### **ASX Announcement**



December quarterly business update and Appendix 4C 31 January 2025

## KEY MILESTONES ACHIEVED IN DIAGNOSTICS AND THERAPEUTICS

- EXO-NET customers growing across US, Europe and Asia
- Ovarian Cancer Screening test delivers outstanding diagnostic performance
- CAR-NK-exosome Proof-of-Concept achieved for killing breast cancer cells
- Disease specificity testing completed for neuCA15-3 Breast Cancer monitoring test
- R&D Tax Incentive refund of \$1m received
- Cash balance of \$9.476m at 31 December 2024

Summarising the quarterly update, Chairman David Williams said: "INOVIQ delivered key development milestones across its exosome diagnostic, exosome therapeutic and SubB2M diagnostic programs. Our exosome diagnostic for screening ovarian cancer delivered outstanding accuracy, our CAR-NK-exosome therapeutic achieved *in vitro* anti-cancer efficacy in breast cancer cells and our neuCA15-3 breast cancer monitoring test showed disease specificity. These results further validate INOVIQ's technology platforms and substantially de-risk our diagnostic and therapeutic pipeline for breast and ovarian cancer.

I am also pleased to report that our EXO-NET business continues to grow with Promega increasing EXO-NET customers to 41 in mid-December. EXO-NET and NEURO-NET evaluations are progressing with larger research institutes, diagnostic and biopharma customers, with more expected in the next quarter."

#### 1 EXOSOME PROGRAMS

#### 1.1 PAN-EXOSOME CAPTURE TECHNOLOGY (EXO-NET)

EXO-NET is a pan-exosome capture tool for isolating extracellular vesicles (EVs) from body fluids for biomarker discovery and diagnostics. EXO-NET is commercially available worldwide through our distribution partner Promega Corporation.

Promega grew the EXO-NET customer base from 29 to 41 during the quarter across academic/government, pharmaceutical/biotech and clinical laboratories/hospital customer types. Customer numbers were highest in Europe, followed by North America and Asia-Pacific. Applications were diverse including diagnostics research for Oncology, Neurology, Cardiac Disease, Transplant Rejection, Sepsis and fundamental EV research.



Customer type	Profile	#
Academic/ Government	Exosome KOLs validating EXO-NET across expanded applications & delivering <i>publications &amp; presentations</i> . Small-vol biomarker discovery & validation data.	22
Pharma/ Biotech	Focus on <i>patient selection &amp; monitoring MRD</i> . Mid-vol biomarker discovery, companion diagnostics & target identification.	7
Clinical/ Hospital	Key customers requiring a <i>scalable EV isolation solution</i> . Higher-vol sales as projects progress thru development to registration to market.	10
Other		2
TOTAL		41

INOVIQ and Promega attended and presented at several conferences including GiVEX (Oct-24, Spain), AMP (Nov-24, Canada) and IMPACT Conference: Biomarkers in Psychiatry and Gynecology (Dec-24, Chile). EXO-NET posters were presented at each conference showcasing the speed, specificity and scalability of EXO-NET for high-throughput EV isolation, biomarker discovery and diagnostic development. These posters provide key data to enable EV researchers to understand the benefits of using EXO-NET to develop accurate, high-throughput exosome diagnostics that can be implemented in pathology laboratories.

Promega updated its EXO-NET catalogue webpages to enhance its search engine optimisation and drive traffic to the webpage from promotional activities. INOVIQ and Promega undertook joint research on Applications Development to provide validated data and 'Application Notes' to support customer applications for urine-based workflows, flow cytometry of isolated EVs and miRNA/mRNA sequencing. Promega also invested in developing EXO-NET/RNA combination products that integrate with its Maxwell systems and consumables, providing flexible, scalable solutions for EV isolation and diagnostics.

Engagement with academia and industry worldwide is ongoing to secure collaborations and sales of EXO-NET and combination products to enable development of more accurate and reliable exosome diagnostics. Multiple evaluations of EXO-NET and NEURO-NET are being progressed for biomarker discovery and diagnostic development across cancer, cardiology and neurological diseases. Successful evaluations are expected to drive sales of EXO-NET in exosome diagnostic projects over the next 12-months and underpin revenue growth.

#### 1.2 BRAIN-DERIVED EXOSOME CAPTURE TECHNOLOGY (NEURO-NET)

NEURO-NET is a specific exosome capture tool designed for isolation of brain-derived EVs for use in neurological applications. NEURO-NET has been analytically and clinically validated for isolation of brain-derived EVs in Alzheimer's Disease (AD) and Parkinson's Disease (PD). NEURO-NET is now available to academic and industry researchers for research collaborations.

INOVIQ filed international PCT application AU2024/051103 entitled 'Extracellular vesicle compositions and uses thereof' protecting its NEURO-NET technology for isolation of brain-derived exosomes on 18 October 2024.

During the quarter, INOVIQ progressed discussions and evaluations with several academic groups, diagnostic and biopharma companies to assess NEURO-NET's potential in diagnostic applications for brain cancer, neurodegenerative and neuropsychiatric disorders. Successful outcomes from these



evaluations are anticipated to result in research collaborations and/or supply agreements for NEURO-NET.

The next milestones for NEURO-NET include collecting further clinical validation data and fostering collaborations with both academic institutions and industry leaders in the field of neurological conditions.

#### 1.3 EXOSOME OVARIAN CANCER SCREENING TEST (EXO-OC)

The Exosome Ovarian Cancer test is an exosome multi-marker test in development for the early detection of ovarian cancer in asymptomatic women. The test is being developed in collaboration with The University of Queensland (UQ) using EXONET for exosome capture and UQ biomarker IP.

During the quarter, INOVIQ announced that its blood test for ovarian cancer screening had successfully completed an independent validation of its biomarkers and diagnostic performance, delivering outstanding test results with accuracy of over 94%. These results represent a major advancement in OC testing.

In this study, exosomes were isolated from more than 500 blood samples, using INOVIQ's EXO-NET® on a fully-automated high-throughput robotic platform. Exosomal ovarian cancer biomarkers, previously identified in the OC97 study, were measured using targeted mass spectrometry. All targeted biomarkers were identified in ovarian cancer samples and their diagnostic performance was confirmed using ROC curve analysis and multivariate modelling.

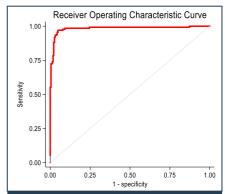


Figure 1: Receiver Operating
Characteristic Curve for the EXO-OC
test. The EXO-OC test combines EXONET isolated ovarian cancer
biomarkers using a cross-validated
machine learning algorithm. The area
under the curve (AUC) = 0.98,
indicative of very high accuracy.

When these high performing EXO-NET-isolated biomarkers were combined in 10-fold cross validated machine learning algorithms, overall test accuracy exceeded 94%. When test specificity was set at 96%, sensitivity was 92% for all stages of ovarian cancer and 91% for Stage I alone.

The next phase in developing the EXO-OC test is optimization on a commercial instrument platform and additional clinical validation to deliver the test as an LDT or IVD in a clinical laboratory. The regulatory strategy is currently under review by INOVIQ's regulatory advisors. The next milestones are securing samples from a large OC biobank (underway), commencing a larger clinical validation study to evaluate the EXO-OC test for detection of OC (H1 CY25), and publication of results.

#### 1.4 EXOSOME THERAPEUTICS (CAR-EV) – THIRD GENERATION CAR-THERAPY

INOVIQ's exosome therapeutics program uses chimeric antigen receptor (CAR)-exosomes that are released from genetically engineered CAR-T or CAR-NK cells. CAR-exosomes have enormous potential as cell-free therapeutics with manufacturing, safety and efficacy advantages over autologous cell therapies for treating solid tumours. CAR-exosomes inherit the tumour-targeting and cytotoxic capabilities of their parent CAR-T/NK cells, specifically targeting and killing cancer cells.

During the quarter, INOVIQ announced that it had successfully completed stage 1 of its development program for an exosome therapeutic for breast cancer. In this in vitro proof-of-concept (POC) study, immortalised natural killer (NK) cells were engineered to continuously produce exosomes that specifically target and kill breast cancer cells. The specific targeting was achieved by incorporating a chimeric antigen receptor (CAR) on the surface of the exosomes. This receptor recognizes and binds to a protein that is overexpressed by breast cancer cells. This innovation allows the killing activity of CAR-NK-exosomes to be directly delivered to breast cancer cells, increasing therapeutic efficacy and reducing off-target effects (to non-cancer cells).

INOVIQ's proprietary EXO-ACE technology<sup>1</sup> was utilised to isolate CAR-exosomes released by NK cells. Treatment of triple-negative breast cancer (TNBC) cells, a particularly aggressive type of breast cancer, with CAR-NK-exosomes resulted in dose dependent cancer cell death (Figure 2). At the highest dose evaluated, CAR-NK-exosomes killed over 30% of breast cancer cells and showed significantly greater efficacy than exosomes isolated from NK cells as reported in other studies<sup>2</sup>.

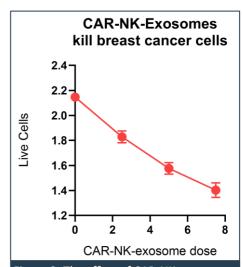


Figure 2. The effect of CAR-NK-exosomes on breast cancer cells (Hs 578T cells) grown in cell culture. CAR-NK-exosomes killed cancer cells in a dose-dependent manner (p < 0.002, ANOVA). Data presented represent the mean ± SE. Dose is number of exosomes/cell x 10<sup>5</sup>. Live cells are represented as absorbance units in a cell death assay.

INOVIQ has established a robust production process to prepare therapeutic exosomes that target and kill breast cancer cells. The next milestones in the exosome therapeutics program are 1) in vitro studies to enhance the yield and potency (tumour killing activity) of the CAR-exosomes by prestimulating cells under various conditions and activators, and 2) in vivo studies to evaluate optimal dosing and tumour killing activity in animal models, as a prequel to preclinical studies.

#### SUBB2M PROGRAMS FOR CANCER MONITORING 2

neuCA15-3 is a simple, accurate and affordable blood test in development for monitoring breast cancer in women. The assay uses a CA15-3 monoclonal antibody combined with INOVIQ's SubB2M detection reagent to specifically identify CA15-3 produced by cancer cells. This enhances cancer detection and may reduce false positives. The test has been analytically and clinically validated to detect breast cancer across all stages (81% sensitivity and 93% specificity), key breast cancer types and subtypes and is effective for monitoring breast cancer.

During the quarter, INOVIQ announced the successful completion of disease specificity testing for breast cancer. The purpose of this study was to show that the neuCA15-3 test was positive and specific for cancer and had low false positives for non-cancer diseases. CA15-3 concentrations were measured in serum samples obtained from healthy individuals and patients with breast cancer or other non-cancer diseases where CA15-3 could be elevated, including endometriosis, rheumatoid arthritis, Crohn's disease and type II diabetes. The test showed positive results for breast cancer, with the average CA15-3 concentration being five-fold greater than that observed in healthy individuals. The results were negative for 97.4% of non-breast cancer samples, confirming the specificity for breast cancer.

The same samples were also tested by an independent accredited pathology laboratory using a leading FDA-approved comparator CA15-3 test. Average CA15-3 concentrations were not significantly different between healthy and non-breast cancer patients for the comparator, indicating the superiority of the INOVIQ test.

The next steps to commercialise the neuCA15-3 test include publication of a scientific paper, transfer to a high-throughput instrument platform, additional in-clinic breast cancer monitoring study and securing a laboratory partner for commercialisation.

#### **3 FINANCIAL UPDATE**

INOVIQ had \$9.476m cash at 31 December 2024.

Operating cash receipts during the quarter included:

- \$1.018m rebate related to the FY24 R&D Tax Incentive scheme;
- \$85k from EXO-NET and hTERT sales during the quarter (September 2024 quarter \$52k); and
- \$120k of bank interest (September 2024 quarter \$81k).

Net cash used in operating activities for the quarter was \$542k with the main outflows being:

- Research and Development (R&D) expenditure of \$842k (September 2024 quarter \$699k);
- Non-R&D staff costs of \$455k (September 2024 quarter \$397k); and
- Administration, corporate and leased asset costs of \$413k (September 2024 quarter \$358k).

Payments in section 6.1 of the accompanying Appendix 4C relate to Director fees and superannuation paid during the quarter.

#### 4 CORPORATE UPDATE

#### **Investor Presentations and Interviews**

INOVIQ delivered the following investor presentations during the quarter:

- **Bell Potter Healthcare Conference Presentation**: On 18<sup>th</sup> November CEO Dr Leearne Hinch presented at the Bell Potter Healthcare Conference: <u>Bell Potter Presentation</u>.
- **Share Cafe Interview**: On 6<sup>th</sup> December CEO Dr Leearne Hinch was interviewed by Share Cafe about the 'Breakthrough results for INOVIQ's ovarian cancer test': Share Cafe interview.
- Share Cafe Hidden Gems Webinar: On 13<sup>th</sup> December, CEO Dr Leearne Hinch presented at the Share Cafe's Hidden Gems, 'Sip and Learn' webinar: Share Cafe Presentation.

#### **2024 Annual General Meeting**

The 2024 INOVIQ Annual General Meeting was held on 28 November 2024. All resolutions were comfortably carried and for those interested parties unable to attend in person or via the webinar, an edited recording of the business update is available via the following link: <u>AGM Recording</u>.

The Company's priorities over the next 12-months are:

- expanding our exosome isolation tools,
- partnering our lead SubB2M diagnostics,
- accelerating the development of our exosome diagnostics and therapeutics pipeline, and
- growing revenues from EXO-NET product sales and partnering.

Authorised for release by the INOVIQ Limited Board of Directors.

#### **FURTHER INFORMATION**

**Dr Leearne Hinch**Chief Executive Officer
Chairman

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#### **ABOUT INOVIQ LTD**

INOVIQ Ltd (ASX:IIQ) is a biotechnology company pioneering next-generation diagnostics and therapeutics for cancer. INOVIQ has commercialised its fast, efficient and specific EXO-NET exosome isolation technology for biomarker discovery and diagnostics development, and the hTERT test as an adjunct test for bladder cancer. The company is advancing clinical-stage diagnostics for detection and monitoring of ovarian and breast cancers, and early-stage exosome therapeutics for solid tumours. Learn more about INOVIQ at www.inoviq.com.



<sup>&</sup>lt;sup>1</sup> EXO-ACE™ – a scalable column-based technology for isolating exosomes for therapeutic use.

<sup>&</sup>lt;sup>2</sup> Kim et al., 2023 Functional enhancement of exosomes derived from NK cells by IL-15 and IL-21 synergy against hepatocellular carcinoma cells: The cytotoxicity and apoptosis in vitro study. doi: 10.1016/j.heliyon.2023.e16962

## **Appendix 4C**

# Quarterly cash flow report for entities subject to Listing Rule 4.7B

#### Name of entity

INOVIQ LIMITED

#### ABN Quarter ended ("current quarter")

58 009 070 384 31 December 2024

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	85	137
1.2	Payments for		
	(a) research and development (including allocated staff costs)	(842)	(1,541)
	(b) advertising and marketing	(47)	(142)
	(c) product manufacturing and operating costs	(5)	(43)
	(d) staff costs (other than R&D staff)	(455)	(851)
	<ul><li>(e) administration and corporate costs</li><li>(f) leased assets</li></ul>	(341) (72)	(613) (159)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	120	200
1.5	Interest and other costs of finance paid	(5)	(12)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,018	1,018
1.8	Other	-	-
1.9	Net cash from / (used in) operating activities	(544)	(2,006)

2.	Cash flows from investing activities	
2.1	Payments to acquire:	
	(g) entities	-
	(h) businesses	-
	(i) property, plant and equipment	(6)
	(j) investments	-
	(k) intellectual property	-

ASX Listing Rules Appendix 4C (17/07/20)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
	(I) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other	-	-
2.6	Net cash from / (used in) investing activities	(6)	(55)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	2,629
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(3)	(327)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	(3)	2,302

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	10,024	9,233
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(544)	(2,006)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(55)
4.4	Net cash from capital raising (item 3.10 above)	(3)	2,302
4.5	Effect of movement in exchange rates on cash held	5	2
4.6	Cash and cash equivalents at end of period	9,476	9,476

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	455	503
5.2	Call deposits	9,021	9,521
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	9,476	10,024

# 6. Payments to related parties of the entity and their associates 6.1 Aggregate amount of payments to related parties and their associates included in item 1 6.2 Aggregate amount of payments to related parties and their associates included in item 2 Current quarter \$A'000 92

Payments in 6.1 relate to Director fees and superannuation paid during the quarter.

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

#### 7. Financing facilities

Note: the term "facility' includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 Total financing facilities

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
20	-
-	-
-	-

#### 7.5 Unused financing facilities available at quarter end

20

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Relates to the corporate credit card facility with the National Australia Bank.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	(544)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	9,476
8.3	Unused finance facilities available at quarter end (Item 7.5)	20
8.4	Total available funding (Item 8.2 + Item 8.3)	9,496
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	17.5

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

- 8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:
  - 8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

#### **Compliance statement**

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 31 January 2025

Authorised by: By the Board of Directors

Authorised for release by Company Secretary – Mark Edwards

(Name of body or officer authorising release – see note 4)

#### Notes

- 1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.