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ASX Announcement

December 2025 Quarterly Activities Report

Highlights

- **Appointment of CLEO's first U.S. Key Opinion Leader, Dr Nicholas Lambrou, to support early adoption, clinical advocacy and market entry**
- **CLEO's Total Addressable Market significantly expanded, with U.S. insurance data identifying ~2.0m women per year as the immediate pre-surgical opportunity**
- **U.S. pivotal clinical trial continues with CLEO to hit its recruitment target imminently**
- **Completion of Stage 1 of the MDSAP, a key milestone toward ISO13485 certification and FDA submission**
- **$5 million raised via a strongly supported placement and $1.7 million R&D Tax Incentive refund received**
- **Company well-funded to execute on commercial launch with cash balance of A$9.6m as at 31 December 2025.**

MELBOURNE, AUSTRALIA, 29th January 2026: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO**, or **the Company**) is pleased to provide the market with an update on its activities in the December 2025 Quarter (**the Quarter**) as it develops its simple and accurate blood test for the detection of ovarian cancer.

Appointment of First U.S. Key Opinion Leader

During the Quarter, CLEO appointed its first U.S. Key Opinion Leader (**KOL**), Dr Nicholas Lambrou, a highly respected gynaecologic oncologist, surgeon and clinical researcher. Dr Lambrou brings deep expertise in ovarian cancer management and is actively involved in recruiting patients into CLEO's pivotal U.S. clinical trial.

Under the engagement, Dr Lambrou will support clinical advocacy, data interpretation, publication development and the presentation of CLEO's research at major U.S. scientific meetings. The appointment represents an important early-market engagement milestone and forms a core pillar of CLEO's U.S. commercialisation strategy, supporting credibility, awareness and early adoption among specialist clinicians.

Total Addressable Market Expanded Supported by U.S. Insurance Data

In the previous Quarter, CLEO commissioned Norstella, a market-leading global pharma intelligence solution provider, to reassess its initial pre-surgery patient market in the U.S. using open insurance claims data across commercial, Medicare and Medicaid channels.

Analysis identified approximately 3.4 million U.S. women per year presenting with a suspected ovarian or adnexal mass, of whom an average of ~2.0 million proceed to further diagnostic investigation

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Directors
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Chief Executive Officer and Executive Director Dr Richard Allman
Chief Scientific Officer and Executive Director Dr Andrew Stephens
Non-Executive Director and Lead Medical Advisor Professor Tom Jobling
Non-Executive Director Lucinda Nolan

consistent with current pre-surgical triage pathways. This ~2.0 million cohort represents CLEO's immediate Total Addressable Market (**TAM**) for its Pre-Surgical Ovarian Cancer Test, materially expanding prior estimates.

The data reinforces the significant unmet clinical need and commercial potential for CLEO's technology and will inform ongoing health economic modelling to support reimbursement strategy, payer engagement and early revenue generation following Food and Drug Administration (**FDA**) approval. CLEO anticipates the delivery of its Health Economic Study in Q1 of CY2026.

U.S. Clinical Trial Recruitment on Track for Completion ~Q1 CY2026

During the Quarter, CLEO continued to recruit women into its pivotal U.S. clinical trial, building on the addition of several high-volume metropolitan surgical centres in the prior Quarter. CLEO is on track to meet its initial 500 subject target in Q1 2026. As is standard in clinical trials, patient recruitment will continue beyond this point to ensure sufficient usable samples and complete pathology datasets are available to support analysis.

In parallel, CLEO has advanced to final discussions with its manufacturing partner with an Agreement expected to be executed in Q1 CY2026. Following preliminary development activities, the Company will commence commercial manufacturing of its test kits to be used for sample testing.

Sample testing will be followed by analysis and reporting, which is anticipated to take ~1-2 months. The resulting data will underpin CLEO's planned FDA 510(k) submission, which is intended to be lodged following completion of this work.

Regulatory Progress Following Completion of Stage 1 MDSAP

CLEO successfully completed Stage 1 of the Medical Device Single Audit Program (**MDSAP**) during the Quarter, representing a key milestone in the Company's global regulatory roadmap and ISO 13485:2016 Quality Management System certification pathway.

The MDSAP framework enables alignment with the regulatory requirements of multiple major jurisdictions, including the U.S. FDA, through a single harmonised audit process. CLEO received positive feedback on the clarity, completeness and regulatory alignment of its quality system documentation. Stage 2 of the MDSAP audit is scheduled for Q2 CY2026 and will assess full implementation and ongoing compliance, further strengthening CLEO's pathway toward FDA submission and commercial launch.

Corporate Activities

The Company had cash reserves of A$9.6m as at 31 December 2025. Payments to related parties of the entity and their associates (*refer Section 6 of attached Appendix 4C*) totalled $150k and relate to fees and salaries paid to executive and non-executive Directors.

Research Coverage on Cleo Diagnostics

During the Quarter, Petra Capital initiated research coverage on CLEO with lead Healthcare Analyst, Tanushree Jain, publishing an independent research report on the Company. The initiation of coverage reflects growing institutional interest in CLEO's clinical progress and U.S. commercialisation strategy. In addition, Evolution Capital also initiated coverage on CLEO during the Quarter, with research authored by healthcare analyst, Jacob Hoenig.

Please contact your Petra Capital and/or Evolution Capital advisor/s to obtain a copy of the report/s. Alternatively, please reach out to Dayna Louca at CLEO using the contact details below.

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$5m Placement to Support Market Entry and Accelerate Screening Test Development

In December, CLEO raised $5 million via a well-supported placement at $0.60 per share. The placement attracted new institutional and high net worth investors, alongside strong support from existing shareholders, reflecting confidence in CLEO's clinical and commercial strategy.

Funds raised will be used to support market entry and commercial launch for the Pre-Surgical Ovarian Cancer Test, including reimbursement initiatives and commercial manufacturing. Proceeds will also accelerate development of CLEO's screening test and provide general working capital.

R&D Tax Incentive Refund Further Strengthens Cash Position

During the Quarter, CLEO received a cash refund of ~$1.7 million under the Australian Government's R&D Tax Incentive program in respect of its FY25 claim.

The refund further strengthened CLEO's balance sheet and funding position, supporting continued execution of near-term priorities including completion of the U.S. pivotal clinical trial, regulatory activities and preparation for FDA submission. CLEO's R&D program remains central to its staged execution strategy, delivering value accretive milestones across pre-surgical testing and longer-term screening applications.

Annual General Meeting

CLEO held its Annual General Meeting on 24 November 2025. All resolutions were determined by poll, as called by the Chairman, and were passed.

In accordance with Listing Rule 3.13.2 and section 251AA of the Corporations Act 2001 (**Cth**), details of the resolutions and proxies received for the meeting are set out in the below proxy summary.

RESOLUTION DETAILS				PROXY VOTES				POLL RESULTS			
	Resolution	Decided by Show of Hands (S) or Poll (P)	Resolution Type	FOR	AGAINST	PROXY'S DISCRETION	ABSTAIN*	FOR	AGAINST	ABSTAIN*	Result
1	Resolution 1 - Remuneration Report	P	Ordinary	14,227,745 99.98%	2,500 0.02%	0 0.00%	5,700	14,927,745 99.98%	2,500 0.02%	255,700	Carried
2	Resolution 2 - Re-election of Director - Professor Thomas Jobling	P	Ordinary	16,233,445 99.98%	2,500 0.02%	0 0.00%	0	31,433,445 99.99%	2,500 0.01%	0	Carried
3	Resolution 3 - Re-election of Director - Ms Lucinda Nolan	P	Ordinary	16,233,445 99.98%	2,500 0.02%	0 0.00%	0	31,433,445 99.99%	2,500 0.01%	0	Carried
4	Resolution 4 - Approval of 10% Placement Facility	P	Special	16,230,445 99.97%	5,500 0.03%	0 0.00%	0	31,430,445 99.98%	5,500 0.02%	0	Carried
5	Resolution 5 - Approval of Employee Securities Incentive Plan	P	Ordinary	16,224,745 99.93%	11,200 0.07%	0 0.00%	0	31,424,745 99.96%	11,200 0.04%	0	Carried
6	Resolution 6 - Approval of potential termination benefits under the New Plan	P	Ordinary	16,214,745 99.93%	11,200 0.07%	0 0.00%	10,000	31,414,745 99.96%	11,200 0.04%	10,000	Carried

*Abstain votes are provided for information only and are not included in the calculation of total available votes.

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Marketing Activities

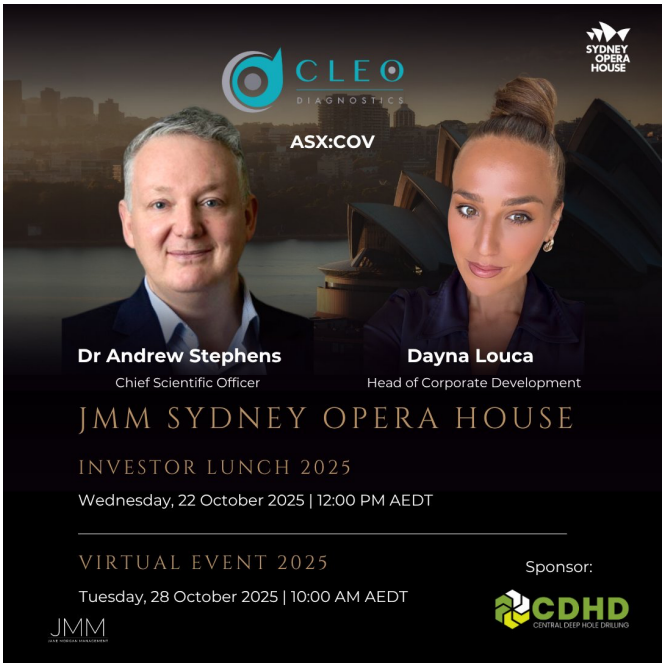
Sydney Opera House Event

CLEO Chief Scientific Officer (**CSO**), Dr Andrew Stephens and Head of Corporate Development, Dayna Louca, presented at the JMM Australia Investor Event held at the Sydney Opera House on Wednesday 22nd October 2025.

The event was attended by over 150+ retail, private and institutional investors.

The Company provided an overview on key milestones and its strategy to deliver on its first patient market in the U.S. in 2026.

The urgent clinical unmet need for earlier detection continues to exist with ovarian cancer often being diagnosed late, resulting in an alarming 5-year survival rate of just 49%, compared to other cancer such as breast cancer which has a 92% 5-year survival rate.



-ENDS-

This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board.

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Forward Looking Statements: This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of Cleo and certain of the plans and objectives of Cleo with respect to these items. These forward-looking statements are not historical facts but rather are based on Cleo's current expectations, estimates and projections about the industry in which Cleo operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of Cleo, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Cleo cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Cleo only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. Cleo will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

About Cleo Diagnostics Ltd ASX:COV

CleoDX aims to bring to market a simple blood test for the accurate and early diagnosis of ovarian cancer based on the novel patented biomarker, CXCL10, which is produced early and at high levels by ovarian cancers but is largely absent in non-malignant disease. The test aims to distinguish benign from malignant growths in a standard format that will be readily compatible with existing equipment used by diagnostic laboratories worldwide.

The platform is backed by over 15 years of scientific Research & Development at the Hudson Institute of Medical Research, with two clinical studies conducted with over 500 patients. Pursuant to a licence agreement with the Hudson Institute of Medical Research, Cleo has a worldwide exclusive licence to commercialise the intellectual property which underpins its operations and the ovarian cancer tests.

The clinical unmet worldwide need is urgent. An accurate and early detection blood test could shift survivability for ovarian cancer significantly as seen with other cancers. Cleo is advancing the availability of its simple blood test, under a modular execution strategy which is designed to eventually address all ovarian cancer detection markets with specific tests including surgical triage, recurrence, high risk, and early-stage screening.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

CLEO DIAGNOSTICS LTD

ABN	Quarter ended ("current quarter")
13 655 717 169	31 DECEMBER 2025

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development *(including R&D staff costs)*	(1,191)	(2,680)
	(b) product manufacturing and operating costs		-
	(c) advertising and marketing	(106)	(137)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(150)	(315)
	(f) administration and corporate costs	(130)	(400)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	36	129
1.5	Interest and other costs of finance paid		-
1.6	Income taxes paid		-
1.7	Government grants and tax incentives	1,717	1,717
1.8	Other (provide details if material)		-
1.9	**Net cash from / (used in) operating activities**	**176**	**(1,686)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(2)	(2)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.2	Proceeds from disposal of:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	-
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) 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**	**(2)**	**(2)**

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5,000	5,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	9	9
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(356)	(356)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**4,653**	**4,653**

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,599	6,461
4.2	Net cash from / (used in) operating activities (item 1.9 above)	176	(1,686)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(2)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4,653	4,653

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**9,426**	**9,426**

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	6,399	748
5.2	Call deposits	3,027	5,713
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)**	**9,426**	**6,461**

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 *Payment to Directors fees*	150
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.

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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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	176
8.2	Cash and cash equivalents at quarter end (item 4.6)	9,426
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	9,426
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

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.

Date: 29 January 2026

Authorised by: The Board
(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.

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