ASX Announcement

June 2026 Quarterly Activities Report

Highlights

- **CLEO on track to meet FDA 510(k) submission target of H1 CY2027, having entered the Analytical Validation phase following completion of all preparatory milestones**
- **Staged test kit manufacturing program commenced with Bio-Techne, with production of the first of three validation batches underway**
- **Reimbursement pathway established; CLEO to enter U.S market using miscellaneous CPT code 81599 immediately post-FDA clearance, enabling early billing and real-world utilisation data capture**
- **Company well-funded to execute on key clinical, regulatory and commercial milestones with cash balance of A$6.2m as at 30 June 2026.**

29th July 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 June 2026 Quarter (**the Quarter**) during which the Company continued to execute against its regulatory and commercial pathway to U.S. FDA submission and commercialisation of its blood test for the detection of ovarian cancer.

CLEO Commences Kit Manufacturing Program Ahead of FDA Submission

This major milestone follows the successful completion of patient recruitment and prospective blood sample collection for the Company's pivotal U.S. clinical trial (*refer to ASX Announcement dated 31 March 2026*). CLEO commenced its staged manufacturing program with Bio-Techne Corporation (**Bio-Techne**) in late April, establishing the pathway to produce clinical-grade test kits for analytical validation (**AV**) and FDA submission. This milestone materially de-risks CLEO's transition from development to commercial-scale production.

Work was completed during the Quarter on the development and optimisation of critical assay components, including antibody production and preparation of selected biomarkers within CLEO's proprietary biomarker panel. These activities are foundational to ensuring assay consistency, reproducibility and manufacturing readiness.

Following Quarter end, CLEO progressed the program into the formal AV phase as detailed below.

CLEO Enters Analytical Validation Phase

Subsequent to Quarter end (*refer to ASX Announcement dated 13th July* 2026), CLEO entered the formal AV phase. This phase is the first formal regulatory study of CLEO's commercial assay under a prescriptive FDA validation framework, which follows completion of assay development, key preparation activities and CLEO's kit manufacturing program with Bio-Techne (*refer above)*. From this

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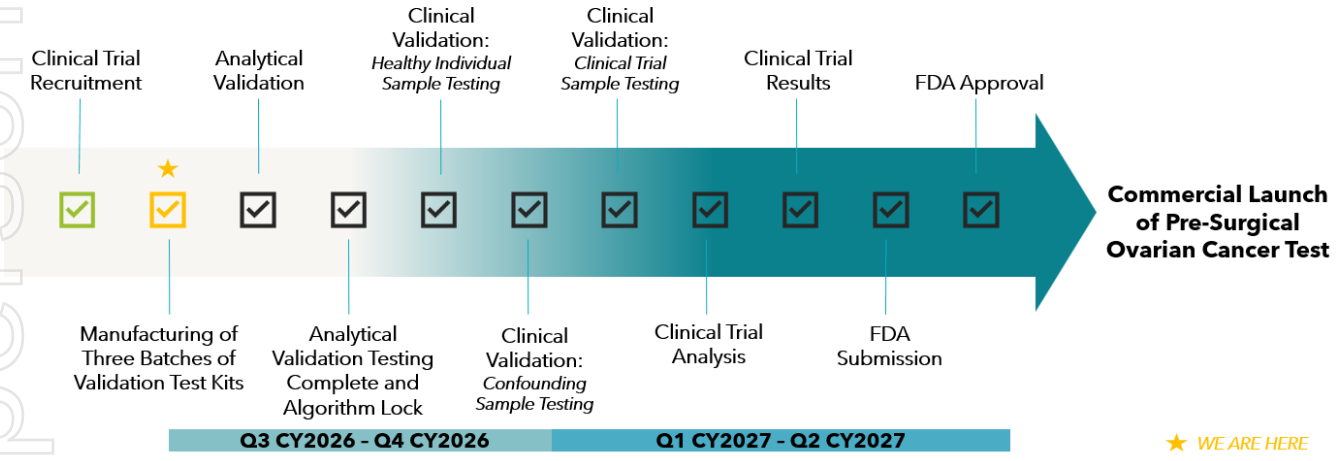
point forwards the Company's activities are focused on generating the analytical and clinical data required for regulatory submission.

In preparation for AV commencement, CLEO commissioned three additional Ella™ instruments which have arrived into the Company's facilities in Melbourne. Formal AV testing will commence upon receipt of CLEO's first production batch of test kits, expected from Bio-Techne in the coming weeks, generating the first major analytical dataset supporting the Company's planned FDA 510(k) submission.

As part of the study, CLEO will evaluate three independently manufactured production batches to demonstrate assay reproducibility, manufacturing consistency and overall analytical robustness. Successful completion of this three-batch validation program will generate the analytical evidence required to progress to Clinical Validation (**CV**), the final study supporting the Company's planned FDA 510(k) submission.

Preparations for CV are underway, including engagement of an external laboratory and finalisation of study protocols. Upon completion of AV, CV will evaluate the samples collected through the Company's pivotal U.S. clinical trial, together with confounding condition samples and healthy individual samples, finalising the clinical evidence package supporting CLEO's planned FDA submission.

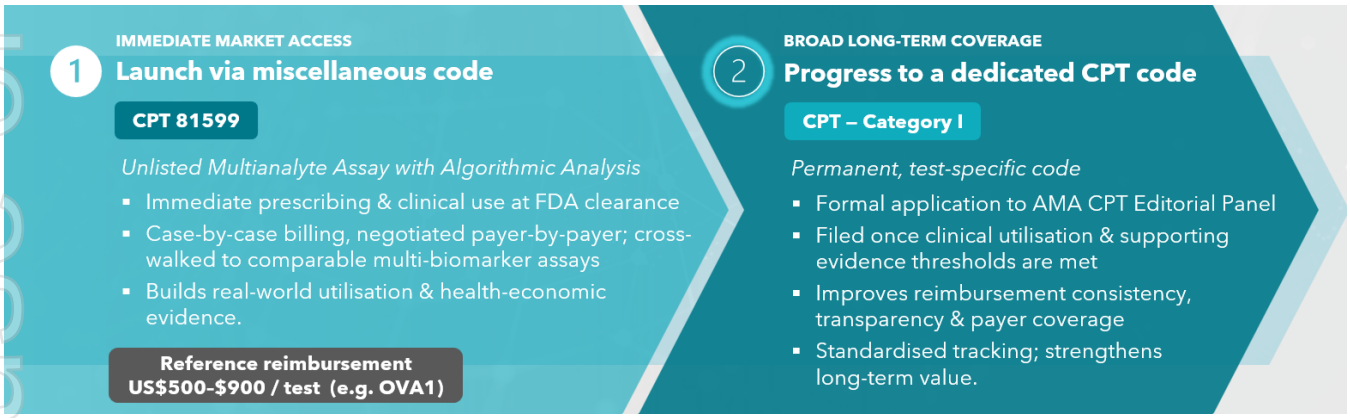
CLEO's development and regulatory pathway remain on track. Subject to any changes in the manufacturing timeline from Bio-Techne, AV is expected to take ~4 months to complete with The Company targeting FDA submission in H1 CY2027 (*refer to ASX Announcement dated 13th July* 2026).



U.S. Reimbursement Pathway Established to Support Early Revenue and Scalable Adoption

During the Quarter, CLEO established the first stage of its U.S. reimbursement strategy for its Pre-Surgical Ovarian Cancer Test (*refer ASX Announcement dated 20 May 2026*), representing a key milestone in the Company's commercialisation pathway ahead of its planned FDA submission. Following FDA clearance, CLEO intends to launch under the existing miscellaneous CPT code 81599, a recognised pathway for novel diagnostic tests entering the U.S. market. This approach will support immediate market entry, early revenue generation and the collection of real-world clinical and utilisation data.

Reimbursement under CPT code 81599 will be determined through cross-walking to comparable multi-biomarker diagnostic tests, which have reported reimbursement levels of approximately US$500–US$900 per test (payer dependent). CLEO's longer-term reimbursement strategy includes applying for a dedicated CPT code following initial commercial utilisation, supporting broader payer coverage and long-term commercial scale. In parallel, CLEO continues to advance health economics, budget impact modelling and key opinion leader engagement to support commercial adoption following FDA clearance.



Market Activities

During the Quarter, the Company presented at the Gold Coast Investment Showcase on the 11th – 12th June. In addition, Dayna Louca, Head of Corporate Development, will be presenting at the following upcoming events in July and August:

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

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

Corporate Activities

The Company had cash reserves of A$6.2m as at 30 June 2026. Payments to related parties of the entity and their associates (*refer Section 6 of attached Appendix 4C*) totalled $198k and relate to fees and salaries paid to executive and non-executive Directors.

-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 JUNE 2026

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)*	(1,026)	(4,824)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(111)	(286)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(531)	(1,225)
	(f) administration and corporate costs	(83)	(584)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	79	246
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,717
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,672)**	**(4,956)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(7)	(9)
	(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 (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(7)**	**(9)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	5,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	75	84
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(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**	**75**	**4,728**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,828	6,461
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,672)	(4,956)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(9)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	75	4,728

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**	**6,224**	**6,224**

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	1,159	2,187
5.2	Call deposits	5,065	5,641
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)**	**6,224**	**7,828**

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*	198
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)	(1,672)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,224
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,224
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.72

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 July 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.