ASX Announcement

CLEO Receives First Batch of Commercially Manufactured Test Kits

Highlights

- **Analytical Validation set to commence following receipt of first production batch of test kits manufactured by Bio-Techne (NASDAQ:TECH)**
- **Three independently manufactured batches will be evaluated to demonstrate assay precision, reproducibility, manufacturing consistency and analytical robustness**
- **First batch to establish core performance characteristics of CLEO's eight-biomarker assay, providing reference for subsequent production batches to be evaluated**
- **AV will generate critical analytical performance data required to progress CLEO's commercial assay into next clinical validation phase**
- **CLEO continues to target planned FDA 510(k) submission in H1 CY2027.**

3rd September 2026: Ovarian cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce that Analytical Validation (AV) of its Pre-Surgical Ovarian Cancer Test is set to commence, following receipt of the first production batch of commercial test kits manufactured by Bio-Techne (**NASDAQ: TECH**).

Manufacturing and delivery of batch 1 follows completion of assay development and optimisation activities required to translate CLEO's technology into its commercial test format and represents a significant milestone in the Company's regulatory program. CLEO received 125 test kits as part of the first batch, which will now undergo standard internal quality control and documentation procedures ahead of formal commencement of Analytical Validation (**AV**). CLEO expects this process to take 1-2 weeks.

AV is designed to demonstrate that the assay performs reliably and reproducibly from an analytical perspective, generating a critical component of the regulatory evidence required to support the Company's planned FDA 510(k) submission in H1 CY2027.

Analytical Validation Program

CLEO's AV program will evaluate three independently manufactured production batches of commercial test kits manufactured by U.S.-based Bio-Techne. The program is designed to establish the analytical performance of CLEO's eight-biomarker assay and demonstrate that this performance can be reproduced consistently across separate manufacturing runs.

Testing of the first production batch will establish the core analytical performance characteristics and validated operating parameters for each of the eight biomarkers comprising CLEO's commercial

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assay. This will provide the foundational reference dataset against which subsequent independently manufactured production batches will be evaluated.

The second and third production batches will then be used to demonstrate that the analytical performance established through the first batch is reproducible across independent manufacturing runs and is not dependent on an individual production lot.

Evaluation across three independently manufactured batches therefore provides important evidence of both assay robustness and manufacturing consistency, demonstrating that CLEO's commercial test can deliver consistent analytical performance as the Company progresses towards regulatory submission and future commercial production.

CLEO currently anticipates receiving the second and third production batches from Bio-Techne during Q4 CY2026, with testing to occur as part of the ongoing AV program. The Company is targeting completion of AV by the end of CY2026.

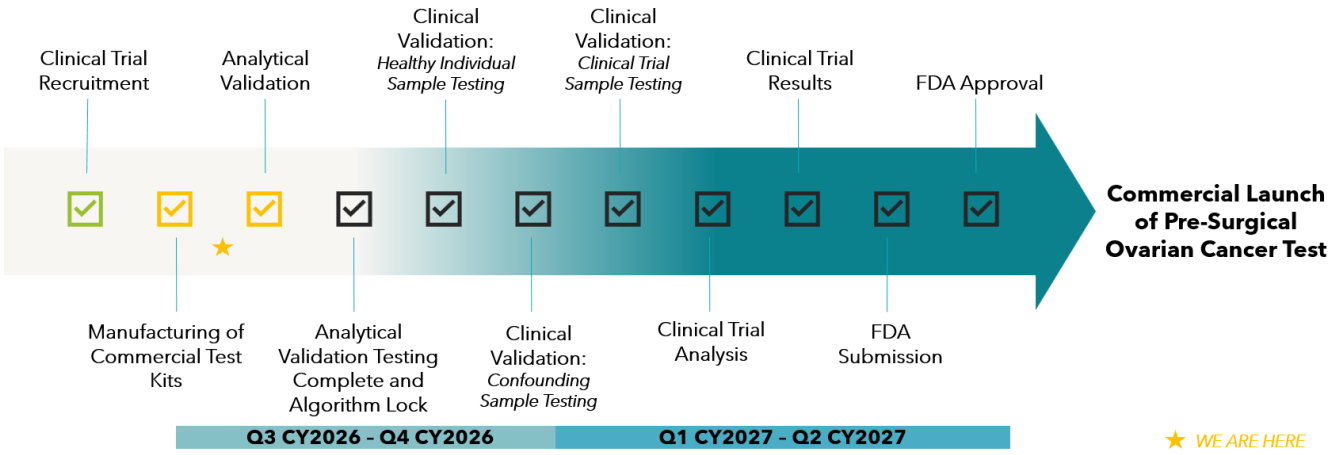
Remaining Pathway to FDA Submission

AV represents the commencement of the formal validation phase required to generate the analytical and clinical evidence supporting CLEO's planned FDA 510(k) submission. Following successful completion of AV and finalisation of the commercial assay algorithm, CLEO will progress into Clinical Validation (**CV**), which will evaluate the test's clinical performance in its intended patient population.

CV will include analysis of the prospective blood samples already collected through CLEO's pivotal U.S. clinical trial, together with samples from healthy individuals and patients presenting with relevant confounding conditions. Preparations for CV are well underway, with the Company in final negotiations with a CLIA-certified laboratory to conduct the clinical testing program.

The remaining major milestones prior to FDA submission are:

- 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; and
- FDA 510(k) submission.



CLEO's Chief Executive Officer, Richard Allman, commented:

"Receipt of the first batch of test kits is an important milestone for CLEO because it means we are almost ready to begin generating the formal regulatory data that will support our planned FDA submission. It also represents the culmination of significant work undertaken to translate CLEO's technology into a reproducible commercial assay. Importantly, our three-batch validation program is designed to demonstrate that the performance of the test can be consistently reproduced across independent manufacturing runs.

From here, the pathway is clearly defined. We will conduct AV across the three manufactured batches before progressing into CV, where we will generate the pivotal clinical performance data for our test.

With our prospective clinical samples already collected and the first commercial test kits now undergoing validation, we are entering an important period of execution for CLEO as we progress towards clinical results, FDA submission and ultimately commercialisation."

-ENDS-

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.