ASX Announcement

CLEO Commences Kit Manufacturing Program Ahead of FDA Submission

Highlights

- **Initial phase of staged manufacturing program now underway with Bio-Techne to support production of CLEO's test kits**
- **Follows completion of sample collection for CLEO's pivotal U.S. clinical trial, marking transition to analytical validation and clinical sample testing**
- **Staged approach designed to reduce technical and manufacturing risk ahead of full-scale test kit production and FDA 510(k) submission.**

28th April 2026: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce that it has commenced a staged manufacturing and development program with Bio-Techne Corporation (**Bio-Techne**) to support production of its ovarian cancer test kits, marking a key milestone towards analytical validation (**AV**) and FDA submission.

This announcement follows CLEO's recent milestone achievement of completing sample collection for its pivotal U.S. clinical trial, with patients recruited across 19 clinical trial sites (*refer to ASX Announcement dated 31st March 2026*). The Company has now transitioned into the final execution phase of its clinical and regulatory program, with commencement of manufacturing and assay development activities supporting progression through AV and subsequent clinical sample testing.

Bio-Techne (**NASDAQ: TECH**) is a leading global life sciences company with extensive expertise in immunoassay development and commercial-scale manufacturing. Its selection as CLEO's preferred partner brings proven capability in manufacturing and production, supporting CLEO's development, manufacturing and subsequent regulatory execution activities.

Initial Phase of Staged Manufacturing Program Underway

CLEO has adopted a staged manufacturing and development program with Bio-Techne, building on its established collaboration using Bio-Techne's Ella™ platform as the dedicated instrument to deliver its Pre-Surgical Ovarian Cancer Test (*refer to ASX Announcement dated 18th February 2026*). The Company has been utilising the Ella™ platform in-house and has confirmed its capability to deliver CLEO's biomarker panel with high sensitivity, precision and reproducibility.

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.

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Pathway to Clinical Trial Completion and FDA Submission

Commencement of the staged manufacturing program represents a key milestone as CLEO transitions from completion of trial sample collection into AV and clinical sample testing. The manufacturing program will generate the test kits required for AV and the subsequent evaluation of the clinical samples collected as part of the Company's pivotal U.S. study.

AV is a critical step and a key requirement for CLEO's planned FDA 510(k) submission, demonstrating reliable and reproducible performance of the test kits prior to clinical sample analysis. By progressing reagent development, antibody preparation and assay optimisation in a staged manner, CLEO is reducing technical and manufacturing risk ahead of full-scale kit production.

The data generated from AV and clinical sample testing will form the core evidence package for the Company's FDA 510(k) submission.

Next Steps

The Company is now focussed on executing the final development and validation activities required to generate the clinical dataset supporting its planned FDA 510(k) submission.

- Completion of reagent and antibody production, and finalisation of assay components for CLEO's test kits
- Manufacture of multiple production batches of test kits for use on the Ella™ platform supporting AV
- Completion of AV to demonstrate consistent and reproducible assay performance
- Testing of clinical trial samples using the validated test configuration
- Analysis of clinical trial data to generate the evidence package for FDA 510(k) submission.

Cleo Diagnostics Chief Executive Officer, Richard Allman, commented:

"Commencing our manufacturing program with Bio-Techne is an important milestone for CLEO as we transition from clinical sample collection into AV and sample testing.

The staged approach allows us to optimise critical assay components and reduce technical and manufacturing risk ahead of full-scale kit production. Importantly it enables generation of the data required to support our planned FDA 510(k) submission.

As a global leader in assay manufacturing, we have full confidence in Bio-Techne's ability to help deliver our project. With clinical sample collection completed and manufacturing activities now underway, CLEO is nearing the final execution phase of its U.S. clinical and regulatory program."

About Bio-Techne

Bio-Techne Corporation (NASDAQ: TECH) is a global life sciences company providing innovative tools and bioactive reagents for research and clinical diagnostic communities. Bio-Techne products assist scientific research into biological processes and the nature and progress of specific diseases. The Company aids in drug discovery efforts and provide the means for accurate clinical tests and diagnoses. With a substantial portfolio of products, Bio-Techne generated over $1.2 billion in net sales in fiscal 2025 and has approximately 3,100 employees worldwide.

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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

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.