

March 2024 Quarterly Activities Report

Highlights

- Design transfer activities completed, with reliable and reproducible data supporting progression to prototype manufacture
- Publication of second peer-reviewed dataset confirms substantial performance advantage over current standard of care testing using CA125
- CLEO's strategic U.S. market access and reimbursement program underway with appointment of New York-based industry partner HcFocus
- U.S. clinical trial established, with U.S.-based Lindus Health managing site logistics and patient recruitment
- Physician engagement commenced in Australia
- **A\$9.973M cash at bank at 31 March 2024.**

MELBOURNE, AUSTRALIA, 29 April, 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 March 2024 quarter as it develops its simple and accurate blood test for the early detection of ovarian cancer.

2nd PEER REVIEWED PUBLICATION

The article, entitled 'Reclassification of patients with ambiguous CA125 for optimised pre-surgical triage' was published in the peer reviewed medical journal, Diagnostics.

A copy of the publication is available here: <https://www.mdpi.com/2075-4418/14/7/671>

The article concluded:

- a) CLEO's test correctly identified most cancer cases missed by CA125, including a majority of patients with early stage cancers;
- b) The test provided superior identification of benign disease to eliminate the majority of "false positive" results obtained using CA125; and
- c) The test efficiently discriminated malignant from benign samples.

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](#)

Background

Further data for CLEO's ovarian cancer triage test has been published in the peer-reviewed international journal 'Diagnostics'.

Whilst these clinical studies are complex documents to interpret for the lay-reader, they form an integral part of Cleo's commercialisation strategy. They are crucial for providing documentary evidence of Cleo's test performance and will be used:

- To support Cleo's case to be included in national and international medical guidelines;
- To support Cleo's applications for private insurance coverage in the USA; and
- To inform clinicians of Cleo's test performance to drive uptake.

The latest study assessed the use of CLEO's triage test to rescue those cases where CA125 provided an incorrect indication. Accurately identifying cancer patients early is critical to provide immediate referral to a gynaecological oncology specialist for surgery; whilst allowing better management of patients with non-malignant disease.

The study compared the potential clinical benefit to patients if CLEO's Test was used for initial diagnostic work-up instead of CA125, the current gold standard ovarian cancer biomarker.

CLEO's triage test accurately re-assigned the majority of "missed" cancers that were incorrectly identified as low risk using CA125, and was effective in both pre- and post-menopausal patients.

False negative detections (i.e. a "missed" cancer case) were reduced by ~71% for post-menopausal patients and ~54% for pre-menopausal patients, many of whom had early-stage disease. This is particularly important in the pre-surgical setting, where rapid identification and triage to a gynaecological oncology surgeon is critical to achieve greatest benefit for patients.

Similarly, false positive detections (i.e. where CA125 incorrectly classified benign disease as "high-risk") were reduced by ~57% and ~75% for post- and pre-menopausal patients respectively. This is essential to reduce unnecessary surgical interventions, which has significant relevance for pre-menopausal women where cancer diagnoses are typically rare and fertility preservation strategies are highly important.

Improvement Over Existing Technology

The current "gold-standard" tumour biomarker Cancer Antigen 125 (**CA125**) has poor accuracy, particularly for the detection of early-stage disease and discrimination between benign versus malignant status.

Around 20% of ovarian cancers do not express CA125, and it is often in the "normal" range in patients with early-stage disease. False negative CA125 results (where cancers are "missed") are common, and complicate the referral of cancer patients to a gynaecologic oncology specialist for primary surgery.

Conversely the abnormal elevation of CA125 in non-malignant conditions (e.g. endometriosis, fibroids, pelvic inflammatory disease and others) results in high false positive detection (where benign cases are



incorrectly suspected to be cancer). Unsurprisingly, post-surgical diagnoses of benign disease outnumber malignancy by ~9:1.

CLEO's latest data highlights the use of its triage test to rescue those cases where CA125 proves inaccurate, and demonstrates significant potential to improve the initial clinical management for patients with malignancy – particularly at an early stage.

The importance of the latest release of data for Cleo, is that starts to layout for the medical guideline bodies and the private payors how well Cleo's technology performs compared to the existing paradigm.

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 will partner with New York-based strategic healthcare consultancy, HcFocus, appointing the company now to assist it with commencing 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 is 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 will partner 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.

Design Transfer

Cleo completed the design transfer in February for the CXCL10 active ratio test into a more rigorous laboratory environment, ensuring the capability to deliver reproducible and reliable results. This advancement enhances the performance of the test, transitioning it from academic methodologies to a compliant and robust laboratory setting. The test will continue to progress through the development pathway, culminating in an FDA 510K application for regulatory approval.

As outlined in the clinical validation study publication (see ASX Announcement 6 November 2023), the CXCL10 active ratio measures changes in a key immune process to give an indication of the presence of a tumour, and is an important component of Cleo's biomarker panel to be incorporated within its commercially available test kits.



Cleo's first product to market will be a pre-surgical triage test, designed to determine the likelihood that a pre-surgical ovarian mass is either benign or malignant prior to referral for surgical intervention. The test will be used in conjunction with clinical and radiological evaluation of a patient by physicians, to improve the referral process and better inform clinical decision making workflows. Ovarian masses (typically benign cysts) are very common and non-life threatening; around 10% of women will have surgery during their lifetime for investigation of an ovarian mass, representing a significant market opportunity for Cleo's first product.

The completion of design transfer forms the basis for Cleo to progress technology transfer to a manufacturer as the next step. The Company is currently finalising a tender process for the selection of an antibody manufacturer and expects it will be in a position to announce a partner shortly, with completion of technology transfer to follow shortly thereafter.

Market And Clinician Engagement

During the quarter, CLEO held a special presentation with a number of doctors in Melbourne to showcase the Company's ground-breaking new diagnostic blood test for ovarian cancer. The event was hosted by CLEO Lead Medical Advisor and Non-Executive Director, Professor Tom Jobling OAM, Chief Scientific Officer and Executive Director, Dr Andrew Stephens, and Chief Executive Officer, Dr Richard Allman.

The presentation covered an overview of the current standard of care, science and potential impacts for CLEO's revolutionary ovarian cancer diagnostic test as well as opportunities to develop insights, network, collaborate during clinical trials, and ultimately calling for support for integration into clinical practice.

CORPORATE

The Company had cash reserves of A\$9.973M as at 31 March 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 31 March 2024 (\$'000)
Year One		
Triage Test	\$1,486	\$657
Screening Test and Recurrence Test	\$200	-
Antibody manufacturing and other business development	\$2,125	\$67
General administration and working capital^	\$1,045	\$916
Costs of the Offer#	\$1,082	\$1,030
Infrastructure, equipment, lab space	\$240	\$35

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	-

* 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.

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\$136k, 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.



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Appendix 4C

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

Name of entity

CLEO DIAGNOSTICS LTD

ABN

13 655 717 169

Quarter ended ("current quarter")

31 MARCH 2024

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 (<i>including R&D staff costs</i>)	(317)	(724)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(14)	(191)
(d) leased assets	-	-
(e) staff costs (<i>excluding R&D staff costs</i>)	(94)	(257)
(f) administration and corporate costs	(104)	(468)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	184	227
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	211	211
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(134)	(1,202)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(35)
(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	-	(35)

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	10,107	240
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(134)	(1,202)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(35)
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 (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	9,973	9,973

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	1,952	1,091
5.2	Call deposits	8,021	9,016
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)	9,973	10,107

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	136
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	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
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)	(134)
8.2 Cash and cash equivalents at quarter end (item 4.6)	9,973
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	9,973
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	74
<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:29 April 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.

