ASX Announcement

September 2023 Quarterly Activities Report

Highlights

- **U.S. patent granted for key novel ovarian cancer biomarker supporting CLEO's commercialisation pathway into its primary U.S. target market**
- **Early progress delivered against development program with the selection of biomarkers panel for Cleo's ovarian cancer test-kit finalised**
- **Antibody development advanced increasing confidence for commercial assay development and upscaling for commercial manufacturing**
- **Evaluation of four commercial antibody manufacturing partners progressed in late stage as part of a robust tender process**
- **Board capacity enhanced with Chief Scientific Officer and Executive Director, Dr Andrew Stephens, expanding responsibilities to full-time**
- **A$10.73M cash at bank at 30 September 2023**

MELBOURNE, AUSTRALIA, 30 October, 2023: 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 2023 quarter as it develops its simple and accurate blood test for the early detection of ovarian cancer.

U.S. PATENT

The granted Patent (U.S. Patent No: US 11,725,048, "CXCL10 Binding Proteins and Compositions Thereof") covers CLEO proprietary biomarkers and antibody formulations, which comprise the core technology of the Company's ovarian cancer diagnostic blood test. This Patent family is directed towards C-X-C motif chemokine ligand 10 (**CXCL10**) binding proteins and methods of diagnosing a condition, such as a malignancy, comprising determining a level of CXCL10 in a subject. Determination of the level of CXCL10 may also be utilised to monitor tumour burden, malignancy progression or likelihood of tumour recurrence in a subject.

The U.S. Patent expands the Company's Intellectual Property (**IP**) portfolio, adding to the patent granted in Australia earlier this year (patent number 2020404453). Additional patent applications are currently pending in Europe, China, India, Japan, Korea, Israel, New Zealand and Singapore.

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U.S. MARKET OPPORTUNITY

The U.S. is the largest diagnostic market in the world, and represents the Company's primary target market for its potentially lifesaving simple diagnostic blood test. Ovarian cancer survival rates are much lower than other cancers that affect women, largely due to the fact that existing testing is insufficient to identify early stage cancers or differentiate from benign disease. Diagnosis is only made following radical surgery to remove the ovaries. The 5 year survival rate for ovarian cancer is 49%, compared to 92% for breast cancer[1] where early detection screening exists.

A significant unmet clinical need exists and CLEO plans to bring to market a suite of ovarian cancer diagnostic blood tests based on the novel patented CXCL10 biomarker, which is expressed early and at high levels by ovarian cancers, but not in non-malignant disease. The tests aim to distinguish benign from malignant growths in a standard format that will be readily compatible with existing equipment used by pathology laboratories worldwide.

The U.S. Patent complements CLEO's regulatory approval strategy designed to access target markets and secure a path to reimbursement approvals in the future. The Company is also currently preparing for the submission of a 510(k) U.S. Food and Drug Administration (**FDA**) application.

CLEO is initially targeting the delivery of its blood test for the surgical triage market, however has a staged execution strategy that de-risks a pathway to all ovarian cancer diagnostic markets:

- Surgical Triage Distinguishes benign from malignant disease to allow appropriate design of treatment before surgical intervention is considered;
- Recurrence Identifies relapse for earlier intervention to control/manage disease progression
- High Risk Screening Testing women with known BRCA status or extensive family history; and
- Early Stage Screening Systematic national screening to identify early stage ovarian cancers in patients without symptoms, to allow medical intervention before cancer spreads.

Early detection is vital. When ovarian cancers are diagnosed at stage 1, patients have over a 90% 5 year survival rate. However, this rate reduces rapidly to <40% if diagnosed once the cancer has spread beyond the ovaries.

TEST-KIT BIOMARKERS PANEL FINALISED

Cleo has finalised the selection of biomarkers to be used in its ovarian cancer test-kit, along with completing the development for a prototype of the proprietary scoring algorithm. The performance metrics of the test were evaluated in a clinical study of 334 patients, the results of which are being prepared for publication in a peer-reviewed medical journal. The Company expects the publication outcome to be reported to the market by the end of CY2023. The data cannot be released prior to publication due to the nature of the peer-review process. Concurrently, Cleo is also preparing a further patent application based on the findings.

[1] World Health Organisation, Australian Institute of Health and Welfare supplemented by American Cancer Society, and World Ovarian Coalition.

ANTIBODY DEVELOPMENT

A key objective for the Company is to develop its own antibodies and target proteins which will allow control of supply, quality, cost and high-performance of key reagents that will underpin the consistent and reliable manufacture of test-kits. Cleo can confirm that Surface Plasmon Resonance Analysis has shown that the core antibodies of the CXCL10 active ratio test are binding to their respective targets with high affinity and are suitable for commercial assay development and upscaling in commercial manufacturing. Hybridomas to produce the supporting biomarker antibodies are also well progressed, with expected completion of the full test-kit panel in Q2 CY2024.

SELECTION PROCESS FOR ANTIBODY MANUFACTURING PARTNER

Cleo is in the late stages of evaluating four commercial antibody manufacturing partners as part of a robust tender process. The evaluation process considers a competitive review of the capabilities of each potential partner to ensure that the partner ultimately selected can deliver commercial product to the standard required by Cleo, which is largely set by regulatory bodies such as the Food and Drug Administration (FDA) and potential customer groups.

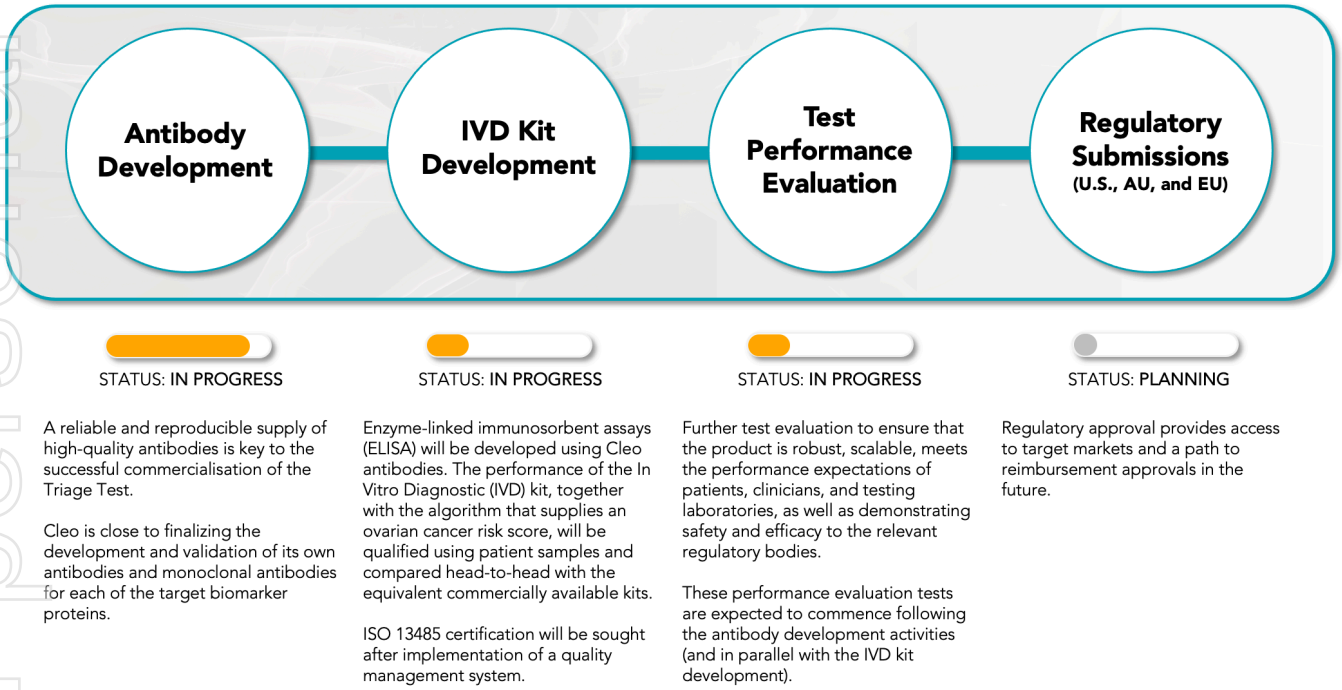

Figure 1: Indicative high-level timeline for the commercial development of Cleo's ovarian cancer test-kit for the initial Surgical Triage Test market.

CORPORATE

The Company had cash reserves of A$10.73M as at 30 September 2023.

ASX Listing

Cleo Diagnostics successfully completed its listing of shares on the Australian Securities Exchange (ASX) on 22 August 2023, after an Initial Public Offering (**IPO**) raising a total of A$12 million (before costs) in capital by issuing 60,000,000 shares at $0.20 per share. The lead manager of the IPO was Taylor Collison.

Ovarian cancer is an insidious disease defined by the highest mortality rate of all female cancers with a 5-year survival of only 49%. Present diagnostic methodologies, like transvaginal ultrasound and serum CA-125 measurements, lack the specificity needed for accurate and early detection. Consequently, the majority of cases are identified at an advanced stage, leading to poor prognoses for most patients. There is currently no accurate, pre-surgical method to diagnose ovarian cancer, or to accurately differentiate between cancerous versus much more common non-cancerous (benign) disease. Yet, the numbers speak clearly; if detected early, 94% of patients could live longer than five years post-diagnosis[2].

Cleo is committed to addressing this urgent, unmet need. The successful listing of Cleo Diagnostics on the ASX is a watershed moment for all stakeholders, effectively setting our course toward positively transforming the health outcomes for women worldwide. We can all feel confident about the Company's prospects to advance the commercialisation of our cancer diagnostics platform. The proposition is simple:

- Cleo has a simple blood test developed for accurate and early detection of ovarian cancer;
- There is a clear and significant global addressable cancer diagnostics market;
- The technology is underpinned by a novel and patented biomarker with over 10 years Research and Development at the Hudson Institute of Medical Research (largely funded by the Ovarian Cancer Research Foundation), two clinical studies completed and IP protection in place;
- We have a de-risked and staged execution strategy focused on an achievable pathway to target markets; and
- An experienced leadership team in place with the credentials to execute on our plan.

The Company's product portfolio under development aims to transform ovarian cancer diagnosis and is focused on three key markets across pre-surgical triage testing, recurrence detection, and broader screening programs. Cleo has a defined pathway to deliver a significant advancement in ovarian cancer detection.

[2] World Health Organisation, Australian Institute of Health and Welfare supplemented by American Cancer Society, and World Ovarian Coalition.

Board Enhancement

The Company confirmed current Chief Scientific Officer and Executive Director, Dr Andrew Stephens, role would move to full-time effective 1 October, 2023. Following the Company's successful listing on the ASX in August, Dr Andrew Stephens agreed to expand his commitment to the Company by moving his Chief Scientific Officer and Executive Director responsibilities to full-time, up from three days per week part-time. All remaining terms and conditions of Dr Stephens employment agreement are unchanged.

The enhancement to Cleo's Board capacity was designed to direct clear executive focus on the Company's phased development strategy to deliver a simple and accurate blood test capable of detecting ovarian cancer at every stage.

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 ($'000)	Actual use of funds - quarter end 30 June 2023 ($'000)
Year One		
Triage Test	$1,486	$170
Screening Test and Recurrence Test	$200	-
Antibody manufacturing and other business development	$2,125	$22
General administration and working capital^	$1,045	$325
Costs of the Offer#	$1,082	$966
Infrastructure, equipment, lab space	$240	$35
TOTAL	**$6,178**	**$1,517**
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.

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$94k, 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 SEPTEMBER 2023

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)*	(192)	(170)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(75)	(75)
	(d) leased assets	-	-
	(e) staff costs *(excluding R&D staff costs)*	(62)	(84)
	(f) administration and corporate costs	(187)	(187)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
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**	**(516)**	**(516)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(35)	(35)
	(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:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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)**	**(35)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	12,000	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	(966)	(966)
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**	**11,034**	**11,034**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	240	240
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(516)	(516)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(35)	(35)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	11,034	11,034

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**	**10,723**	**10,723**

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	1,723	240
5.2	Call deposits	9,000	-
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)**	**10,723**	**240**

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 $94k*	94
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)	(516)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,723
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,723
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	20

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: 30 October 2023

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.