ASX Announcement

September 2024 Quarterly Activities Report

Highlights

- **FDA-enabling U.S. clinical trials commenced with:**
  - **The trial designed to benchmark CLEO's technology, with recruitment targeting a minimum of 500 patients including diversity representative of the U.S. population;**
  - **Eight medical trial locations established and active;**
  - **First patients recruited and samples collected; and**
  - **Pathway set toward FDA submission in CY2025.**
- **Initial pre-submission meeting held with the U.S. Food & Drug Administration (FDA) where CLEO outlined its submission framework and clinical plan**
- **International test-kit manufacturer appointment imminent**
- **A$8.3M cash at bank at 30 September 2024.**

MELBOURNE, AUSTRALIA, 16 October, 2024: 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 September 2024 quarter as it develops its simple and accurate blood test for the early detection of ovarian cancer.

Commencement of U.S. Clinical Trials

CLEO's pivotal FDA-enabling clinical trial has commenced in the United States, with first patients recruited into the study. The trial is designed to benchmark CLEO's technology, with recruitment targeting a minimum of 500 patients with diversity representative of the U.S. population. The data collected will underpin a submission to the Food and Drug Administration (FDA) seeking approval for clinical use of CLEO's ovarian cancer detection blood test in the world's largest diagnostic market.

Eight participating medical institutions, located across 6 U.S. states, are recruiting patients. Eligible patients at these sites will be identified by their primary physician and given the opportunity to participate during their consultation. Additional sites may also be included as the trial progresses.

CLEO's clinical trial design was reviewed and approved in both the U.S. and Australia. Institutional Review Board (**IRB**) approval is a legal requirement for any clinical trial, to ensure trial activities are ethically sound and compliant with federal regulations.

<u>Australian Clinical Trials</u>

Human Research Ethics Committee Approval (**HREC**) was obtained for a similar trial design to be conducted in Australia. Whilst the U.S. arm will provide the full complement of samples for CLEO's FDA application, any supplementary samples obtained locally will be used to further refine CLEO's technology and test algorithms prior to commercial launch.

Commencement of U.S. Regulatory Process

An initial pre-submission meeting was held with the U.S. Food and Drug Administration (**FDA**) where the Company outlined its submission framework and clinical plan for its ovarian cancer detection blood test. The pre-submission meeting is designed to permit CLEO to receive early guidance from FDA review teams prior to an eventual application submission.

The meeting was interactive with the FDA providing constructive and positive feedback on CLEO's approach to obtaining regulatory approval in the U.S. for its ovarian cancer detection blood test. This outcome provides confidence that CLEO's clinical trial designs and strategic direction are appropriately aligned with FDA requirements.

Early interaction with the FDA is important as a part of CLEO's U.S. market access strategy for a number of reasons, as the guidance outcomes allow CLEO to:

- Refine its clinical trial design to maximise resourcing and quality of data;
- Reduce the possibility of rework;
- Shorten the potential timeframe to application submission; and
- Operate with an open and transparent approach.

CLEO is pursuing expedited FDA approval for its first ovarian cancer detection product - the pre-surgical Triage test - via the 510(k) application pathway. This approach provides the quickest pathway to achieve regulatory approval for devices that achieve "substantial equivalence" to an existing predicate.

Market Activities

CLEO supported various initiatives during September for Gynaecological Cancer Awarenesss Month. The Company also noted that U.S. President Biden released a proclamation for September as National Ovarian Cancer Awareness Month to further highlight the importance for a reliable method for asymptomatic screening and detection. The Presidential brief can be access at this link: https://bit.ly/3Z8QoZ6

CORPORATE

The Company had cash reserves of A$8.3M as at 30 September 2024.

Annual General Meeting

The 2024 Annual General Meeting of the shareholders of the Company is scheduled to be held at the offices of FB Rice, Level 33, 477 Collins Street, Melbourne Victoria 3000 on Wednesday, 27 November 2024 at 10.30am (AEDT) (the **Meeting**).

In accordance with section 110D(1) of the Corporations Act 2001 (Cth) (Corporations Act), the Company will not be sending hard copies of the Notice of Meeting (**NOM**) to shareholders unless a shareholder has requested a hardcopy of the NOM or made an election for the purposes of 110E of the Corporations Act to receive documents from the Company in physical form. The NOM is made available to shareholders electronically. The Notice of the Meeting can be viewed, accessed and downloaded at https://www.cleodx.com/asx-announcements or via the following direct link to the ASX announcements platform of the Company: https://www.asx.com.au/markets/company/cov

Those shareholders who receive their company communications in the post will therefore receive a printed copy of this announcement and their personalised proxy form.

Alternatively, shareholders who receive their communications electronically will receive an email from the Company's share registry, Xcend Pty Ltd, with links directing them to this notice and the online voting portal https://investor.xcend.app

Shareholders are strongly encouraged to vote by lodging a directed proxy appointing the Chairman before 10.30am (AEDT) on Monday 25 November 2024. A personalised proxy form is included in the printed copy sent to shareholders. Proxies can be lodged in accordance with instructions on the personalised proxy form.

Change of Share Registry Address

In accordance with ASX Listing Rule 3.15.1, Cleo Diagnostics Ltd advised that with effect from Thursday, 8 August 2024, the office of its share registry, Xcend Pty Ltd (Xcend), moved to:

XCEND
Level 2
477 Pitt Street
Haymarket NSW 2000

PO Box R1905
ROYAL EXCHANGE NSW 1225
Phone: +61 (2) 7208-8033
Email: support@xcend.co
Website: www.xcend.co

Annual Report

The Company's FY2023 Annual Report to 30 June 2024 was released on 27th August. A copy can be accessed and downloaded at www.cleodx.com/asx-announcements or via the following direct link to the ASX announcements platform of the Company: www.asx.com.au/markets/company/cov

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 ($'000)	Actual use of funds - Quarter Ended 30 Sept 2024 ($'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	$446
Screening Test and Recurrence Test	$2,154	-
Antibody manufacturing and other business development	$200	$45
General administration and working capital^	$1,186	$319
Costs of the Offer#	-	-
Infrastructure, equipment, lab space	$240	-
TOTAL	**$6,190**	**$810**

* 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$187k, 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.

For more information, contact:

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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.

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	30 SEPTEMBER 2024

	Consolidated statement of cash flows	Current quarter $A'000	Year to date (3 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)*	(684)	(684)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(21)	(21)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(144)	(144)
	(f) administration and corporate costs	(291)	(291)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	111	111
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**	**(1,029)**	**(1,029)**

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 (3 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	9,373	9,373
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,029)	(1,029)
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 (3 months) $A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**8,344**	**8,344**

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	1,228	7,323
5.2	Call deposits	7,116	2,000
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)**	**8,344**	**9,323**

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 of $187k, payment to Hudson Institute of Medical Research for research and development services of $178k*	365
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)	(1,029)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,344
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,344
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	8

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: .....16 October 2024.....

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.