ASX Announcement

March 2025 Quarterly Activities Report

Highlights

- **Critical milestone achieved toward the commercial production of CLEO's first Ovarian Cancer diagnostic test following the commencement of technology transfer**
- **Final negotiations continue with selected FDA-registered CMO ahead of transition to large-scale manufacturing**
- **U.S. clinical trials are progressing with patient recruitment ongoing**
- **CLEO remains focused on submission to U.S. Food & Drug Administration (FDA) which will enable access to first U.S. patient markets in CY2026**
- **A$6.425m cash at bank as at 31 March 2025.**

MELBOURNE, AUSTRALIA, 11 April, 2025: Ovarian Cancer diagnostics company, Cleo Diagnostics Limited (**ASX:COV**) (**CLEO**, or **the Company**) is pleased to provide the market with an update on activities in the March 2025 Quarter (**the Quarter**) as it develops its simple and accurate blood test for the early detection of Ovarian Cancer.

Technology Transfer

After successfully completing design transfer to a more rigorous laboratory environment, CLEO has commenced the next phase of its strategic development with the commencement of technology transfer. This process involves the transfer of its in-house development activities, including hybridoma cell line development, antibody production and testing, and selection and finalisation of reagents, to a manufacturer to facilitate commercial production.

To assist with this, CLEO has engaged U.S. based Company, R&D Systems, Inc., a global leader in immunoassay technology and a subsidiary of the Bio-Techne Group, to scale-up and assemble CLEO's proprietary antibodies for use in CLEO's initial Ovarian Cancer test targeted at the pre-surgical triage market. With state-of-the-art production facilities and globally recognised expertise, the partnership with R&D Systems, Inc. ensures the successful progression to commercial prototype development, and supports CLEO's transition to large-scale manufacturing. R&D Systems, Inc. will undertake the remaining steps towards pre-production kit assembly and testing, while CLEO completes in-house alpha prototype testing.

Manufacturing

Following successful testing, CLEO's selected Contract Manufacturing Organization (**CMO**) will assist in scaling production capability, in addition to optimisation, verification and validation activities, ensuring the production of GMP and ISO13485 compliant in-vitro diagnostic (**IVD**) kits for clinical deployment. These test kits will support the completion of CLEO's ongoing clinical trials in the U.S.

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and Australia, which will enable CLEO to submit its 510(k) application to the FDA. Negotiations with key FDA-approved CMO's are in their final stages, with the ultimate decision to be based upon manufacturing capability, regulatory compliance and ability to scale to production to meet demand upon product launch.

Clinical Trials

In the U.S., CLEO's pivotal clinical trial has continued to progress, with patient recruitment ongoing across multiple gynaecologic oncology medical centres. Patient recruitment and sampling from these U.S. sites and subsequent testing results will be integral to generating the clinical evidence required for CLEO's planned submission to the U.S. Food and Drug Administration (FDA) via the 510(k) pathway. The trial is targeting pre-surgical women with adnexal masses, which directly aligns with CLEO's first U.S. patient market, which the Company plans to enter next year following FDA clearance. Interim results are expected to inform the final product configuration and regulatory inputs, with CLEO remaining on track to finalise its submission to the FDA in CY2026.

In Australia, CLEO continues engagement across networks of clinical collaborators to support validation activities and collect prospective samples, which will be vital in supporting both U.S. submissions and informing CLEO's future applications to the Therapeutic Goods Administration (TGA) for domestic market access.

Ultimately, successful clinical trials and regulatory filings in the U.S. and Australia will provide the foundation for future expansion into additional patient markets, clinical applications, and countries for recurrence monitoring and early screening.

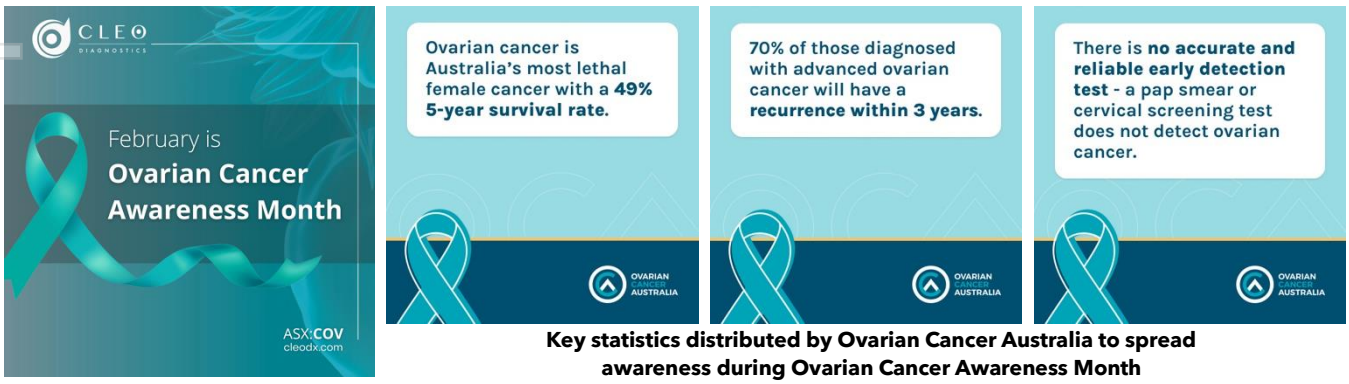
Market Activities

Ovarian Cancer Awareness Month

The Company was pleased to acknowledge and support various events and activities acknowledging the annual Ovarian Cancer Awareness Month initiative.

The stark reality is that Ovarian Cancer is the deadliest women's cancer with only 49% of women surviving 5 years from diagnosis, compared to a 92% survival rate for breast cancer. Early and accurate detection is critical, and unfortunately, there is no cancer diagnostic test that exists today for Ovarian Cancer, with definitive diagnosis only occurring following radical surgery. This leads to high recurrence and low survival rates

CLEO is proud to be bringing to market a simple blood test for the early and accurate detection of Ovarian Cancer that will transform the diagnostic sector and ultimately positively impact women's health.



Key statistics distributed by Ovarian Cancer Australia to spread awareness during Ovarian Cancer Awareness Month

CORPORATE

The Company had cash reserves of A$6.425m as at 31 March 2025.

Use of Funds

A comparison of the use of funds since the date of admission, to the use of funds statement contained within the Company's Prospectus, as required by ASX Listing Rule 4.7C.2 is as follows:

Allocation of funds*	Expenditure described in Use of Funds in Prospectus ($'000)	Actual use of funds - Quarter Ended 31 Mar 2025 ($'000)
Year One		
Triage Test	$1,486	$1,351
Screening Test and Recurrence Test	$200	-[1]
Antibody manufacturing and other business development	$2,125	$100[1]
General administration and working capital^	$1,045	$1,255
Costs of the Offer#	$1,082	$1,030
Infrastructure, equipment, lab space	$240	$36
TOTAL	**$6,178**	**$3,772**
Year Two		
Triage Test	$2,410	$697
Screening Test and Recurrence Test	$2,154	$1,025
Antibody manufacturing and other business development	$200	$210
General administration and working capital^	$1,186	$686
Costs of the Offer#	-	-
Infrastructure, equipment, lab space	$240	$70
TOTAL	**$6,190**	**$2,688**

* Refer to the Cleo Replacement Prospectus of 18 August 2023 for full details.

^ Working capital expenditure is to be applied towards funds required to expand the business and towards administration costs associated with the Company. These costs include costs for wages and salaries, occupancy costs, professional consultants' fees, compliance and reporting costs associated with running an ASX-listed company, as well as other typical administration costs. Working capital also includes surplus funds and funds that may be applied to future acquisitions.

The expenses paid or payable by the Company in relation to the Offers are summarised in Section 8.8 of the Prospectus.

[1] The Company expects that such costs will be incurred in the forthcoming year.

PAYMENTS TO RELATED PARTIES

As outlined in section 6 of the attached Appendix 4C, payments to related parties of the entity and their associates, totals A$138k, relate to fees and salaries paid to executive and non-executive Directors during the quarter.

-ENDS-

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

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Forward Looking Statements: This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of Cleo and certain of the plans and objectives of Cleo with respect to these items. These forward-looking statements are not historical facts but rather are based on Cleo's current expectations, estimates and projections about the industry in which Cleo operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of Cleo, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Cleo cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Cleo only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. Cleo will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

CLEO DIAGNOSTICS LTD

ABN	**Quarter ended ("current quarter")**
13 655 717 169	31 MARCH 2025

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development *(including R&D staff costs)*	(746)	(2,363)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(33)	(70)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(111)	(345)
	(f) administration and corporate costs	(83)	(408)
1.3	Dividends received (see note 3)		-
1.4	Interest received	87	238
1.5	Interest and other costs of finance paid		-
1.6	Income taxes paid		-
1.7	Government grants and tax incentives		-
1.8	Other (provide details if material)		-
1.9	**Net cash from / (used in) operating activities**	**(886)**	**(2,948)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
2.2	Proceeds from disposal of:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	-
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,311	9,373
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(886)	(2,948)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**6,425**	**6,425**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	1,274	1,165
5.2	Call deposits	5,151	6,146
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**6,425**	**7,311**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1 *Payment to Directors fees*	138
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(886)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,425
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,425
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: ...11 April 2025.....

Authorised by: .....The Board.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.