ASX Announcement

CLEO Confirms Next Generation Platform to Deliver its Ovarian Cancer Test

Highlights

- **CLEO selects Bio-Techne's Ella™, a next-generation automated ELISA platform, as the immunoassay instrument for its ovarian cancer blood test**
- **Bio-Techne (NASDAQ: TECH) is a global developer, manufacturer and supplier of high-quality reagents, analytical instruments and immunoassay technologies**
- **The Ella™ platform can deliver materially improved assay sensitivity, precision and automation compared with conventional ELISA platforms**
- **Binding agreement discussions well progressed with Bio-Techne for analytical validation to enable sample testing and clinical trial completion**
- **Both parties aligned to enter long-term manufacturing supply agreement following completion of these activities.**

MELBOURNE, AUSTRALIA, 18th February 2026: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce that it has selected Bio-Techne's Ella™ platform to deliver its ovarian cancer technology to market.

Next-Generation Ella™ 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 uses microfluidic cartridges to measure CLEO's proprietary biomarker panel, which form the key inputs of the algorithm underpinning the Company's patented technology.

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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 Ella™ in-house since September last year and has confirmed the platform's capability to deliver its ovarian cancer technology. Both parties are well progressed in discussions to enter into a binding agreement to commence analytical validation (**AV**) of CLEO's test kits. To assist in this, Bio-Techne has already commenced preliminary development activities in the United States (**U.S.**), allowing for immediate commencement of work once formally engaged. Timeline to complete AV will be confirmed upon signing. The finished kits will then be used test the ~500 blood samples collected as part of CLEO's pivotal clinical trial.

Importantly, these results will allow for the completion of CLEO's clinical trial and form the primary data package of its upcoming 510(k) FDA submission. Both parties are aligned to enter into a long-term commercial supply agreement following successful completion of these activities.

Next Steps

1. Execute binding agreement with Bio-Techne
2. Commence kit manufacture for analytical validation
3. Analytical validation
4. U.S clinical trial sample testing
5. Analysis and results
6. FDA submission
7. Long-term commercial supply agreement.

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.