ASX Announcement

September 2025 Quarterly Activities Report

Highlights

- **Continued positive engagement with the U.S. FDA, with encouraging feedback at CLEO's second pre-submission meeting**
- **~1,600 biobank samples secured, establishing significant internal resource to support algorithm refinement, product development and regulatory readiness**
- **Health Economic Study commenced to quantify economic benefit of CLEO's test, supporting U.S. market entry and reimbursement**
- **U.S. clinical trial recruitment completion and sample analysis scheduled Q1 CY2026**
- **Momentum building as CLEO advances towards entry into U.S. market in 2026**
- **A$4.6m cash at bank as at 30 September 2025.**

MELBOURNE, AUSTRALIA, 31st October 2025: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO**, or **the Company**) is pleased to provide the market with an update on activities in the September 2025 Quarter (**the Quarter**) as it develops its simple and accurate blood test for the detection of ovarian cancer.

CLEO Progresses Regulatory Activities with Positive FDA Meeting

Following its initial meeting with the FDA last year, CLEO has completed its second pre-submission meeting with the Company's Director of Quality and Regulatory Affairs, Emma Lester, attending in person at the FDA Headquarters in Silver Spring, Maryland. The discussion focused on key technical aspects including:

- Clinical trial design;
- Sample stability;
- Use of biobank samples to support critical studies;
- Clinical specificity (the ability of its test to correctly identify ovarian cancer without mistakenly identifying other conditions); and
- Intended use and clinical workflow.

The meeting was highly constructive, with the FDA offering positive and detailed feedback. The guidance reinforces confidence that CLEO's clinical trial and broader strategic direction remain well aligned with regulatory expectations.
This feedback enables CLEO to further enhance the robustness of its pivotal clinical trial design and data collection processes to support a high-quality 510(k) submission, helping reduce regulatory risk ahead of submission next year. CLEO will continue its proactive engagement with the FDA ahead of planned submission.

CLEO Acquires ~1,600 Biobank Samples for Internal Testing to Support FDA Submission and Fast Track Screening Test Development

CLEO has now secured approximately 1,600 biobank samples, establishing a significant and stable internal resource to accelerate its research and regulatory programs.

In the previous Quarter, CLEO announced successful access to two world-renowned biobanks - the United Kingdom Collaborative Trial of Ovarian Cancer Screening (**UKCTOCS**) biobank (*refer to ASX Announcement dated 28th April 2025*). The Company is pleased to announce it has received the first tranche of 200 samples from UKCTOCS, the world's largest ovarian cancer screening trial conducted to date.

Additional samples have also been secured from Hudson Institute of Medical Research's Ovarian Cancer Tissue Bank (**Hudson**) and the Victorian Cancer Biobank Consortium (**VCB**), broadening CLEO's in-house development capacity and strengthening its internal research infrastructure to support ongoing commercialisation activities.

Samples To Strengthen FDA Submission and Support Algorithm Refinement

Samples and clinical information encompass a broad range of ovarian cancer types, grades and stages, including 187 rare high-grade Stage I cancers. This critical resource will facilitate both refinement of the Pre-Surgical Ovarian Cancer test, as well as enable CLEO to fast-track the development of its screening and recurrence tests.

Accompanying information for majority of samples includes:

- Ultrasound imaging reports at referral, or obtained by the specialist gynaecological consultant
- Pathology reports detailing post-surgical diagnosis
- Pre-surgical serum titres for CA125
- Genetic markers indicating predisposition (e.g. BRCA1/2, RAD51, HNPCC status)
- Other relevant clinical history (e.g. medications, familial histories, etc).

Collectively this "sample library" will be used to materially strengthen the supporting scientific evidence base underpinning CLEO's upcoming FDA 510(k) submission and provides a secure internal resource from a diverse patient population, accelerating development across its product pipeline. The Company looks forward to keeping the market updated with its internal testing progress over the next Quarter.

~1,100 Samples Received from Hudson Institute of Medical Research

Hudson is one of the largest Australian repositories of ovarian cancer tumour samples for use in research, housing ~2,500 ovarian tissue samples used to advance diagnosis and treatment. CLEO is pleased to have recently received ~1,100 of these samples, with an approximate ratio of 1:1 for benign versus cancer samples to ensure a representative dataset is obtained.

~300 Samples Received from Victorian Cancer Biobank Consortium

Since 2006, VCB's consortium of hospital-integrated tissue banks has collected material from about 40,000 patients across multiple tumour streams. Comprising a wide range of banked donor tissue and blood derivatives, each sample is accompanied by matched basic clinical data, offering researchers a wealth of information and insights. CLEO is pleased to have received a combination of serum samples, comprising cancerous, benign, healthy <=49yo, and healthy >49yo.

Health Economic Study Supporting U.S. Market Access Commences

Cleo has engaged EntityRisk, a specialist in health economics and value modelling, to quantify the economic benefits of CLEO's Pre-Surgical Test for Ovarian Cancer. The project will leverage the expertise of Managed Markets Insight & Technology, LLC (**MMIT**), a Norstella company, whose market access and payer intelligence capabilities ensure that economic modelling is informed by comprehensive U.S. reimbursement data. The study will deliver a robust, evidence-based justification to support payor engagement, reimbursement strategy and CLEO's U.S. market access strategy. CLEO anticipates the study to be complete by year end.

Targeted Market Entry

CLEO will also leverage Norstella's extensive health system and claims databases to identify and prioritise U.S. regions with the highest clinical need and strongest commercial potential. This targeted approach will maximize early adoption and accelerate early revenue generation, supporting a successful market launch following FDA submission in 2026.

Strengthened Investor Confidence with Accurate Market Data

Norstella's database of over 300 million U.S. lives updated weekly and comprehensive analysis of physician procedural trends, payer policies, and claims data will deliver a refined, evidence-based Total Addressable Market (**TAM**) estimate for CLEO's Ovarian Cancer Pre-Surgical Test. CLEO expects this data to be received imminently.

This granular market sizing will not only guide manufacturing scale-up and operational planning but also provide a credible foundation for discussions with potential U.S. commercial partners, payors, and investors. By quantifying the true scope of the market opportunity with precision, CLEO will be equipped to negotiate from a position of strength, accelerate strategic decision-making, and instil confidence across its stakeholder base.

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

During the Quarter, CLEO has continued to recruit patients into its pivotal U.S. clinical trial, with the addition of several high-volume metropolitan surgical centres. Trial recruitment is estimated for completion by Q1 CY2026. Following recruitment completion, samples will be tested using commercial test kits. Analysis of sample results is scheduled within the same Quarter, with completion timing dependant on commercial kit manufacturing.

Market Activities

During the Quarter, CLEO attended several industry, corporate and investor events including:

- Bioshares Biotech Summit in Hobart (6th - 8th August)
- TechKnow Invest Roadshow (19th August)
- JMM Sydney Opera House Event (subsequent to Quarter end on 22nd October)

CORPORATE

The Company had cash reserves of A$4.6m as at 30 September 2025.

Annual Report

The Company released its Financial Year 2025 Annual Report. A copy can be found in the Investor/Reports section of the CLEO website or using at link: https://bit.ly/COVFY25AnnualReport.

Use of Funds

A comparison of the use of funds since the date of admission, to the use of funds statement contained within the Company's Prospectus, as required by ASX Listing Rule 4.7C.2 is as follows:

Allocation of funds*	Expenditure described in Use of Funds in Prospectus ($'000)	Actual use of funds Quarter End 30 Sept 2025 ($'000)
Year One		
Triage Test	$1,486	$1,351
Screening Test and Recurrence Test	$200	- [1]
Antibody manufacturing and other business development	$2,125	$100 [1]
General administration and working capital^	$1,045	$1,255
Costs of the Offer#	$1,082	$1,030
Infrastructure, equipment, lab space	$240	$36
TOTAL	**$6,178**	**$3,772**
Year Two		
Triage Test	$2,410	$833
Screening Test and Recurrence Test	$2,154	$1,929
Antibody manufacturing and other business development	$200	$914
General administration and working capital^	$1,186	$1,371
Costs of the Offer#	-	-
Infrastructure, equipment, lab space	$240	$254
TOTAL	**$6,190**	**$5,301**

* Refer to the Cleo Replacement Prospectus of 18 August 2023 for full details.

^ Working capital to be applied towards funds required to expand the business and administration costs associated with the Company. These costs include costs for wages, occupancy costs, consultant fees, compliance, administration and reporting costs associated with running an ASX-listed company. Working capital also includes surplus funds and funds that may be applied to future acquisitions.

The expenses paid or payable by the Company in relation to the Offers are summarised in Section 8.8 of the Prospectus.

[1] The Company expects that such costs will be incurred in the forthcoming year.

PAYMENTS TO RELATED PARTIES

As outlined in section 6 of the attached Appendix 4C, payments to related parties of the entity and their associates, totals $150k, relate to fees and salaries paid to executive and non-executive Directors during the Quarter.

-ENDS-

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

For more information, contact:

Richard Allman
Chief Executive Officer
+613 9614 0000
office@cleodx.com

Dayna Louca
Head of Corporate Development
+61 409 581 972
dayna.louca@cleodx.com

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.

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	30 SEPTEMBER 2025

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	-	-
1.2	Payments for		
	(a) research and development *(including R&D staff costs)*	(1,489)	(1,489)
	(b) product manufacturing and operating costs		-
	(c) advertising and marketing	(31)	(31)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(165)	(165)
	(f) administration and corporate costs	(270)	(270)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	93	93
1.5	Interest and other costs of finance paid		-
1.6	Income taxes paid		-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)		-
1.9	**Net cash from / (used in) operating activities**	**(1,862)**	**(1,862)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(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:		
	(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**	**-**	**-**

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	-	-
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.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,461	6,461
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,862)	(1,862)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**4,599**	**4,599**

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	1,599	748
5.2	Call deposits	3,000	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)**	**4,599**	**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.

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)	(1,862)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,599
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,599
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.5

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: 31 October 2025

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.