ASX Announcement

Cleo Commences Health Economic Study to Support U.S. Market Entry

Highlights

- **Partnership with EntityRisk to provide evidence-based insight into the economic value of Cleo's Ovarian Cancer Pre-Surgical Test in the U.S.**
- **Partnership with Norstella to examine detailed physician and claims data to identify high-value launch markets and maximise early adoption potential**
- **Refined Total Addressable Market estimate to accelerate payor reimbursement negotiations, and drive investor confidence ahead of commercialisation.**

MELBOURNE, AUSTRALIA, 18th August 2025: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce it has engaged and commenced work with EntityRisk and Norstella to deliver a United States (**U.S.**) focused health economic analysis and market assessment for its first commercial product, the Ovarian Cancer Pre-Surgical Test.

U.S Market Access and Reimbursement Support

EntityRisk, a specialist in health economics and value modelling, will lead the development of a model to quantify the economic benefits of adopting Cleo's Pre-Surgical Test for Ovarian Cancer. The project will also leverage the expertise of Managed Markets Insight & Technology, LLC (**MMIT**), a Norstella company, whose market access and payer intelligence capabilities will ensure the modelling is informed by comprehensive U.S. reimbursement data. Together, these outputs will provide robust, evidence-based justification to support payor engagement, identify optimal reimbursement arrangements, and underpin Cleo's commercialisation pathway in the U.S. healthcare market.

Ken Browe, Senior Vice President at Norstella, commented:

> *"Our collaboration with Cleo represents exactly the kind of partnership we are passionate about – EntityRisk's rigorous health economic modelling, combined with MMIT's payer and market access intelligence, to demonstrate clear value to the U.S. healthcare system. By integrating these insights, we aim to support a compelling reimbursement case that accelerates adoption of Cleo's Ovarian Cancer Pre-Surgical Test and delivers meaningful benefits for patients and providers alike."*

Targeted Market Entry

Cleo will also leverage Norstella's extensive health system and claims databases to refine its launch markets in the U.S., focusing on those regions with the highest clinical need and greatest commercial potential. This targeted approach is aimed at maximizing early adoption and accelerating early revenue generation, which is forecast for next year directly following FDA submission.

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Strengthened Investor Confidence with Accurate Market Data

Norstella's comprehensive analysis of physician procedural trends, payer policies, and claims data will deliver a refined, evidence-based Total Addressable Market (**TAM**) estimate for Cleo's Ovarian Cancer Pre-Surgical Test. This granular market sizing will not only guide manufacturing scale-up and operational planning but also provide a credible foundation for discussions with potential U.S. commercial partners, payors, and investors. By quantifying the true scope of the market opportunity with precision, Cleo will be equipped to negotiate from a position of strength, accelerate strategic decision-making, and instil confidence across its stakeholder base.

Commenting on the Agreement, CLEO Chief Executive Officer, Dr Richard Allman, said:

> *"Cleo is very pleased to partner with Norstella and EntityRisk to progress these important strategic initiatives. Their expertise will ensure our market entry is focused, data-driven, and positioned for success in the competitive and complex U.S. healthcare environment.*
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> *This integrated approach will equip payors with a clear, evidence-based understanding of the clinical and economic value of our Ovarian Cancer test, helping to facilitate reimbursement decisions and support successful entry into the U.S. market. We expect completion of the health economic analysis before year end, with the results to be published shortly thereafter."*

About EntityRisk

EntityRisk, is revolutionizing drug value assessment and evidence planning. EntityRisk's proprietary PROVEN™ Python-driven software solution, combined with its leading experts in health economics provides unparalleled efficiency, speed, and flexibility. This empowers HEOR, Market Access, and Commercial Development professionals to better understand uncertainty, make informed evidence investment decisions, and more effectively demonstrate value.

About Norstella

Our mission is simple: to smooth the path to lifesaving therapies for patients and providers. Norstella consists of prominent pharmaceutical solutions providers that have joined forces to offer a full range of solutions and consultancy services. Through its brands—Citeline, Evaluate, MMIT, Panalgo and The Dedham Group—Norstella supports biopharma companies in making smarter, faster decisions across the drug development and commercialization lifecycle. For more information visit Norstella and follow us on LinkedIn.

-ENDS-

This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board.

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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

CLEO 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.