

INOVIQ REPORTS INDEPENDENT TECHNICAL REVIEW FINDINGS AND CONFIRMS EXO-OC™ LDT COMMERCIALISATION PATHWAY

- An independent US-based expert reviewer with established reputation in diagnostics development has completed a thorough assessment of INOVIQ's technical review following the outcomes of the OC2200 study.
- The independent reviewer confirmed that the analysis performed by INOVIQ, and provided to the market, accurately identified pre-analytical sample collection and handling differences as the largest source of study variability. Furthermore, these issues could only be identified after program completion.
- The reviewer confirmed the biological relevance of EXO-OC™ and recommended the program focus on optimising tumour-specific EV capture to increase signal-to-noise ratio, refine the biomarker panel and implement consistent sample collection protocols before further clinical evaluation.
- The Company has reviewed its go-forward program and has established a staged optimisation, verification and laboratory validation program to progress EXO-OC™ towards US Laboratory Developed Test commercialisation within 12-18 months, targeting H1 CY2028.

Melbourne, Australia, 30 September 2026: INOVIQ Limited (ASX:IIQ) (INOVIQ or the **Company**), a biotechnology company developing next-generation exosome-based diagnostics and therapeutics, today announced completion of its review of the issues associated with the OC2200 verification study and outlined a revised development program to advance EXO-OC™ towards commercialisation as a Laboratory Developed Test (LDT) in the United States.

Review Completed

The Board previously announced that the OC2200 study could not be completed because variability in biorepository samples materially affected biomarker measurement and prevented meaningful evaluation of EXO-OC™ performance (ASX: 1 July 2026). The Company provided further detail in a webinar presentation (ASX: 14 July 2026).

In addition to continuing analysis by the Company's scientific personnel, the Board commissioned an independent review by Dr Mathew Moore PhD, Principal of US-based contract diagnostics organisation ResearchDx.

The review aimed to independently assess the Company's internal findings, identify the factors contributing to the study outcome, and recommend a path forward for the EXO-OC™ program.

Key findings by Dr Moore include:

- ResearchDx recomputation of the OC2200 study results confirmed that the Company's technical assessment was accurate, reproducible and appropriately interpreted.
- **Pre-analytical sample collection and handling differences were the largest identified source of study variability.** Differences across the five commercial biorepositories in blood collection, sample processing and specimen handling materially affected biomarker measurements.
- **OC2200 samples contained substantially lower measurable miRNA biomarker levels than the earlier OC500 study.** The majority of miRNA panel measurements were at or above the assay's

reliable measurement range or did not amplify, limiting the amount of quantifiable biomarker data available for analysis.

- **The reduced amount of quantifiable biomarker data prevented meaningful evaluation of the EXO-OC algorithm across the full OC2200 cohort.** Accordingly, the study did not provide sufficient data to reliably assess the performance of the multi-marker algorithm.
- **The review confirmed evidence supporting the underlying biological relevance of EXO-OC™.** Within samples sourced from a single collection site, EXO-OC™ distinguished ovarian cancer from benign gynaecological conditions supporting the continued development of the technology.
- **The review recommended a clear path for further development,** with recommendations that the EXO-OC™ program focus on optimising tumour-specific EV capture to increase signal-to-noise ratio, refining the biomarker panel and implementing consistent sample collection protocols before further clinical evaluation.

In summary, Dr Mathew Moore, advised: *“My independent review confirmed that INOVIQ’s analysis of the OC2200 study was accurate, reproducible and appropriately interpreted. The data indicate that differences in sample collection and handling across multiple biorepositories was the largest contributor to study variability, highlighting the importance of standardised specimen collection in diagnostic test development. Importantly, EXO-OC™ distinguished ovarian cancer from benign gynaecological conditions within a single collection site, supporting the biological relevance of the biomarker panel. The findings provide a clear framework for assay optimisation and verification studies that can further strengthen analytical performance and support progression towards clinical deployment.”*

EXO-OC Optimisation and Validation Program

In conjunction with this review, INOVIQ and its scientific advisers have established a staged program to advance EXO-OC™ toward US LDT readiness in a capital-efficient, risk-managed manner.

- **Stage 1: Assay Optimisation (Commenced Q3 CY2026)**
Enhancement of EXO-NET® technology for tumour-specific EV capture and refinement of the EXO-OC™ biomarker panel to enhance assay performance.
- **Stage 2: Clinical Verification**
Verification of the EXO-OC™ assay in an independent cohort including average and high-risk women with ovarian cancer collected under a standardised protocol to confirm clinical performance.
- **Stage 3: Laboratory Validation (Target completion – H1 CY2028)**
Technology transfer, optimisation and laboratory validation of EXO-OC™ will be conducted with a US CAP/CLIA-certified laboratory partner.
- **Stage 3: Laboratory Validation (Target completion – H1 CY2028)**
Technology transfer, optimisation and laboratory validation of EXO-OC™ will be conducted with a US CAP/CLIA-certified laboratory. Existing EXO-OC™ research workflows are compatible with clinical laboratory integration and support automated, high-throughput processing.
- **Stage 4: LDT Commercialisation**
Following successful laboratory validation, EXO-OC™ would be positioned for deployment as a US Laboratory Developed Test (LDT), with commercial launch, pricing and reimbursement activities led by the laboratory partner.

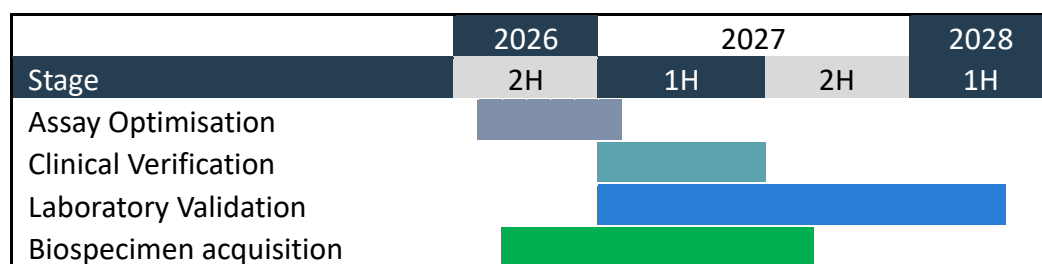


Figure 1: EXO-OC™ Optimisation and Validation Program

Biospecimen Acquisition Strategy

The use of retrospective biobanked samples is an established and recognised phase of diagnostic test development and is the basis on which early clinical validity is established before committing to prospective sample collection¹. Regulators accept biobanked specimens for this purpose, subject to evidence that storage and handling do not affect assay results. Consistent with industry practice, diagnostic tests are iteratively refined and validated in additional sample collections and independent cohorts as development progresses.

To support planned verification, validation, regulatory and reimbursement activities, INOVIQ is actively evaluating selected biobanks and academic and speciality clinical sites across Australia and the United States capable of providing clinical specimens collected retrospectively or prospectively under consistent protocols. The Company expects to undertake these activities in collaboration with a specialist contract research organisation and future laboratory partner, with sample acquisition and laboratory validation activities conducted in parallel to support an efficient pathway towards commercialisation.

Chairman Peter Gunzburg said: “As I said in the Annual Report, the Board was very disappointed that the poor quality of the biobank samples led to the discontinuation of the OC2200 study. However, the thorough review, including Dr Moore's report, validates the Company's technical assessment and gives us additional confidence that we understand the key factors that contributed to the OC2200 study outcome. Importantly, the review confirmed that these factors are addressable through assay optimisation and standardised sample collection protocols. The Board believes that notwithstanding the OC2200 results, our science is sound and we now continue to advance the EXO-OC™ test towards commercialisation in the US with an enhanced understanding of what is required to succeed.”

Authorised for release by the INOVIQ Limited Board of Directors.

FURTHER INFORMATION

Dr Leearne Hinch
Chief Executive Officer
E lhinch@inoviq.com
M +61 400 414 416

Peter Gunzburg
Chairman
E peter.gunzburg@gmail.com
M +61 412 927 773

ABOUT INOVIQ LTD

INOVIQ Ltd (ASX: IIQ) is a leader in exosome technology advancing next-generation diagnostics and therapeutics that transform cancer care. Our product portfolio includes commercial-stage exosome isolation products, a clinical-stage diagnostic for early detection of ovarian cancer, and a cutting-edge preclinical CAR-exosome therapeutic program for solid tumours. INOVIQ is shaping the future of cancer detection and treatment to improve patient outcomes. For more information on INOVIQ, visit www.inoviq.com.

ABOUT EXO-OC™ OVARIAN CANCER TEST

EXO-OC™ is INOVIQ's exosome-based blood test in development for the early detection of ovarian cancer in asymptomatic women. It uses INOVIQ's proprietary EXO-NET® technology to isolate exosomes and combines multiple exosomal miRNA biomarkers with CA125 in an AI/machine learning algorithm to enable early and accurate cancer detection.

EXO-OC™ has demonstrated strong early detection performance with 92.3% stage I/II and 92.5% all-stage sensitivity at 98% specificity in a 498-sample retrospective case-control study (ASX: 2 June 2025). Early detection represents the greatest opportunity to improve outcomes in ovarian cancer, which is often diagnosed at a late stage when survival rates are poor.

INOVIQ's commercial strategy is to first advance EXO-OC™ as a Laboratory Developed Test (LDT) in the United States for women at elevated risk of ovarian cancer, creating a potential pathway to earlier patient access, revenue generation and clinical adoption.

Beyond the initial LDT pathway, INOVIQ intends to further develop EXO-OC™ as an In Vitro Diagnostic (IVD) for broader ovarian cancer screening, supporting expanded market reach, reimbursement opportunities and long-term growth.

OVARIAN CANCER DIAGNOSTICS MARKET

Ovarian cancer remains one of the most lethal gynaecological cancers, with approximately 330,000 cases and 207,000 deaths worldwide each year². The global ovarian cancer diagnostics market is expected to reach US\$3.1 billion by 2035³, reflecting the significant clinical and commercial opportunity for more effective early detection solutions.

¹ Pepe MS, Etzioni R, Feng Z, et al. *EDRN five-phase framework: Phases of biomarker development for early detection of cancer*. J Natl Cancer Inst 2001;93(14):1054–61 (PMID 11459866)

² [Global Cancer Observatory, Cancer Today - Ovary Factsheet](#)

³ [Grand View Research 2025, Ovarian Cancer Diagnostics Market, 2025-2033](#)