

ASX Announcement

December 2024 Quarterly Activities Report

Highlights

- **U.S. clinical trials progressing with patient recruitment ongoing**
- **Supporting Australian trial expanded with the inclusion of Siles Health and The Royal Womens Hospital Melbourne**
- **Trials will validate the use of CLEO's ovarian cancer diagnostic blood test for the U.S. market**
- **CLEO remains on track for submission to U.S. Food & Drug Administration (FDA)**
- **A\$7.311M cash at bank at 31 December 2024.**

MELBOURNE, AUSTRALIA, 31 January, 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 December 2024 quarter as it develops its simple and accurate blood test for the early detection of ovarian cancer.

U.S. Clinical Trials

CLEO completed all onboarding and activation initiatives associated with the U.S. medical recruitment centres. Patient recruitment is ongoing with the trials designed to validate the use of CLEO's ovarian cancer diagnostic blood test for the U.S. market. The Company is transitioning now to broaden the number and scope of participating medical centres and ramp up patient recruitment to ensure collection milestones are met. An additional 6 sites are currently being considered to join the 7 current operational trial sites.

Supporting Australian Clinical Trials

CLEO has expanded its ovarian cancer Australian trial with the inclusion of the Royal Women's Hospital (**The Womens**) as a participating site, with eminent gynaecological oncology specialist, Associate Professor Orla McNally, acting as Principal Investigator. The Women's is Australia's leading specialist hospital for women's health.

In addition, the Siles Health network of 13 clinics across Melbourne and regional Victoria also joined the trial. Siles Health is a prominent women's health and ultrasound specialist, with Associate Professor Charles Siles, acting as Principal Investigator.

Market Activities

CLEO Chief Scientific Officer, Dr Andrew Stephens, presented at the Sydney Opera House JMM Australia Investor Lunch, outlining the clear need for the Company's simple blood test for the accurate and early diagnosis of ovarian cancer. Link to video replay of the presentation: <https://bit.ly/3OpvPAS>

Cleo Diagnostics Ltd ASX:COV

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Directors

Chair and Non-Executive Director **Adrien Wing**
Chief Executive Officer and Executive Director **Dr Richard Allman**
Chief Scientific Officer and Executive Director **Dr Andrew Stephens**
Non-Executive Director and Lead Medical Advisor **Professor Tom Jobling**
Non-Executive Director **Lucinda Nolan**



Figure 2: CLEO Chief Scientific Officer, Dr Andrew Stephens presenting to investors

Corporate

The Company continues to progress its product development strategy for its initial pre-surgical triage market, and has aligned negotiations with CLEO's preferred manufacturing partner against completion of alpha prototype testing. Appointment of the manufacturing partner will be announced in due course. As a part of the process, CLEO has appointed Mr Nathan Hodgson as Head of Operations. Mr Hodgson was most recently engaged with Merck Germany, and he will bring a wealth of experience to CLEO managing contract manufacturing relationships and supply chain requirements.

CLEO also continues to strategically develop and broaden its capabilities for pre-launch physician engagement, development of strategic educational materials and broader stakeholder engagement. CLEO's medical affairs strategy will be developed in collaboration with U.S.-based Dr Karla Loken DO FACOOG. Dr Loken has extensive expertise in medical affairs with specific expertise in the medical device area.

The Company had cash reserves of A\$7.311M as at 31 December 2024.

Annual General Meeting

Cleo Diagnostics held its Annual General Meeting of shareholders of the Company on 27 November 2024 at 10.30am (AEDT).

All resolutions considered at the Annual General Meeting were put to a vote on a Poll, called by the Chairman, and were passed.

In accordance with Listing Rule 3.13.2 and section 251AA of the Corporations Act 2001 (Cth), details of the resolutions and proxies received for the meeting are set out in the attached proxy summary.

RESOLUTION DETAILS		PROXY VOTES				POLL RESULTS				
RESOLUTION	Decided by Show of Hands (S) or Poll (P)	Resolution Type	FOR	AGAINST	PROXY'S DISCRETION	ABSTAIN	FOR	AGAINST	ABSTAIN*	RESULT
1 Remuneration Report	P	Ordinary	16,941,603 97.81%	60,000 0.35%	20,000 0.12%	300,000 1.73%	17,461,603 99.66%	60,000 0.34%	1,800,000 N/A	Passed on a poll
2 Re-election of Director – Adrien Wing	P	Ordinary	31,801,603 99.94%	0 0.00%	20,000 0.06%	0 0.00%	33,821,603 100.00%	0 0.00%	0 N/A	Passed on a poll
3 Re-election of Director – Dr Andrew Stephens	P	Ordinary	31,801,603 99.94%	0 0.00%	20,000 0.06%	0 0.00%	33,821,603 100.00%	0 0.00%	0 N/A	Passed on a poll
4 Approval of 10% Placement Facility	P	Special	31,594,603 99.29%	72,000 0.23%	20,000 0.06%	135,000 0.42%	33,614,603 99.79%	72,000 0.21%	135,000 N/A	Passed on a poll
5 Approval for change of Auditor	P	Ordinary	31,801,603 99.94%	0 0.00%	20,000 0.06%	0 0.00%	33,821,603 100.00%	0 0.00%	0 N/A	Passed on a poll

*Abstain votes are provided for information only and are not included in the calculation of total available votes.



Figure 1: CLEO Annual General Meeting voting results

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 Dec 2024 (\$'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	\$542
Screening Test and Recurrence Test	\$2,154	\$544
Antibody manufacturing and other business development	\$200	\$132
General administration and working capital [^]	\$1,186	\$128
Costs of the Offer [#]	-	-
Infrastructure, equipment, lab space	\$240	\$21
TOTAL	\$6,190	\$1,367

* 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\$145k, 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 by:

Richard Allman, Chief Executive Officer.

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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 DECEMBER 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development (<i>including R&D staff costs</i>)	(933)	(1,617)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(16)	(37)
(d) leased assets	-	-
(e) staff costs (<i>excluding R&D staff costs</i>)	(90)	(234)
(f) administration and corporate costs	(34)	(325)
1.3 Dividends received (see note 3)		-
1.4 Interest received	40	151
1.5 Interest and other costs of finance paid		-



Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
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	(1,033)	(2,062)

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	-	-
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	-	-



Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
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	8,344	9,373
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,033)	(2,062)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	7,311	7,311

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	1,165	1,228
5.2	Call deposits	6,146	7,116
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)	7,311	8,344

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 <i>Payment to Directors fees</i>	145
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 <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	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)	(1,033)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,311
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,311
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	7
	<i>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.</i>	
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	
	<i>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.</i>	

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:31 January 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.