ASX Announcement 31 October 2024
Optiscan Imaging Ltd (ASX:OIL)

APPENDIX 4C
QUARTERLY ACTIVITIES & CASHFLOW REPORT
QUARTER ENDED 30 SEPTEMBER 2024

Optiscan Imaging Limited (ASX:OIL) ('**Optiscan**' or '**The Company**'), a leader in medical imaging using confocal laser endomicroscopy, herewith is pleased to release its Appendix 4C Quarterly Cashflow Report along with a business activities update for the quarter ended 30 September 2024 (Q1 FY25). All financial results included in this announcement are unaudited and in Australian dollars.

Highlights for the Quarter

- Cash receipts from customers over Q1 FY25 totalled $638k, its highest level over the last 12 months.
- Optiscan sells ViewnVivo® life sciences device to a large Chinese university through China-based distributor.
- Memorandum of Understanding (MOU) signed with University of Minnesota College of Veterinary Medicine, aimed at assisting Optiscan's expansion into the veterinary market.
- Ethical clearance received from Royal Melbourne Hospital Human Research Ethics Committee for Breast Cancer Study utilising recently unveiled InVue™ precision surgery imaging platform.
- Company undertakes investor roadshow in Sydney and Melbourne generating significant interest and positive feedback from retail and institutional investors, research analysts and capital markets.

Optiscan's Chief Executive Officer and Managing Director, Dr. Camile Farah, commented:

"*I am immensely proud of the development milestones delivered by Optiscan over its September 2024 quarter. In the latest addition to our list of strategic partnerships, we signed an MOU with the University of Minnesota College of Veterinary Medicine. This MOU provides clear evidence that our technology platform is attracting the attention of healthcare professionals in the companion animal market segment. In another significant achievement, we sold a ViewnVivo® life sciences device to a Chinese university – the latter following a competitive tender process. This transaction demonstrates that our efforts to penetrate the lucrative Asian markets has 'green shoots'. All this while our team has been hard at work laying the groundwork for the next stage of our growth journey. Thanks to their efforts, the number of clinical studies testing the effectiveness of our medical technology was expanded, and the Company's R&D program was advanced. Progress on the latter front means we are now at the point where some new additions to our existing product suite could soon be revealed, including a minimum viable product (MVP) of Optiscan's telepathology cloud-based streaming platform.*"

Product Development Strategy and Clinical Studies Further Progressed

Following the signing of the Know-How agreement with the Mayo Clinic in mid calendar 2024 (see ASX announcement dated 13 May 2024), the Company has been working in collaboration with representatives of the latter prestigious US-based hospital group to define and conceptualise new confocal probe designs aimed at compatibility and integration with soft tissue surgical robotic platforms and surgical workflows. This conceptual design work and collaboration has extended into Optiscan's Q2 FY25 reporting period, and is expected to progress to a formal detailed design stage by Q3 FY25.

In alignment with the Company's announced partnerships, significant time and effort has been devoted to detailed planning, documentation, construction and testing of systems to support these partnerships, and planned clinical studies. Optiscan progressed sterilisation validation and testing to suit a range of commercially available sterilisation methods and facilities to increase the utility of its devices.

Steady progress has been made towards delivery of InVue® investigational systems to clinical study sites with finalised sterilisation validation expected by the end of Q2 FY25. Ethical clearance was received during Q1 FY25 from Royal Melbourne Hospital Human Research Ethics Committee for the Breast Cancer Study, utilising the recently unveiled InVue® precision surgery imaging platform. Commencement of the Royal Melbourne Hospital breast study and its first patient recruitment is expected to occur in Q3 FY25. This study will provide early data and insight before a more extensive study planned for commencement with the Mayo Clinic in Q4 FY25 subject to a US Food and Drug Administration (FDA) review and approval process.

In another important Q1 FY25 development, work progressed at an accelerated pace on developing the Company's third clinical device designed specifically for diagnostic pathology use, and as a digital replacement to the frozen section biopsy, opening up other commercial markets for Optiscan's platform technology. Final enhancements are being incorporated into the device before its planned unveiling in Q3 FY25.

Additionally, the Company made significant progress in the completion of a clinical flexible endomicroscope aimed for gastroenterology and integrated with Optiscan's current scanning technology. The assembly and construction of the clinical prototype represents a significant milestone in the CRC-P project granted to the Company in FY24. This phase of the project will be completed by the end of Q2 FY25 and will progress to clinical testing in collaboration with Professor Ralf Kiesslich and his team at University Mainz Hospital in Germany, with commencement planned for early Q3 FY25. This study will provide valuable data for the development of the new generation scanning technology currently being designed by the Company's engineering group, and which will facilitate the goal of providing for an endomicroscope that will fit the biopsy channels of commonly used colonoscopes and gastroscopes. This product development is aligned with the Optiscan's strategic focus of maintaining independence of scope manufacturers thereby broadening the addressable market for its flexible device.

Finally, development of Optiscan's cloud-based telepathology platform through minimum viable product (MVP) continued to progress well during the Company's Q1 FY25. This phase implements the concepts demonstrated in the beta phase. Key tasks include the development of a robust web portal for remote users to efficiently participate in telepathology sessions, and the ability to generate reports. Software on the clinical devices is being updated in parallel to integrate with the cloud platform. The device-cloud platform is being continually tested to identify areas of improvement and to uncover any coding glitches before clinical testing commences. The project is on track for completion in Q3 FY25.

Business Development MOU Announced

The Company continued to advance strategic partnerships in its focus areas of digital pathology and precision surgery over its Q1 FY25. During this time period, the Company announced an MOU with the University of Minnesota College of Veterinary Medicine, which effectively combines Optiscan's technology with the University of Minnesota's research capabilities, veterinary facilities and expertise. This collaboration complements the ongoing partnership with the Mayo Clinic and paves the way for future business development opportunities in veterinary surgery and pathology over the coming months.

Discussions with FDA on regulatory pathway for InVue® and InVivage®

During Q1 FY25, the Company continued its discussions with the FDA. This dialogue had two purposes. It sought clarification on the regulatory pathway for Optiscan's InVue® and InVivage® products (with a surgical use case the favoured option), and also entailed work on documentation for a formal Pre-submission meeting with the FDA.

These interactions with FDA personnel over Q1 FY25 helped Optiscan advance its documentation and clinical planning processes, as the Company aims to finalise its Pre-submission package by the end of Q2 FY25, with a response expected from the FDA for a formal meeting in Q3 FY25. The outcomes of that meeting will determine the next steps for the Company in relation to regulatory pathway, clinical trial design, data collection and ultimate submission. Concurrently, clinical trial design and documentation is progressing with collaborators in readiness for investigational device exemption clearance by the FDA in order to minimise any delay to patient recruitment. Separately, the Company is in the preliminary documentation phase aimed at seeking regulatory clearance for a veterinary application.

Sales Pipeline Builds on Marketing Strategy Milestones

Optiscan continued to progress its sales and marketing strategy over Q1 FY25. This work saw the sales pipeline for its ViewnVivo® life-sciences device expand, especially in the US, with intensification of activities of the US-based business development team.

USA: Optiscan attended the World Molecular Imaging Congress in Montreal, Canada, generating significant interest and leads, which are now being actively pursued. This represented the first formal conference attendance in North America. Conference participation resulted in dozens of new prospect interactions, revenue opportunities and additional market awareness within the life science, veterinary and pharmaceutical market segments. This also established a critical sales execution process within the US and Canadian markets to support further growth opportunities. Direct sales activities over Optiscan's Q1 FY25 resulted in $750K of new opportunities and pipeline growth for the US. Additionally, the team continued to make progress with existing leads through targeted sales activities, maintaining engagement in the US market.

Europe: Ongoing market entry activities included live demonstrations across four potential customer sites in Germany and Switzerland, leading to promising discussions and possible leads. Conversations with these leads are advancing, and the sales pipeline will be further bolstered by additional leads, supported by our business development partner in Europe.

China: Through our China-based distribution partner, the Company secured an additional sale of the ViewnVivo® to a large Chinese university following success in a competitive tender process. Additionally, participation in Austrade's "From GBA to China" tour in Hong Kong and Shenzhen has led to some new potential opportunities in the region.

Marketing, Communications & Public Relations Initiatives

Optiscan's visibility and media presence continued to grow throughout its Q1 FY25. The Company undertook an investor roadshow in Sydney and Melbourne in early July 2024, which resulted in follow-up meetings, discussions and interest from retail and institutional investors, research analysts and capital markets, including at the Bioshares Summit subsequently held in Western Australia. Additionally, the Company met with interested parties in Singapore, enhancing its international presence and engagement.

Further outreach included participation in a Sharewise investor webinar and the ASX Briefs podcast, in addition to various other media appearances, all of which provided a platform for the Company to communicate recent advancements and strategic goals to a broader audience.

People & Culture

Optiscan continued to build on its team capabilities, appointing a new Mechanical Engineer to support R&D and operational needs. As part of Optiscan's efforts to support its near-term growth plans, a key priority over Q1 FY25 was ensuring staff alignment with FY25 objectives.

Optiscan achieved several key milestones in compliance and operational efficiency over the course of its Q1 FY25. Internal audits for ISO 13485:2016 standards were completed, and the Company's supplier relationships were strengthened with signed supplier quality agreements and an upgrade to an "A" grade supplier. Significant procedural updates were made to document control, contamination control, and the quality manual, enhancing Optiscan's adherence to regulatory requirements. Overall, the Q1 FY25 period was marked by progress in quality management and operational enhancements.

Corporate Update and Outlook

Optiscan's list of strategy deliverables in FY24, including the signing of the Know-How agreement with the Mayo Clinic and the unveiling of the InVue® next-gen microscopic medical imaging device for precision surgery, were added to in its Q1 FY25, with the past quarter seeing:

- *The formation of strategic partnerships for new addressable markets* – MOU signed with the University of Minnesota College of Veterinary Medicine
- *Commercialization & business development* successes– Sale of ViewnVivo® life sciences device and a growing sales lead pipeline worldwide
- *Further product development* – Advanced progress in multiple projects, including the development of an MVP of the Company's telepathology cloud-based streaming platform.

Q1 FY25's cash receipts from customers of $638k was the highest quarterly figure over the last 12 months. This reflects continuing strength of sales from existing and new customers, with a growing sales lead pipeline expected to bolster these results further over the year.

Increased work was undertaken to accelerate the Optiscan business over Q1 FY25, in line with the Company's strategic transformation plan – this to ensure the Company is well positioned for additional growth over the coming year. The investment in R&D over Q1 FY25 of ($1.2m) enabled the Company to advance its product portfolio in multiple applications, such as in Breast, Oral, Pathology, GI and Telepathology. Overall, this investment in the Optiscan business contributed to the net cash outflow from operating activities of ($2.1m) in Q1 FY25, but, at the same time, ensured that significant milestones were achieved and, that the development of multiple products progressed to the point where they should be revealed over the coming two quarters. With the current balance sheet that includes $9.1m in cash and term deposits, the Company is on track to deliver on its budgeted milestones.

Leveraging the significant milestones achieved last financial year, Optiscan's FY25 has commenced positively for the Company, with an expectation for ongoing and building momentum during the course of the current financial year.

Note: 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 commercial stage medical technology company creating a suite of digital pathology and precision surgery hardware and software solutions that enable live optical biopsy for life sciences, diagnostic and surgical applications. Optiscan pioneered the development and manufacturing of miniaturised digital endomicroscopes with spatial resolution more than 1000x that of medical CT and MRI.

Using a revolutionary "tissue contact" method, Optiscan's patented technology produces super high resolution digital pathology images for cancer diagnosis and surgical treatment, to unlock real-time insights during surgery, diagnostics, and pre-clinical research. By enabling live, non-destructive, 3D, in-vivo digital imaging at the single-cell level, Optiscan's technology supports earlier disease detection, precision treatment, and improved patient outcomes across a wide selection of clinical applications and settings.

The global addressable market for Optiscan's medical imaging technology extends beyond traditional surgery and pathology, to also encompass the fast-growing digital health market including robotic surgery. With an expanding product suite and increased demand for digital health solutions, Optiscan is uniquely positioned to bridge the gap between surgery and pathology and deliver better outcomes for healthcare professionals and their patients.

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	30 SEPTEMBER 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	638	638
1.2	Payments for		
	(a) research and development	(1,249)	(1,249)
	(b) product manufacturing and operating costs	(410)	(410)
	(c) advertising and marketing	(94)	(94)
	(d) leased assets	-	-
	(e) staff costs	(800)	(800)
	(f) administration and corporate costs	(197)	(197)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	57	57
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(19)	(19)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,074)**	**(2,074)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(1)	(1)
	(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 (term deposits > 3 months maturity)	10	10
2.6	**Net cash from / (used in) investing activities**	**9**	**9**

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	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(41)	(41)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payments for lease liabilities)	(58)	(58)
3.10	**Net cash from / (used in) financing activities**	**(99)**	**(99)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,102	6,102
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,074)	(2,074)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	9	9

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(99)	(99)
4.5	Effect of movement in exchange rates on cash held	(9)	(9)
4.6	**Cash and cash equivalents at end of period**	**3,929**	**3,929**

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	1,929	3,027
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (short-term deposit)	2,000	3,075
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**3,929**	**6,102**

As at 30 September 2024, the total cash (and equivalents) and investments in term deposits with an original maturity of greater than 3 months is $9,117k (30 June 2024 : $11,301k)

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	(259)
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)	(2,074)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,929
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,929
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.89*

*Note – The Company has $5.2m in term deposits maturing next quarter. These deposits are currently not classified as Cash and Cash equivalents as they have an original maturity of greater than 3 months. If these deposits were factored into the 'estimated quarters of funding available', the result would be 4.4 quarters of funding available.

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: No, cash inflow should increase as we expect grant payments to be made in the next quarter. Additionally, see note 8.5. As noted above, the Company also has $5.2m in a term deposit which is proposed to mature in late November 2024 and is not included in the current cash balance above.

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: See note 8.5 that there is $5.2m in term deposits maturing next quarter.

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: Yes, see point above.	

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.

31 October 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.