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

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

Optiscan Imaging Limited (ASX:OIL) ('**Optiscan**' or '**The Company**'), a leader in medical imaging using confocal laser endomicroscopy, is pleased to announce its Appendix 4C Quarterly Cashflow report and business update for the quarter ended 30 June 2024 ('the Quarter'). All financial results are in Australian dollars and are unaudited.

Highlights for the Quarter

- Optiscan signed a know-how agreement with top-ranked US-based Mayo Clinic to co-develop a new endomicroscopic imaging system for use in robotic surgery.
- Optiscan unveiled InVue™ imaging device for precision surgery with first use case in breast cancer imaging.
- Optiscan received $0.919 million in grant payments, as part of $3m CRC-P project to develop its Edge-AI-enabled gastrointestinal flexible endomicroscope.
- Optiscan received ISO 13485:2016 certification up until June 2027.
- After the end of June 2024 quarter, Optiscan announced the achievement of key development milestones and deliverables for its cloud-based telepathology streaming platform.
- After the end of June 2024 quarter, Optiscan received ethical clearance to undertake in vivo human imaging for breast cancer.

Optiscan's Chief Executive Officer and Managing Director, Dr. Camile Farah, commented:
"This Quarter was an inflection point for the Company in its transformation from being an original equipment manufacturer (OEM) to a private label manufacturer (PLM) with the unveiling of the Company's next-generation InVue™ microscopic medical imaging device for precision surgery. This came on the back of the Company signing a Know-How agreement with the top-ranked US-based Mayo Clinic to co-develop a digital confocal laser endomicroscopic imaging system for use in robotic surgery, with initial focus on robotic-assisted breast cancer surgery. The robotic-assisted surgery market is experiencing significant growth and we want to ensure that Optiscan is well positioned to be a leader in microscopic visualisation as the robotic surgery service market continues to expand driven by technological advancements.
Subsequent to the end of the Quarter, we were pleased to receive ethical clearance from the Royal Melbourne Hospital Human Research Ethics Committee to undertake an in vivo clinical study for assessment of cancer margins in patients presenting for surgical treatment of breast cancer. Completion of this study will provide us with significant data to progress to a larger scale clinical trial required for regulatory approval of the InVue™ device.

This was soon followed by us delivering a major development milestone with the completion of the beta phase of our cloud-based telepathology streaming platform which is designed to enhance digital pathology capabilities, allowing remote users to make immediate, informed decisions, and leverages Optiscan's confocal imaging technology to enable real-time, remote collaboration on patient imaging sessions.
Collectively these developments bring us closer to addressing the needs of the fast-growing digital health market including robotic surgery, and to being uniquely positioned to bridge the gap between digital pathology and precision surgery."

Major R&D Projects are Further Progressed

Optiscan continued to progress its research and development (R&D) projects as set out in the scope of work to be undertaken in last year's capital raising initiative, and highlighted in the Company's recent Investor Update (see ASX announcement dated 16 May 2024).

The Company's second clinical device, InVue™, designed for intraoperative surgical use, was completed and unveiled to significant positive feedback. This next-gen imaging device tailors Optiscan's patented technology to the surgical market, and can be used in a wide range of clinical settings, including cancer diagnosis and treatment. The first intended use of InVue™ is for breast cancer surgery and margin determination.

The InVue™ device reveal is tangible evidence that Optiscan is successfully expanding its product portfolio, in the process delivering a core component of the Company's growth strategy. Leveraging Optiscan's patented technology, the device is designed to be used by surgeons to gain immediate pathology insights in the operating theatre, to enable on-the-spot decision making, treatment adjustments and precision surgery.

The InVue™ has a spatial resolution of 0.55µ and is more than 1000x more powerful than traditional CT and MRI scanners with a typical resolution of 0.5-1mm. The InVue™ is DICOM-compliant and PACS-enabled and designed to integrate with Optiscan's cloud-based telepathology streaming platform. The latter platform, which is expected to be unveiled in 2025, will allow surgeons and pathologists to collaborate on surgical cases in real-time from anywhere in the world.

During the Quarter, work progressed at an accelerated pace on developing Optiscan's third clinical device designed specifically for diagnostic pathology use, as a digital replacement to the frozen section biopsy, opening up another use case for the Company's platform technology. This device has been built at the Company's headquarters in Mulgrave and designed in assistance with Design+Industry. Additional software enhancements and other minor modifications are being incorporated into the device before its planned unveiling in Q2 FY25.

The Company has also made steady progress towards R&D of its second generation flexible confocal endomicroscope for gastroenterology. This endomicroscope will fit the biopsy channels of commonly used colonoscopes and gastroscopes, unlocking commercial opportunities across the full spectrum of the gastrointestinal endoscopy market with its scope-agnostic approach. This flexible device will mark the Company's fourth clinical device, with its R&D program expected to run until Q4 FY26. The Cooperative Research Centres - Projects (CRC-P) grant awarded by the Federal Government to the Company is well underway, with initial work carried out on new optics and electronics. During this phase, Optiscan has benefited from grant payments of $0.919 million from the successful $3m grant announced earlier in the year.

Clinical planning for a prototype flexible endomicroscope is underway with the Company's clinical collaborator, Professor Ralf Kiesslich based in Germany.

Development of Optiscan's Telepathology Streaming Materially Progressed

After the end of the Quarter, Optiscan announced the achievement of further milestones in its platform development strategy. Its cloud-based telepathology streaming platform, which is being developed in partnership with Canadian-based Prolucid Technologies Inc, has successfully completed its beta phase (see ASX announcement dated 29 July). Key deliverables in the beta phase included the ability to register, authenticate, and securely connect devices to the cloud platform. As a package, these achievements demonstrate that Optiscan devices can stream images to the cloud platform as they are acquired, enabling real-time visualisation by remote users. The session data can also be pushed to cloud storage for post-session review.

Proof of concept for post-session review, image annotation, and session data comparison workflows have also been successfully implemented, and development of the commercial version is currently underway. User authentication, data transmission latency, patient privacy protection, data encryption, synchronization, and management have been implemented, ensuring compliance with stringent cybersecurity requirements.

This development is a further evolution in Optiscan's imaging technology, allowing real-time collaboration and quick decision-making between clinicians and pathologists all over the world. By leveraging cloud-based technology, Optiscan aims to bring sophisticated digital pathology to anyone, anywhere, anytime. This has great potential for telehealth consultations in regional, rural, and remote areas where pathology expertise is often unavailable, and can help improve patient outcomes, no matter where they live.

The next phase of the project - development of a minimum viable product - has commenced with anticipated completion in Q3 FY25. All the Company's clinical products are designed for future integration with the telepathology platform.

United States Food and Drug Administration (FDA)

Due to the complexity of the FDA regulatory pathway required for Optiscan's combination (device/drug) suite of products, the Company appointed a US-based Head of Regulatory Affairs and engaged a US-based combination products consultancy expert to further assist in its strategy and discussions with the FDA. Both appointments have been highly beneficial to enhancing Optiscan's skillset and improving its existing processes to meet the FDA-prescribed standards of best practice and guidance.

The Company continued to work with the FDA on the suitability of its topical fluorescein approach for oral tissue imaging following feedback received from the Agency previously. Concurrently, Optiscan has been exploring alternative approaches for non-topical (intravenous) fluorescein use. It is expected that this may facilitate the progress of the InVivage® submission through an alternative surgical means, which is expected to be similar to that of the Company's recently unveiled surgical device, the InVue™.

Given the importance of the contrast agent for successful deployment of the Optiscan devices, coupled with the regulatory changes, the Company has also been exploring options in relation to the supply and manufacture of the drug component of the combination (device/drug) suite of products. Optiscan has been

in discussions with drug manufacturers to find appropriate pathways to resolve the changes made by the FDA in relation to the regulation of fluorescein.

The Company expects to finalise its discussions with the FDA, allowing a clearly defined path to market, for both the InVue™ and InVivage® favouring a surgical use case, which fully accommodates the FDA's feedback and the recent US legislative changes relating to contrast agents.

Business Development

Optiscan continues to make significant progress establishing strategic partnerships and collaborations as it pushes ahead with its strategy to focus on digital pathology and precision surgery opportunities.

During the Quarter, the Company entered into a collaboration through a Know-How agreement with the highly regarded Mayo Clinic to co-develop a digital confocal laser endomicroscopic imaging system for use in robotic surgery. The collaboration combines Optiscan's engineering expertise in digital endomicroscopic hardware and software development with the Mayo Clinic's know-how in robotic surgery and quality patient care. The agreement, which covers a 24-month co-development plan, will bring together experts from both Optiscan and the Mayo Clinic to develop a robot-compatible endomicroscopic imaging system with an initial focus on robotic-assisted breast cancer surgery.

The collaboration is part of Optiscan's wider strategic focus on the US market, and its plan to embed its platform technology as a key component of intraoperative oncological surgery workflows in a variety of settings and clinical applications to provide surgeons with real-time microscopic information of cancer clearance for the potential to reduce missed cancers and minimise repeat surgeries due to residual disease.

Sales Pipeline

Optiscan materially progressed its sales and marketing strategy over the June 2024 quarter. The Company continues to make progress with the sales pipeline of its ViewnVivo® life-sciences device, especially in the US with intensification of activities of the US-based business development team.

USA: In the Quarter, the US life-sciences business development team continued to engage the market with numerous promising leads generated from outbound sales activities, on-site demonstrations and industry engagements leading to $1.8m worth of potential opportunities advancing through the sales pipeline with multiple opportunities in various stages of funding. It is expected that several of these will result in sales over the coming two quarters given the long sales cycle for capital equipment and the dependencies of most organisations on grant funding outcomes to support capital expenditure. This is a promising sales pipeline which is expected to increase further over coming quarters given the substantial increase in sales outreach across different channels including promotion at international conferences and trade exhibitions.

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. Prospects are likely to be further enhanced by changes made to distributor agreements including increased unit pricing, improved sales margins, and expanded sales territories for both distributors.

Europe: Targeted sales pilots and market entry assessments continued in Germany and Switzerland, with significant market awareness of the ViewnVivo® product across these jurisdictions. Based on this positive feedback, the Company executed a live demonstration roadshow to selected medical research institutions and universities in Germany that expressed interest in potential purchase of the life-sciences product. The Company is working through the feedback received from the roadshow and will continue to refine its target customer base including cancer research centres and large pharmaceutical companies in both countries.

Marketing, Communications & Public Relations Initiatives

Optiscan's visibility and media engagement continues to increase. 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. The Company has worked hard to communicate news flow to its shareholder base and the wider investment market, including a non-deal roadshow in Sydney and Melbourne after the end of the June 2024 quarter.

People & Culture

Optiscan continued to strengthen its team to support its ambitious growth plans over the Quarter. Several new staff commenced employment with the Company over this period, including roles in Regulatory and Clinical Affairs, Systems Engineering, Marketing and Communications, and Digital Content. The Company also appointed The Capital Network (TCN) as its Investor & Public Relations agent, and engaged Kaylene Dawson as its General Counsel.

Importantly, the Company appointed Minnesota-based Nicole Williams as US Head of Regulatory Affairs to support its ongoing engagement with the FDA and to provide local assistance with the Company's robotic surgery collaboration with the Mayo Clinic and other US-based clinical partners.

Additionally, the Company took up premises at the Minnesota BioBusiness Center adjacent to the Mayo Clinic to further enhance collaborations and local support for future clinical studies and trials to be rolled out over the coming year.

Finally, the Company made progress in enhancing the quality management system and ensuring compliance with ISO 13485:2016 standards. The Quarter was marked by rigorous internal audits and external audits conducted by notified bodies for which the Company received ISO 13485:2016 certification up until June 2027. The Company carried out strategic training initiatives to maintain high standards of compliance and operational efficiency for multiple processes throughout the organisation.

Corporate Update and Outlook

During the Quarter, the Company achieved several key milestones such as the Know-How agreement signed with Mayo Clinic and unveiled its InVue™ next-gen microscopic medical imaging device for precision surgery. These significant milestones have been well received by the market, based on feedback from investor roadshows in Sydney and Melbourne where CEO Dr Camile Farah met with multiple analysts, financial institutions, and other key stakeholders.

From a financial standpoint, this Quarter's cash inflows from operating activities have been the strongest this year partly due to the receipt of CRC-P grant of around $0.9m, and interest income and customer receipts totalling $0.5m. This resulted in the lowest quarterly net cash outflow from operating activities over FY24 of ($0.7m).

Investment in R&D continues to be a focus with ($1.1m) spent during the Quarter on various R&D activities and product development, which are on target and on budget.

With strong strategic partnerships formed with Mayo Clinic and other parties, significant know-how and efficiencies can be gained that will result in a more efficient use of capital in the long run for both product development and clinical trial activity. Overall, the balance sheet remains strong with total cash at hand of $11.3m, made up of cash and term deposits.

The Company met significant milestones over both the Quarter and FY24 as a whole, with strong progress made as the Company pivots from its historical base as an OEM provider to a strategically focussed and diversified (hardware and software) private label business. The Company's patent-protected technology platform continues to provide large opportunities in lucrative markets that are set to grow exponentially with the rise of minimally invasive surgery and digital health solutions. The outlook for Optiscan over the coming year and beyond is positive, with the growing momentum now evident positioning the Company well for future growth.

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.

For further information, please contact:

Shareholder & General Enquiries
Optiscan Imaging Ltd
Dr Camile Farah
T: +61 3 9538 3333
E: ceo@optiscan.com

Media & Investor Enquiries
The Capital Network
Julia Maguire
T: +61 2 7257 7338
E: julia@thecapitalnetwork.com.au

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 JUNE 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	287	906
1.2	Payments for		
	(a) research and development	(1,077)	(3,996)
	(b) product manufacturing and operating costs	(277)	(1,346)
	(c) advertising and marketing	(24)	(104)
	(d) leased assets	-	-
	(e) staff costs	(657)	(2,903)
	(f) administration and corporate costs	(101)	(390)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	202	496
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	919	1,592
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(728)**	**(5,745)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(39)	(87)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (term deposits > 3 months maturity)	(146)	(5,146)
2.6	**Net cash from / (used in) investing activities**	**(185)**	**(5,233)**

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	(61)	(204)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payments for lease liabilities)	(38)	(207)
3.10	**Net cash from / (used in) financing activities**	**(99)**	**16,208**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,120	875
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(728)	(5,745)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(185)	(5,233)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(99)	16,208
4.5	Effect of movement in exchange rates on cash held	(6)	(3)
4.6	**Cash and cash equivalents at end of period**	**6,102**	**6,102**

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	3,027	4,083
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (short-term deposit)	3,075	3,037
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**6,102**	**7,120**

As at 30 June 2024, the total cash (and equivalents) and investments in term deposits with an original maturity of greater than 3 months is $11,301k (31 March 2024 : $12,173k)

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)	(728)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,102
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,102
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	8.38

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.

31 July 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.