ASX Announcement

CLEO Commences Ovarian Cancer Screening Test Development

Highlights

- **Prototype development of CLEO's multi-marker screening blood test is underway**
- **Screening represents a $150B global addressable market for population screening, to identify early-stage ovarian cancers in asymptomatic women**
- **Screening test development will run in parallel with CLEO's initial pre-surgical test that is on track for FDA submission in H1 CY2027**
- **Initial proof-of-concept screening test data expected early next Quarter, with the Company targeting finalisation of test panel architecture by end of CY2026.**

24th September 2026: Ovarian cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce it has commenced prototype development of its multi-biomarker screening blood test, targeting the Company's ultimate $150B global addressable market for population screening to identify early-stage ovarian cancers in asymptomatic women.

Advancing CLEO's Staged Commercial Strategy

CLEO's strategy is to address all ovarian cancer diagnostic markets in phased execution – from a $1.6B near-term pre-surgical triage entry point to a $150B+ transformative screening opportunity.

The Pre-Surgical Ovarian Cancer Test remains CLEO's primary commercial product, which is progressing towards scheduled FDA 510(k) submission in H1 CY2027.

In parallel, commencement of screening test development represents the next stage of CLEO's growth strategy, targeting a substantially larger addressable market while leveraging the Company's existing biomarker technology, clinical datasets and development infrastructure. The development work is being progressed as a separate workstream and does not alter the Company's current regulatory and commercial focus on advancing it's Pre-Surgical Ovarian Cancer Test toward U.S. market entry.

The program also builds on the Company's prior investment in establishing access to two internationally significant screening biobanks that provide representative intended-use populations for future development and evaluation. This includes its collaboration with University College London (**UCL**) to access the UK Collaborative Trial of Ovarian Cancer Screening (**UKCTOCS**) biobank (*refer to ASX Announcement dated 28th April 2025*) and its granted access to the parallel Prostate, Lung, Colorectal and Ovarian (**PLCO**) biobank in the U.S. (*refer to ASX Announcement dated 25th June 2025*).

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CLEO's approach is deliberately designed to address the screening gap by setting a rigorous, evidence-based performance bar before development begins, to proactively construct ovarian cancer screening tools that provide real risk detection for tangible survival benefit.

Performance Requirements Established for Screening

Ovarian cancer screening presents different performance requirements to pre-surgical triage due principally to the significantly lower prevalence of ovarian cancer within asymptomatic populations. The Company will pursue the following minimum performance requirements, based on best-practice screening literature.

Target Population	Minimum Sensitivity	Minimum Specificity
High-risk (e.g. hereditary) screening	90.0%	90.0%
General population screening	75.0%	99.6%

Table 1 – Targeted Minimum Performance Thresholds for Screening Test

These thresholds are set according to calculated predictive probabilities required for clinical use, accounting for both negative and positive predictive values (**NPV** and **PPV**) appropriate to a low-prevalence disease. A high specificity bar is required for general population screening, where false positive results carry significant downstream cost and patient impact. These targets are intended to support both clinical credibility and regulatory positioning as the program progresses.

Staged Evaluation Pipeline Designed to Build Confidence and Reduce Risk

CLEO will progress the screening test through a staged evaluation pipeline:

1. **Initial proof-of-concept studies** using a 250-patient cohort, specifically enriched for Stage I ovarian cancers, to establish initial proof-of-concept performance
2. **Bridging and secondary confirmation studies** in an expanded cohort to confirm overall performance with improved statistical power
3. **Evaluation in prospectively collected intended-use populations**, reflecting real-world screening conditions across both high-risk and general population settings.

This staged design allows the Company to build statistical confidence progressively, reducing technical and regulatory risk before committing to evaluation in prospective clinical trials. CLEO is aiming to confirm first proof of concept screening test data early in the next quarter, with the Company targeting finalisation of test panel architecture by end of CY2026.

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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

Cleo Diagnostics (ASX:COV) is an Australian medical technology company developing a simple blood test for the early and accurate detection of ovarian cancer – a disease with the highest five-year mortality rate of all cancers affecting women, with 51% of patients dying within five years, primarily due to late diagnosis and the lack of effective screening tools. Each year, hundreds of thousands of women are diagnosed only after the disease has advanced, highlighting a critical unmet need for earlier detection.

CLEO's patented technology is based on the CXCL10 biomarker, supported by over 15 years of scientific research and development. CXCL10 is produced early and at high levels in ovarian cancer but is largely absent in benign disease, making it a powerful discriminator between malignant and non-malignant growths.

The Company is executing a staged development strategy, starting with a pre-surgical triage test, then expanding into recurrence monitoring and ultimately global screening – creating clear value inflection points along the ovarian cancer detection pathway. CLEO is currently conducting its pivotal clinical trial, with FDA submission and commercial launch expected next year, reinforcing its goal to redefine the standard of care and enable earlier, smarter, life-changing diagnosis for women worldwide.