

Letter from the CEO to Shareholders

MELBOURNE, AUSTRALIA, 1 September, 2023: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:COV) (CLEO, or the Company) is pleased to present a letter from the CEO to all shareholders.

Dear Shareholders,

On behalf of the Board of Directors and our dedicated staff, it gives me immense pleasure to welcome you as a shareholder of Cleo Diagnostics (ASX:COV), as we embark on this transformative journey, to deliver a simple and accurate blood test capable of detecting ovarian cancer at every stage.

Ovarian cancer is an insidious disease defined by the highest mortality rate of all female cancers with a 5-year survival of only 49%. Present diagnostic methodologies, like transvaginal ultrasound and serum CA-125 measurements, lack the specificity needed for accurate and early detection. Consequently, the majority of cases are identified at an advanced stage, leading to poor prognoses for most patients. There is currently no accurate, pre-surgical method to diagnose ovarian cancer, or to accurately differentiate between cancerous versus much more common non-cancerous (benign) disease. Yet, the numbers speak clearly; if detected early, 94% of patients could live longer than five years post-diagnosis¹.

At Cleo, we are committed to addressing this urgent, unmet need. The successful listing of Cleo Diagnostics on the ASX is a watershed moment for all stakeholders, effectively setting our course toward positively transforming the health outcomes for women worldwide. We can all feel confident about the Company's prospects to advance the commercialisation of our cancer diagnostics platform. The proposition is simple:

- Cleo has a simple blood test developed for accurate and early detection of ovarian cancer;
- There is a clear and significant global addressable cancer diagnostics market;
- The technology is underpinned by a novel and patented biomarker with over 10 years Research and Development at the Hudson Institute of Medical Research (largely funded by the Ovarian Cancer Research Foundation), two clinical studies completed and IP protection in place;
- We have a de-risked and staged execution strategy focused on an achievable pathway to target markets; and
- An experienced leadership team in place with the credentials to execute on our plan.

¹ World Health Organisation, Australian Institute of Health and Welfare supplemented by American Cancer Society, and World Ovarian Coalition.

Our product portfolio under development aims to transform ovarian cancer diagnosis and is focused on three key markets across pre-surgical triage testing, recurrence detection, and broader screening programs. Cleo has a defined pathway to deliver a significant advancement in ovarian cancer detection.

Finally, I would like to thank you, our shareholders, for your support and trust placed in the Company as we embark on this next phase to reshape the future of ovarian cancer diagnosis.

-ENDS-

This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board by:

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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 CXCL10 biomarker, 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 10 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.

