ASX : COV

CLEO DIAGNOSTICS

Making earlier detection of ovarian cancer a reality

CORPORATE PRESENTATION FEBRUARY 2024

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Corporate Overview

Cleo Diagnostics is making accurate and early detection of ovarian cancer a reality.

Cleo Diagnostics Limited (ASX:COV) is bringing to market a simple blood test for the accurate and early diagnosis of ovarian cancer, using its novel patented CXCL10 biomarker.

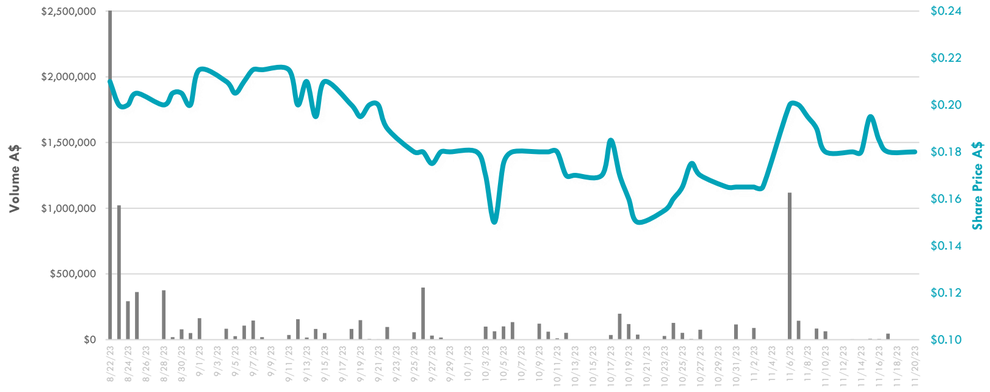
Cleo's first test - AdnexaSure™ is designed to distinguish benign from malignant growths and will be compatible with standard diagnostic laboratory workflows worldwide.

The platform is backed by over 10 years of scientific Research & Development at the Hudson Institute of Medical Research, with two clinical studies conducted in 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 underpinning its operations and the ovarian cancer tests.

Cleo is advancing the availability of its simple blood test, under a modular execution strategy to ultimately address all ovarian cancer detection markets with specific tests including surgical triage, recurrence, high risk, and early-stage screening.

Capital Structure

ASX Ticker	COV
Share Price (12 February 2024)	$0.18
Shares on Issue	128.5M
Options	14M
Market Capitalisation (fully diluted)	$23M
Cash (as at 31 December 2023)	$10.1M



Cleo Diagnostics

Is **bringing to market** a **simple blood test** to **accurately detect** Ovarian Cancer **early**.

Why Cleo Diagnostics :

- A simple blood test for accurate and early detection of Ovarian Cancer
- Significant global total addressable cancer diagnostics market opportunity
- Technology supported by gold-standard clinical evidence
- Strong intellectual property position with core foundational patent granted in Australia and USA (pending worldwide)
- Staged execution strategy focused on an achievable pathway to target markets
- Experienced leadership team with credentials to execute

Ovarian cancer: the deadliest of all female reproductive cancers

Accurate and early detection of ovarian cancers will significantly increase survival

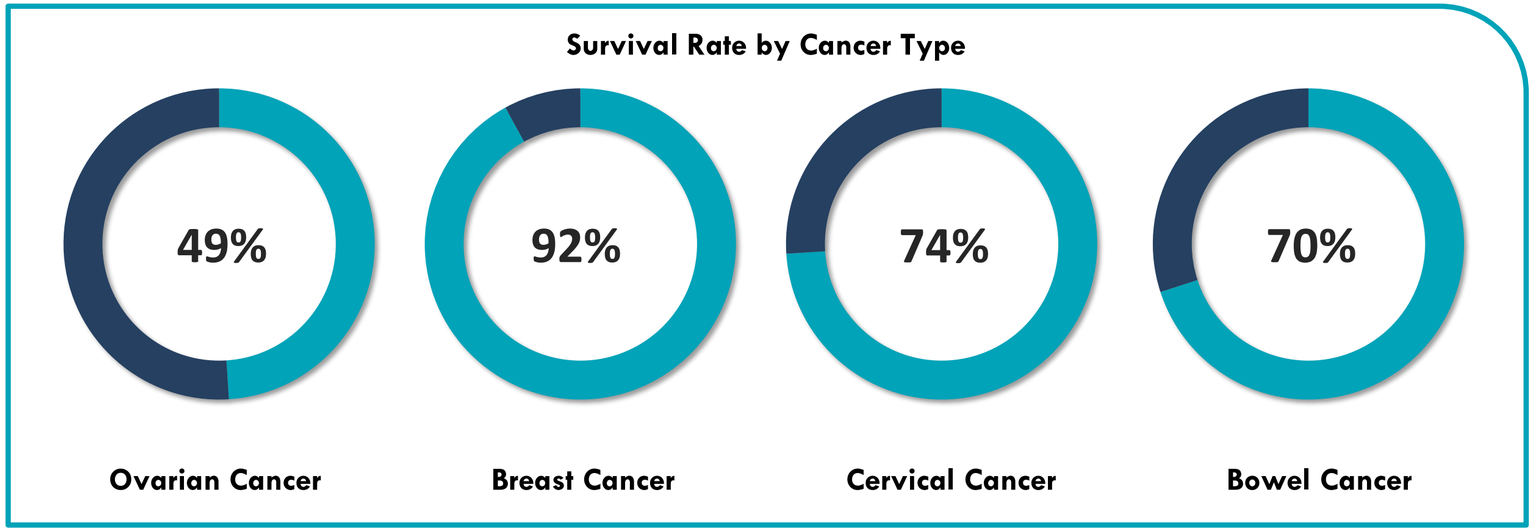
- **DIFFICULT** to detect and diagnose
- **POOR SPECIFICITY** of existing tests
- **NO SCREENING** for early disease detection

300k New cases every year

207k Women die each year globally

2.8M Women living with Ovarian Cancer

23 Women die every hour



Source: World Health Organisation, Australian Institute of Health and Welfare supplemented by American Cancer Society.

World Ovarian Coalition

Current Standard Of Care is Inadequate

- **CA125 biomarker** has only ~50% accuracy for detection of early stage cancer
- **ULTRASOUND + CA125 (gold standard clinical care)** is incorrect >20% of the time
- **NO SCREENING TEST** exists for early disease detection

Diagnosis only occurs following radical surgery.

Initial Eliminations

Unexplained weight loss

Vague abdominal pain or pressure

Feeling of abdominal fullness, gas, nausea, indigestion

Sudden abdominal swelling, weight gain or bloating

Persistent changes in bowel or bladder patterns

Low backache or cramps

Abnormal vaginal bleeding

Initial triage of symptoms by Doctor to determine possibility of Ovarian Cancer

Available Testing

ROMA™
(Risk of Ovarian Malignancy Algorithm)

OVA1™
(Protein Biomarker Test)

RMI
(Risk Malignancy Index)

CA125

Transvaginal Ultrasound
(TVU)

Varied testing effectiveness which is biased toward late stage diagnosis

Diagnosis is made following radical surgery

High recurrence rate due to late stage diagnosis

Majority of cases recur within 18 months

Cleo Technology: How it works

BLOOD TEST

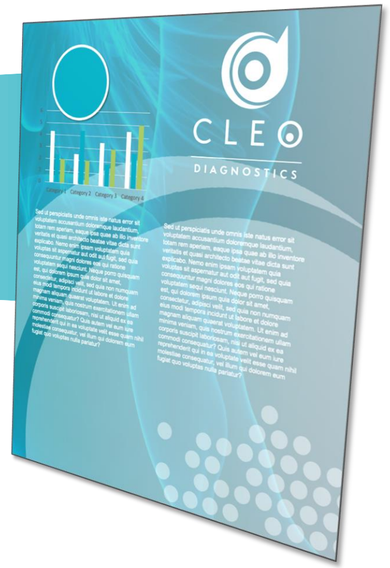
Blood collected via a simple blood draw. Part of a standard panel of tests ordered by a doctor.

PATHOLOGY

Enzyme-linked immunosorbent assay (ELISA) conducted on standard pathology lab equipment

RESULT

An easy to understand Report is prepared and sent to the patient's doctor for surgical triage



Cleo Diagnostics : World-class Technology

CleoDX technology is underpinned by the CXCL10 novel biomarker

CXCL10 novel biomarker discovered in Ovarian cancers

- Over-expressed in ovarian cancers
- Not expressed in benign disease
- Remains throughout the lifetime of the cancer
- Provides a robust indicator at all stages of cancer

PROTOTYPE TRIAGE TEST

5-biomarker panel for cancer detection:

Specificity = 95%
Sensitivity = 95%

Early stage cancer detection:*

- *AdnexaSure™ ~ 80%*
- *RMI identified ~45%*
- *ROMA identified ~ 68%*

* Stephens AN *et al* (2023). A Novel Predictive Multi-Marker Test for the Pre-Surgical Identification of Ovarian Cancer. doi: 10.3390/cancers 15215267

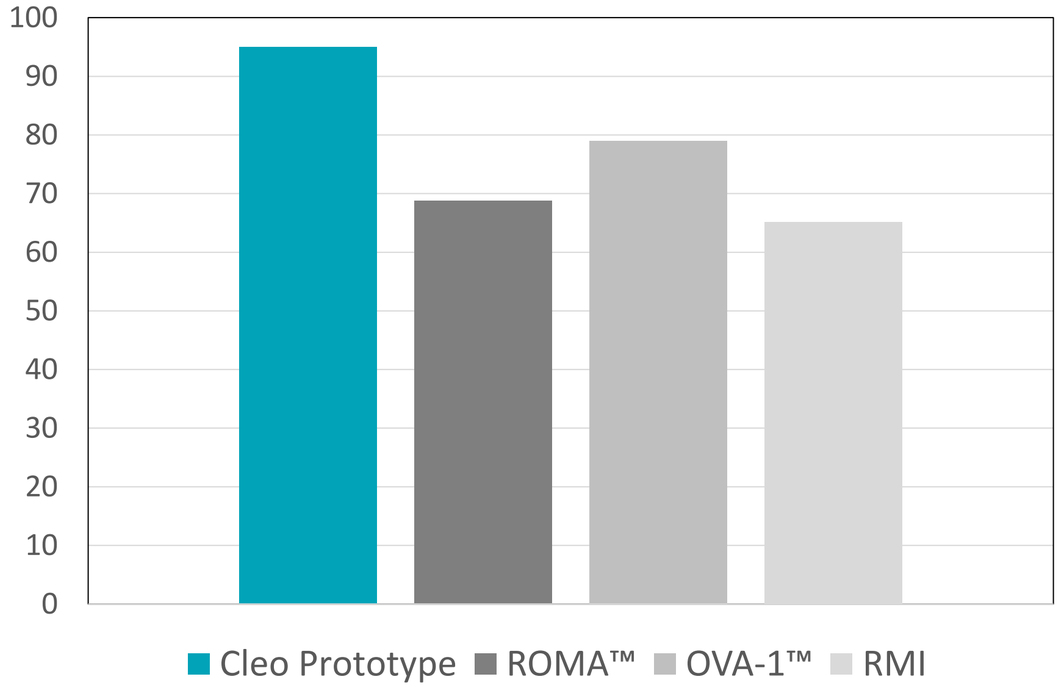
Strong Intellectual Property position:

CXCL10 novel biomarker patent granted in USA & Australia, pending worldwide

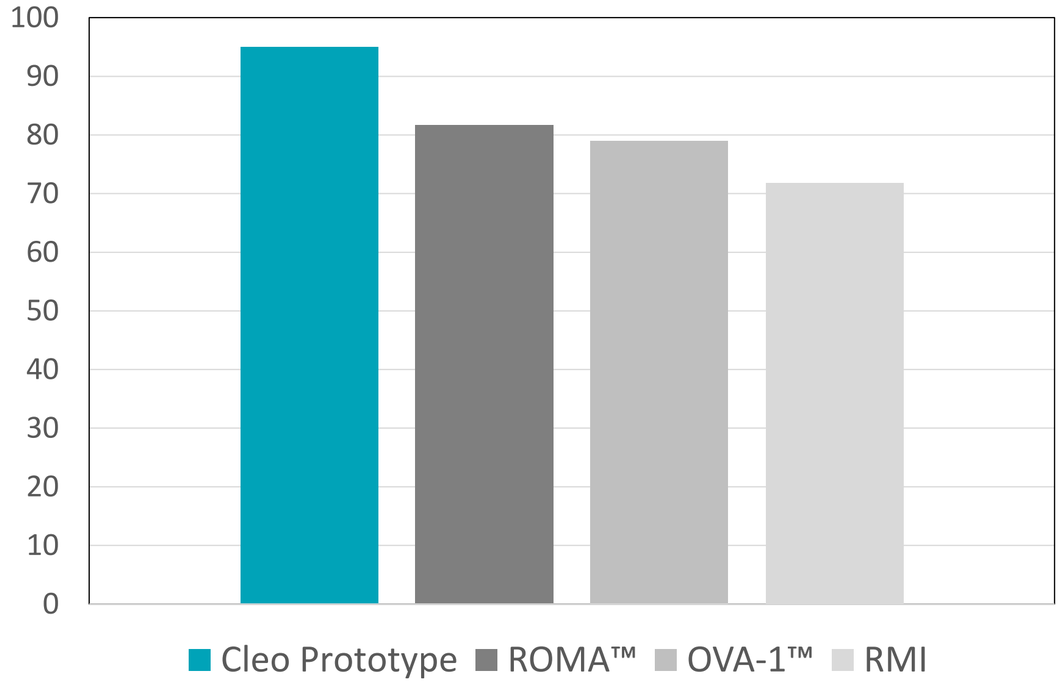
Cleo AdnexaSure™ : Outperforms existing clinical tests

Exceptional performance in both Pre- *and* Post-Menopausal women

Sensitivity @ 90% Specificity Pre-Menopausal



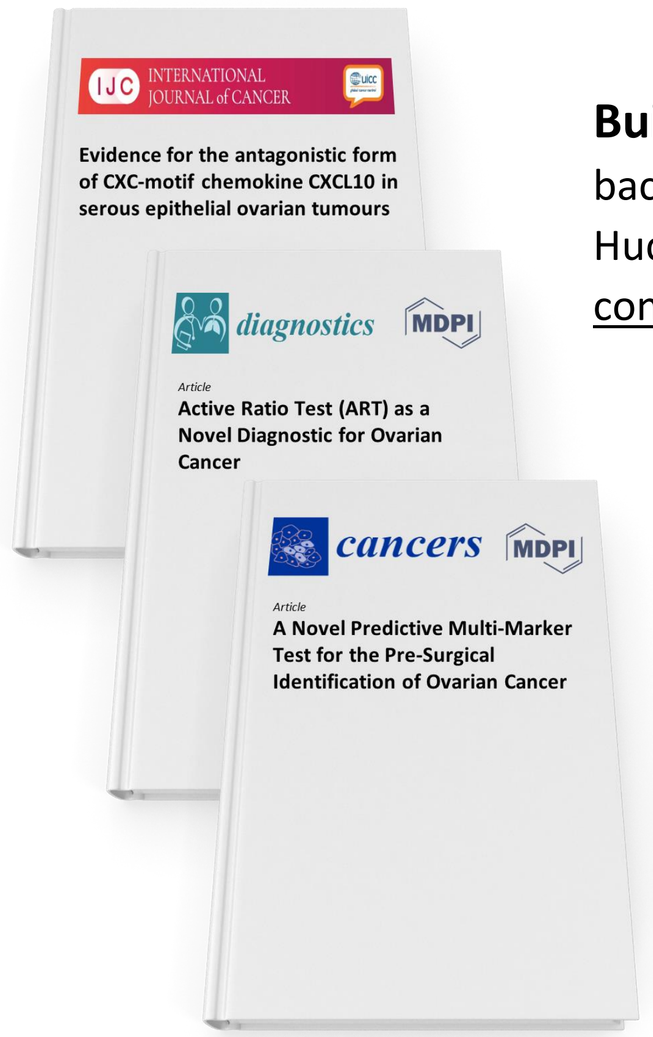
Sensitivity @ 90% Specificity Post-Menopausal



Specificity locked at 90% to allow like-for-like comparison

1. Davenport, C., et al., *Menopausal status, ultrasound and biomarker tests in combination for the diagnosis of ovarian cancer in symptomatic women.* Cochrane Database Syst Rev, 2022. **7**(7): p. CD011964.
2. Fritsche, H.A. and R.G. Bullock, *A reflex testing protocol using two multivariate index assays improves the risk assessment for ovarian cancer in patients with an adnexal mass.* Int J Gynaecol Obstet, 2023. **162**(2): p. 485-492.
3. Bristow, R.E., et al., *Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay.* Gynecol Oncol, 2013. **128**(2): p. 252-9.

Cleo Diagnostics : Generating Gold-standard Clinical Evidence



Building a portfolio of peer-reviewed scientific evidence backed by over 10 years of scientific Research & Development at the Hudson Institute of Medical Research, with two clinical studies conducted in over 500 patients.

Cleo's evidence-based gold standard;

- supports the Company's case for reimbursement of the commercialised test
- provides a strategic foundation for clinical implementation and uptake

Significant global total addressable market opportunity

Staged execution strategy with initial focus on triage test de-risks pathway to national screening market.

Initial Market 1 → 2025

Surgical Triage Test

1M
women

- All Ages
- USA Initially
- Testing as required

Predicate device application upon FDA guidance document and comparative tests in market

Market 2 → TBC

Recurrence Test

1.2M
tests

- All Ages
- USA Initially
- Testing 3 Monthly

Clinical study – dependent upon prospectively collected pre-op and post- op samples from ovarian cancer patients

Market 3 → TBC

High Risk Screening

14.8M
women

- All Ages
- USA Initially
- Testing Bi-Annually

Clinical study in women with known BRCA status or extensive family history in the first instance

Screening Program

148M
women

- >50 Years of age
- USA / Europe / Australia
- Testing Annually

Clinical study requirement – dependent upon prospective sample collection from asymptomatic women of screening age

Priority Countries

USA

EUROPE

AUSTRALIA

Addressable market for the Triage Test restricted to the USA following the well-defined FDA pathway.

Market estimate based upon CPT coding and reimbursement analysis provided by Clarivate www.clarivate.com

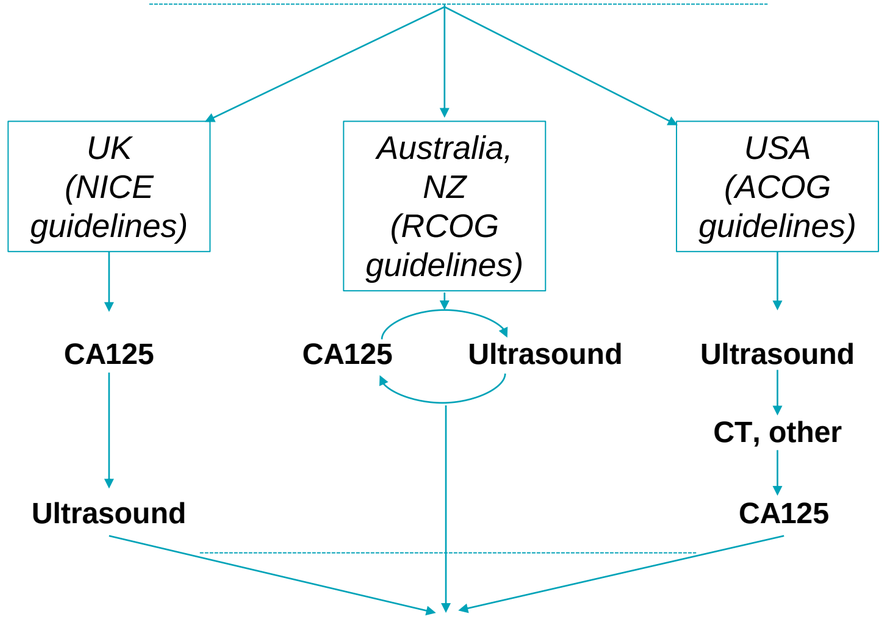
Access to addressable markets is limited by items such as patent protection, regulatory approvals and access to distribution, amongst other factors. There are no guarantees that CleoDX will be able to receive approval to distribute its products in its target addressable markets or adequately enforce its intellectual property in such markets.

Understanding the Medical Guidelines and Triage Market

Diagnostic Workflow

Initial assessment

- Symptoms review
- Physical examination
- Family & medical history



Proceeding to surgery:
~ 1,000,000 *per annum (US)*

- **CA125 is used off label for surgical triage**
  - Reimbursed in all jurisdictions

(1) Whiteman, M. K*et al* (2010) Inpatient hospitalization for gynecologic disorders in the United States. DOI: 10.1016/j.ajog.2009.12.013

(2) Greenlee, R. T *et al* (2010) Prevalence, incidence, and natural history of simple ovarian cysts among women >55 years old in a large cancer screening trial. DOI: 10.1016/j.ajog.2009.11.029

Cleo Diagnostics : Designing Tests That Make a Difference

Cleo is bringing to market three tests, to address the clinical unmet worldwide need for ovarian cancer diagnosis, monitoring and screening.

Cleo's technology exploits the novel blood marker "CXCL10" that is found at high levels in ovarian cancer patients, but not those with benign growths. Produced throughout the lifetime of the cancer, CXCL10 provides a robust indicator of malignancy from very early to late-stage disease.

AdnexaSure™

[in manufacturing] pre-surgical triage test to be used early in consultation for patients with an adnexal mass, to determine the likelihood of malignancy prior to surgical referral.

Post-surgical recurrence test

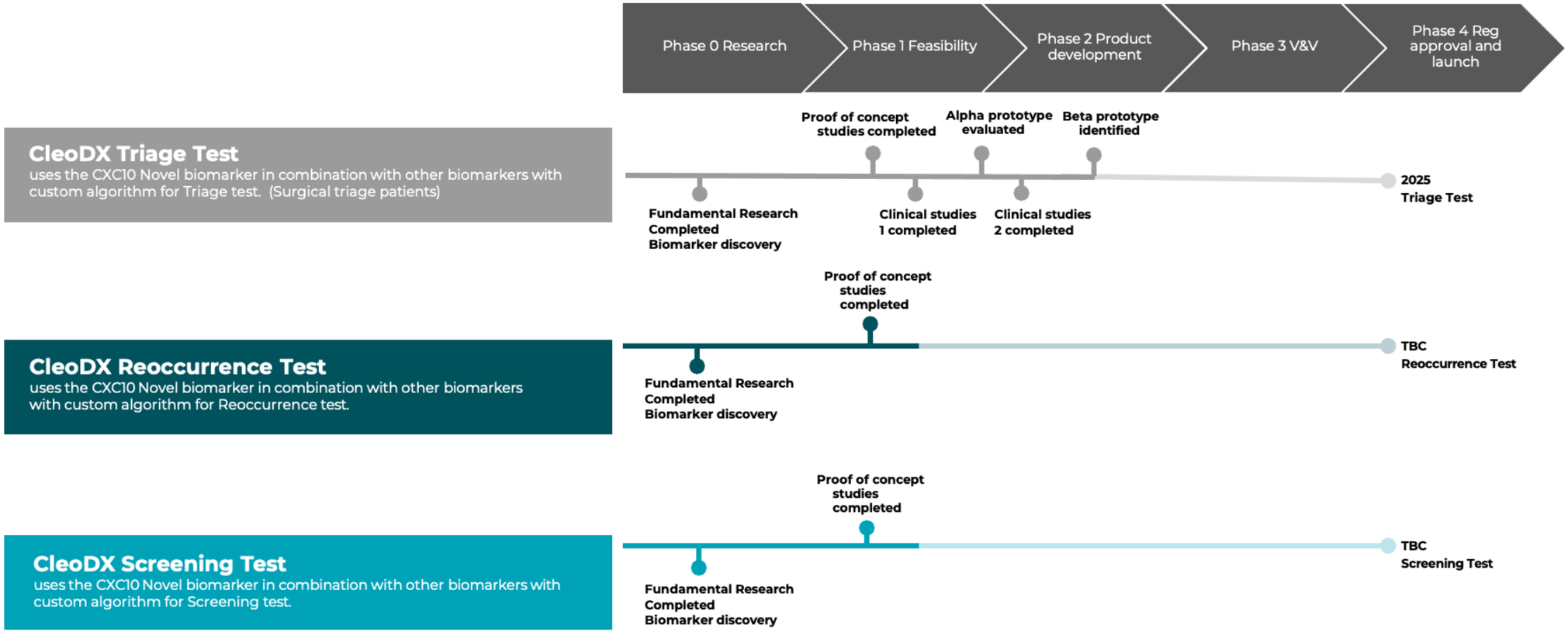
[in development] will provide improved detection of cancer recurrence for previously treated patients, allowing earlier intervention and management.

Ovarian cancer screening test

[in development] to identify early-stage ovarian cancers in patients WITHOUT symptoms, and allow medical intervention BEFORE cancer spread, when treatment is most effective.

Cleo Diagnostics : Path to Market

Staged execution strategy with initial focus on triage test de-risks pathway to national screening market



Note: The timeline is indicative and subject to change.

Cleo Diagnostics : Developing the Clinical Implementation Pathway

Cleo is developing a multi-faceted strategy to facilitate clinical implementation & early revenue generation

A clear focus on delivery and execution

Post IPO Milestones Achieved

- Foundational CXCL10 Patent Granted in USA
- Triage Test biomarker panel finalized
- In-house performance verification of CXCL antibodies complete
- Proprietary provisional patent filed covering the Triage Test biomarker panel
- First clinical validation study published
- Production of in-house antibodies for all biomarkers 90% complete
- Due diligence on 4 manufacturing partners complete
- Initial documentation for first FDA meeting under review by Regulatory consultant

Catalyst rich path to first test product - AdnexaSure™

Numerous inflection points planned over next 24 months

2023/24

- Sign clinical trial sites
- Commence Australian Trials
- Commence USA Trials
- Complete reagent development
- Complete reagent optimisation
- Pre-IDE strategic development
- Manufacturing establishment of Cleo Triage kit
- Sign key opinion leaders
- Publication of European study results
- Commencement of recurrence test studies
- Commencement of screening test studies

2024/25

- Establish & accreditation of ISO13485 quality system
- Perform & finalise validation of the CleoDX Kit
- Perform & finalise verification of the CleoDx Kit
- Analysis & publication of USA and Australian prospective clinical trial results
- FDA Pre-IDE submission
- FDA 510(k) submission & approval
- CE Regulatory submission & approval
- TGA regulatory submission & approval

The Team to Execute

Experienced team with deep domain experience

ADRIEN WING

Non-Executive Chairman

Mr Wing is CPA qualified and works with a number of public companies listed on the Australian Securities Exchange as a corporate/ accounting consultant and company secretary. Strong track record in life sciences as a founder of Rhythm Biosciences (ASX:RHY).

Bachelor of Business (Accountancy) from Royal Melbourne Institute of Technology (RMIT) and Certified Practicing Accountant (CPA).

DR RICHARD ALLMAN

Executive Director and CEO

Dr. Allman has wide experience in research leadership, innovation management, and intellectual property strategy, covering oncology, diagnostics, and product development.

PhD (Microbiology) from The University of Wales.

DR ANDREW STEPHENS

Executive Director and CSO

Career research scientist and inventor of the CleoDx core technology. Dr Stephens has over 60 academic publications and numerous patents (pending and provisional) in the cancer therapeutic and diagnostic space.

PhD (Molecular Biology) from Monash University Australia.

LUCINDA NOLAN

Non-Executive Director

Ms Nolan was most recently the CEO of the Ovarian Cancer Research Foundation. Notable as the first female CEO of the Country Fire Authority and Deputy Commissioner of Victoria Police. She is an alum of the Advanced Management Programme at Harvard University.

Master of Arts from Melbourne University, Batchelor of Arts with Honours from Melbourne University, Alumni of the Advanced Management Programme at Harvard University.

PROFESSOR TOM JOBLING

Executive Director and Medical Advisor

Dr Jobling is a surgeon who has been treating ovarian cancer for more than 30 years. Dr Jobling is the head of gynaecological oncology at Monash Health and visiting medical officer at the Peter MacCallum Cancer Centre is a cofounder and former chairman of the OCRF.

Bachelor of Medicine, Bachelor of Surgery, Fellow of the Royal College of Obstetricians and Gynaecologists, Fellow of Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Certificate of Gynaecological Oncology, Doctor of Medicine, Head of Gynaecological Oncology at Monash Health.

Summary

- Owner of world-class technology
- Building a team to deliver
- Designing tests that make a difference
- Generating Gold-Standard clinical evidence
- De-risking the path to market with a staged execution strategy
- Experienced leadership team with credentials to execute
- Developing the clinical implementation pathway
- Building the value chain for investors

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