ASX Announcement

June 2024 Quarterly Activities Report

Highlights

- **U.S. regulatory process commenced with FDA following initial pre-submission meeting held where CLEO outlined its submission framework and clinical plan**
- **A benchmarking study published in scientific journal "Cancers" demonstrated that CLEO's ovarian cancer blood test outperforms current clinical benchmark**
- **FDA-enabling U.S. clinical trials commencing this quarter, targeting recruitment of 500 patients to verify CLEO's pre-surgical ovarian cancer test**
- **CLEO's U.S. market access and reimbursement program bolstered by appointment of New York-based healthcare industry consultancy HcFocus**
- **A$9.373M cash at bank at 30 June 2024**

MELBOURNE, AUSTRALIA, 24 July, 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 June 2024 quarter as it develops its simple and accurate blood test for the early detection of ovarian cancer.

Commencement of U.S. Regulatory Process

CLEO completed an initial pre-submission meeting 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 allow 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.

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Clinical Trial Activity

CLEO's clinical trial design has now been 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.

Trial sites are being formally contracted, and patient recruitment is targeted to commence this quarter. The U.S. trial will provide ~500 patients, enabling validation of CLEO's pre-surgical ovarian cancer test and contributing to generation of CLEO's 510k application for FDA approvals. CLEO is working with U.S.-based Contract Research Organization (**CRO**), Lindus Health to manage the international arm of the trial.

CLEO's Blood Test Far Superior to Current Standard of Care

The article, entitled 'Utility of a Multi-Marker Panel with Ultrasound for Enhanced Classification of Adnexal Mass' was published in peer reviewed medical journal, "Cancers".

A copy of the publication is available here: https://www.mdpi.com/2072-6694/16/11/2048

The benchmarking study compared CLEO's ovarian cancer blood test against the current standard clinical workflows that use CA125 and ultrasound to predict malignancy. The outcomes of the study build on previous results (see ASX Announcements 6 November 2023, and 25 March 2024) which clearly demonstrate that CLEO's ovarian cancer blood test is far superior to all routine clinical tools used by doctors to 'predict' the diagnosis of an adnexal mass prior to surgery.

Importantly, CLEO's test correctly detected 90% of early-stage cancers compared to only 50% using current standard of care workflows of CA125 and ultrasound.

Clinical Evidence Supports Commercial Pathway

As a part of CLEO's commercialisation program, the Company is focusing on a number of initiatives in parallel that will deliver appropriate routes to adoption of its tests following regulatory approval and market launch. CLEO's publication strategy continues to deliver gold-standard clinical evidence which provides a strategic foundation for clinical implementation and uptake, and critically supports the Company's case for reimbursement of the blood test to enable early revenue.

Over the past 6 months CLEO has generated significant performance data for its initial test aimed for the pre-surgical triage market. The test has now been benchmarked against all of the routinely available clinical tools which aid in the assessment of an adnexal mass. The Company is pleased to report that our prototype test is superior to all of those existing tools.

Current Standard of Care Inadequate

When a physician identifies a suspected adnexal mass, the patient will typically be referred for ultrasound imaging and a CA125 test to 'predict' the risk of malignancy. Ovarian cancers are only diagnosed after extensive and radical surgical intervention, and currently up to 90% of suspected malignancies are post-surgically diagnosed as benign. Conversely, less than half of cancer patients receive primary referral to an oncology surgeon, delaying (and sometimes compromising) their treatment. This is a major failing in the pre-surgical clinical evaluation process that impacts both patient treatment outcomes and the allocation of healthcare resources.

Despite its poor performance CA125 is exclusively recommended in medical guidelines, and represents over $1 billion market with an estimated CAGR ~4%1. Its ubiquitous use has remained largely unchallenged since its introduction in the 1980s.

For this reason, CLEO has focused on generating strong evidence to show doctors how the CLEO test can provide an important and material improvement to their current clinical practice. The test has been developed in a format familiar to clinicians prescribing standard panel blood tests, and will integrate seamlessly into current workflows. It is minimally invasive, economical and will utilise existing pathology lab infrastructure.

U.S. Market Access Program

The U.S. represents CLEO's largest market opportunity for its ovarian cancer blood test and is the focus for initial regulatory approval through the Food and Drug Administration (**FDA**). In order to successfully execute on its U.S. market entry plan, CLEO has partnered with New York-based strategic healthcare consultancy, HcFocus, appointing the company to assist it with commercial activities.

HcFocus specialises in helping med-tech companies access the U.S. healthcare market by leveraging their deep healthcare industry experience and networks to deliver market access results.

CLEO will leverage HcFocus' expertise to navigate the complexities of U.S. health systems and regulatory environment, with the companies to focus on a roadmap to achieve:

- FDA approval for CLEO's ovarian cancer blood test;
- Reimbursement, including with private insurers;
- Clinical trials;
- Support KOL appointments; and
- Industry and doctor engagement.

The move to advance the U.S. market access program was well timed following two initial peer-reviewed publications recently released assessing the performance and benchmarking of CLEO's ovarian cancer blood test. These publications detail the performance characteristics of the prototype triage test, which significantly exceeded comparable tests on market and the existing gold-standard biomarker, CA125 – the current guideline mandated test (See ASX Announcements 6 November 2023 and 25 March 2024).

CLEO's publication strategy will underpin market access activities and is designed to publicise the test performance parameters and develop the clinical utility message, essentially building the clinical evidence bank required for doctors and insurers to support and adopt the prescribing of CLEO's ovarian cancer blood test. HcFocus will be able to quickly assess the results from the initial peer-reviewed publications and provide guidance to ensure that CLEO's evidence package will meet the needs of U.S. reimbursement bodies, including the private insurers. Further clinical evidence will be delivered in the coming months as the Company progresses towards the initial FDA 510(k) application for the pre-surgical triage test.

About HcFocus LLC

HcFocus is a boutique firm with deep connections to payors, including decades of experience obtaining reimbursement and helping high-impact companies achieve success in the U.S. market. HcFocus offers innovative, comprehensive consultancy services to companies including medical device, biotech and pharma, seamlessly integrating reimbursement, regulatory and medical affairs teams to achieve clients' financial goals.

U.S. Ovarian Cancer Clinical Trials

As a part of CLEO's U.S. market access program, the Company has partnered with U.S.-based CRO, Lindus Health, appointing it to manage the successful execution of its ovarian cancer U.S. clinical trials. Lindus Health was chosen following a robust process to identify a partner with the proven experience, technology and high standards capable of delivering on CLEO's objectives.

Lindus Health specialises in collaborating with med-tech companies to conduct clinical trials worldwide, leveraging their innovative patient recruitment and trial management technology platform to deliver efficient and timely outcomes.

Comprehensive U.S. patient data is essential for a successful regulatory application through the Food and Drug Administration (**FDA**). CLEO will leverage Lindus Health's expertise to execute a cost-effective and rapid clinical study that will support its subsequent FDA 510(k) application.

The study will benchmark CLEO's pre-surgical ovarian cancer triage test and provide the core data requirements for the FDA 510(k) application. Up to 500 U.S.-based patients will be recruited, with the trial scheduled over 10 months following ethic approvals and site engagement.

An Australian arm of the trial will also run concurrently and be managed directly by CLEO. This dual-arm strategy mitigates risk to the timelines due to patient recruitment, and will provide additional patient samples for kit verification following manufacture.

The study data will be published in the mainstream medical literature as a part of CLEO's rigorous publication strategy.

CORPORATE

The Company had cash reserves of A$9.373M as at 30 June 2024.

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 ($'000)	Actual use of funds - Quarter Ended 30 June 2024 ($'000)
Year One		
Triage Test	$1,486	$1,187
Screening Test and Recurrence Test	$200	- [1]
Antibody manufacturing and other business development	$2,125	$70 [1]
General administration and working capital^	$1,045	$1,118
Costs of the Offer#	$1,082	$1,030
Infrastructure, equipment, lab space	$240	$36
TOTAL	**$6,178**	**$3,441**
Year Two		
Triage Test	$2,410	-
Screening Test and Recurrence Test	$2,154	-
Antibody manufacturing and other business development	$200	-
General administration and working capital^	$1,186	-
Costs of the Offer#	-	-
Infrastructure, equipment, lab space	$240	-
TOTAL	**$6,190**	**-**

* 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. Due to timing differences, the Company expects that such costs will be incurred in Year Two.

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$128k, 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:
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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 JUNE 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 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)*	(533)	(1,257)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(104)	(295)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(73)	(330)
	(f) administration and corporate costs	(25)	(493)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	136	363
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	211
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(599)**	**(1,801)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(1)	(36)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**(1)**	**(36)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	12,000
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	-	(1,030)
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**	**-**	**10,970**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	9,973	240
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(599)	(1,801)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1)	(36)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	10,970

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**9,373**	**9,373**

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	7,323	1,952
5.2	Call deposits	2,050	8,021
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)**	**9,373**	**9,973**

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: Director payments	128
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)	(599)
8.2	Cash and cash equivalents at quarter end (item 4.6)	9,373
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	9,373
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	15

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: .....24 July 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.