29th December 2025

ASX Announcement

End of Year Letter to Shareholders

Dear Shareholders,

As we approach the end of 2025, on behalf of the Board of Directors, I would like to take this opportunity to thank you for your continued support of CLEO, and to reflect on a year of meaningful progress toward our mission to improve outcomes for women impacted by ovarian cancer.

Ovarian cancer remains one of the most lethal cancers impacting women globally, largely due to the absence of accurate and timely diagnostic tools and/or tests. Too often, diagnosis occurs late in the disease course when treatment options are limited, and survival rates are poor. This global clinical unmet need continues to underscore the importance of CLEO's technology and reinforces our commitment to advancing a simple, accurate blood-based test that can meaningfully change clinical decision-making and patient outcomes.

During 2025, CLEO achieved several important milestones that materially advanced the Company's strategy and positioned us for the next phase of growth. Key highlights included continued progress of our U.S. pivotal clinical trial activities, strengthening of our regulatory pathway toward FDA submission, significant expansion of our total addressment market, and advancement of our staged commercialisation framework that is designed to support early market entry, clinical adoption, and long-term reimbursement. We also expanded our engagement with key opinion leaders (**KOL**) and industry stakeholders, including the onboarding of our first KOL, ensuring CLEO's technology is aligned with real-world clinical needs and workflows.

Importantly, these achievements were delivered while maintaining a disciplined approach to capital management and execution, reflecting the Board's focus on building a sustainable platform capable of long-term global impact. Each step taken this year has been guided by a clear objective: to enable earlier and more accurate diagnosis of ovarian cancer and to support clinicians with more useful information at critical decision points.

Looking ahead to 2026, CLEO will remain firmly focused on execution. The coming year represents a pivotal period as we complete our U.S. clinical trial and advance to FDA 510(k) submission, commence commercial manufacturing, prepare for market launch, and continue to build the clinical and economic evidence required to support broad adoption. In addition, CLEO will increase its focus on the accelerated development of its mass screening program. The Company remains committed to transparent communication with shareholders as we advance through these milestones.

The Board is confident that CLEO's technology, underpinned by 15 years of R&D and a clear clinical value proposition, has the potential to address a significant global unmet need. This has been further

Cleo Diagnostics Ltd ASX:COV
Level 2, 480 Collins Street, Melbourne, VIC, 3000
ACN 655 717 169 **T** +61 3 9614 0600 **E** office@cleodx.com

endorsed in the last week as we welcomed new institutional shareholders to the register as a part of a well-supported capital raise that will position the Company strongly into the new year.

On behalf of the Board, I thank our shareholders for their ongoing support and our management team for their dedication and execution throughout the year. We look forward to updating you as CLEO continues its journey toward improving outcomes for women worldwide.

Yours sincerely,

Adrien Wing
Chairman
Cleo Diagnostics Ltd

-ENDS-

This ASX announcement was authorised for release on behalf of the Cleo Diagnostics Ltd Board.

For more information, contact:

Richard Allman
Chief Executive Officer
+613 9614 0600
office@cleodx.com

Dayna Louca
Head of Corporate Development
+61 409 581 972
dayna.louca@cleodx.com

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.