CLEO Enters Analytical Validation Phase

Highlights

- **Following completion of commercial assay development and key preparation activities, CLEO now enters the formal pre-FDA submission validation phase**
- **Analytical validation expected to commence next month upon receipt of first manufactured batch of CLEO's test kits from Bio-Techne**
- **Three-batch validation design adopted to demonstrate assay reproducibility and manufacturing consistency in accordance with FDA requirements**
- **Clinical validation preparations advanced, supporting efficient progression towards FDA 510(k) submission in CY2027.**

13th July 2026: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce it has completed the final development and preparation activities required to commence Analytical Validation (**AV**), marking the Company's transition into the formal phase of data collection 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*), and the commencement of CLEO's kit manufacturing program with Bio-Techne (*refer to ASX Announcement dated 28 April 2026*). From this point forward, the Company's activities are focused on generating the analytical and clinical data required for regulatory submission.

In preparation for AV commencement, CLEO has commissioned three additional Ella™ instruments, which have now arrived into the Company's facilities in Melbourne. Testing is due to commence upon receipt of CLEO's first production batch of test kits that are expected from Bio-Techne next month, generating the first major analytical dataset supporting the Company's planned FDA 510(k) submission. AV is the first formal regulatory study performed using CLEO's commercial assay. Unlike the research, optimisation and development activities completed to date, AV is conducted under a prescriptive validation framework designed to demonstrate the analytical performance of the test kit under FDA requirements.

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

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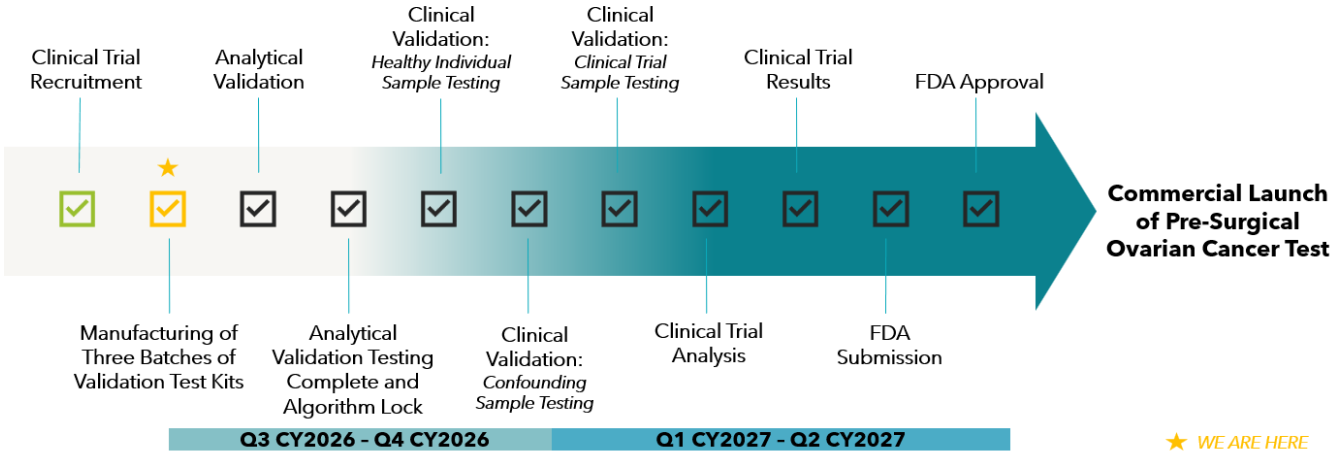
Company's pivotal U.S. clinical trial, together with confounding condition samples and healthy individual samples, generating the clinical evidence package supporting CLEO's planned FDA submission.

Subject to any changes in the manufacturing timeline from Bio-Techne, the Company expects AV to take ~4 months to complete. Based on the above, CLEO anticipates FDA submission to occur in H1 CY2027.

Remaining Pathway to FDA Submission

CLEO expects to progress through the remaining major regulatory milestones supporting its planned FDA submission:

- Analytical validation (including testing of three production batches)
- Finalisation of commercial assay algorithm
- Clinical validation (including testing of pivotal clinical trial and control samples)
- Clinical data analysis and trial results
- FDA 510(k) submission.



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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.

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