enhance and improve user and patient outcomes.

During the Quarter, investment into R&D activities were further bolstered with $672k received from the R&D tax incentive. With increased R&D activities and product development over the Quarter, this resulted in a net cash outflow for R&D of ($1.1m), which contributed to the net cash outflow from Operating activities for the Quarter of ($1.4m). Overall, the balance sheet remains strong with a total of $12.2m made up of cash and term deposits.

Customer orders and production continue to progress on schedule with orders of about $300k shipped during the Quarter. This will result in higher cash receipts in the subsequent Quarter. With growing global market opportunities and demand for the ViewnVivo® life sciences device, it is anticipated that revenues from this product will increase over the coming quarters particularly from the US.

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.

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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* digital 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.
To learn more about Optiscan, visit www.optiscan.com or follow us on LinkedIn, X or Instagram.

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 2024

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	27	620
1.2	Payments for		
	(a) research and development	(1,154)	(2,919)
	(b) product manufacturing and operating costs	(159)	(1,068)
	(c) advertising and marketing	(52)	(79)
	(d) leased assets	-	-
	(e) staff costs	(723)	(2,246)
	(f) administration and corporate costs	(57)	(289)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	79	294
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	672	672
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,367)**	**(5,015)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(15)	(48)
	(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 (term deposits > 3 months maturity)	-	(5,000)
2.6	**Net cash from / (used in) investing activities**	**(15)**	**(5,048)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	16,699
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	24
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(104)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(82)	(142)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payments for lease liabilities)	(75)	(169)
3.10	**Net cash from / (used in) financing activities**	**(157)**	**16,308**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,652	875
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,367)	(5,015)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(15)	(5,048)

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)	(157)	16,308
4.5	Effect of movement in exchange rates on cash held	7	-
4.6	**Cash and cash equivalents at end of period**	**7,120**	**7,120**

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	4,083	5,652
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (short-term deposit)	3,037	3,000
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**7,120***	**8,652**

*As at 31 March 2024, the total cash (and equivalents) and investments in term deposits with an original maturity of greater than 3 months is $12,173k (31 December 2023: $13,705k)

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.	**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	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

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.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,367)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,120
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,120
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5.21

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.

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

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.

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 2024

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.