ASX Announcement

June 2025 Quarterly Activities Report

Highlights

- **U.S. clinical trial recruitment ongoing and on track for completion by Q4 2025**
- **Alpha testing completed delivering a critical milestone toward commercial production of CLEO's first Ovarian Cancer diagnostic test**
- **Access granted to world renowned biobanks to support two pivotal studies focused on pre-surgical and screening markets, including:**
  - **U.S. based PLCO biobank, considered a 'gold standard resource' from one of the largest and most influential longitudinal cancer studies conducted to date**
  - **UKCTOCS, the world's largest ovarian cancer screening trial conducted to date.**
- **$845k Research and Development Tax Incentive received for FY24**
- **CLEO remains focused on submission to FDA to enable access to first U.S. patient markets in 2026**
- **A$6.46m cash at bank as at 30 June 2025.**

MELBOURNE, AUSTRALIA, 21st July 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 June 2025 Quarter (**the Quarter**) as it develops its simple and accurate blood test for the early detection of ovarian cancer.

U.S Clinical Trial Update

CLEO's pivotal FDA-enabling clinical trial continues to recruit patients in the U.S. Initial clinical trial recruitment has been focused on regional general practice clinics to satisfy patient diversity requirements in-line with FDA guidelines. The next and final phase of recruitment is targeting high-volume metropolitan surgical centres.

During the Quarter, CLEO announced additional centres were in the final stages of onboarding *(refer to ASX Announcement dated 25th June 2025*). The Company is pleased to confirm that the University of Florida, Jacksonville is now actively recruiting, and the Cleveland Clinic, Columbia University Medical Centre and Beth Israel Deaconess Medical Centre / Dana Faber Cancer Institute are expected to commence patient recruitment by the end of July. The remaining sites, including Rush University Medical Centre, Yale University Medical Centre, and Duke University Medical Centre, are scheduled to commence recruitment in August.

Together with existing recruitment sites, CLEO remains on track to meet its completion target of Q4 CY2025.

Alpha Testing Completion

Alpha testing involved in-house testing of 120 blood samples using fully functional commercial prototypes provided by R&D Systems, a Food and Drug Administration (**FDA**) approved Contract Manufacturing Organisation (**CMO**). Testing confirmed performance metrics of the individual assay components across analytical precision, reproducibility and measurement range.

The Company is aligning these observations with customer needs expectations and laboratory workflows as we progress to manufacturing and scale-up.

Strategic Biobank Partnerships to Strengthen Regulatory and Clinical Pathway

During the Quarter, CLEO announced the Company was granted access to two world renowned biobanks, including the United Kingdom Collaborative Trial of Ovarian Cancer Screening (**UKCTOCS**) biobank (*refer to ASX Announcement dated 28th April 2025*) and the Prostate, Lung, Colorectal and Ovarian (**PLCO**) biobank (*refer to ASX Announcement dated 25th June 2025)*. CLEO will use samples from the biobanks to conduct the following two studies:

- **Study 1:** Pre-Surgical Market – Evaluation of the ability for CLEO's Pre-Surgical Test to correctly discriminate a benign from malignant adnexal mass in a prospectively collected cohort; and
- **Study 2:** Screening Market – Evaluation of CLEO's technology to improve early detection and increase diagnostic lead time (targeting cancer identification up to three years prior to diagnosis) in an average, asymptomatic population.

Access to these biobanks forms a critical pillar of CLEO's regulatory strategy. More specifically, it provides the Company with access to complementary longitudinal datasets encompassing both U.S. and U.K. populations. Leveraging these unique cohorts enhances the totality of clinical evidence to support CLEO's planned FDA 510(k) submission, and de-risks key regulatory and commercial milestones. Strategically, these agreements also advance CLEO's broader development pathway by enabling earlier assessment of test performance in asymptomatic populations, accelerating screening test development, and supporting future commercial claims.

In more detail, while CLEO's pivotal U.S. trials will provide the core evidence package, these additional studies can help to bolster the overall submission in multiple ways:

- Strengthens the totality of evidence using data from a US population, typically preferred by regulators;
- Pre-emptively addresses specific FDA questions that may arise prior to or during the submission review;
- Improves regulatory confidence;
- Helps to support labelling claims; and
- Enables a more efficient review process.

Crucially, CLEO's studies will progress in a sample population that accurately reflects real-world ovarian cancer incidence. This is essential to generate meaningful, translatable performance metrics – critical for clinical adoption, payer reimbursement, and regulatory approval.

About the PLCO Trial

The PLCO Cancer Screening Trial is one of the largest and most influential longitudinal cancer studies conducted in the U.S. to date. Sponsored by the NCI, it enrolled over 155,000 participants and followed them for more than a decade. The PLCO biobank contains extensively annotated, rigorously collected biospecimens, offering a gold-standard resource for the development of early cancer detection technologies. Access to this cohort is highly competitive and reflects the quality, scientific credibility, and strategic importance of CLEO's diagnostic program.

This milestone marks a significant advancement in CLEO's clinical development journey, reinforcing the Company's commitment to improving early detection and outcomes in ovarian cancer.

About the UKCTOCS Trial

The UK Collaborative Trial of Ovarian Cancer Screening is a multi-centre randomised controlled trial conducted by the Medical Research Council (**MRC)** Clinical Trials Unit at UCL that evaluated whether it would be possible to save lives using population screening to detect Ovarian Cancer earlier. In the UK, Ovarian Cancer causes more deaths than all the other gynaecological cancers combined. Majority of patients present with advanced disease, which is associated with poor survival. In contrast, five-year survival rates for women diagnosed with Stage I Ovarian Cancer are over 90%, suggesting that early detection through screening is likely to improve outcomes.

The trial involved over 200,000 postmenopausal women aged 50-74 in the UK, who donated their data and over 500,000 samples for secondary studies. UKCTOCS ran for more than 20 years and is estimated to have cost around £30 million. Funding was provided by the MRC, National Institute for Health and Care Research (**NIHR**), Cancer Research UK, and The Eve Appeal (charity funding).

The UKCTOCS trial ultimately concluded that current Ovarian Cancer screening measures cannot be recommended in the general population. In addition to the following:

- Current gold-standard tests comprising CA-125 and ultrasound were not suitable for screening average-risk women
- Annual multimodal screening (**MMS**) using the CA-125 blood test and Risk of Ovarian Cancer Algorithm (**ROCA**) and second line transvaginal ultrasound resulted in a 10% reduction in late-stage diagnoses, but this did not translate into a reduction in deaths due to Ovarian Cancer
- Due to the lack of mortality reduction, routine Ovarian Cancer screening for asymptomatic average risk women using current testing technologies is not recommended
- Research using large-scale valuable data and samples collected prior to cancer diagnosis in one of the largest trial biobanks may help refine future detection methods to identify better screening strategies.

Given the emergence of novel diagnostic tests, UCL is looking to leverage the bioresource established during UKCTOCS to find and assess Ovarian Cancer screening technologies that can detect the disease early enough to reduce the impact on mortality.

Market Activities

During the Quarter, CLEO completed various market activities summarised below in addition to ongoing shareholder engagement and corporate meetings.

Date	Activity	Link
29th April 2025	**UKCTOCS Presentation**	Click here
12th June 2025	**Updated Investor Presentation**	Click here
25th June 2025	**Investor Webinar and Q&A**	Click here

The Company will also be attending the upcoming 19th Bioshares Biotech Summit in Hobart on the 6th- 8th August, and presenting at the TechKnow Invest Roadshow on the 19th August in Melbourne.

CORPORATE

The Company had cash reserves of A$6.46m as at 30 June 2025.

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 ($'000)	Actual use of funds - Quarter Ended 30 June 2025 ($'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	$794
Screening Test and Recurrence Test	$2,154	$1,235
Antibody manufacturing and other business development	$200	$526
General administration and working capital^	$1,186	$906
Costs of the Offer#	-	-
Infrastructure, equipment, lab space	$240	$103
TOTAL	**$6,190**	**$3,564**

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

^ Working capital expenditure is to be applied towards funds required to expand the business and towards administration costs associated with the Company. These costs include costs for wages and salaries, occupancy costs, professional consultants' fees, compliance and reporting costs associated with running an ASX-listed company, as well as other typical administration costs. 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 A$147k, 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.

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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 CXCL10 biomarker, 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 10 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 JUNE 2025

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	-	-
1.2	Payments for		
	(a) research and development *(including R&D staff costs)*	(657)	(3,020)
	(b) product manufacturing and operating costs		-
	(c) advertising and marketing	(21)	(91)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(143)	(488)
	(f) administration and corporate costs	(56)	(464)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	70	308
1.5	Interest and other costs of finance paid		-
1.6	Income taxes paid		-
1.7	Government grants and tax incentives	845	845
1.8	Other (provide details if material)		-
1.9	**Net cash from / (used in) operating activities**	**38**	**(2,910)**

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	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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)	-	-
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	6,425	9,373
4.2	Net cash from / (used in) operating activities (item 1.9 above)	38	(2,910)
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)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**6,461**	**6,461**

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	748	1,274
5.2	Call deposits	5,713	5,151
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)**	**6,461**	**6,425**

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*	147
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)	38
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,461
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,461
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: 21/07/2025.....

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.