ASX Announcement

CLEO Completes Biomarker Panel Optimisation Ahead of FDA 510(k) Submission

Highlights

- **Biomarker panel expanded from five to eight biomarkers, improving analytical robustness, reproducibility and commercial manufacturability**
- **Optimised panel has been designed for high throughput Ella™ platform, supporting scalable global deployment without compromising performance**
- **Binding manufacturing agreement imminent, with partner aligned and experienced in development and production of the selected biomarkers**
- **Test kit production to support FDA analytical validation activities to commence immediately following execution.**

23rd March 2026: Ovarian cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce it has optimised the biomarker panel underpinning its Pre-Surgical Ovarian Cancer Test, expanding from five to eight biomarkers to support commercial-scale deployment and regulatory progression. The optimised panel has been specifically designed to improve analytical robustness, inter-assay reproducibility and compatibility with manufacturing processes – key requirements for regulatory approval and wider clinical adoption.

CLEO's original biomarker panel demonstrated strong diagnostic performance in distinguishing benign from malignant ovarian disease, establishing a solid foundation for the Company's development program. CLEO's patented CXCL10 biomarker remains central to the panel and continues to underpin the Company's proprietary technology.

Over the past six months, CLEO has undertaken expanded in-house assay development using the next-generation Ella™ immunoassay platform (*refer to ASX Announcement dated 18th February 2026*). The Ella™ platform's microfluidic cartridge architecture enables the simultaneous measurement of multiple biomarkers within a single sample, allowing expansion of the biomarker panel without compromising workflow efficiency, throughput or sample utilisation.

The inclusion of additional biomarkers reduces reliance on any single analyte, and mitigates variability often observed in early-stage assay production. This significantly strengthens assay reproducibility and reduces technical risk ahead of analytical validation and regulatory submission.

CLEO has also worked closely with its preferred manufacturing partner to align on the revised panel. The partner brings established expertise in the development and production of assays for these biomarkers, significantly reducing scale-up and manufacturing risk.

A binding agreement for kit manufacturing to support analytical validation activities is expected imminently. Manufacturing of analytical validation lots is anticipated to commence immediately following execution of this agreement, supporting CLEO's planned FDA 510(k) submission.

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

"This represents a critical milestone in transitioning CLEO's Pre-Surgical Ovarian Cancer Test from research into a commercial-ready kit.

The expanded biomarker panel improves assay robustness and reproducibility under real-world conditions, whilst maintaining strong clinical performance. Leveraging the capabilities of the Ella™ platform has allowed us to enhance our panel without compromising workflow.

Importantly, alignment with our manufacturing partner positions us to commence analytical validation imminently – the next key milestone towards our planned FDA submission and entry into the U.S. market."

-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

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.