ASX Announcement

September 2026 Quarterly Activities Report

Highlights

- **Analytical Validation in progress following receipt of first batch of test kits**
- **Statement of Work executed with CLIA-certified U.S. laboratory, Asuragen, to undertake the pivotal Clinical Validation testing program**
- **Screening Test development program commenced with initial proof-of-concept study exceeding performance thresholds**
- **Two new provisional patent applications filed relating to candidate biomarker combinations and their application to the early detection of ovarian cancer**
- **510(k) FDA submission remains on track for H1 CY2027**
- **Company well-funded to execute on key clinical, regulatory and commercial milestones with cash balance of A$4.4m as at 30 September 2026.**

30 October 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 for the September 2026 Quarter (**the Quarter**). During the Quarter, CLEO advanced the regulatory validation pathway for its lead Pre-Surgical Ovarian Cancer Test while progressing its broader ovarian cancer screening strategy.

First Production Batch of Test Kits Received; Analytical Validation Progressing

During the Quarter, CLEO received the first production batch of commercial test kits manufactured by Bio-Techne Corporation (**NASDAQ:TECH**), marking an important step in the Company's transition from assay development into formal regulatory validation. The kits were subject to routine internal verification and associated quality documentation before commencement of formal AV testing.

CLEO's AV program is designed to evaluate three independently manufactured batches to establish assay precision, reproducibility, manufacturing consistency and analytical robustness. The resulting dataset will form a key component of the evidence package supporting the planned U.S. FDA 510(k) submission. Following the AV assay precision studies and finalisation of the commercial assay algorithm, CLEO intends to progress to CV testing at the end of November, with results expected in January. The Company continues to target FDA 510(k) submission in H1 CY2027.

U.S. Clinical Validation Laboratory Engaged

In September, CLEO executed a Statement of Work with Asuragen, Bio-Techne's CLIA-certified U.S. laboratory, to conduct the pivotal clinical testing program for the Pre-Surgical Ovarian Cancer Test. The engagement establishes the laboratory infrastructure for testing prospective samples collected through CLEO's pivotal U.S. clinical trial, alongside confounding-condition and other control samples.

Preparatory work includes assay transfer, laboratory establishment, sample procurement and finalisation of study protocols. The integrated relationship with Bio-Techne across kit manufacturing, the Ella™ testing platform and clinical testing is intended to support a coordinated validation program. Clinical testing will follow completion of the requisite analytical validation and algorithm finalisation activities.

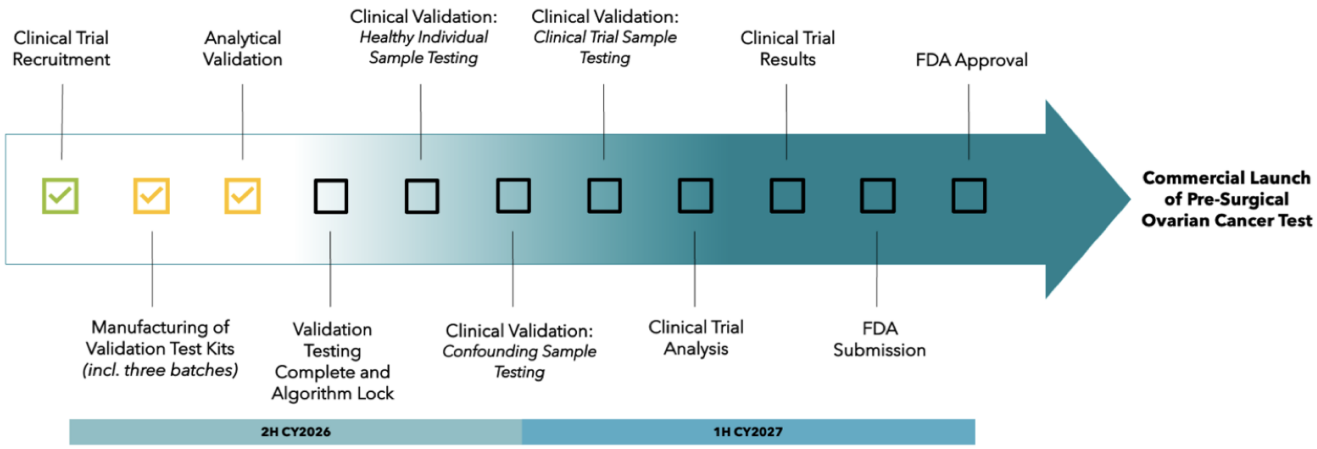


Figure 1: CLEO's remaining major milestones prior to FDA submission

Ovarian Cancer Screening Test Development Program Commences

During the Quarter, CLEO advanced development of its ovarian cancer screening program, which aims to identify ovarian cancer risk in asymptomatic women. The program builds on CLEO's proprietary biomarker platform and is being investigated for potential applications in both high-risk and general-population screening.

Screening represents a longer-term expansion opportunity alongside the Company's lead pre-surgical triage product. CLEO's initial commercial focus remains the U.S. pre-surgical market, providing a defined regulatory and market-entry pathway while the screening program progresses through research and clinical development.

Market Activities

During the Quarter, Dayna Louca, Head of Corporate Development, presented at the following events in July and August:

- JMM East Coast Investor Lunch in Sydney on the 28 July;
- 20th Bioshares Biotech Summit in Queenstown on the 5 – 7 August.

Copies of these presentations will be available from Dayna Louca upon request.

Corporate Activities

The Company had cash reserves of A$4.4m as at 30 September 2026. Payments to related parties of the entity and their associates (*refer Section 6 of attached Appendix 4C*) totalled $200k and relate to fees and salaries paid to executive and non-executive Directors.

Subsequent Events

Screening Development Program – Proof-of-Concept Study Results

Following Quarter end, CLEO announced initial proof-of-concept results from its ovarian cancer screening program on 21 October 2026. The Company successfully met and exceeded its

performance targets, providing strong data to support the progression to the next stage of its screening development pathway.

CLEO's first-stage retrospective study was performed in a cohort of 247 women, comprising healthy individuals (n=87), women with benign gynaecological disease (n=67), and women with ovarian cancer (n=93); and included 62 cases of early (Stage I) ovarian cancer - representing the stage at which diagnosis has the greatest survival benefit.

To successfully clear this first hurdle, CLEO set minimum performance benchmarks informed by best-practice [1,2] for the following intended-use cases:

(i) **High-risk population screening:** Minimum 90% sensitivity and 90% specificity, targeting women with hereditary or genetic factors that predispose to ovarian cancer development;

(ii) **General population screening:** Minimum 75% sensitivity and 99.6% specificity, targeting asymptomatic women within the broader population.

CLEO's Screening Test performance for (i) early-stage cancer (ii) all-stage cancer is summarised below:

Intended Target Population	**High Risk Population** (sensitivity % / specificity %)	**General Population** (sensitivity % / specificity %)
Minimum requirement	90% / 90%	75.0% / 99.6%
Stage I cancer detection	**92.2% / 98.7%**	**75.0% / 100.0%**
All-stage cancer detection	**90.2% / 97.4%**	**75.8% / 100.0%**

***Table 1: CLEO Prototype Screening Test Performance**. Sample size n=247, including 62 Stage I cancers. Results are estimates from a retrospective proof-of-concept cohort and require confirmation in larger, independent and intended-use populations.*

These results represent an early research milestone and should be distinguished from prospective clinical validation or regulatory clearance.

CLEO Files Patents for its Ovarian Cancer Screening Test

The Company announced that it filed two new provisional patent applications to protect intellectual property (**IP**) arising from the development of its screening test.

The filings followed the commencement of its screening development program (refer to ASX Announcement dated 24 September 2026) and establish an initial priority position around candidate biomarker combinations and their application to the early detection of ovarian cancer.

CLEO also intends to file an international application under the Patent Cooperation Treaty (**PCT**) within the 12-month priority period as it seeks protection across key commercial markets. Importantly, the applications were filed ahead of CLEO's initial proof-of-concept screening data results. The Company continues to progress development while protecting IP generated through the program.

Development of the screening test builds on the biomarker platform and clinical expertise established through CLEO's more advanced Pre-Surgical Ovarian Cancer Test program, which is progressing towards FDA submission. The new filings further expand CLEO's existing IP portfolio and support the Company's broader strategy to apply its biomarker technology across multiple applications of the ovarian cancer detection pathway.

-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.

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 2026

	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)*	(2,757)	(2,757)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(50)	(50)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(219)	(219)
	(f) administration and corporate costs	(380)	(380)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	79	79
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**	**(3,327)**	**(3,327)**
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 (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**	**(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	1,472	1,472
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**	**1,472**	**1,472-**

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,224	6,224
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,327)	(3,327)
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)	1,472	1,472

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**	**4,367**	**4,367**

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	2,867	1,159
5.2	Call deposits	1,500	5,065
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)**	**4,367**	**6,224**

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 and salaries*	200
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)	(3,327)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,367
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,367
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.3

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: No. The September 2026 quarter included significant research and development expenditure associated with the US clinical trial. As previously advised, recruitment for the trial has been completed and the Company has progressed to triage test development and activities associated with its planned FDA submission. The timing and nature of these activities are expected to result in variations in quarterly operating cash outflows. Accordingly, the Company does not expect the September quarter operating cash outflow to represent a consistent quarterly run rate.

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: At 30 September 2026, the Company held $4.367 million in cash and cash equivalents. The Company expects to receive a material R&D tax incentive refund in Q4 CY2026, although the final amount and timing of receipt remain subject to the relevant assessment and payment processes of the ATO. No specific capital raising initiatives are currently contemplated in the short term. Cleo continues to assess its future funding requirements and potential funding alternatives as part of its ordinary financial planning. No assurance can be given as to the availability or terms of any future financing.

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Yes. The Company's current cash-flow forecasts support its expectation that it can continue operations and progress its planned business objectives, taking into account existing cash resources, forecast expenditure and the anticipated R&D tax incentive refund. The Company will continue to monitor its cash position and align expenditure with the timing and priorities of its triage test development and planned FDA submission and screening activities. Further funding may be required to support longer-term objectives.

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: 30th October 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.