INOVIQ

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Leveraging Exosome Advantage

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NEED TO KNOW

- **New global Promega agreement extends relationship**
- **Promising research into exosome-based therapeutics shows good initial data on cancer cell death; scalable technology**
- **3Q result – cash at healthy levels**

Promega agreement validates INOVIQ's position in exosome market: INOVIQ has announced a global supply and distribution agreement with Promega which builds on last year's Co-Marketing Agreement between the two companies. The deal gives Promega the right to market, sell and distribute INOVIQ's EXO-NET® technology. We view this initial 3-year agreement as meaningful, validating and strengthening INOVIQ's position in the exosome market. The company has indicated that a first order is imminent.

Looking at expanding from diagnostics into therapeutics: INOVIQ has recently filed an Australian Provisional Patent Application (APPA) for its EXO-ACE technology platform. EXO-ACE underpins the research stage exosome therapeutics program that engineers exosomes to target and kill cancer. The therapy is designed to be manufactured at scale and to circumvent many common problems and shortcomings with CAR-T therapies. This represents INOVIQ's first foray into exosome therapeutics and would significantly expand the company's portfolio.

Adequate cash: INOVIQ has announced its 3QFY24 results, with cash of $4.5m and operating cash outflows of $1.4m.

Investment Thesis

Diversified portfolio of proprietary technology platforms and products: IIQ's portfolio is wide, with its EXO-NET and SubB2M technologies creating substantial new opportunities across its research tool and diagnostics business and potential future royalties from BARD1.

Collaboration with UQ to develop ovarian cancer screening test using EXO-NET technology: This collaboration combines best-in-class exosome capture technology with University of Queensland (UQ) biomarkers for application in exosome-based liquid biopsies.

SubB2M platform: strong data in ovarian, breast cancers support potential to supercharge current tests and monitor disease progression: INOVIQ expects that the SubB2M-CA15-3 breast cancer test could be ready for partnering with a clinical laboratory for commercialisation as a LDT in CY25.

Valuation

Our analysis suggests a valuation of A$299m, equating to A$3.25 per share on an undiluted basis (or $2.96 per share on a fully diluted basis).

Risks

Key risks to our valuation include demonstrating efficacy, establishing clinical utility, and meeting regulatory requirements.

INOVIQ is developing and commercialising next-generation exosome capture tools and precision diagnostics to improve the diagnosis and treatment of cancer and other diseases. The company has commercialised the EXO-NET pan-exosome capture tool for research purposes and the hTERT test as an adjunct to urine cytology testing for bladder cancer. Its cancer diagnostic pipeline includes blood tests in development for earlier detection and monitoring of ovarian, breast and other cancers. www.inoviq.com

Valuation	**A$3.25** *(from A$2.31)*
Current price	**A$0.50**
Market cap	**A$46m**
Cash on hand	**A$4.5m** *(31 March 2024)*

Upcoming Catalysts / Next News

Period	
2HCY24	- Exosome diagnostic agreement
2HCY24	- NEURO-NET validation data
2HCY24	- EXO-OC biomarker validation data
2HCY24	- Exosome therapeutic in-vitro data
2HCY24	- SubB2M BC monitoring study

Share Price (A$)

Source: FactSet, MST Access

INOVIQ LTD IIQ — IIQ-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.50**
52 week high / low	$	0.47-0.94
Valuation	**$**	**3.25**
Market capitalisation	$m	45.5
Shares on issue (basic)	**m**	92
Options / rights	m	9.0
Other equity	m	0.0
Shares on issue (diluted)	**m**	**101.0**

12-MONTH SHARE PRICE PERFORMANCE (A$)

INVESTMENT FUNDAMENTALS		FY22A	FY23A	FY24E	FY25E	FY26E
Reported NPAT	$m	(18.2)	(9.0)	(9.0)	(8.4)	(3.9)
Underlying NPAT	**$m**	**(18.2)**	**(9.0)**	**(9.0)**	**(8.4)**	**(3.9)**
Reported EPS (diluted)	¢	(20.0)	(9.7)	(9.8)	(7.5)	(3.2)
Underlying EPS (diluted)	**¢**	**(20.0)**	**(9.7)**	**(9.8)**	**(7.5)**	**(3.2)**
Growth	%					
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**nm**
Operating cash flow per share	¢	(6.7)	(7.6)	(6.9)	(5.9)	(2.3)
Free cash flow per share	¢	(7.1)	(8.0)	(7.3)	(6.0)	(2.4)
Price to free cash flow per share	**x**	**nm**	**nm**	**nm**	**nm**	**nm**
FCF Yield	%	nm	nm	nm	nm	nm
Dividend	**¢**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	**%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	**$m**	**31.2**	**31.2**	**38.5**	**36.7**	**38.9**
EV/EBITDA	x	(1.7)	(4.0)	(5.0)	(5.1)	(14.2)
EV/EBIT	x	(1.5)	(3.5)	(4.3)	(4.4)	(10.1)
Price to book (NAV)	x	1.6	2.3	2.7	3.5	4.5
Price to NTA	x	2.7	5.1	5.0	6.9	10.3

KEY RATIOS		FY22A	FY23A	FY24E	FY25E	FY26E
EBITDA margin	%	nm	nm	nm	nm	nm
EBIT margin	%	nm	nm	nm	nm	nm
NPAT margin	%	nm	nm	nm	nm	nm
ROE	%	nm	nm	nm	nm	nm
ROA	%	nm	nm	nm	nm	nm
Net tangible assets per share	$	0.2	0.1	0.1	0.1	0.0
Book value per share	$	0.3	0.2	0.2	0.2	0.1
Net debt/(cash)	$m	(14.4)	(14.4)	(7.1)	(8.9)	(6.6)
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	nm	nm
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm

DUPONT ANALYSIS		FY22A	FY23A	FY24E	FY25E	FY26E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	0.0	0.0	0.0	0.1	0.6
Return on Assets	%	nm	nm	nm	nm	nm
Leverage	x	1.1	1.1	1.1	1.1	1.1
Return on Equity	%	nm	nm	nm	nm	nm

KEY PERFORMANCE INDICATORS	FY22A	FY23A	FY24E	FY25E	FY26E
SubB2M			0.0	0.0	0.0
SubB2M			0.0	0.0	0.0
EXO-NET Research Use Only			0.0	0.6	1.2
EXO-NET DX (Clinical)			0.0	0.0	0.0
hTert	0.5	0.27	0.4	0.3	0.3

HALF YEARLY DATA		2H21	1H22	2H22	1H23	2H23
Product revenue	$m	0.3	0.1	0.2	0.2	0.2
Operating expenses	$m	(11.9)	(4.4)	(17.9)	(6.3)	(4.5)
EBITDA	$m	(9.9)	(3.3)	(14.9)	(5.6)	(3.4)
EBIT	$m	(10.8)	(3.3)	(17.0)	(5.6)	(3.4)
PBT	$m	(10.8)	(3.3)	(17.0)	(5.6)	(3.4)
Reported NPAT	$m	(7.9)	(2.7)	(15.5)	(5.6)	(3.4)

PROFIT AND LOSS		FY22A	FY23A	FY24E	FY25E	FY26E
Product revenue	**$m**	**0.3**	**0.4**	**0.9**	**1.6**	**8.2**
Other income	$m	1.8	1.5	0.9	1.1	1.1
Operating expenses	$m	(22.3)	(10.9)	(10.7)	(10.7)	(10.8)
EBITDA	**$m**	**(18.2)**	**(7.8)**	**(7.7)**	**(7.1)**	**(2.7)**
Depreciation & Amortisation	$m	(2.1)	(1.2)	(1.3)	(1.2)	(1.1)
EBIT	**$m**	**(20.3)**	**(9.0)**	**(9.0)**	**(8.4)**	**(3.9)**
Interest expense	$m	(0.1)	0.0	(0.1)	(0.1)	(0.1)
Pretax Profit	$m	(20.3)	(9.0)	(9.0)	(8.4)	(3.9)
Tax expense	$m	2.1	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(18.2)**	**(9.0)**	**(9.0)**	**(8.4)**	**(3.9)**
Weighted average diluted shares	m	92.0	92.0	111.6	121.4	121.4

GROWTH PROFILE		FY22A	FY23A	FY24E	FY25E	FY26E
Revenue	%	(41.5)	32.6	(16.9)	5.0	5.0
EBITDA	%	38.4	(56.9)	(1.6)	(7.1)	(61.7)
EBIT	%	44.4	(55.7)	0.7	(7.2)	(54.0)
Reported NPAT	%	63.2	(50.7)	0.7	(7.2)	(54.0)

BALANCE SHEET		FY22A	FY23A	FY24E	FY25E	FY26E
Cash	$m	15.4	7.8	9.3	6.8	3.9
Receivables	$m	1.7	1.2	1.2	1.2	1.2
Other	$m	0.4	0.4	0.4	0.4	0.4
Current assets	**$m**	**17.5**	**9.4**	**10.9**	**8.4**	**5.5**
PPE	$m	0.8	0.9	1.3	1.3	1.3
Intangible assets	$m	11.7	10.7	9.5	8.4	7.5
Goodwill	$m	0.0	0.0	0.0	0.0	0.0
Other	$m	0.9	0.6	0.5	0.4	0.4
Non current assets	**$m**	**13.3**	**12.1**	**11.3**	**10.2**	**9.2**
Total assets	**$m**	**30.8**	**21.5**	**22.1**	**18.5**	**14.7**
Trade and other payables	$m	1.0	0.8	0.8	0.8	0.8
Lease liabilities	$m	0.4	0.4	0.2	(0.0)	(0.0)
Other	$m	0.4	0.4	0.4	0.4	0.4
Current liabilities	**$m**	**1.8**	**1.5**	**1.4**	**1.2**	**1.2**
Lease liabilities	$m	0.6	0.4	0.2	0.2	0.2
Other liability	$m	0.0	0.0	0.0	0.0	0.0
Non current liabilities	**$m**	**0.7**	**0.4**	**0.2**	**0.2**	**0.2**
Total liabilities	**$m**	**2.5**	**1.9**	**1.6**	**1.3**	**1.3**
Net assets	**$m**	**28.3**	**19.6**	**20.6**	**17.2**	**13.3**
Share capital	$m	69.1	69.1	79.1	84.1	84.1
Retained earnings	$m	(41.9)	(51.1)	(60.1)	(68.5)	(72.3)
Other	$m	1.1	1.6	1.6	1.6	1.6
Total equity	**$m**	**28.3**	**19.6**	**20.6**	**17.2**	**13.3**

CASH FLOW		FY22A	FY23A	FY24E	FY25E	FY26E
Net loss for period	**$m**	**(18.2)**	**(9.0)**	**(9.0)**	**(8.4)**	**(3.9)**
Depreciation & Amortisation	$m	(2.1)	(1.2)	(1.3)	(1.2)	(1.1)
Changes in working capital	$m	(1.1)	0.2	0.0	0.0	0.0
Other	$m	15.2	2.9	2.7	2.5	2.2
Operating cash flow	**$m**	**(6.1)**	**(7.0)**	**(7.7)**	**(7.1)**	**(2.7)**
Payments for PPE	$m	(0.4)	(0.3)	(0.5)	(0.2)	(0.2)
Other	$m	0.0	0.0	0.0	0.0	0.0
Investing cash flow	**$m**	**(0.4)**	**(0.3)**	**(0.5)**	**(0.2)**	**(0.2)**
Equity	$m	18.5	0.0	10.0	5.0	0.0
Lease liability payments	$m	(0.3)	(0.3)	(0.3)	(0.2)	0.0
Other	$m	(1.2)	0.0	0.0	(0.0)	0.0
Financing cash flow	**$m**	**17.0**	**(0.3)**	**9.7**	**4.8**	**0.0**
Cash year end	**$m**	**15.4**	**7.8**	**9.3**	**6.8**	**3.9**
Free cash flow	**$m**	**(6.6)**	**(7.3)**	**(8.2)**	**(7.3)**	**(2.9)**

Source: Company reports, MST Access estimates

Business Updates: Keeping the Ball Rolling with New Commercial Arrangements; 3Q Results

New supply and distribution agreement with Promega: a global platform for EXO-NET®

Promega and INOVIQ extend their relationship with a new agreement

Existing agreement kicked off the collaboration: INOVIQ signed a global joint marketing agreement (the 'Co-Marketing Agreement') in July 2023 with Promega Corporation, a company that provides tools and technical support to the life sciences industry. Since this time, the two companies have been collaborating to develop, validate and promote solutions for high-throughput exosome isolation and RNA extraction for biomarker discovery, diagnostic and therapeutic applications.

New agreement puts EXO-NET® in the spotlight globally: On 15 April 2024, INOVIQ and Promega signed a global supply and distribution agreement for INOVIQ's EXO-NET® tool. This new agreement will allow Promega to market EXO-NET®, designed to capture a wide range of exosomes, alongside its own products for purifying genetic material. This collaboration aims to provide researchers with advanced isolation tools, potentially leading to the discovery of new biomarkers and diagnostic tests.

Details of the agreement

Key terms: Building upon last year's successful Co-Marketing Agreement, this agreement extends the commercial relationship between the two companies, granting Promega the right to market, distribute, and sell INOVIQ's EXO-NET Pan-Exosome Capture products. The initial term of the agreement is 3 years. The agreement is worldwide, allowing researchers and industry easy access to exosome research tools and solutions.

Immediate benefit: Industry leading partner to market EXO-NET® globally with first order imminent.

Longer-term benefit: We believe that this relationship will validate INOVIQ's technology offering and strengthen its position within the exosome space.

Who is Promega?

Promega is a leading global provider of tools and technical support to the life sciences industry. The company's portfolio of over 4,000 products supports a range of life science work across areas such as cell biology; DNA, RNA and protein analysis; drug development; human identification and molecular diagnostics. Its products are used globally by scientists and technicians in labs for academic and government research, forensics, pharmaceuticals, clinical diagnostics and agricultural and environmental testing. Promega is based in the US with branches in 16 countries and over 50 global distributors.

3QFY24 update – cash adequate given outgoings

INOVIQ ended 3QFY24 with a cash balance of $4.5m. Customer receipts for the quarter were $119k, and the company also earned $64k in bank interest. Operating activities used $1.44m in cash during the quarter, largely driven by research and development (R&D) expenses ($638k), non-R&D staff costs ($424k), and administrative, corporate, and leased asset costs ($424k).

Figure 1: INOVIQ's products and pipeline (multi-stage diagnostics and therapeutics pipeline)

TECHNOLOGY	RESEARCH TOOLS	INDICATION	USE	RESEARCH	VERIFICATION	VALIDATION	IN-MARKET
Exosomes	EXO-NET	Multiple	Pan-EV Capture	RUO			
Exosomes	NEURO-NET	Neurology	Brain Derived-EV Capture	RUO			
Exosomes	TEXO-NET	Oncology	Tumour Derived-EV Capture	RUO			
	DIAGNOSTICS	**INDICATION**	**USE**	**RESEARCH**	**ASSAY DEVELOPMENT**	**CLINICAL DEVELOPMENT**	**IN-MARKET**
hTERT	hTERT ICC[1]	Bladder Cancer	Adjunct to Cytology				IVD-CLASS 1 USA
SubB2M	neuCA15-3	Breast Cancer	Monitoring			LDT	
SubB2M	neuCA125	Ovarian Cancer	Monitoring		LDT		
Exosomes	EXO-OC[2]	Ovarian Cancer	Screening		IVD		
	THERAPEUTICS	**INDICATION**	**USE**	**RESEARCH**	**PRE-CLINICAL**	**CLINICAL**	**APPROVAL**
Exosomes	EEV-001	Breast Cancer	Therapeutic				

Source: INOVIQ

Expanded Exosome Portfolio: EXO-ACE Enables Exosome Therapy with Large-Scale Isolation

In March 2024, INOVIQ extended its exosome IP portfolio by filing an Australian Provisional Patent Application (APPA) for its novel EXO-ACE™ technology. Unlike EXO-NET technology, which focuses on biomarker discovery and diagnostics, EXO-ACE is used for large-scale isolation of exosomes for therapeutic use to develop weaponised exosomes that target and kill cancer cells. Achieving exosome isolation on a large scale is a critical step for the development of exosome-based therapeutics.

The APPA details the compositions used to capture these extracellular vesicles (EVs), specifically with a focus on enabling large-scale commercial applications.

EXO-ACE – targeting and killing cancer cells with exosome-derived therapeutics

INOVIQ is working on a promising new technology, EXO-ACE, which aims to target and kill cancer cells using weaponised exosomes as 'cell-free therapeutics', a concept which has many potential advantages over CAR-T cell therapy (see below), from a manufacturing, safety and efficacy angle. The exosomes derived and isolated from immune cells retain the tumour-targeting and cytotoxic abilities of their parent cells. The initial indication is metastatic breast cancer; INOVIQ has established in-vitro proof of concept in breast cancer cells with >75% cancer cell death.

Description of EXO-ACE technology

EXO-ACE is an EV isolation platform which is used with exosomes produced in bioreactors. The technology uses an affinity chromatography method capable of isolating exosomes on a large scale for use in therapeutic applications.

Current status of the technology

The technology, which is in the research stages, has been the subject of multiple in-house studies, in which INOVIQ:

- evaluated various immune cell lines that release exosomes
- designed and tested proprietary cancer antigens to target solid tumours (CARs)
- assessed the purity and yield of the isolated exosomes
- performed in-vitro efficacy studies to assess the killing activity of the weaponised exosomes across various cancer cell lines.

Next steps

INOVIQ plans to report data on this program starting in 2QCY24. More in vitro and in vivo studies are planned in CY24 and CY25.

EXO-ACE studies suggest promising results at scale – high recovery, purity

Prior studies using EXO-ACE have demonstrated promising results, achieving over 80% recovery and 95% purity of exosomes isolated from immune cells. These isolated exosomes are currently undergoing evaluation within INOVIQ's exosome therapeutics program.

Potential application: engineered exosomes address limitations of CAR-T therapy

Building on the impressive clinical results of immunotherapies in the 2010s, CAR-T therapy–engineered immune cells emerged as a promising new tool against cancer. While advancements in T-cell modification overcame initial hurdles, recent years have exposed both the power and limitations of this technology in treating tumours. Clinical trials brought exciting results, especially for childhood leukemia leading to the first FDA approval in 2017, but also revealed challenges.

Limitations of CAR-T therapy

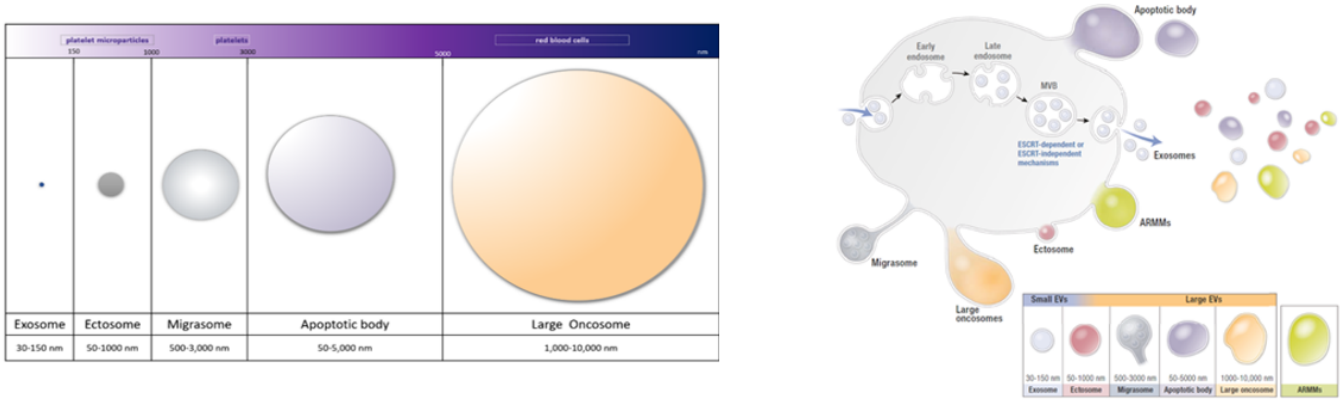
Limitations of CAR-T therapies include:

- **clinical safety issues** such as severe side effects (cytokine release syndrome and neurologic toxicities), limited efficacy in solid tumours, development of graft-versus-host disease, limited persistence of the therapy in the body, and relapse of the cancer
- **logistical problems** such as finding matching donors, high costs and challenges with manufacturing at large scale.

How exosome-based therapies can help – weaponising exosomes

Extracellular vehicles (EVs) are a broad category of microscopic sacs released by cells, carrying various cellular cargo and influencing recipient cells (Figure 2). However, exosomes are a specific type of EV, originating from a defined cellular pathway and smaller in size. While all exosomes are EVs, not all EVs are exosomes, highlighting the more specialized role exosomes might play in targeted communication between cells.

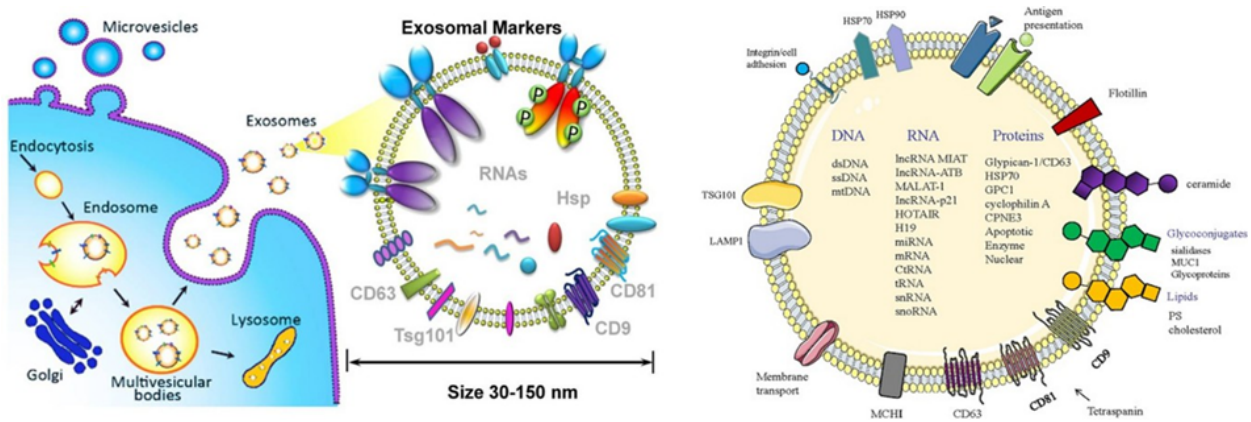
Figure 2: Relative sizes of EVs – exosomes are tiny (left); the formation of exosomes (right)



Source: : Extracellular Vesicles and their Emerging Roles as Cellular Messengers in Endocrinology: An Endocrine Society Scientific Statement, Salomon et al (2022).

Exosomes are essentially cellular messengers, microscopic sacs released by various cells throughout the body (see Figure 3). They carry important biological cargo, including proteins, lipids (fats), and RNA (ribonucleic acid), which can influence the function of recipient cells. Their ability to deliver these molecules to specific cells makes them exciting candidates for targeted drug delivery in treatments such as cancer therapy.

Figure 3: Exosomes – the tiny messengers of the cell



Source: Microfluidic Exosome Analysis toward Liquid Biopsy for Cancer; He et al (2016), https://www.jcancer.org/v12p5035.htm (see appendix X: Common protein components of exosomes).

INOVIQ's exosome-based therapies offer a potential solution to the problems with CAR-T therapies, with early research suggesting exosomes derived from CAR-T cells could overcome these hurdles (see Figure 4). Exosomes can be loaded with specific therapeutic properties and inherit the targeting ability of CAR-T cells – in effect 'weaponising' the exosomes against cancer.

Figure 4: CAR-T cells vs. exosomes as therapeutic agents

	CAR-EVs	CAR-Cells	Comments
Risk of secondary T-cell tumours	NO	YES	Use of genetically-modified CAR cells is associated with a risk of developing secondary tumours
Risk of immune response and cytokine storm	NO	YES	Use of genetically modified CAR cells is associated with a risk of triggering a host immune response and life-threating cytokine storm
Effective for blood cancers	YES	YES	Both are able to access blood tumours
Effective for solid tumours	YES	Less effective	CAR-cells are less able to penetrate solid tumours than EVs
Effective for brain tumours	YES	NO	CAR-cells are not able to access the brain
Immunological memory	YES	YES	The immune sysytem can retain a memory of cancer cells. This allows for a rapid and large response upon recurrence. Cell therapy does this by the persistence of genetially-modifed cells remaining in the body long after the inital treatment. Exosome therapy achieves this by presenting cancer antigen to the immune system that then makes the body's own lymphocyes that recognise cancer.
Ease of manufacture	YES	NO	New CAR-cells have to be made from stem cells for each batch - a 3 month process. CAR-EVs can be produced continuously
Distribution logistics	Acellular	Live cells	Live CAR-cells have to be distributed and administered to patients. CAR-EVs are not living cells
Cost per dose	Lower	High	Easier and continuous manufacturing and distribution of CAR-EVs will deliver lower costs per dose.

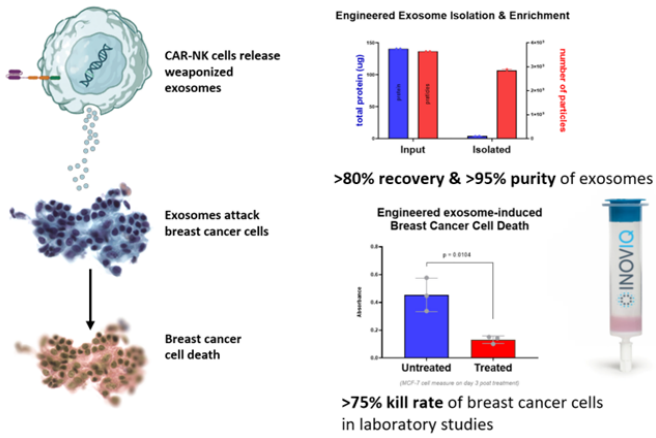
Source: INOVIQ

Instead of using the engineered immune cells (CAR-T/NK cells) themselves, INOVIQ's exosome therapy harnesses exosomes released by these cells. These exosomes are like tiny messengers that inherited the targeting ability of their parent cells. They can recognise and bind to cancer cells based on special markers on their surface. Once attached, these exosomes deliver a signal that activates the immune system to destroy the cancer cells (see Figure 5).

The exosomes can be engineered to target cancer cells and can be loaded with anti-cancer drugs, tumour-suppressing RNA, or immune-boosting proteins. This targeted delivery system minimises damage to healthy tissue.

Furthermore, exosomes loaded with CAR molecules could act as stand-ins for CAR-T cells, delivering the same tumour-targeting ability to NK cells, or they could be used alongside CAR-T/NK therapy to further activate the immune system's attack on cancer cells.

Figure 5: EXO-ACE: promising study results for exosome-based therapy – overcoming problems with CAR-T methods



Source: INOVIQ

Valuation: $3.25/Share Implies Strong Upside; Changed Assumptions on FX, Risk Weighting

We have adjusted our valuation of INOVIQ to reflect the time value of money and the company's progress in the development of both its SubB2M breast cancer and ovarian cancer monitoring programs, in the context of revised timelines as stated by management. Our valuation is now A$3.25 per share, vs. A$2.31 previously.

Adjusted assumptions

Our modelling now incorporates:

- launch of SubB2M breast cancer monitoring LDT by CY25 (previously CY23) with a 60% (previously 40%) probability of success
- launch of SubB2M ovarian monitoring LDT by CY26 (previously CY23) with a 40% (previously 20%) probability of success
- unchanged timelines around the EXO-NET DX ovarian cancer screening trial
- cash on hand of A$4.5m as of 31 March 2024
- INOVIQ's share of Promega's list price for EXO-NET at 60%
- an AUD/USD assumption of 0.65, compared with 0.73 previously.

Our analysis suggests a valuation of A$299m, which equates to A$3.25 per share on an undiluted basis or $2.96 fully diluted after incorporating 8,955,756 options outstanding. This figure is derived using the risk-adjusted net present value (rNPV) method, which discounts future cash flows consistent with the expiry life of patent families.

Figure 6: Breakdown of sum-of-parts, rNPV-based valuation model

Technology platform	Indication	Application	Launch (CY)	NPV (US$m)	Probability of success	rNPV (A$m)
SubB2M	Ovarian Cancer	Monitoring	2026 (LDT)	23,821,919	30%	11
SubB2M	Breast Cancer	Monitoring	2025 (LDT)	79,325,710	60%	73
EXO-NET DX (Clinical)	Ovarian Cancer	Screening	2027 (LDT), 2030 (IVD)	1,029,094,564	12%	183
EXO-NET Research Use Only	Various	RUO	On market	60,959,814	100%	94
EXO- ACE therapeutic program	TBD	TBD	TBD	TBD		
hTert	Bladder cancer	Adjunct test	On market			2
Other Income (R&D tax credits)						3
Operating expenses FY24-FY36						-71
					Cash on hand	5
					Total	299
					Shares on Issue (m)	92.0
					rNPV per share (A$)	3.25
					Options (m)	9.0

Source: MST Access

At this point, the main value driver for IIQ, in our opinion, remains the collaboration with UQ on the exosome-based screening test for ovarian cancer. We have assumed this program will result in the launch of an LDT in 2027, at which point the company will out-licence to a major diagnostic partner who will assume all subsequent costs for ultimate FDA approval under a 510(k) pathway. We assume an upfront payment of US$30m in 2027, based on recent exosome licencing deals, albeit in the therapeutic space, and a 12% royalty stream paid to IIQ from 2027 onwards.

Exosome therapeutics program

We are not currently ascribing value to INOVIQ's recently announced exosome therapeutics program given its early stage. However, we think this is a highly meaningful new development for the company and one that could add significant value in the short term given recent transactions and therapeutic deals for exosomes and cell therapies.

Sensitivities and risks

Demonstrating **efficacy in detection** of specified cancer and meeting **requirements of regulatory authorities** across different markets represent the two key risks for IIQ. Others are detailed below.

Technology transfer

The success of IIQ's development programs rely on both the validation of the underlying mechanism of action/target of interest and the development of test formats (SPR, immunoassay) for measuring these targets. The development of various testing formats brings into question choice of reagents, antibodies other laboratory tools. This in effect represents a risk related both to technology and its transfer across testing formats.

Funding

In the absence of a development partner and with A$4.5m in cash (as at 31 March 2024), the potential need for funding remains high. Adding to funding requirements will be the choice of regulatory pathway (LDT, 510 (k), IDE) which in turn may require additional clinical trials to be conducted.

Competition

Targeting earlier detection of cancer remains an area of strong clinical interest and research development. Nonetheless, ovarian and breast cancers lack an early blood test detection standard which suggests there is room for new entrants.

Development and commercialisation

New product development of IVDs rely on the translation of promising clinical data to date to testing formats that can be validated in retrospective trials using large blood sample banks (such as the UK ovarian cancer biobank). Further, for commercialisation of the tests IIQ will need to demonstrate the benefits of adding to current standards. Central to commercialisation of the SubB2M test will be the development of ELISA formats which are typically low-cost and commonly used in industry.

Regulatory approval

Regulatory oversight of diagnostic tests is fragmented. There are multiple frameworks under which diagnostic tests can seek regulatory approval.

As such the risks will be dependent on whether IIQ seeks FDA clearance or approval or alternatively under CLIA regulations enters the market as a laboratory developed test (LDT). Notably, all IVDs (including LDTs and reagents) are categorised as medical devices, but the FDA has historically not exercised its regulatory authority with respect to LDTs. While the regulation of LDTs comes under CLIA regulation, the FDA has been pursuing control over LDTs for more than a decade, citing concerns over the level of rigour in validation and resultant safety in use.

Reimbursement

Reimbursement of the test may be a key determinant of its adoption and ultimate commercial success. This will be determined by ultimate cost and efficacy relative to current options.

Intellectual property

A solid patent position represents a significant barrier to entry in medical technology. IIQ's current patent portfolio is expanding.

Appendix 1: A Recap of INOVIQ's EXO-NET® – Harnessing the Power of Extracellular Vesicles

Understanding exosomes and extracellular vesicles

The potential of EVs: carriers of biological 'messages in a bottle'

Extracellular vesicles (EVs) are lipid-bound vesicles which are released by all cell types, carrying precious cell-derived biomolecules, including nucleic acids (RNA and DNA), lipid, proteins, and metabolites. EVs are found in all biofluids and are involved in cell-to-cell communication and cell maintenance between local and distant cells. The delivery and uptake of their 'cargo' by other recipient cells facilitates both normal physiological and pathological (disease) processes in these other cells. EVs and their cargo represent valuable sources of critical information, with potential uses in both diagnostics (transport carriers of biomarkers) and therapeutics (optimising active cargo for drug delivery, and/or intrinsic properties related to cell of origin).

Exosomes – tiny carriers of biomolecular material have great potential, given their many roles as messengers of health and disease

Exosomes are a type of small EVs which are found in various body fluids and secreted by all cells in the body. Exosomes communicate with other cells and regulate their function. By capturing exosomes using EXO-NET, their molecular information can be used to identify changes in the cell's function and the early onset of diseases, including cancer.

Many varied biomolecules have been identified from exosomes (4,400 proteins, 194 lipids, 1,639 mRNAs, 764 miRNAs), highlighting the complexity of information carried and diversity of roles performed. These pathways can be used for diagnosis of disease or for therapeutic interventions, and the cargo carried by exosomes can be altered to deliver therapeutic agents.

Clinical applications of exosomes: research uses, disease identification (diagnostics) and treatment (therapeutics)

Diagnostics: Exosomes derived from different cell types have different functional characteristics given both their 'cargo' of specific proteins, lipids, and nucleic acids[1] and transmembrane proteins or nucleic acids of the exosome lipid membrane itself. As such, exosomes carry rich sources of information about their origin (parent) cell. This supports the use of exosome-based biomarker approaches to understand the underlying pathology of different types of parent cells (e.g., liver, ovaries, heart, blood, brain). Further, the composition of secreted exosomes can change as different pathologies progress, making the detection of variations valuable as diagnostic and prognostic biomarkers as well as potential therapeutic targets of disease.

Therapeutics: Beyond diagnostics, exosomes have shown potential as drug delivery systems stemming from their capacity to deliver complex payloads. This, along with their ability to interact with and be taken up by target cells, has raised hopes of using exosomes as targeting carriers of therapeutic drugs.

The technical hurdles – why the potential of exosomes has not yet been fully realised and where EXO-NET provides a high-throughput solution

The two main hurdles to date for the clinical use of exosomes generally (and liquid biopsy techniques in particular) have been to efficiently: (1) **scale the extraction process** to ensure optimal and reproducible enrichment and yield for the reliable measurement of biomolecules of interest (e.g., tumour-derived exosomes); and (2) **separate exosomes of interest** from other EVs and biomolecules of similar size. This has led to a lack of standardisation, source heterogeneity and source matrix complexity and reproducibility. Various methods have been used over the past decade; however, no practical technology can currently isolate EVs completely from other non-EV components. Factors include the complexity of biological fluids; the considerable overlap of the physicochemical and biochemical properties among the exosomes, lipoproteins, virus, and other EVs; and the heterogeneity of exosomes themselves.

Ref: Exosomes: biogenesis, biologic function, and clinical potential. Zhang et al (2019)

Ref: Progress, opportunity, and perspective on exosome isolation - Efforts for efficient exosome-based theranostics: Yang et al (2020)

An overview of INOVIQ's EXO-NET® technology

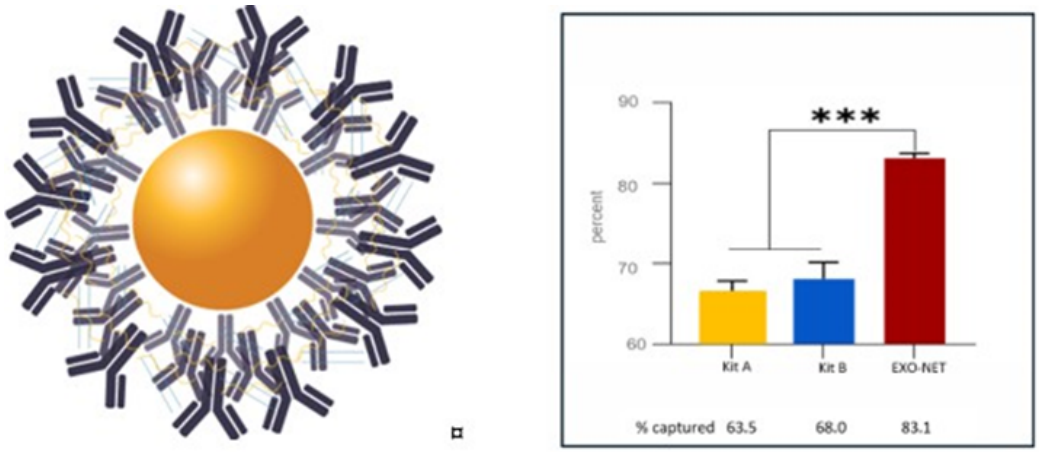
IIQ's EXO-NET® is a proprietary magnetic bead–based immunoaffinity capture technology for isolating EVs, including exosomes, from small clinical sample volumes of biofluids (plasma, urine, saliva, and cell-conditioned medium).

Innovative design – flexible, customisable, and compatible with other test formats

Magnetic bead–based capture of specific targets is a well-established and proven technology. However, IIQ has adapted this approach to build an exosome capture system, using a panel of monoclonal antibodies in a proprietary three-dimensional matrix (EXO-NET®) constructed on nanobeads (Figure 7).

Unlike other magnetic bead constructs using single layers of antibody molecules, EXO-NET® is composed of a collection of exosome-specific antibodies covalently linked to form a 3D multilayered antibody matrix. This matrix construct has been shown to increase binding avidity and analyte capture and outperform the more time-intensive ultra-centrifugation and size exclusion chromatography (SEC) methods, which to date have been considered the gold standard. EXO-NET captures 83.1% of small EVs (exosomes) from samples.

Figure 7: EXO-NET® technology: conceptual schematic (left); EXO-NET captures 83.1% of small EVs (right)

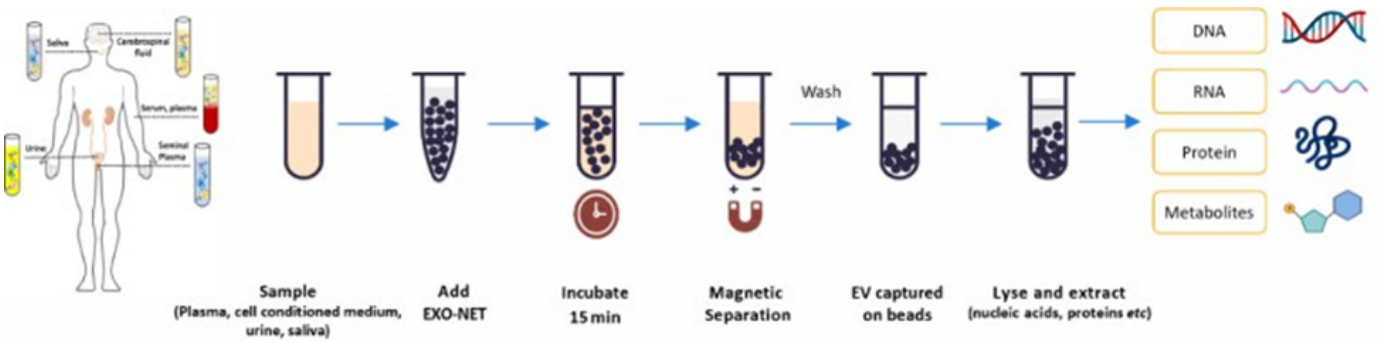


Source: INOVIQ. NB. Kit A and Kit B are two other bead-based EV isolation kits.

How it works: EXO-NET® captures EV targets in 4 simple steps

The technology comprises a proprietary molecular matrix, made of antibodies, designed to capture targets of interest (wide range of EVs from different cell types), which is applied to magnetic beads (nanobeads). The use of the three-dimensional matrix increases the density and surface area occupied by the antibodies, thereby increasing the accessibility of ligand binding sites and extraction efficiency. The antibody matrix attached to these beads has been designed to capture a wide range of EVs from different cell types (Figure 8). IIQ can customise the mix of antibodies in the matrix to capture different types of exosomes.

Figure 8: EXO-NET – workflow for exosome capture within 15 minutes



Source: INOVIQ

The competitive advantages of EXO-NET®: rapid, efficient, pure, scalable

Immunomagnetic bead capture scores highly vs commonly used EV isolation techniques. The Endocrine Society Scientific Statement, published in 2022, reported that immunomagnetic bead capture approaches were found to outperform commonly used EV enrichment (isolation) techniques when assessed using the key features of:

- time: length of operation time
- cost: cost of the equipment and consumables
- scalability: the ease of scaling the technique to process large volumes of fluids recovery (yield): the percentage of EVs in fluids that could be extracted
- specificity: ratio of EVs extracted relative to total protein.

Figure 9: Comparison of the key features in commonly used extracellular vesicle enrichment techniques

Method / Advantage	Immuno-affinity	Phospholipid-affinity	Charge	Size Exclusion	Precipitation	Ultra-centrifugation
Speed	+++	+++	+++	++	+++	+
Cost-Effectivness	+++	+++	++	++	++	++
Scalability	High	High	High	Med	Manual	Manual
Contaminants	Low	Med	Med	Med	High	High
Specificity	++++	++	++	++	+	+
Lab Compatibility	Yes	Yes	Yes	No	No	No
Customisable	Yes	No	No	No	No	No

Source: Endocrine Reviews: Salomon et al (2022). (+ denotes the desirability of the feature, from +: least to ++++: most desirable).'NB. PEG = Polyethylene glycol precipitation

EXO-NET® technology advantages suggest it's a 'best-in-class' EV isolation system

Product features and major technological advantages of EXO-NET® include:

- rapid isolation of an enriched population of EVs from any biofluid (within 15–20 minutes)
- cost effective to use (avoiding time-consuming workflows of the current gold standard methods)
- scalable for high-throughput sample processing and can be fully automated
- flexible enough to be deployed on most lab test modalities (well plates, polymer beads, magnetic beads, and lateral flow devices)
- higher yield: recovery by isolating EVs results in higher yield of useful targets
- high purification of exosomes eliminating contaminants and reducing background noise
- simple (4 steps) and compatible with downstream testing formats (Mass Spec, RNA Seq etc for proteomic and RNA analysis)
- customisable: EXO-NET® is designed to capture a wide range of biological targets subject to proteins that are present on their surface being recognised by the capture ligands incorporated in the matrix (or NET) which can be adjusted

Good Manufacturing Practice (GMP) compliance also underpins competitive advantage

The ability to scale the process for high-throughput processing, combined with the time saved compared to other methods, supports high throughput requirements of most commercial laboratories. The company is in the process of converting its main lab in Australia to GMP[1] standards. As such, clinical and large-scale production of EXO-NET® under GMP-compliant standards would differentiate EXO-NET® and provide a clear competitive advantage for all future applications of the technology. [1] Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently produced and controlled according to a set of prescribed quality standards.

Company disclosures

The companies and securities mentioned in this report, include:

INOVIQ (IIQ.AX) | Price A$0.50 | Valuation A$3.25;

Price and valuation as at 07 May 2024 (not covered)*

Additional disclosures

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