INOVIQ

IIQ.AX

MST Access

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US deal = Clear pathway to market

- **Deal with Sonic USA offers independent recognition of EXO-OC™ test opportunity & starts commercialisation journey**
- **Opportunity: data supporting IIQ's EXO-OC™ early-detection of ovarian cancer remains compelling & unparalleled**
- **Once validated? MSTe FY29 launch & fast adoption in women at high risk, with self-pay; reimbursement to follow**

INOVIQ Ltd (ASX:IIQ) has signed a validation & licence-option agreement with Sonic Healthcare USA (ASX:SHL), establishing a potential pathway to US commercialisation of its EXO-OC ovarian cancer (OC) blood test. SHL will validate the test at its certified NY laboratory over the next 12-18mths, targeting completion in 2028. Concurrently, IIQ plans fresh US clinical-sample collection to repeat the assessment of EXO-OC's diagnostic (Dx) rigour (follows sample-quality issues that undermined OC2200). While the deal is a solid independent recognition of EXO-OC diagnostic approach, MST does not under-estimate the 'make or break' challenge of the next 2yrs in which IIQ will seek to: (1) prove & validate EXO-OC; & (2) kickstart IIQ's commercialisation journey. Validation allows SHL/IIQ to seek text reimbursement; which is its own challenge.

EXO-OC offers a compelling ovarian cancer test for unrivalled early-stage, asymptomatic diagnosis, which has potential to maximise survival outcomes. Initially targeting women at elevated risk, including those with BRCA1/2 gene (infers elevated risk for ovarian cancer). To recap - IIQ's retrospective study of 498 samples reported 92.3% sensitivity for stage I/II disease and 92.5% across all stages, at 98% specificity. The unmet need is substantial: 54% of US ovarian cancers are diagnosed after distant spread, with five-year relative survival of 32%, versus 92% for localised disease.

MST forecasts: Assume a US launch in 2HFY29, capturing 5-10% penetration of US addressable market within 2yrs, at average realised test price of US$1,000 (self-pay/reimbursed) and expansion beyond the US within 5-10 years. **1QFY27 result:** IIQ holds A$7.65m cash & has now received a A$1.78m R&D tax refund, taking pro forma cash to ~A$9.43m. Cash outflow at 1Q was A$1.69m; on MSTe further funding may be required before commercialisation.

Investment Thesis

IIQ's early data remains unmatched & the IIQ/SHL deal sets up a pathway to fully prove, validate & launch EXO-OC within 12-18mths. Listed and private Ovarian Cancer Dx test peers trade at 0.7-36x IIQ's current market cap despite being at similar stage of development or offering 'late diagnosis'. IIQ stock still carries the negative sentiment of its undermined OC2200 trial - this is misplaced anger - sample-quality issues are not uncommon (see Annex A).

Figure 1: Precedent Dx M&A: Top, Median & Bottom; IIQ undervalued?

Stage	Date	Dx / Tx	Target/Acquirer	Description	Total Deal Value US$b	Inferred IIQ Value A$ps
Commercial	2025	Dx	Exact Sciences/ Abbott	**Top**	23.000	0.23
				Median	0.575	5.84
Clinical	2025	Dx	Freenome/Roche	**Bottom**	0.200	0.00

Source: Various, MST

Valuation & Risks

Valuation: MST values IIQ at A$2.76ps (note Equity Value A$388m is below median Dx precedent transactions - see Figure 1) using DCF on risk adjusted FCF estimates, the latter considers that IIQ's EXO-OC Dx is yet to clear significant validation, regulatory and commercialisation/funding hurdles, each important de-risking milestones. **Risks:** Validation outcomes, launch timing, uptake, realised pricing and the commercialisation/reimbursement process.

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INOVIQ Ltd (ASX:IIQ) is a biotechnology company developing next-generation diagnostics and therapeutics for cancer. INOVIQ has commercialised its fast, efficient and scalable EXO-NET® exosome isolation technology for biomarker discovery and diagnostics development. The company is advancing clinical-stage diagnostics for detection and monitoring of ovarian and breast cancers, and early-stage exosome therapeutics for solid tumours.

Valuation	**A$2.76ps** *(was $3.56)*
Current price	**A$0.14ps**
Market cap	**A$20m**
Cash on hand	**~A$9.4m** *(Sep-26)*

Upcoming Catalysts / Next News

Period	
25-Nov-26	AGM
1HCY27	EXO-OC Assay Optimisation
1HCY27	EXO-OC Clinical Verification

IIQ Share Price ($A)



Source: FactSet, MST Access

IIQ financial summary

Year end Jun	Units	FY25	FY26	FY27E	FY28E	FY29E
PE	**x**	**nm**	**-2.4**	**-1.9**	**-2.5**	**2.2**
EV/EBITDA	x	nm	-2.5	-1.9	-2.5	1.5
EV/EBIT	x	nm	-2.4	-1.9	-2.4	1.5
Div yield	%	0.0%	0.0%	0.0%	0.0%	0.0%
FCF yield	%	-25.4%	-34.1%	-46.1%	-43.2%	27.3%

Stock information	
Ticker	**IIQ.AX**
Share Price ($)	0.14
Target price ($)	2.76
Enterprise value (A$m) (at FY27E)	19
Market capitalisation (A$m)	20

Income statement	Units	FY25	FY26	FY27E	FY28E	FY29E
Revenue (Incl other income)	**A$m**	**1.8**	**2.2**	**5.7**	**9.4**	**30.8**
growth y/y	%	*0.0%*	*22.0%*	*158.4%*	*63.7%*	*229.4%*
EBITDA	**A$m**	**-7.3**	**-7.9**	**-10.0**	**-7.8**	**12.9**
EBITDA margin	%	*-404.6%*	*-357%*	*-175%*	*-83%*	*42%*
EBIT	**A$m**	**-7.6**	**-8.1**	**-10.2**	**-7.9**	**12.8**
EBIT margin	%	*-418.1%*	*-368%*	*-179%*	*-85%*	*41%*
PBT	**A$m**	**-7.2**	**-7.7**	**-10.2**	**-7.9**	**12.8**
PBT margin	%	*-395.4%*	*-350%*	*-179%*	*-85%*	*41%*
NPAT	**A$m**	**-7.2**	**-7.7**	**-10.2**	**-7.9**	**8.9**
NPAT margin	%	*-395.4%*	*-350%*	*-179%*	*-85%*	*29%*
Reported NPAT	**A$m**	**-7.3**	**-7.5**	**-10.0**	**-7.7**	**9.1**
Reported NPAT margin	%	*-399.6%*	*-341%*	*-175%*	*-83%*	*30%*

1H26	2H26	1H27E	2H27E	1H28E	2H28E
1.1	**1.1**	**4.2**	**1.6**	**5.4**	**4.0**
0.0%	*11.3%*	*273.9%*	*41.1%*	*30%*	*nm*
-4.1	**-3.8**	**-2.5**	**-7.6**	**-2.4**	**-5.3**
-370%	*nm*	*-59%*	*nm*	*-45%*	*nm*
-4.1	**-4.0**	**-2.5**	**-7.7**	**-2.5**	**-5.4**
-370%	*nm*	*-61%*	*nm*	*-46%*	*nm*
-4.0	**-3.8**	**-2.5**	**-7.7**	**-2.5**	**-5.4**
-355%	*nm*	*-61%*	*nm*	*-46%*	*nm*
-4.0	**-3.8**	**-2.5**	**-7.7**	**-2.5**	**-5.4**
-355%	*nm*	*-61%*	*nm*	*-46%*	*nm*
-3.9	**-3.7**	**-2.4**	**-7.6**	**-2.4**	**-5.3**
-345%	*nm*	*-58%*	*nm*	*-44%*	*nm*

Per share data	Units	FY25	FY26	FY27E	FY28E	FY29E
Average diluted shares	m		132	141	141	141
EPS	**cps**		**-5.9**	**-7.3**	**-5.6**	**6.3**
growth y/y	%		*nm*	*nm*	*-22.3%*	*-212.5%*
Reported EPS	**cps**		**-5.7**	**-7.1**	**-5.5**	**6.5**
growth y/y	%		*nm*	*nm*	*-22.8%*	*-218.0%*
DPS	**cps**		**0.0**	**0.0**	**0.0**	**0.0**
Payout ratio	%		*0%*	*0%*	*0%*	*0%*

1H26	2H26	1H27E	2H27E	1H28E	2H28E
123	141	141	141	141	141
-3.2	**-2.7**	**-1.8**	**-5.4**	**-1.8**	**-3.9**
0.0%	*-14.7%*	*-43.7%*	*102.3%*	*-1.7%*	*-29.1%*
-3.1	**-2.6**	**-1.7**	**-5.4**	**-1.7**	**-3.8**
0.0%	*-15.1%*	*-44.6%*	*107.4%*	*-1.8%*	*-29.5%*
0.0	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
0%	*0%*	*0%*	*0%*	*0%*	*0%*

Balance sheet	Units	FY25	FY26	FY27E	FY28E	FY29E
Cash	A$m	7	9	0	-8	-3
Trade receivables	A$m	2	2	0	1	3
Inventories	A$m	0	0	1	1	1
Property, plant & equipment	A$m	1	1	1	1	1
Right-of-use assets	A$m	0	0	0	0	0
Goodwill	A$m	0	0	0	0	0
Intangibles	A$m	9	8	8	8	8
Other assets	A$m	1	0	0	0	0
Total assets	**A$m**	**18**	**20**	**10**	**2**	**11**
Trade payables	A$m	1	1	1	1	1
Provisions	A$m	0	1	1	1	1
Borrowings	A$m	0	0	0	0	0
Lease liabilities	A$m	0	0	0	0	-1
Other liabilities	A$m	0	0	0	0	0
Total liabilities	**A$m**	**2**	**2**	**2**	**2**	**1**
Total equity	**A$m**	**17**	**19**	**9**	**1**	**10**
Invested capital	A$m	10	10	8	9	13
Net debt (pos)	**A$m**	**-7**	**-9**	**0**	**8**	**3**

Performance metrics	FY26	FY27E	FY28E	FY29E
ROE (%)	-44%	-74%	-168%	171%
ROIC (%)	nm	nm	nm	nm
Gearing (%)	-98%	-3%	92%	23%
Adj ND / EBITDA (x)	0.6	0.0	-0.5	0.1
NWC (A$m)	1	0	0	3
NWC % of sales (%)	59%	1%	5%	10%
Gross OCF / EBITDA (%)	80%	88%	105%	80%
Capex / sales (%)	7.6%	1.8%	2.0%	3.0%
P/FCF (x)	-2.9	-2.2	-2.3	3.7
P/BV (x)	1.0	2.3	26.4	2.0

Cash flow statement	Units	FY25	FY26	FY27E	FY28E	FY29E
EBITDA	A$m	-7	-8	-10	-8	13
Change in NWC	A$m	0	0	1	0	-3
Other	A$m	3	1	0	0	0
Gross operating cash flow	A$m	-5	-6	-9	-8	10
Net interest	A$m	0	0	0	0	0
Tax paid	A$m	0	0	0	0	-4
Operating cash flow	**A$m**	**-5**	**-6**	**-9**	**-8**	**6**
Capital expenditure	A$m	0	0	0	0	-1
Acquisitions	A$m	0	0	0	0	0
Asset sales	A$m	0	0	0	0	0
Other	A$m	0	0	0	0	0
Investing cash flow	**A$m**	**0**	**0**	**0**	**0**	**-1**
Net borrowings	A$m	0	0	0	0	0
Dividends paid	A$m	0	0	0	0	0
New shares issued / other	A$m	2	9	0	0	0
Financing cash flow	**A$m**	**2**	**9**	**0**	**0**	**0**
Net change in cash	**A$m**	**-3**	**3**	**-9**	**-9**	**5**
Free cash flow	**A$m**	**-5**	**-7**	**-9**	**-9**	**5**

Source: IIQ, MSTe

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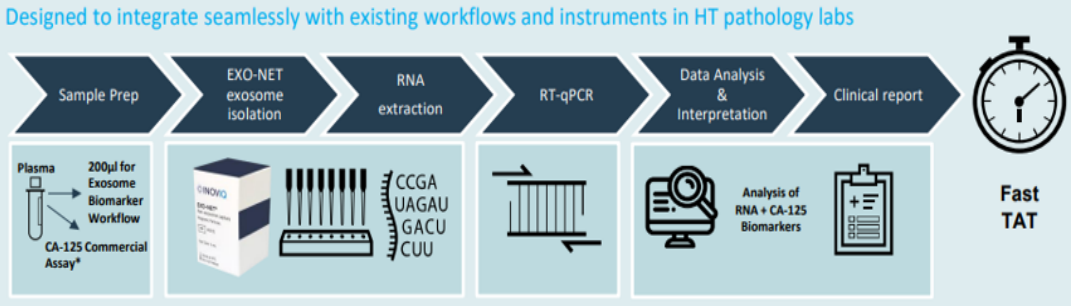
SONIC PUTS EXO-OC™ SCIENCE TO THE TEST

What is the EXO-OC™ test?

EXO-OC is INOVIQ's (IIQ) exosome-based blood test being developed for the early detection of ovarian cancer in asymptomatic women. The test uses IIQ's proprietary EXO-NET® technology to isolate exosomes (small extracellular vesicles containing molecular information) from blood samples. Multiple exosomal microRNA (miRNA) biomarkers are then combined with the established ovarian cancer biomarker CA125 in an AI/machine-learning algorithm to identify cancer-associated signals.

In a 498-sample retrospective case-control study, EXO-OC demonstrated 92.3% sensitivity in stage I/II ovarian cancer and 92.5% across all stages, at 98% specificity. These results remain subject to independent validation and have not established performance in a prospective screening population.

Figure 2: Simplified workflow for the EXO-OC™ diagnostic test



Source: IIQ

What has this deal achieved for IIQ?

- **Independent validation:** Establishes a pathway for SHL to independently assess EXO-OC's laboratory performance, beyond IIQ's internally generated results.
- **US commercialisation:** Provides SHL with a non-exclusive option to license EXO-OC as an LDT, subject to successful validation and commercial negotiations.
- **Technical de-risking:** Successful transfer and validation would demonstrate the feasibility of operating EXO-OC outside IIQ's facilities, although no commercial commitment has been secured.

Timeframe

INOVIQ expects the optimisation and validation program to take approximately 12–18 months, targeting early calendar 2028. Timing and potential commercialisation remain conditional on validation outcomes and further commercial discussions.

Company-reported results from a 498-sample retrospective case-control study showed 92.3% sensitivity for stage I/II disease and 92.5% all-stage sensitivity at 98% specificity. Sonic has not independently validated these results or endorsed the test's clinical performance.

INOVIQ plans parallel US clinical-sample collection to support clinical validation, regulatory and reimbursement activities. The announcement provides a potential commercial pathway but does not disclose agreed commercial economics or establish a firm launch date.

A Laboratory Developed Test (LDT) is a diagnostic test designed, manufactured and performed within a single clinical laboratory, rather than distributed as a commercial test kit.

Benefits over other ovarian cancer diagnostics - would patients pay?

EXO-OC's main advantage is its potential to detect ovarian cancer at an early, more treatable stage (I/II), before symptoms or an ovarian mass appear.

IIQ's updated algorithm achieved 92.3% stage I/II sensitivity and 92.5% all-stage sensitivity at 98% specificity in a retrospective study (n=498). Around 54% of US ovarian cancers are diagnosed after distant spread, with five-year relative survival of 32%, versus 92% for localised disease.

The initial commercial strategy targets asymptomatic women at elevated ovarian cancer risk through a US LDT, with broader screening via an in vitro diagnostic (IVD) a longer-term objective.

Early stage detection is the core selling point for EXO-OC - the potential to detect ovarian cancer at stage I/II (identifying disease earlier in asymptomatic women rather than waiting for symptoms or an ovarian mass to be investigated), before symptoms develop, particularly in women already known to be at elevated risk. It is a test for possible cancer present now, not a genetic test identifying future cancer risk. Note the EXO-OC proposition remains to be independently validated and must ultimately translate into survival benefit.

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Why would patients or reimbursement agencies pay? IIQ initially targets asymptomatic women at elevated risk, including BRCA1/2 mutation carriers and those with a strong family history. A convenient blood test detecting cancer before symptoms could enable earlier intervention and potentially reduce advanced disease burden. A 2025 ovarian cancer screening preference study (n=250) ranked mortality reduction as the leading screening consideration, suggesting demand for effective early detection. However, earlier diagnosis does not necessarily improve survival, which remains unproven for EXO-OC.

MSTe Average price realised (cash / reimbursement) US$1,000/test: Pricing precedents include ClearNote's Avantect Ovarian, which received a US$1,160 CMS payment determination, and Australian distributor BCAL's Avantect offering at A$1,495 per test.

Reimbursement will likely materially affect adoption: a US survey (n=1,043) found 75% willing to undergo multi-cancer screening with insurance coverage, versus 17% at US$1,000 out of pocket. IIQ's pricing power ultimately depends on independently reproducing diagnostic accuracy, demonstrating clinical utility and securing reimbursement. EXO-OC's clinical and economic benefits remain unproven.

Figure 3: Peers: fall short on asymptomatic/early stage, but have paved way on pricing

Test & ~USD Price	Early detect: Asymptomatic / known mass?	Evidence & limitations
ClearNote Health Avantect Ovarian Cancer Test **CLFS fee $1160**	Closest direct commercial competitor. Supports earlier diagnosis in women with elevated genetic or familial risk, including BRCA1/2 carriers and women with Lynch syndrome or a strong family history.	Analyses cell-free DNA for cancer-associated epigenetic signals. Received UKCA marking in 2025. This positioning is very similar to EXO-OC's intended high-risk application but does not itself establish a screening mortality benefit.
GRAIL Galleri **$949 list**	Yes, as a multi-cancer blood test intended for adults at elevated cancer risk, including asymptomatic people. Ovarian cancer is among the cancers it detects.	Grail's published validation figures show ovarian cancer sensitivity of 50% at stage I, 80% at stage II and 83.1% across all stages. Galleri is not currently included in cancer-screening guidelines.
Serial CA125 interpreted using ROCA, w/ultrasound follow-up **$295/test historical**	Tracks changes in CA125 over time vs relying only on a single threshold; studied prospectively in asymptomatic high-risk.women (ROCA = Risk of Ovarian Cancer Algorithm)	In UKFOCSS phase II, 4,348 high-risk women underwent 4mthly testing. Showed shift toward less advanced disease, but its design could not establish an ovarian-cancer mortality benefit.
CA125 & transvaginal ultrasound w/o ROCA **$236–390**	Can identify some cancers before symptoms but is an inadequate established screening solution.	Annual CA125/ultrasound screening is not recommended for high-risk women in the cited review; screening is not routinely recommended even in this group.

Source: Various, MST. Note: ROCA = Risk of Ovarian Cancer Algorithm

Observations: We note, CA125 and ultrasound screening have not demonstrated reduced ovarian cancer mortality, highlighting the need for more reliable early detection.

ROCA (Risk of Ovarian Cancer Algorithm) already demonstrates that early detection in high-risk women is possible. In UKFOCSS phase II, five of 13 screen-detected ovarian/fallopian-tube cancers were stage I/II. Including six occult cancers identified at surgery, 10 of the 19 cancers diagnosed within a year of screening were stage I/II. Importantly, those surgery-detected cancers should not all be counted as cancers found by the screening test.

Sonic Healthcare (SHL) - validation & re-run of OC2200 trial

Sonic Healthcare is an established global pathology provider, with its USA arm servicing ~20m physicians and patients across the USA. Validation of EXO-OC will be undertaken at its CAP/CLIA-certified molecular diagnostics laboratory in Rye Brook, New York.

Independent validation is particularly important for an exosome-based diagnostic, where pre-analytical sample handling, exosome isolation and miRNA measurement can materially influence results. SHL will validate whether EXO-OC can deliver reproducible analytical performance in an external laboratory.

Concurrently, IIQ plans fresh US clinical-sample collection to repeat the assessment of EXO-OC's diagnostic performance following sample-quality issues that undermined OC2200.

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Landing the LDT in the USA with Sonic

This means EXO-OC could initially be offered through Sonic's specialised US laboratory. Patient blood samples would be collected elsewhere and sent to that facility for analysis, where exosome isolation, miRNA quantification and algorithm execution are standardised. IIQ's initial target population is women at elevated risk of ovarian cancer, before potentially expanding into broader screening through a separately developed In Vitro Diagnostic (IVD).

In the US, LDTs are generally performed in CLIA-certified laboratories and have historically been subject to different regulatory requirements from FDA-cleared or approved commercial diagnostic tests.

Rationale

- **Regulatory pathway:** May reach the US market without obtaining FDA premarket clearance or approval, depending on applicable requirements.
- **Lower development costs:** Avoids the initial expense of producing, validating and distributing commercial diagnostic kits.
- **Analytical control:** Testing is performed in one laboratory, reducing variability in equipment, operators and testing procedures.
- **Earlier revenue generation:** Enables initial commercial testing while the company gathers additional clinical and operational evidence.
- **Clinical validation:** Provides an opportunity to establish real-world performance and physician adoption before broader distribution.
- **Commercial flexibility:** Allows refinement of the testing process without coordinating changes across multiple external laboratories.

Implications for EXO-OC™: Advantages and limitations

The LDT pathway allows IIQ to centralise EXO-OC testing within a specialised laboratory, standardising exosome isolation, miRNA quantification and algorithm execution. However, this does not eliminate the pre-analytical challenges identified in OC2200, including variability in blood collection, storage and transportation.

While an LDT may enable earlier revenue generation and clinical adoption, broader distribution through commercial diagnostic kits would require additional manufacturing scale, laboratory-to-laboratory reproducibility and regulatory validation. Importantly, LDTs can support nationwide testing through a central laboratory; the distinction relates to how a test is manufactured and performed, rather than its clinical purpose.

In the US, the FDA's 2024 rule expanding LDT oversight was vacated in Mar-25. LDTs remain subject to CLIA laboratory requirements, including analytical performance validation, although CLIA certification alone does not establish clinical validity.

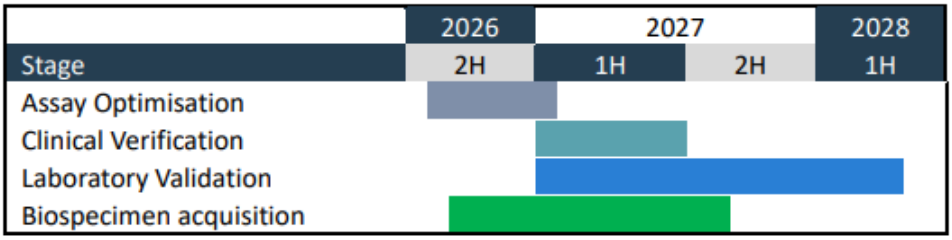
Validating Next Steps: Timeline

- **Nov-26 - Agreement executed:** Sonic granted a licence to transfer, optimise and validate EXO-OC.
- **Technology transfer and optimisation:** Establish EXO-OC within Sonic's laboratory workflow.
- **Independent validation:** Assess analytical performance and reproducibility within Sonic's laboratory.
- **Parallel clinical validation:** Collect additional US patient samples to support clinical, regulatory and reimbursement activities.
- **Early CY28 - Potential commercialisation:** Target LDT launch following a 12-18-month validation program, subject to successful validation and a definitive commercial agreement.

Key milestones: Independent validation outcomes, analytical reproducibility, performance in the intended clinical population, Sonic's commercial licence decision, reimbursement arrangements and clinician adoption.

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Figure 4: EXO-OC™ optimisation and validation program



Source: IIQ

Competitors and Comparators

Adjacent regulatory and commercial precedents

MDxHealth - ExoDx Prostate (formerly Bio-Techne) = Successful exosome-based LDT commercialisation Urine-based exosomal RNA diagnostic assessing prostate cancer risk. Commercialised as a US LDT without FDA clearance, receiving Breakthrough Device Designation in 2019. Three prospective validation studies (n=1,212) demonstrated 92.3% sensitivity, 30.1% specificity and 90.1% negative predictive value. MDxHealth acquired the business from Bio-Techne in Sep-25 for up to US$15m, demonstrating an established commercial pathway for exosome-based diagnostics.

Guardant Health - Shield = LDT to FDA approval and Medicare reimbursement Blood-based colorectal cancer screening test initially launched as an LDT in May-22. The prospective ECLIPSE study (>20,000 participants) demonstrated 83% sensitivity and 90% specificity, supporting FDA PMA approval in Jul-24. Subsequently secured Medicare coverage and an initial reimbursement rate of US$1,495 per test in Apr-25, demonstrating a pathway from LDT commercialisation to FDA-approved screening and reimbursement.

GRAIL - Galleri = Commercial LDT progressing through FDA approval Blood-based multi-cancer screening LDT, with FDA PMA submitted in Jan-26. Received a favourable FDA advisory committee benefit-risk vote (7-2) in Sep-26, despite the approximately 142,000-participant NHS-Galleri trial failing its primary endpoint for reducing late-stage cancer diagnoses. FDA approval remains pending, highlighting that commercialisation and promising diagnostic performance do not guarantee clinical benefit or regulatory approval.

Pacific Edge - Cxbladder = Reimbursement risk following commercial adoption Urine-based bladder cancer diagnostic commercialised as a US LDT, with Medicare coverage established in 2020 but withdrawn in Apr-25. Medicare-funded testing represented approximately 56% of FY25 operating revenue, with FY26 revenue declining 47% to NZ$11.5m following the coverage loss. A new draft coverage determination was issued in May-26, although reinstatement remained outstanding as of Oct-26, highlighting ongoing reimbursement risk.

Key takeaway:

ExoDx and Shield demonstrate successful LDT commercialisation and potential progression to FDA approval and Medicare reimbursement. Conversely, Galleri and Cxbladder highlight the risks associated with clinical validation and payer coverage.

For IIQ, the LDT pathway may enable earlier market entry, although clinical validation, regulatory requirements and sustainable reimbursement remain critical to commercial success.

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Broader change

Leadership and Board Change

IIQ has announced several leadership and Board changes as it refocuses on EXO-OC validation and commercialisation.

- **CEO departure (Oct-26):** Dr Leearne Hinch stepped down as CEO on 27 Oct-26 following a mutual agreement with the Board, ending ~10yrs of leadership. Chairman Peter Gunzburg assumed the role of interim Executive Chair, without additional remuneration, while IIQ searches for a replacement CEO.
- **Board renewal (Oct-26):** Non-Executive Directors Dr Geoff Cumming & Mary Harney announced their intention to retire at the AGM on 25 Nov-26. Andrew Chapman, founder of Merchant Funds Management, was appointed Non-Executive Director effective 2 Nov-26, representing IIQ's second-largest shareholder. Chapman brings over 25yrs of financial markets experience, including biotech capital raising and financial strategy.
- **Strategic direction:** Following its independent technical review, IIQ has prioritised EXO-OC assay optimisation, clinical verification and external laboratory validation. Management intends to provide a further strategic update at the AGM on 25 Nov-26.

1QFY27 Financials

- **Operating cash flow:** Net operating cash outflow of A$1.69m, comprising A$641k in R&D expenditure (vs A$1.50m in 4QFY26), A$371k in non-R&D staff costs and A$718k in administration and corporate costs. Reduced R&D spending followed elevated EXO-OC sample acquisition and therapeutic development costs in the preceding quarter.
- **Commercial receipts:** Customer receipts declined to A$58k (vs A$138k in 4QFY26), reflecting EXO-NET® and hTERT product sales. EXO-NET® had 96 customers through distributor Promega at quarter-end, although commercial revenue remains modest.
- **Balance sheet:** Cash balance at A$7.65m at 30 September 2026. The company reported approximately 4.5 quarters of available funding based on quarterly operating cash outflows.
- **R&D Tax Incentive:** IIQ subsequently received an A$1.782m R&D tax refund on 26 October 2026 relating to FY26 expenditure. This increases pro forma cash to approximately A$9.43m, excluding subsequent cash movements.
- **Funding outlook:** IIQ continues to prioritise capital allocation towards EXO-OC validation and CAR-exosome development. While the R&D refund strengthens near-term liquidity, further funding may be required depending on development expenditure, clinical validation requirements and commercialisation timelines.

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Forecasts

Total Addressable Market (TAM size and opportunity

Around 1.1% of women in the general population will develop ovarian cancer over their lifetime, or roughly 1 in 91 women.

IIQ plans to target women at elevated ovarian-cancer risk, including carriers of harmful variants in BRCA1/BRCA2 genes that normally help repair damaged DNA. Approximately 0.13–0.25% of the general population carries mutation in either BRCA1 or BRCA2—around 1 in 400–800 people.

BRCA1/2 increases lifetime ovarian-related cancer risk to approximately 39-58% for BRCA1 and 13-29% for BRCA2 carriers (all lifetime, not annual risks). We have used BRCA as the basis for eligibility for EXO-OC.

Testing for high risk / BRCA

The bottleneck is the number of BRCA test performed annually, which identify eligible high-risk women.

Our review of "BRCA genetic testing utilisation and expenditures among privately insured adults in the United States, 2013-2022," Genetics in Medicine (2025) shows peak BRCA-testing rate of 271.2 per 100,000 women which for US implies **~461,000 US women tested annually** (and growing ~7% pa).

However, BRCA test levels do not represent the market for IIQ. The relevant market is women whose BRCA test identifies a BRCA variant.

A review of studies of women referred for BRCA testing, including those with & without previous breast cancer, suggests that 8-18% will return a positive BRCA test.

USA addressable market

The US has ~21,000 new ovarian-cancer cases annually, but the potential testing market is the larger pool of women at elevated risk.

Applying an assumed 8-18% BRCA-positive rate to ~461,000 annual tests implies ~37,000-83,000 positive BRCA results annually.

Using US$1,000/test once annually, this represents approximately US$37-83m of potential annual laboratory revenue from each newly identified cohort, before eligibility deductions and uptake - not IIQ revenue.

Developed ROW TAM & addressable

Using a basket of EU, Japan, China, Canada, Australia & NZ, implies an estimated 2.0-3.1m BRCA1/BRCA2 carriers using an assumed 0.2-0.3% prevalence.

Assuming annual BRCA testing across these markets equals 25% of US volumes (from Myriad testing mix US vs ROW) implies approximately 115,000 tests annually. Applying an assumed 8-18% positivity rate gives approximately 9,200-20,700 newly identified BRCA1/BRCA2 carriers annually.

Using US$500/test once annually, this represents US$4.6-10.4m of potential annual laboratory revenue from each newly identified cohort, before eligibility deductions, uptake and local pricing.

USA lab market and basics

USA lab Market size: US$89bn in 2024, comprising US$58bn physician-channel testing (65%) and US$31bn hospital-channel testing (35%).

Figure 5: USA lab market: US$89bn in 2024 - Annual Diagnostic revenue for Top 3

Company	US$bn	Basis	Market share
Labcorp (LH-USA)	10.88	CY2025 Diagnostics revenue. Pan USA provider.	12.20%
Quest Diag (DGX-USA)	11.04	CY2025 group revenue; predominantly diagnostics. Pan USA.	12.40%
Sonic Healthcare (SHL-ASX)	1.33	FY2026 US laboratory revenue converted from A$; not pan US lab coverage, but coverage for specialty tests	1.50%

Source: IIQ

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How the market works

- Hospital laboratories serve inpatient and hospital-outpatient demand; outreach laboratories also compete for physician referrals.
- Independent laboratories combine collection networks, logistics, testing, billing and payer contracts. Hospitals can outsource reference testing, laboratory management or outreach operations.
- Growth drivers include ageing, chronic disease, advanced diagnostics and preventive testing; Quest estimates total-market growth of 1-3%.

LDT background - relevance to IIQ

- LDT (laboratory-developed test): a test developed and performed within a laboratory, rather than sold as a kit. The laboratory must meet CLIA, the US federal laboratory-quality standards, and establish the test's performance before reporting patient results. CLIA certification is not FDA approval of the individual test.
- **Reimbursement:** Three separate steps determine whether a test gets paid: a billing code identifies the test; a payment rate sets the potential amount; and coverage determines which patients and circumstances qualify.
- **Definitions:**
  - **CPT =** Current Procedural Terminology: the US billing-code system that tells an insurer which medical service or laboratory test was performed.
  - **PLA =** Proprietary Laboratory Analyses: a category within CPT for codes identifying a specific commercial laboratory test, rather than a general procedure.
- **Can IIQ/SHL seek reimbursement with CLIA certification? It's complicated:** The laboratory must also meet payer billing/enrolment requirements, use the correct code and demonstrate that the test meets the payer's coverage requirements. CMS explicitly distinguishes CLIA certification from Medicare programme participation.

Why compelling / novel lab tests are attractive to US labs

Though SHL is a 'distant 3rd' in the USA market, this is not a limiting factor in the marketing and adoption of a compelling / novel lab test which has potential to increase survival rates, given:

- National engagement & referral by engaged specialists
- Fast take-up, given BRCA diagnosis is a 'call to action'
- Willingness to pay cash
- Centralise the test in one location

Figure 6: CLIA certification allows a laboratory to perform and bill for testing…

Term	Description	What it does not establish
LDT laboratory-developed test	The laboratory develops and performs the test itself, rather than selling a kit to other laboratories.	Insurance coverage or payment.
CLIA Clinical Lab Improvement Amendments	US federal standards governing the laboratory staff, quality controls and testing performance.	FDA approval of the test or proof that screening improves patient outcomes.
CPT Current Procedural Terminology	The American Medical Association's billing-code system: tells the payer which medical service or test was performed.	Whether the payer covers it or how much it will pay.
Payment rate	The amount potentially payable for a covered test.	A commitment to pay every claim.

Source: Various, MST

- **Could IIQ/SHL use a common CPT code instead?** Only if an existing code accurately describes EXO-OC. The generic CPT code "81599" applies to "unlisted multianalyte assay with algorithmic analysis".
- **Case study:** Avantect obtained its own test-specific billing code (0507U) and a Medicare payment rate. IIQ would need an appropriate code for EXO-OC, it cannot use Avantect's simply because both detect ovarian cancer. A code and price still do not guarantee insurance coverage or payment.

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Forecast & Valuation

Forecasts & FCF

Key assumptions in MSTe

- USA launch occurs in 2HFY29 after EXO-OC validation phase
- Assume relatively fast take up, at ~5-10% of US addressable early stage market 1st 2yrs
- Average price realised (cash / reimbursement) US$1,000
- Expand to ROW within 5-10yrs
- Broader usage of test (beyond early stage) beyond 5yrs
- From FY35, considers risk adjusted nominal contribution from potential therapy launches/royalties
- R&D rebate continues through to 2031 (15yrs - IIQ established in 2016)

Figure 7: MSTe Key P&L metrics & FCF estimates - latter adjusted for probability of success & PV

	Units	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E	FY33E	FY34E	FY35E
Total sales revenue	A$m	2.9	5.4	26.5	47.6	56.8	67.9	81.1	97.1	116.2
EBITDA	A$m	-10.0	-7.8	12.9	33.8	42.7	48.6	61.4	76.8	95.4
Tax	A$m	0.0	0.0	-3.8	-10.1	-12.7	-14.4	-13.5	-17.2	-21.6
Change in working capital	A$m	4.1	3.6	1.8	4.0	3.9	-0.9	-1.1	-1.3	-1.6
Operating cash flows	**A$m**	**-6.0**	**-4.2**	**10.9**	**27.7**	**33.9**	**33.3**	**46.7**	**58.3**	**72.2**
Capex	A$m	-0.1	-0.2	-0.9	-1.7	-2.0	-2.4	-2.8	-3.4	-4.0
Free cash flow	**A$m**	**-6.1**	**-4.4**	**10.0**	**26.0**	**32.0**	**30.9**	**43.9**	**54.9**	**68.1**
Risk adjusted FCF prob success	**-23%**	**-4.7**	**-3.4**	**7.7**	**20.1**	**24.6**	**23.8**	**33.8**	**42.3**	**52.5**
Free cash flow: Present Value		*0.93*	*0.84*	*0.76*	*0.68*	*0.62*	*0.55*	*0.50*	*0.45*	*0.41*
PV cash flows AUD	**A$m**	**-4.4**	**-2.8**	**5.8**	**13.7**	**15.1**	**13.2**	**16.9**	**19.0**	**21.3**

Source: MSTe

Discounted Cash Flow (DCF)

MST values IIQ at A$2.76ps using a DCF risk adjusted for 2HFY29 EXO-OC launch and nominal therapeutic contributions from FY35. Note the Equity Value of A$388m is below median Dx precedent transactions (see Figure 1).

Investors are exposed to two risks with MST forecasts and valuation:

- **Risk to our FCF estimates:** incl validation outcomes, launch timing, uptake, realised pricing, etc;
- **Market risk:** which is captured in the DCF formula

In more detail:

Risk to our FCF estimates: We apply a 23% blended reduction to FCF reducing forecast sales. This reflects the assumed revenue mix and segment-specific risk adjustments below:

- **Research tools (existing sales):** <5% of sales; 5% risk
- **Diagnostics (Dx):** 90% of sales; at 20% risk
- **Therapeutics (Tx):** nominal sales; at 95% risk

Independent validation and a definitive licence agreement are important de-risking milestones.

Figure 8: DCF assumptions including market risk adjustment

Key Assumptions		
Tax rate	%	30%
Risk free rate	%	4.5%
Beta		1.0
Market Risk Premium	%	6.5%
Cost of Equity	%	11.0%
Debt Premium	%	1.5%
Cost of Debt	%	6.0%
Target gearing	%	0%
WACC	**%**	**11.0%**
Terminal growth rate	%	0.1%

Source: MSTe

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Peer Comps/Precedent Transactions as comparison for IIQ mkt cap

IIQ's preliminary EXO-OC data suggest differentiated early-stage ovarian cancer detection capabilities, with its agreement with Sonic Healthcare (SHL) providing a credible pathway to independent validation and potential commercial launch over the next 12-18 months.

Listed and private Ovarian Cancer Dx test peers trade at 0.7-36x IIQ's current market capitalisation, despite some being at comparable stages of development or primarily targeting later-stage diagnosis. IIQ's valuation also appears to reflect lingering negative sentiment following the invalidated OC2200 trial, although sample-quality issues are not uncommon in diagnostic development and do not necessarily undermine the underlying technology (see Annex A).

Figure 9: Benchmarking IIQ against relevant competitors and comparators within ovarian cancer diagnostics

Company	Product / test	Mkt cap (A$m)	Intended population	Technology	Sensitivity	Specificity	Other clinical evidence	Study context	Regulatory / commercial status	Commentary
INOVIQ	**EXO-OC**	19.7	Initially asymptomatic women at elevated ovarian cancer risk (US LDT); then broader screening	EXO-NET exosome capture; exosomal miRNAs + CA125; machine-learning algorithm	92.5%	98.0%	Stage I/II: 92.3%	Retrospective n=498; optimised algorithm; OC2200 inconclusive	Sonic validation agreement; LDT targeted early CY28	High-risk screening; independent validation outstanding
Aspira Women's Health	OVA1		Women with existing adnexal masses	Multi-protein blood biomarker test	94.0%	54.0%	Stage I/II: 91.0%	Adnexal mass population; not screening	FDA De Novo (2009)	Established regulatory precedent
Aspira Women's Health	OVERA	13.8	Women with existing adnexal masses	Multi-protein blood biomarker test	91.0%	69.0%	Stage I/II: 89.0%	Adnexal mass population; not screening	FDA 510(k) (2016)	Established regulatory precedent
Aspira Women's Health	OvaWatch		Women with existing adnexal masses	Blood-based risk assessment	90.0%	84.0%	Stage I/II: 76.9%; NPV 99.4%	Retrospective n=2,000; lower prospective performance	Commercial US LDT	LDT precedent; different intended use
ClearNote Health	Avantect Ovarian	NA	High-risk women	Blood-based cell-free DNA methylation assay	78.2%	94.0%	Early-stage sensitivity not disclosed	Company-reported case-control data; prospective validation outstanding	Commercial LDT; US reimbursement established	Direct high-risk screening comparator
Mercy BioAnalytics	Evident Ovarian	714.3	Ovarian cancer screening; initially average-risk women	Extracellular vesicle-associated protein biomarkers	82.9%	97.7%	Stage I/II: 88.9% (8/9)	Prediagnostic HGSOC study; limited early-stage cases	FDA Breakthrough + IDE (2026)	Direct EV-based screening competitor
CLEO Diagnostics	Pre-Surgical Ovarian Test	41.3	Women with adnexal masses before surgery	Blood-based multi-biomarker assay	95.0%	95.0%	Stage I/II: 80.0%	Retrospective n=334; earlier assay configuration	FDA 510(k) targeted 1HCY27	Listed regulatory development peer
CLEO Diagnostics	Screening prototype		Asymptomatic high-risk screening (development programme)	Blood-based multi-biomarker assay	90.2%	97.4%	Stage I: 92.2% at 98.7% specificity	Retrospective n=247; high-risk screening threshold; independent validation needed	Investigational; launched program Sep-26	Emerging direct screening competitor

Source: MST

Notably, taking the median deal value for the diagnostics and therapeutics and summing them together equates to an illustrative A$17.00/share price, demonstrating the potential value within the IIQ platform.

Figure 10: Illustrative IIQ platform value based on DX + Tx Precedent Transactions

Stage	Date	Dx / Tx	Target/Acquirer	Valn Comment	Total Deal Value US$m	Inferred IIQ Value A$ps
Various	Various	Dx	Various	Median from MSTe relevant transactions	575	5.84
		Tx			1,100	11.16
Dx + Tx				Total value for the IIQ Platform (Dx + Tx)	1,675	17.00

Source: Various, MST

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Figure 11: Diagnostic (Dx) Transactions (AUDUSD 0.70)

Stage	Date	Dx / Tx	Target/Acquirer	Valn Comment	Total Deal Value US$m	Inferred IIQ Value A$ps
Commercial	2025	Dx	Exact Sciences/ Abbott	Scaled commercial cancer diagnostics business; limited direct comparability to IIQ.	23,000	233.40
Clinical	2025	Dx	Freenome/Roche	Pre-commercial screening platform; demonstrates strategic interest in blood-based diagnostics.	200	2.03
FDA Pending	2025	Dx	Freenome/ Exact Sciences	Late-stage screening licence; significant milestones contingent on regulatory and commercial success.	885	8.98
Clinical	2023	Dx	Haystack/Quest Diagnostics	Clinical-stage liquid biopsy acquisition; relevant precedent for IIQ following validation.	450	4.57
Clinical	2022	Dx	PGDx/Labcorp	FDA-cleared cancer genomics portfolio; more advanced than IIQ.	575	5.84
Clinical	2022	Dx	Freenome/Roche	Strategic investment in blood-based screening; not directly comparable to acquisition valuations.	290	2.94
Commercial	2021	Dx	Inivata/Neo Genomics	Liquid biopsy acquisition; supports potential value following clinical de-risking.	390	3.96
Clinical	2021	Dx	Resolution Bioscience/Agilent	Established NGS platform and CLIA laboratory; premium reflects greater commercial maturity.	695	7.05
Commercial	2018	Dx	ExosomeDx/ Biotechne	Closest exosome technology comparable; marketed LDT supports IIQ's potential post-launch valuation.	575	5.84
					Shares on Issue Year	141 FY27E

Source: Various, MST

Figure 12: Therapeutic (Tx) Transactions (AUDUSD 0.70)

Stage	Date	Dx / Tx	Target/Acquirer	Valn Comment	Total Deal Value US$m	Inferred IIQ Value A$ps
Preclinical	2026	Tx	Orna/Lilly	Preclinical in vivo CAR platform; significant strategic premium, limited direct comparability.	2,400	24.35
Preclinical	2025	Tx	Orbital/Bristol Myers Squibb	Preclinical in vivo CAR platform; supports platform value but distinct from IIQ's EV technology.	1,500	15.22
Phase 1	2025	Tx	Interius/Kite (Gilead)	Early clinical in vivo CAR platform; relevant precedent following clinical de-risking.	350	3.55
Phase 1	2025	Tx	Capstan/AbbVie	Early clinical in vivo CAR platform; premium reflects strategic interest in cell therapies.	2,100	21.31
Phase 1	2025	Tx	EsoBiotec/ AstraZeneca	Phase 1 in vivo CAR platform; contingent milestones reflect further development risk.	1,000	10.15
Phase 1	2024	Tx	Poseida/Roche	Clinical-stage T-cell platform; more advanced and differentiated from IIQ's EV therapeutics.	1,500	15.22
Phase 1b	2023	Tx	Gracell/ AstraZeneca	Clinical-stage T-cell therapies; supports potential value following clinical validation.	1,200	12.18
Phase 1	2022	Tx	Poseida/Roche	Clinical-stage T-cell licensing deal; contingent value not directly comparable to acquisition.	220	2.23
Phase 1	2021	Tx	Kuur/Athenex	Early clinical iNKT therapies; relevant cell therapy precedent but distinct modality.	185	1.88
Preclinical	2020	Tx	Carmine/Takeda	Preclinical RBC-EV technology; relevant EV precedent, with milestone-dependent value.	900	9.13
Preclinical	2020	Tx	Evox/Lilly	Preclinical EV platform; close technology comparable, though deal value is largely contingent.	1,200	12.18
Preclinical	2020	Tx	Evox/Takeda	Preclinical EV platform; supports strategic value of exosome delivery technology.	882	8.95
					Shares on Issue Year	141 FY27E

Source: Various, MST

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RISKS

Risks include validation outcomes, launch timing, uptake, realised pricing and the commercialisation /reimbursement process, as detailed below:

- **Clinical and analytical validation:** IIQ's EXO-OC diagnostic performance remains independently unvalidated following the unsuccessful OC2200 study, which identified significant pre-analytical sample variability. Failure to reproduce previously reported sensitivity and specificity across independent clinical samples could limit commercialisation prospects.
- **Technology transfer:** Successful transfer of EXO-OC to Sonic Healthcare requires reproducible exosome isolation, biomarker quantification and algorithm performance. Differences in laboratory equipment, sample handling and processing protocols could delay validation or require further assay optimisation.
- **Development and commercialisation:** IIQ's progression towards potential US LDT commercialisation in early CY28 depends on successful validation, clinical sample collection and commercial negotiations with Sonic. The agreement does not guarantee a commercial licence, with technical setbacks or execution delays potentially affecting timelines and revenue generation.
- **Funding and dilution:** Continued investment in clinical validation, regulatory activities and therapeutic development may require additional funding ahead of meaningful commercial revenue. Development delays or higher expenditure could necessitate further equity raisings, resulting in shareholder dilution.
- **Regulatory approval and reimbursement:** Commercialisation remains subject to applicable regulatory requirements, with broader screening potentially requiring additional clinical evidence and FDA approval. Sustainable reimbursement will depend on demonstrating clinical utility and cost-effectiveness, with adverse payer decisions potentially limiting adoption and revenue.
- **Competition and market adoption:** IIQ faces competition from emerging ovarian cancer diagnostics, including ClearNote, Mercy BioAnalytics and Cleo Diagnostics. Competing products achieving earlier clinical validation, regulatory approval or reimbursement could constrain market penetration, while clinician adoption will depend on demonstrated diagnostic accuracy and clinical utility.
- **Therapeutic development and manufacturing:** IIQ's CAR-exosome therapeutics remain preclinical, with efficacy and safety in humans unproven. Successful development depends on translating preclinical results into clinical benefit while establishing scalable, reproducible manufacturing processes.

CATALYSTS

- **Ongoing - EXO-OC assay optimisation:** Refinement of exosome enrichment, miRNA biomarkers and sample-processing protocols
- **Ongoing - Independent clinical verification:** Additional US clinical sample collection to assess EXO-OC diagnostic performance
- **Early CY28 - Sonic laboratory validation:** Completion of technology transfer, optimisation and laboratory validation
- **Ongoing - Sonic commercial licence:** Potential exercise of non-exclusive LDT licence option, subject to successful validation and commercial negotiations
- **Early CY28 - EXO-OC US commercialisation:** Potential US LDT launch, subject to successful validation and licensing
- **Ongoing - CAR-exosome manufacturing readiness:** GMP-compatible cell sourcing, CDMO selection and manufacturing optimisation
- **CY28 - CAR-exosome first-in-human studies:** Targeted progression into human clinical development
- **Ongoing - EXO-NET® commercial expansion:** New customers, product sales and additional commercial partnerships

APPENDIX A:

OC2200 study - invalid due to sample degradation - this spoilage is not uncommon

OC2200 Study - Expanded validation unsuccessful (Jul-26)

IIQ's expanded OC2200 study sought to independently evaluate EXO-OC's diagnostic performance across up to 2,000 samples. Analysis of ~1,200 samples sourced from five commercial biorepositories identified significant sample-quality variability. One provider supplied 616 samples, including 69% of cancer cases, exhibiting reduced protein and miRNA levels consistent with degradation. Variability across the remaining providers also materially affected biomarker measurements, rendering the cohort unsuitable for reliable assessment of diagnostic performance.

Importantly, OC2200 failed to validate EXO-OC's clinical performance, rather than demonstrating that the test was ineffective. However, the findings highlighted the test's sensitivity to pre-analytical sample handling and the need to demonstrate reproducibility across collection sites.

Independent Technical Review (Sep-26)

INOVIQ commissioned Dr Mathew Moore, Principal of US-based diagnostics organisation ResearchDx, to independently assess the OC2200 study findings, identify factors contributing to the unsuccessful validation and recommend further development activities.

Key findings:

- **Independent verification:** ResearchDx independently recomputed the OC2200 results, confirming that INOVIQ's technical analysis was accurate, reproducible and appropriately interpreted. The review assessed the company's existing study data rather than conducting a new clinical validation study.
- **Pre-analytical variability:** Differences in blood collection, sample processing and specimen handling across five commercial biorepositories were identified as the largest source of study variability. These differences materially affected the consistency of biomarker measurements between sample providers.
- **Reduced biomarker detection:** OC2200 samples exhibited substantially lower measurable miRNA levels than the original OC500 cohort. Most miRNA measurements were outside the assay's reliable measurement range or failed to amplify, reducing the amount of quantifiable biomarker data available for analysis.
- **Algorithm performance:** Insufficient quantifiable miRNA data prevented meaningful evaluation of EXO-OC's multi-marker algorithm across the full OC2200 cohort. Consequently, the study could not reliably establish the test's clinical sensitivity or specificity.
- **Evidence of biological discrimination:** Within samples obtained from a single collection site, EXO-OC distinguished ovarian cancer from benign gynaecological conditions, supporting the biological relevance of its biomarker panel. However, the review did not establish reproducibility across multiple collection sites or independently validate the original OC500 diagnostic accuracy.

Recommendations and subsequent development:

- **Improve exosome enrichment:** Optimise tumour-specific extracellular vesicle capture using EXO-NET® to increase the signal-to-noise ratio, improving the relative abundance and measurement of cancer-associated biomarkers.
- **Refine biomarker selection:** Optimise the miRNA biomarker panel to improve analytical performance, including the reliability of biomarker detection and quantification.
- **Standardise sample collection:** Implement consistent blood collection, processing and handling protocols to reduce pre-analytical variability in future studies.

Key takeaway: The independent review identified plausible, addressable sources of OC2200's unsuccessful validation and provided supporting evidence for EXO-OC's underlying biological rationale. However, demonstrating reproducible analytical and clinical performance across independently collected samples remains essential. The subsequent agreement with Sonic provides a pathway to undertake external laboratory validation but does not resolve these outstanding questions.

Figure 13: For pre-analytical factors to be fully controlled - only achieved by using prospective samples



Source: MST, IIQ

Prior Examples of Pre-Analytical Validation Challenges and Outcomes:

IIQ's OC2200 study identified substantial variability in sample handling across five biorepositories, resulting in reduced measurable miRNA levels and an inability to establish diagnostic performance. Historical precedents demonstrate how specimen degradation and inconsistent processing can compromise biomarker detection, with some technologies subsequently achieving clinical validation following analytical improvements.

- **OvaCheck - Ovarian cancer (2002-04) = Unsuccessful:** An initial serum-proteomics study reported 100% sensitivity and 95% specificity. Subsequent independent analyses identified inconsistent sample processing, experimental artefacts and poor biomarker reproducibility, potentially confounding cancer-associated signals. The test did not progress to validated commercial use, highlighting how pre-analytical variability can undermine initially promising diagnostic results.
- **PreGen-Plus / Cologuard - Colorectal cancer (2005-14) = Subsequent technological success:** Early stool-DNA testing demonstrated approximately 52% sensitivity, with specimen degradation limiting DNA recovery. Storage at room temperature for ≥36 hours materially reduced recoverable DNA, including an 82% reduction in detection sensitivity for one DNA-integrity marker. Subsequent specimen stabilisation and improved extraction increased prototype sensitivity to 72.5%. Further assay and biomarker development ultimately supported Cologuard's FDA approval in 2014, following a study reporting 92.3% sensitivity.
- **CellSearch - Circulating tumour cells (2004 onward) = Successful validation:** Circulating tumour cells are susceptible to degradation during sample transport and storage. CellSave preservative tubes enabled stable cell recovery for up to 96 hours, with FDA-submitted studies identifying no significant difference in cell counts between approximately 24 and 96 hours ($p>0.90$). CellSearch received FDA clearance in 2004, demonstrating how standardised preservation can support reproducible centralised testing.
- **ExoDx Prostate - Prostate cancer (2016-22) = Successful validation:** A urine-based exosomal RNA diagnostic measuring three gene transcripts, using standardised sample collection, refrigerated storage and centralised laboratory processing. A pooled analysis of three prospective studies (n=1,212) demonstrated approximately 92% sensitivity, 90% negative predictive value and an AUC of 0.70. Commercialised as a US LDT, ExoDx provides a directly relevant precedent for exosome-based diagnostics achieving multicentre clinical validation.

Supporting pre-analytical research:

- **Circulating miRNA diagnostics - Multiple indications (2011) = Pre-analytical limitations identified:** Mayo Clinic researchers demonstrated that blood processing, haemolysis, cellular contamination and RNA extraction materially influenced measured miRNA concentrations. Haemolysis increased three of four biomarkers, while the investigated miRNAs remained stable for 24 hours at room temperature and 72 hours under refrigerated or frozen conditions.
- **Urinary exosome biomarkers - Bladder cancer (2023) = Pre-analytical optimisation:** EV-associated proteins A2M and CLU remained relatively stable for three days at 4°C, but approximately 24 hours at room temperature. The five-patient study highlighted biomarker-specific sensitivity to storage conditions.

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- **Urinary exosomal RNA - Kidney transplant rejection (2023) = Pre-analytical optimisation:** Elevated storage temperatures and freeze-thaw conditions altered exosomal mRNA measurements, with some changes exceeding five PCR cycles. Refrigeration at 4°C maintained RNA integrity for approximately seven days, illustrating how sample degradation can influence multi-marker algorithm outputs.

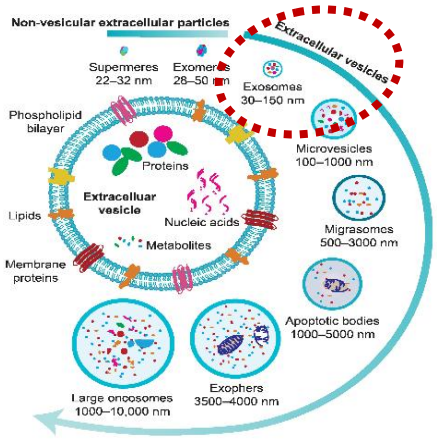
EXO-OC™ combines EXO-NET® technology & exosomes

EVs – tiny particles released by cells

Extracellular Vesicles (EVs) are:

- Tiny membrane-bound particles released by cells into surrounding tissues and bodily fluids, where they can carry messages to other cells.
- Used by cells to send messages and materials to other cells, including proteins, fats, and genetic information.
- Naturally produced by many cell types and can influence how other cells behave.
- An umbrella term that includes different types of cell-released particles – including exosomes.
- Think of EVs as tiny biological packages that cells use to communicate with each other.

Figure 14: Exosomes – a subset of Extracellular Vesicles (EVs)



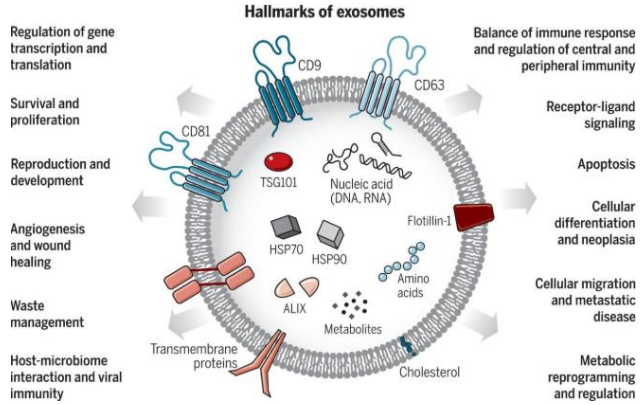
Source: MDPI

Exosomes – a subset of Extracellular Vesicles (EVs)

Exosomes are:

- A smaller, specific type of EV released by cells.
- Formed inside cells before being released into the surrounding environment.
- Used to carry biological messages, including proteins, fats, and genetic material, from one cell to another.
- Often described as natural delivery vehicles because they can transport biological cargo between cells.
- Think of exosomes as tiny messenger parcels that cells send to communicate and influence other cells.

Figure 15: Exosomes – the cell-to-cell messenger nanoparticle



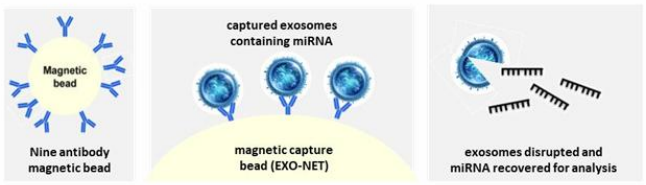
Source: Science

EXO-NET® – proprietary exosome capture tool

EXO-NET® is a commercially available research-use tool used to capture and study exosomes, where:

- Researchers take a biological sample, such as blood, urine, saliva or cell-culture fluid.
- EXO-NET® uses specialised capture technology to pull out exosomes from that sample.
- The captured exosomes can then be analysed to understand what messages or materials they are carrying, such as proteins, fats or genetic information.
- This can help researchers discover disease biomarkers and support the development of future diagnostic tests.

Figure 16: Exosomes are captured using EXO-NET® technology



Proprietary EXO-NET® exosome isolation technology enables EXO-OC™ sample preparation, exosomal biomarker extraction & analyses for multivariate index algorithm

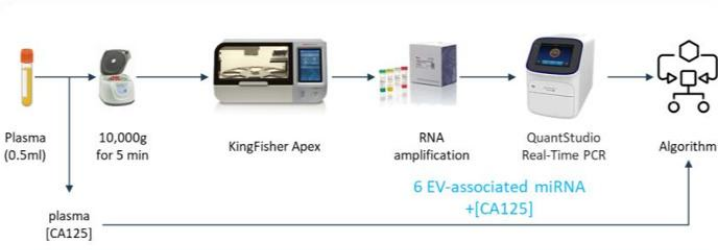
Source: IIQ

EXO-OC™

EXO-OC™ is an exosome-based ovarian cancer blood test, where:

- A simple blood sample is taken from a patient.
- EXO-OC analyses exosomes, which can carry cancer-related signals.
- INOVIQ's EXO-NET® technology is used to capture exosomes from the blood sample.
- The test then looks at multiple biomarkers carried by those exosomes, alongside CA125, to help detect signs of ovarian cancer.
- Early commercialisation is expected as a Laboratory Developed Test (LDT) via a lab partner, before broader development as a regulated In Vitro Diagnostic (IVD) test to support wider reimbursement and market access.

Figure 17: The EXO-OC™ diagnostic test



EXO-OC™ workflow is LDT-ready and scalable for future implementation in HT labs Multiomics signals + AI/ML enable early ovarian cancer detection with high sensitivity and specificity

Source: IIQ

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APPENDIX B:

1. Exosome Biology and Diagnostic Applications

What are exosomes?

Exosomes are small extracellular vesicles (EVs), typically 30-150 nanometres in diameter, released by cells into surrounding fluids, including blood, urine and saliva. They are enclosed by a lipid membrane and carry biological material, including proteins, lipids, DNA and RNA, which can facilitate communication between cells.

- **Role in cancer:** Cancer cells release EVs containing molecular material that can differ from that of healthy cells. Changes in these biomarkers may reflect the presence, type and progression of cancer.
- **Diagnostic potential:** EVs circulate in accessible bodily fluids, enabling non-invasive liquid biopsies that analyse disease-associated molecular signals without requiring tissue biopsies.
- **Biomarker protection:** The lipid membrane can protect enclosed RNA and proteins from degradation, although specimen collection, storage and processing can still materially affect biomarker recovery.
- **Key limitations:** Cancer-derived EVs represent only a fraction of circulating EVs, creating challenges in isolating disease-specific signals. Differences in sample handling, isolation techniques and biomarker quantification can also affect analytical reproducibility.

INOVIQ's EXO-NET® technology

INOVIQ's proprietary EXO-NET® platform uses magnetic beads coated with multiple antibodies to selectively capture EVs based on proteins expressed on their surfaces. Captured EVs can subsequently be analysed for RNA, proteins and other biomarkers.

EXO-NET® is designed for automated, high-throughput isolation from clinical samples. The existing pan-exosome capture technology isolates EVs from multiple cellular sources, while ongoing development aims to improve tumour-specific enrichment.

2. EXO-OC™: Exosome-Based Ovarian Cancer Detection

Technology overview

EXO-OC™ is an investigational blood-based diagnostic being developed to detect ovarian cancer, including early-stage disease. It combines exosomal microRNA (miRNA) biomarkers with CA125, an established ovarian cancer-associated protein marker, using a proprietary machine-learning algorithm.

How the test works:

1. **Blood collection**: Plasma is obtained from a patient sample.
2. **Exosome isolation:** EXO-NET® captures circulating EVs using antibody-coated magnetic beads.
3. **Biomarker measurement:** RNA is extracted from captured EVs and selected miRNAs are quantified using molecular techniques, including RT-qPCR.
4. **Algorithm analysis:** Multiple exosomal miRNA measurements are combined with plasma CA125 to generate a diagnostic classification.
5. **Clinical interpretation:** The resulting classification aims to distinguish ovarian cancer from non-cancer conditions, with performance assessed through sensitivity and specificity.

Why combine miRNA with CA125?

- **miRNA:** Small non-coding RNA molecules involved in regulating gene expression. Their abundance can change with cancer-associated biological activity, providing multiple potential diagnostic signals.
- **CA125:** A commonly used ovarian cancer biomarker that has limited sensitivity in early-stage disease and can also be elevated in certain benign conditions.
- **Combined approach:** The algorithm integrates several biomarker measurements rather than relying on CA125 alone, with the objective of improving cancer detection and reducing misclassification.

Clinical evidence and analytical validation

- **Initial OC500 study (2025):** ~500 retrospective samples demonstrated 77% all-stage sensitivity and 100% Stage I/II sensitivity at 99.6% specificity. The held-out test cohort contained nine early-stage cancers.

- **Algorithm optimisation (2026):** Further optimisation using the original dataset reported 92.5% all-stage and 92.3% stage I/II sensitivity at 98% specificity. These results have not been independently reproduced in a new cohort.
- **Expanded OC2200 study (2026):** ~1,200 samples from five biorepositories exhibited substantial pre-analytical variability and reduced measurable miRNA levels, preventing reliable assessment of diagnostic performance.
- **Independent technical review:** ResearchDx identified sample collection and handling differences as the largest source of variability and recommended optimising tumour-specific EV capture, refining the biomarker panel and standardising sample processing.

Development pathway: Following OC2200, IIQ has signed an agreement with Sonic Healthcare USA to transfer, optimise and validate EXO-OC within its US molecular diagnostics laboratory. In parallel, IIQ intends to collect additional US clinical samples to support clinical validation, regulatory and reimbursement activities. The company is targeting potential LDT commercialisation in early CY2028, subject to successful validation and further commercial negotiations.

3. Exosomes in Cancer Therapeutics:

The science

Beyond diagnostics, exosomes have potential as cancer therapeutics through their ability to transport biological molecules between cells. Engineered exosomes can carry therapeutic molecules or display targeting receptors that recognise tumour-associated markers, potentially enabling more targeted treatment.

Therapeutic potential

CAR-exosomes are engineered extracellular vesicles derived from immune cells modified to recognise cancer-associated targets. Unlike conventional CAR-T therapies, which administer living engineered immune cells, CAR-exosomes are cell-free and could potentially offer off-the-shelf manufacturing, improved tumour delivery and reduced treatment-related toxicity. However, these advantages remain to be established clinically, with challenges including manufacturing consistency, tumour targeting, scalability and safety.

IIQ is developing immune-cell-derived CAR-exosomes for solid tumours, led by an EGFR-targeted candidate for triple-negative breast cancer (TNBC), alongside preclinical applications in lung and ovarian cancers.

- **Triple Negative Breast Cancer - In-vivo proof-of-concept:** EGFR-targeted CAR-NK exosomes achieved a 61.5% reduction in tumour burden in a mouse model, compared with 24.5% for unmodified NK-derived EVs, with no observable adverse effects over the 28-day study.
- **Ovarian cancer - In-vitro proof-of-concept:** CA125-targeted CAR-exosomes demonstrated greater than 90% tumour cell killing within 48 hours in two ovarian cancer cell lines, while responses varied across other tested models.

These findings provide preliminary evidence of anti-tumour activity but remain preclinical. Safety, efficacy and therapeutic benefit in humans have not been established. IIQ is progressing manufacturing development and preclinical optimisation, targeting first-in-human studies in CY28.

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