

## March 2026 Quarterly Activities Report

### Highlights

- **Pivotal U.S. clinical trial sample collection completed, with >500 samples collected to support 510(k) FDA submission dataset**
- **Bio-Techne's Ella™ next-generation platform selected as CLEO's immunoassay instrument for its ovarian cancer blood test**
- **Biomarker panel optimised to improve analytical robustness, reproducibility and manufacturing readiness ahead of validation**
- **Staged manufacturing program commenced with Bio-Techne, advancing toward analytical validation and clinical sample testing**
- **Company well-funded to execute on key clinical, regulatory and commercial milestones with cash balance of A\$7.8m as at 31 March 2026.**

29<sup>th</sup> April 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 March 2026 Quarter (**the Quarter**) as it develops its simple and accurate blood test for the detection of ovarian cancer.

### Sample Collection Target Met for Pivotal U.S. Clinical Trial

During the Quarter, CLEO achieved its recruitment target for its pivotal U.S. clinical trial, marking the completion of a key milestone in the Company's clinical, regulatory and commercialisation pathway.

The Company has now successfully recruited 624 women across 19 clinical trial sites, with 514 samples from eligible patients in storage. The difference between enrolled patients and collected samples reflects standard clinical workflow timing, with final pathology confirmation required prior to inclusion in the FDA submission dataset.

Consistent with standard clinical trial practice, recruitment is continuing beyond the 500-women target to ensure sufficient usable samples for final analysis. This strategy recognises that not all recruited patients will ultimately yield complete blood samples and confirmed pathology suitable for inclusion in the final dataset.

Next steps to generate the clinical dataset required for FDA submission include:

- **Pre-verification:** internal readiness activities to confirm that CLEO's assay, kit components and testing workflow perform as expected prior to formal validation and subsequent clinical sample testing
- **Analytical validation:** formal demonstration that CLEO's assay, kit components and testing workflow perform consistently and reproducibly on the Ella™ platform, providing the technical foundation required to commence clinical sample testing

**Cleo Diagnostics Ltd** ASX:COV

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Directors  
Chair and Non-Executive Director **Adrien Wing**  
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**

- **Clinical sample testing:** testing of collected blood samples from the clinical trial in accordance with approved protocols to generate assay result data using the final CLEO test kit
- **Clinical data analysis and validation:** statistical analysis of assay results against confirmed pathology outcomes to evaluate test performance (e.g. sensitivity, specificity, NPV, PPV) and generate the clinical evidence package required for FDA 510(k) submission.

## Next-Generation Ella™ Platform Confirmed for Commercial Deployment

CLEO selected Bio-Techne's Ella™ platform as the commercial immunoassay system to deliver its ovarian cancer test, representing a key step in aligning the Company's technology with a scalable, automated and globally deployable diagnostic platform.

The Ella™ platform is an automated enzyme-linked immunosorbent assay (**ELISA**) platform designed to deliver accurate, reproducible data with reduced manual input. Using CLEO's test kit, patient blood samples are processed in a laboratory on the Ella™ platform. The platform enables automated, multiplex measurement of CLEO's biomarker panel within a standard laboratory workflow. Selection of Ella™ supports CLEO's strategy to deliver its test in a format compatible with existing laboratory infrastructure, facilitating adoption and scale post-approval.



Key benefits of Ella™ compared to traditional ELISA include:

- = Fast results (90-minute total run time versus 4+ hours per biomarker)
- = Simultaneous analysis of multiple biomarkers
- = Higher analytical sensitivity and precision
- = Reduced manual input and improved reproducibility
- = Scalability and consistency.

CLEO has been using the Ella™ platform in-house since September last year to confirm the platform's capability to deliver its ovarian cancer technology. The Company continues to conduct internal testing to assist in expediting its preliminary development activities in the U.S.

## Biomarker Panel Optimised to Improve Analytical Robustness & Commercial Manufacturability

CLEO optimised the biomarker panel underpinning its Pre-Surgical Ovarian Cancer Test. This included expanding the panel from five to eight biomarkers to support commercial-scale deployment and regulatory progression. The enhanced panel has been designed to improve analytical robustness, inter-assay reproducibility and manufacturing compatibility - key requirements for regulatory approval and broader clinical adoption. CLEO's proprietary CXCL10 biomarker remains central to the panel and continues to underpin the Company's core technology.

The original biomarker panel demonstrated strong diagnostic performance in distinguishing benign from malignant ovarian disease, providing a solid foundation for further development. Building on this, CLEO has expanded its in-house assay development over the past six months using the next-

generation Ella™ immunoassay platform, which enables simultaneous measurement of multiple biomarkers from a single sample without compromising efficiency, throughput or sample utilisation.

The expanded panel reduces single-marker dependency and enhances assay stability, supporting consistent performance across manufacturing batches and clinical testing. In parallel, CLEO has worked closely with its preferred manufacturing partner to align on the revised panel, leveraging their expertise to support efficient scale-up and further de-risk the transition to commercial manufacturing.

### CLEO Commences Kit Manufacturing Program Ahead of FDA Submission

Subsequent to Quarter end, CLEO announced the commencement of its staged manufacturing program with Bio-Techne Corporation (**Bio-Techne**), 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.

Under this framework, key development and manufacturing activities are being progressed in defined phases ahead of full-scale kit production. Work has now commenced and is focused on the development and optimisation of critical assay components, including antibody production and preparation across selected biomarkers within CLEO's proprietary biomarker panel. These activities are foundational to ensuring assay consistency, reproducibility and manufacturing readiness.

Upon completion, CLEO will advance to AV, a critical milestone and core requirement for FDA submission. AV will establish the reliability and reproducibility of the test kits, establishing the technical foundation for clinical sample testing and regulatory submission.

### Market Activities

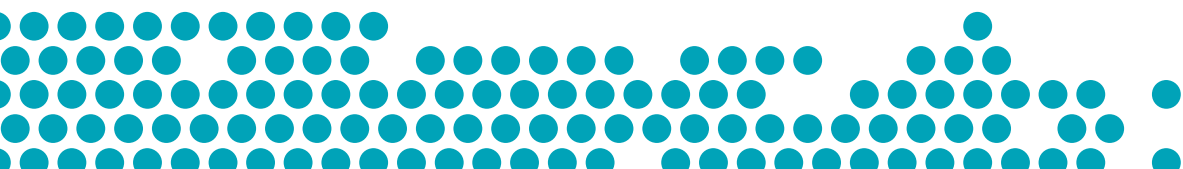
#### Ovarian Cancer Awareness Month

The Company supported a range of initiatives recognising Ovarian Cancer Awareness Month. Ovarian cancer remains the deadliest women's cancer, with ~49% five-year survival compared to ~92% for breast cancer. Outcomes are highly dependent on early and accurate detection; however, no reliable diagnostic test currently exists, with definitive diagnosis typically requiring invasive surgery.

CLEO is advancing a simple blood test designed to enable earlier and more accurate detection, with the potential to transform diagnostic pathways and improve patient outcomes.



Credit: Ovarian Cancer Australia



## Corporate Activities

The Company had cash reserves of A\$7.8m as at 31 March 2026. Payments to related parties of the entity and their associates (*refer Section 6 of attached Appendix 4C*) totalled \$154k 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

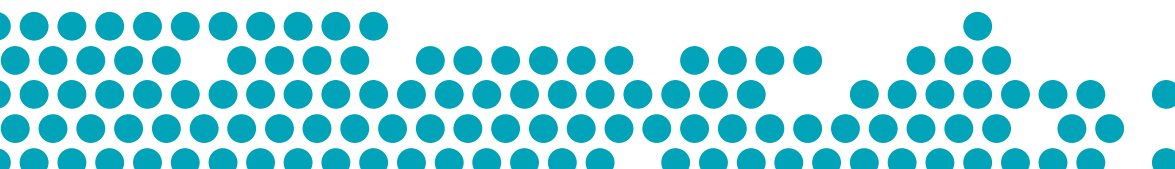
#### ABN

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#### Quarter ended ("current quarter")

31 MARCH 2026

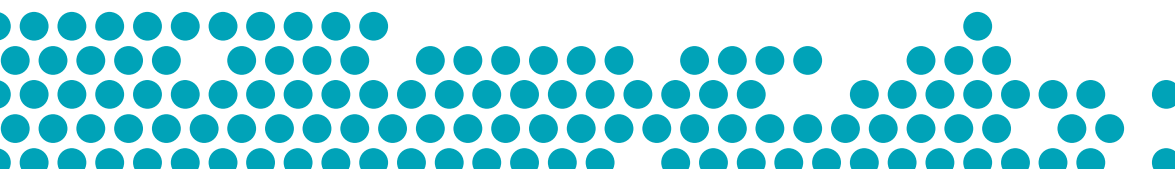
Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
<b>1.</b>	<b>Cash flows from operating activities</b>		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development ( <i>including R&amp;D staff costs</i> )	(1,118)	(2,680)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(38)	(137)
	(d) leased assets	-	-
	(e) staff costs ( <i>excluding R&amp;D staff costs</i> )	(379)	(315)
	(f) administration and corporate costs	(101)	(400)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	38	129
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,717
1.8	Other (provide details if material)	-	-
<b>1.9</b>	<b>Net cash from / (used in) operating activities</b>	<b>(1,598)</b>	<b>(1,686)</b>
<b>2.</b>	<b>Cash flows from investing activities</b>		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(2)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-



<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>(2)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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	-	9
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>4,653</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	9,426	6,461
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,598)	(1,686)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(2)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	4,653

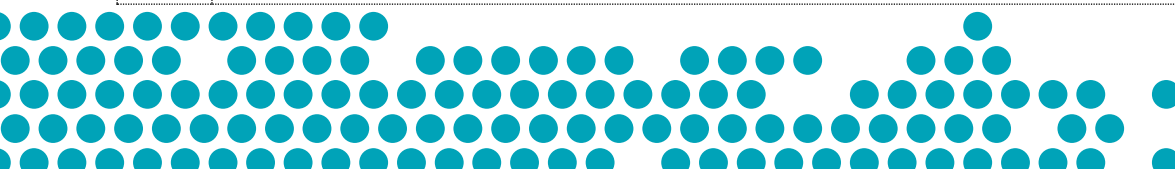


<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>7,828</b>	<b>9,426</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	2,187	6,399
5.2	Call deposits	5,641	3,027
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>7,828</b>	<b>9,426</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1 <i>Payment to Directors fees</i>	154
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

<b>7.</b>	<b>Financing facilities</b> <i>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.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	<b>Total financing facilities</b>	-	-
7.5	<b>Unused financing facilities available at quarter end</b>		-
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.		
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8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,598)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,828
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,828
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	4.9
<p><i>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.</i></p>		
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	
<p><i>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.</i></p>		

## 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 April 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.

