



Making earlier detection of ovarian cancer a reality

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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.

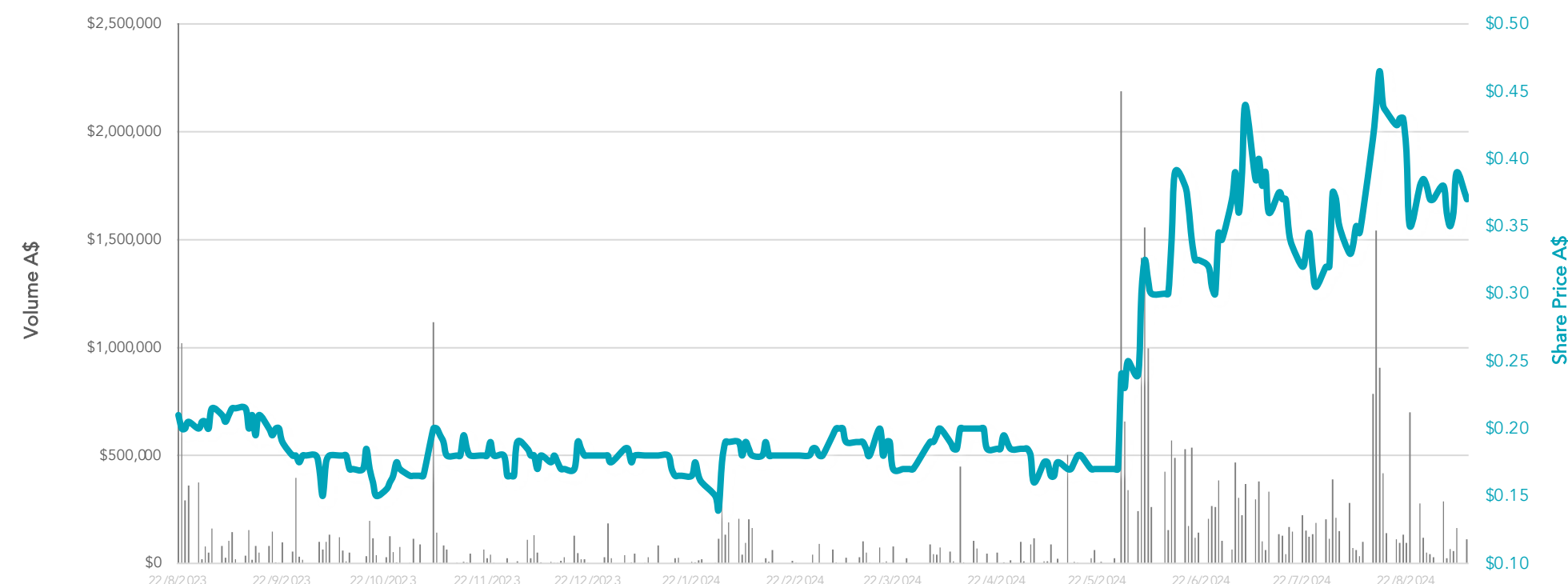
Cleo's first test – A Pre-Surgical Triage Test is designed to distinguish benign from malignant growths and will be compatible with standard diagnostic laboratory workflows worldwide.

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 (9 September 2024)	\$0.37
Shares on Issue	128.5M
Options	14M
Market Capitalisation (fully diluted)	\$48M
Cash (as at 30 June 2024)	\$9.34M





Cleo Diagnostics

Is bringing to market a simple blood test for the accurate and early diagnosis of ovarian cancer

Why Cleo Diagnostics :



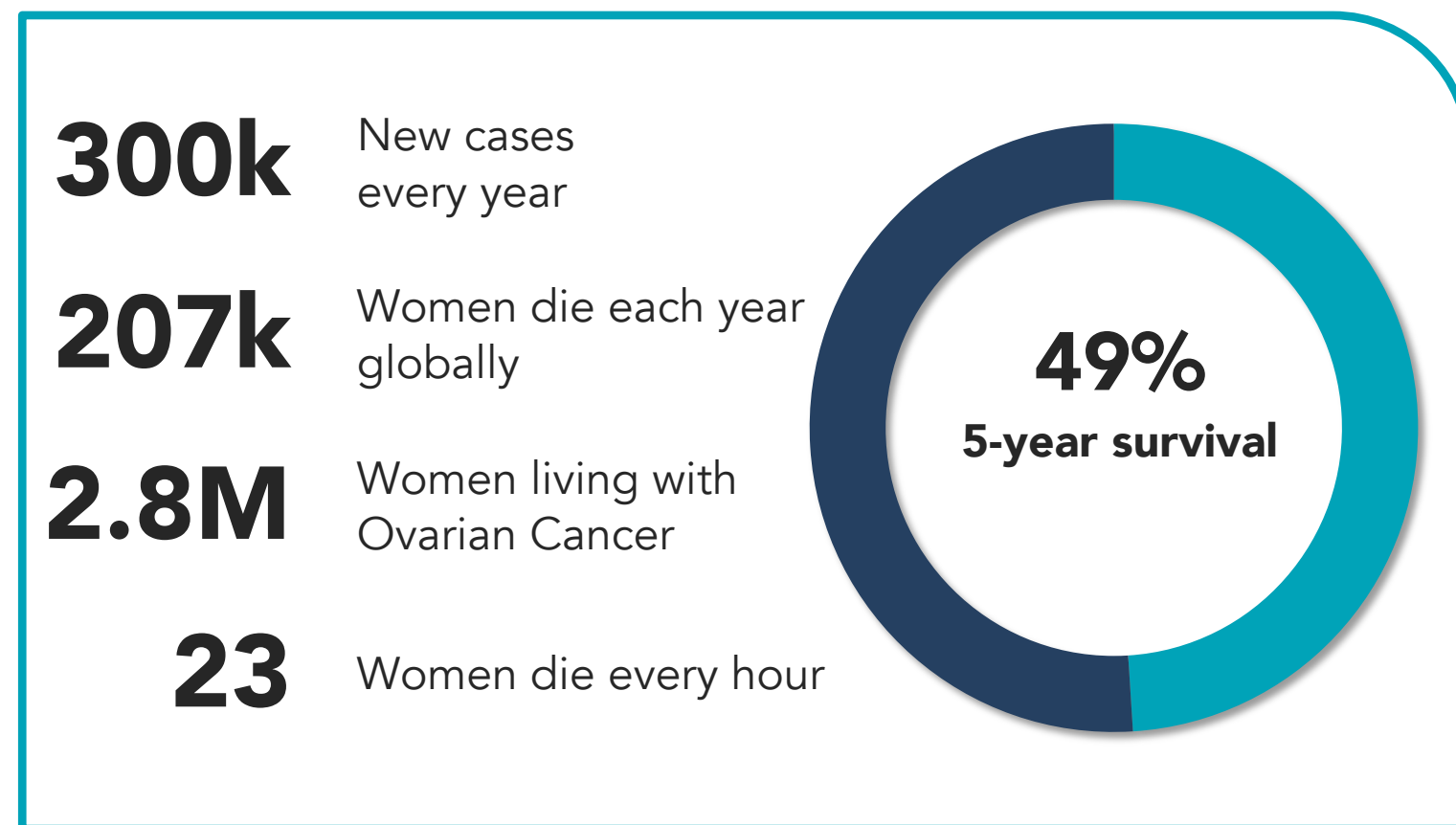
INVESTMENT HIGHLIGHTS

- A simple blood test for accurate and early detection of Ovarian Cancer
- Significant global 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

- **DIFFICULT** to detect and diagnose: *most cases are missed until its too late*
- **POOR SPECIFICITY** of existing tests: *uncertain referrals, delayed diagnoses, inappropriate surgeries*
- **NO SCREENING** for early disease detection: *cannot be identified when treatable*
- **DIAGNOSIS ONLY OCCURS AFTER SURGERY**



Accurate and early detection of ovarian cancers will significantly increase survival

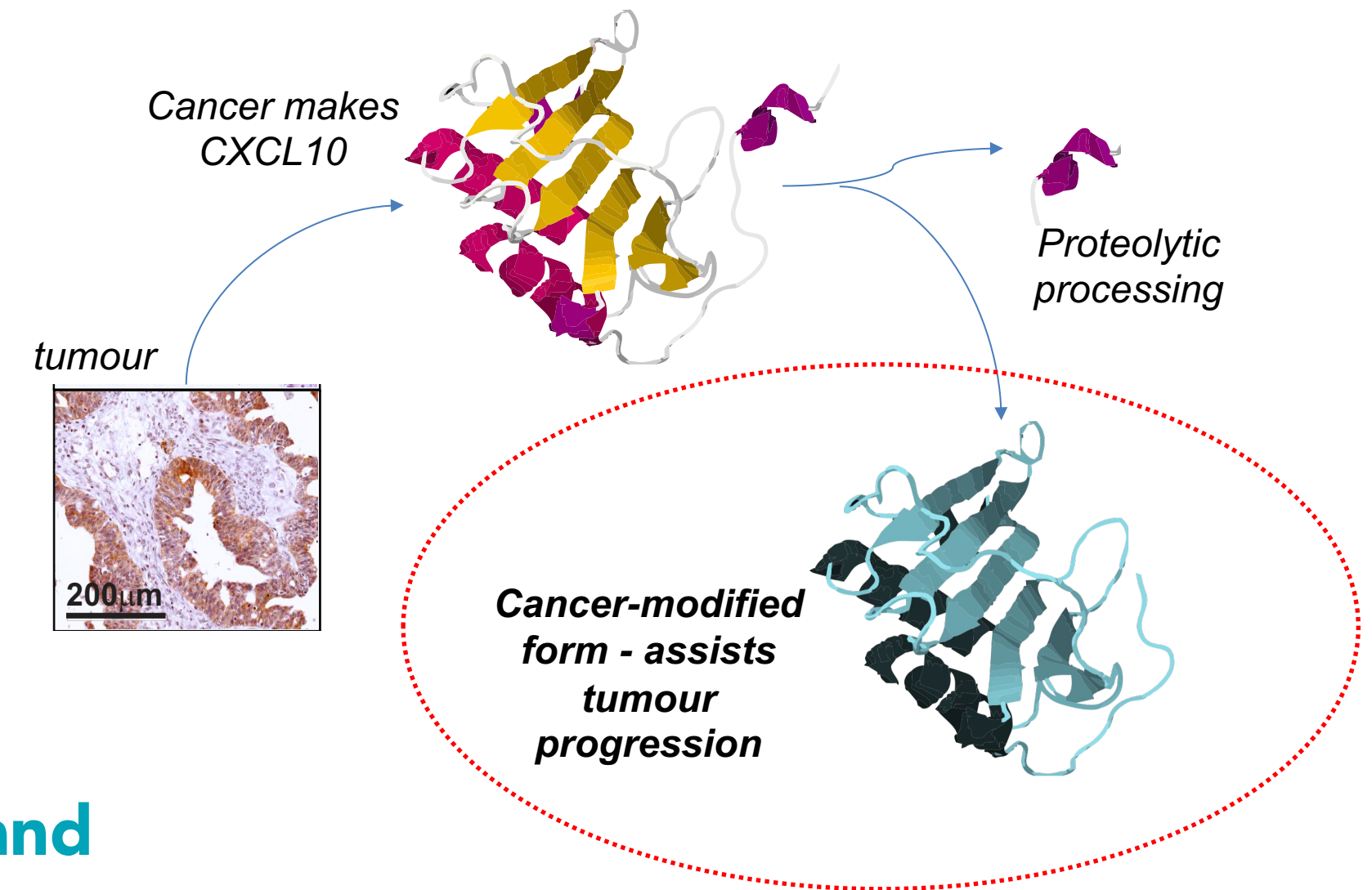
Source: World Health Organisation, Australian Institute of Health and Welfare supplemented by American Cancer Society, World Ovarian Coalition



CleoDX has developed a **simple and accurate blood test** for the detection of ovarian cancer

Leverages the discovery of a **cancer-specific form** of **CXCL10**

- Produced in cancers but not benign disease
- Occurs early in the cancer development
- Robust indicator at ALL stages of cancer progression



Novel intellectual property position granted in US and Australia

Proprietary marker panel assembled and tested for cancer detection

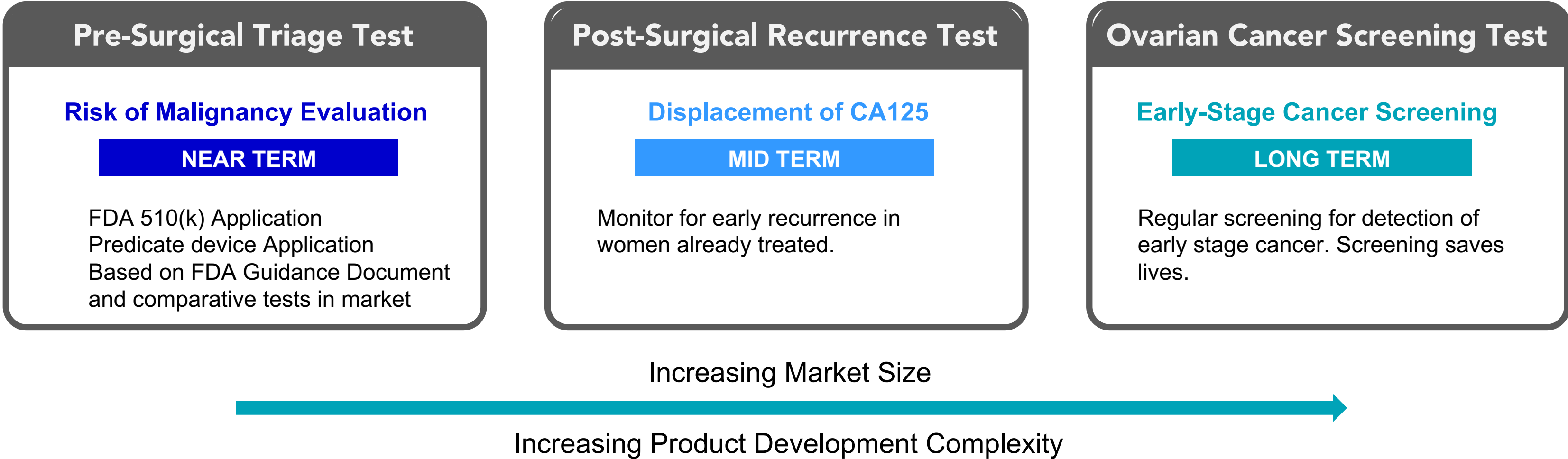
Rainczuk A *et al* (2014). *Int J Cancer* doi: 10.1002/ijc.28393

Cleo Diagnostics : One Platform Multiple Applications



CleoDX technology has **multiple applications** across the spectrum of disease

- underpins 3 testing strategies for product delivery



CleoDX Ovarian Cancer Test Out-Performs All Other Clinical Tests

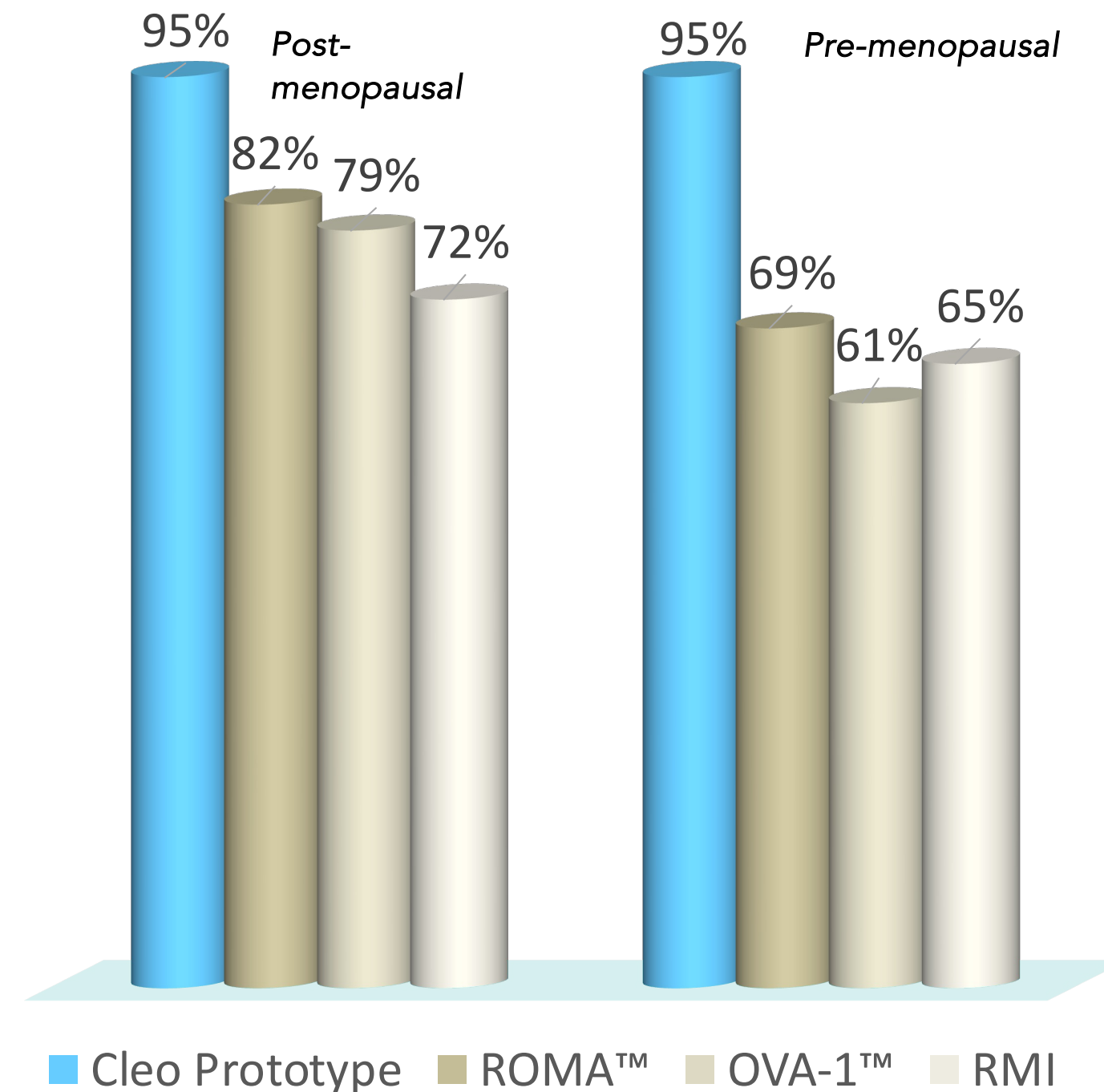


The CleoDX prototype is a disruptive technology which will ultimately replace CA125 testing

PROTOTYPE CleoDX test biomarker panel for cancer detection:

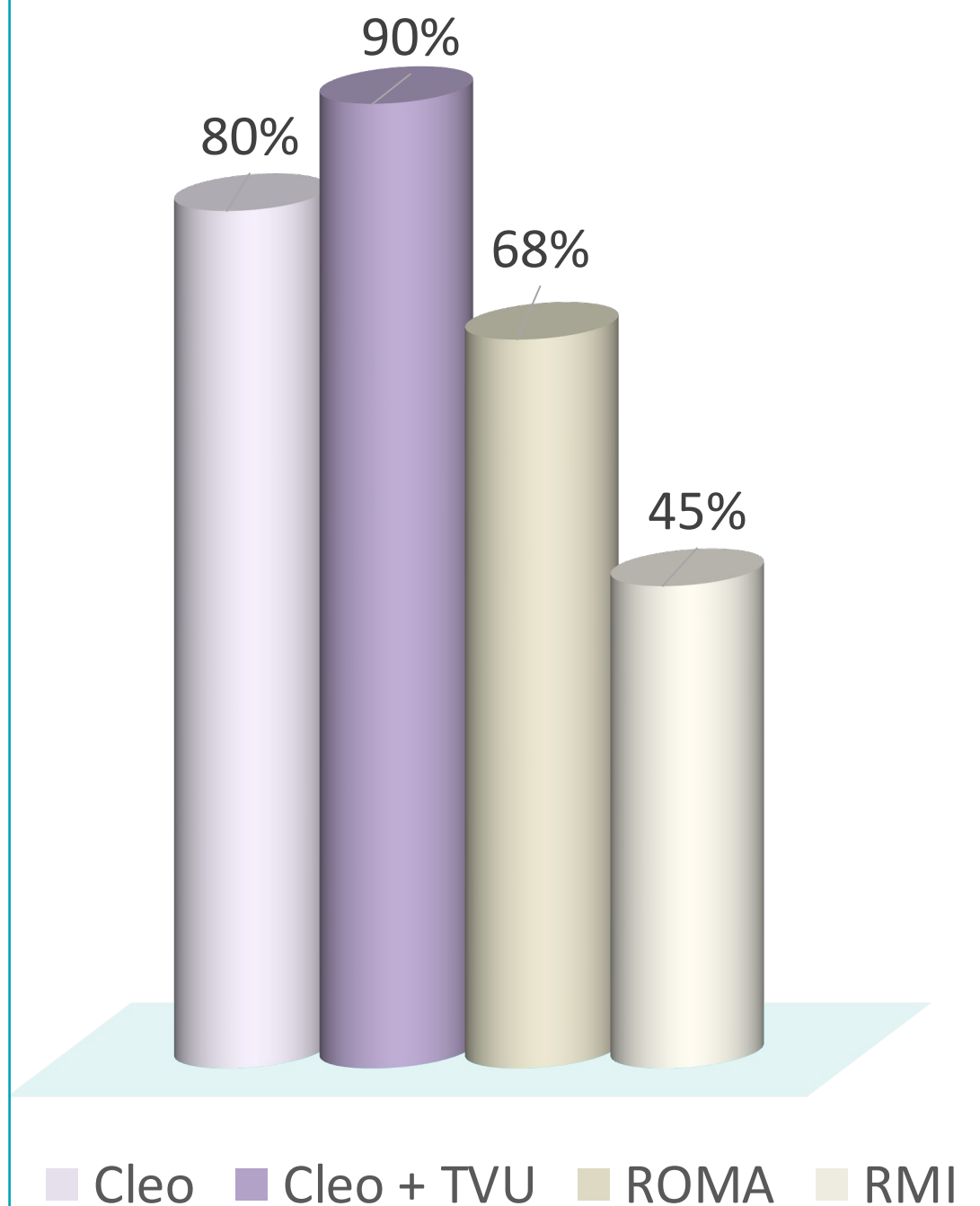
Specificity = 95% PPV = 95%
Sensitivity = 95% NPV = 95%

Sensitivity at 90% Specificity



- Davenport, C., et al., DOI:10.1002/14651858.CD011964.pub2
- Fritsche, H.A. DOI: 10.1002/ijgo.14733
- Bristow, R.E DOI: 10.1016/j.ygyno.2012.11.022

% Early Cancer Detection



- Stephens AN *et al* DOI: 10.3390/cancers15215267
- Stephens AN *et al* <https://doi.org/10.3390/cancers16112048>

Cleo Pre-Surgical Triage Test is Supported by Peer-Reviewed Evidence



- Technology backed by >10 years scientific R&D
- Evidence to drive clinical uptake and implementation by users
- Strategic position for patient reimbursement from medical insurers



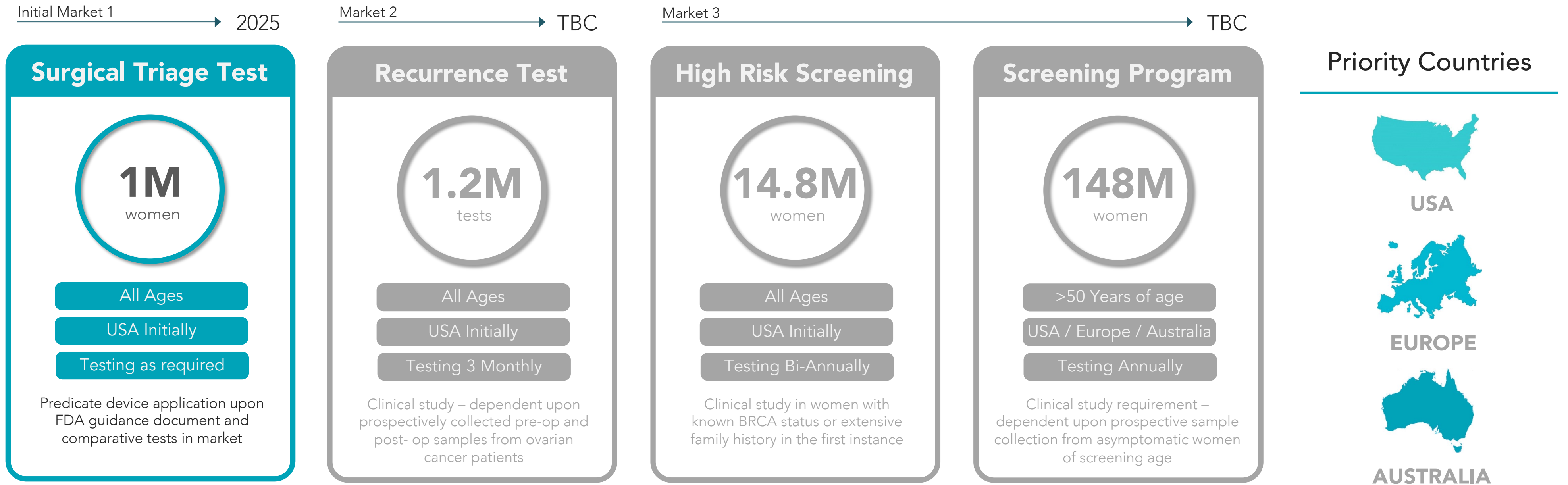
RESEARCH PAPERS

1. Stephens AN, Hobbs SJ, Kang S-W, Oehler MK, Jobling TW, Allman R (2024). **Utility of a Multi-Marker Panel with Ultrasound for Enhanced Classification of Adnexal Mass.** *Cancers* doi: 10.3390/cancers16112048
2. Stephens AN, Hobbs SJ, Kang S-W, Oehler MK, Jobling TW, Allman R (2024). **ReClassification of Patients with Ambiguous CA125 for Optimised Pre-Surgical Triage.** *Cancers* doi: 10.3390/diagnostics14070671
3. Stephens AN, Hobbs SJ, Kang S-W, Bilandzic M, Rainczuk A, Oehler MK, Jobling TW, Plebanski M, Allman R (2023). **A Novel Predictive Multi-Marker Test for the Pre-Surgical Identification of Ovarian Cancer.** *Cancers* doi: 10.3390/cancers15215267
4. Kampan NC, Kartikasari A, Deceneuux C, Madondo MT, McNally OM, Flanagan KL, Aziz NA, Stephens AN, Reynolds J, Quinn MA, Plebanski M (2023). **Combining TNFR2-Expressing Tregs and IL-6 as Superior Diagnostic Biomarkers for High-Grade Serous Ovarian Cancer Masses.** *Cancers* doi: 10.3390/cancers15030667
5. Sung-Woog Kang S-W, Rainczuk A, Oehler MK, Jobling TW, Plebanski M, Stephens AN (2021). **Active Ratio Test (ART) as a Novel Diagnostic for Ovarian Cancer.** *Diagnostics* doi.org/10.3390/diagnostics11061048
6. Wilson AL, Moffitt LR, Wilson KL, Bilandzic M, Wright MD, Gorrell MD, Oehler MK, Plebanski M, Stephens AN (2021). **DPP4 inhibitor sitagliptin enhances lymphocyte recruitment and prolongs survival in a syngeneic ovarian cancer mouse model.** *Cancers* doi.org/10.3390/cancers13030487
7. Moffitt LR, Bilandzic M, Wilson AL, Chen Y, Gorrell MD, Oehler MK, Plebanski M, Stephens AN (2020). **Hypoxia Regulates DPP4 Expression, Proteolytic Inactivation, and Shedding from Ovarian Cancer Cells.** *Int J Mol Sci* doi: 10.3390/ijms21218110
8. Kampan NC, Madondo MT, McNally OM, Stephens AN, Reynolds J, Quinn MA, Plebanski M (2020). **Pre-operative sera interleukin-6 in the diagnosis of high-grade serous ovarian cancer.** *Scientific Reports* doi: 10.1038/s41598-020-59009-z.
9. Rainczuk A, Rao JR, Gathercole JL, Fairweather NJ, Chu S, Masadah R, Jobling TW, Stephens AN (2014). **Evidence for the Antagonistic Form of CXC-motif Chemokine CXCL10 in Serous Epithelial Ovarian Tumours.** *Int J Cancer* **134** 530-41
10. Rainczuk A, Rao J, Gathercole J, Stephens A.N. (2012). **The emerging role of CXC chemokines in epithelial ovarian cancer.** *Reproduction* **144** pp. 303-317

Significant global market opportunity



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



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

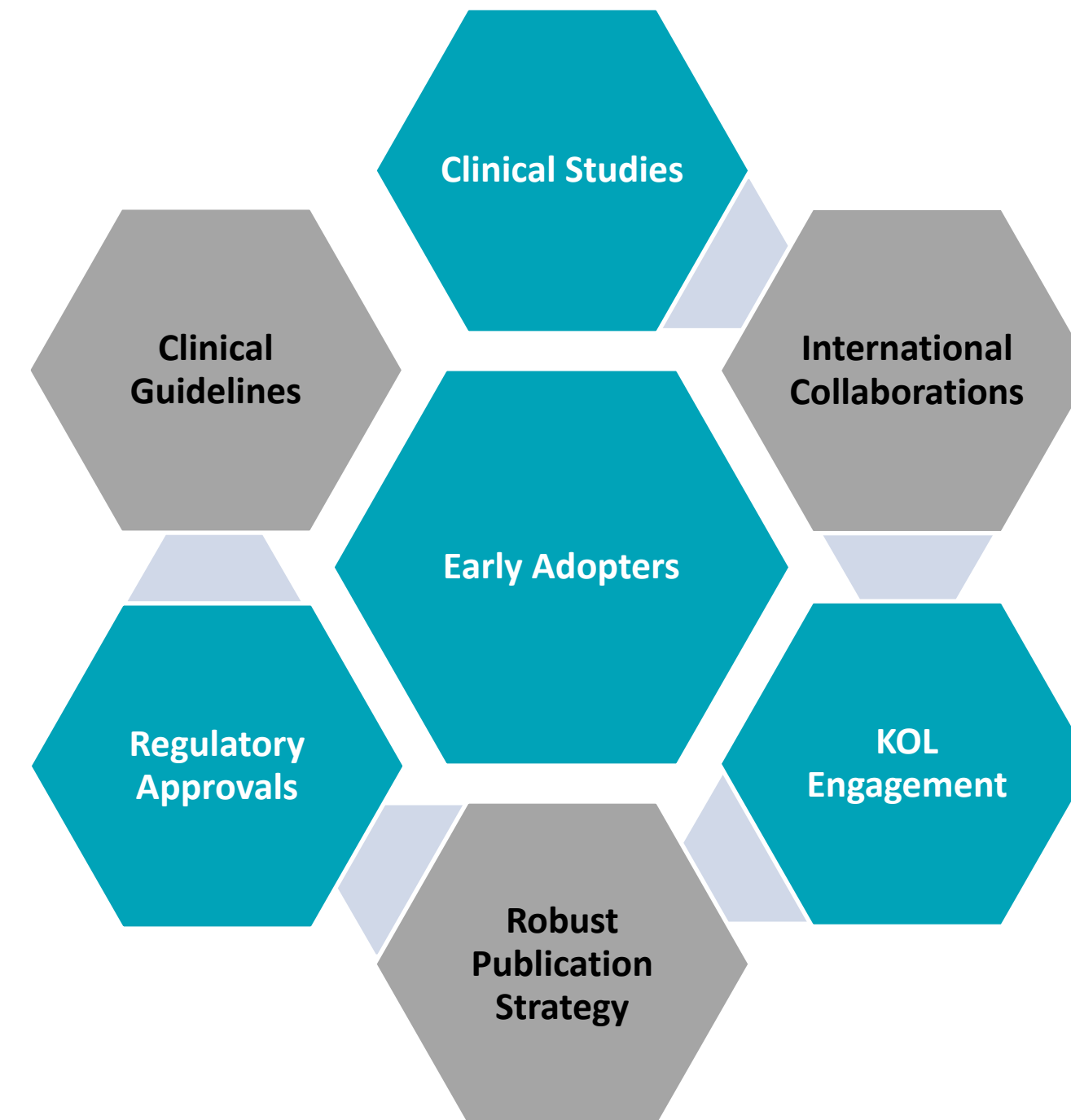
Market estimate based upon CPT coding and reimbursement analysis provided by Clarivate www.clarivate.com

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.

Cleo Diagnostics : A Strategic Plan to Deliver



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



Cleo Diagnostics : Experienced Management team with the Capacity to Deliver



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).



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.



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.



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 Program 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.



- CleoDX – simple, accurate and effective diagnostic test for ovarian cancer
- Gold-standard evidence supported by peer-reviewed literature
- World-class technology with IP protection and development pipeline
- De-risked path to market with a staged execution strategy
- Experienced leadership team with credentials to execute
- Regulatory, market uptake and reimbursement strategies in place
- Building the value chain for investors



Richard Allman

CEO

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Adrien Wing

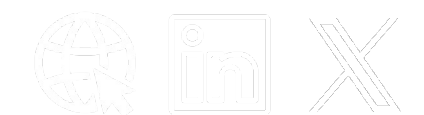
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