

Agrees to develop SubB2M test targeting pan-cancer diagnostic

Positive news – potential clinical and commercial SubB2M validation

IIQ has announced a contract research agreement with Canada-based Nicoya Lifesciences to develop a SubB2M-based test on Nicoya's digital Surface Plasmon Resonance (SPR) platform. Nicoya has already commercialised the platform for research use only, with the Alto™ digital SPR instrument, a next-gen benchtop instrument for the highly sensitive detection of analytes.

This agreement could lead to the development of a world-first benchtop SubB2M-SPR test that would facilitate screening for cancer. Initially, the system will be designed for use as a cancer risk assessment test. The SubB2M-SPR test has the potential to be further developed as a multi-cancer detection test combined with a biomarker panel to determine cancer origin.

While the partnership is in its early stages, we view the announcement as positive because it could advance the clinical validation of IIQ's SubB2M technology as well as create a commercially successful product with Nicoya.

The agreement – developing a SubB2M test on Alto™

Nicoya will provide services to transfer, develop and evaluate a SubB2M-based SPR test on the Alto™ digital SPR instrument. A compact SPR system, combined with IIQ's technology, would provide a competitive advantage for diagnostic applications in general risk assessment for cancer. The project is expected to complete within six months of commencement, with IIQ paying agreed costs (indicated by IIQ as non-material) for work undertaken. IIQ will undertake additional studies on completion to further develop and validate the test.

The SubB2M technology (provided by IIQ): The SubB2M program is the most advanced in IIQ's suite of technologies in development. SubB2M is a proprietary, novel, highly selective ligand that binds to Neu5Gc, a promising new pan-cancer marker found at elevated levels in many human cancers (and not in healthy cells). Compelling data has been rendered for a SubB2M-based SPR test across all stages of ovarian and breast cancers. The technology could potentially significantly improve both detection and monitoring of cancer.

The SPR technology (provided by Nicoya): SPR is an optical biosensor technology that is considered more sensitive than standard ELISA assay formats. Up until now, SPR has been considered too expensive and technically complex for use in commercial labs and is used in research settings.

Valuation – A\$2.11/share

We value IIQ at A\$195m or A\$2.11 per share, using a risk-adjusted net present value (rNPV) method to discount future cash flows through to 2043, consistent with the expiry life of patent families. Key risks to our valuation: demonstrating efficacy, establishing clinical utility, meeting regulatory requirements.

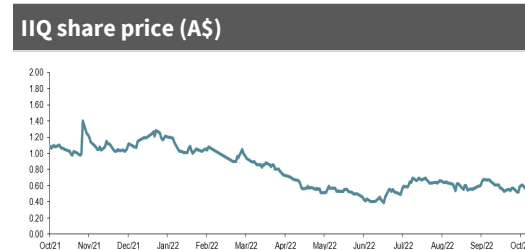


INOVIQ is a development-stage clinical diagnostics company focused on novel biomarker-based assays and exosome-based solutions for early detection of cancers and other diseases. Its portfolio includes three novel liquid biopsy technologies for monitoring and earlier detection of ovarian and breast cancers. Previously commercialised products include: the hTERT test, an ICC (immunocytochemical) test for use as an adjunct to urine cytology testing for bladder cancer, and RUO EXO-NET, a pan-exosome capture tool used in research settings.

Stock	IIQ.ASX
Price	A\$0.59
Market cap	A\$54 m
Valuation	A\$2.11

Company data	
Net cash (as at 30 June 2022)	\$15.3m
Shares on issue	92.0m
Code ASX	IIQ

Share price catalysts – 2H2022	
SubB2M clinical testing – BC and OC monitoring	
Exosome-based OC test development progress	



Source: FactSet.

Chris Kallos, CFA
chris.kallos@mstaccess.com.au

Financials

Exhibit 1: Summary financials

INOVIQ LTD IIQ						IIQ-AU
Year end 30 June, AUD unless otherwise noted						
MARKET DATA						
Price	\$	0.59				
52 week high / low	\$	0.39-1.4				
Valuation	\$	2.11				
Market capitalisation	\$m	53.8				
Shares on issue (basic)	m	92.0				
Options / rights	m	9.3				
Other equity	m	0.0				
Shares on issue (diluted)	m	101.4				
12-MONTH SHARE PRICE PERFORMANCE (AS)						
INVESTMENT FUNDAMENTALS						
		FY20A	FY21A	FY22E	FY23E	FY24E
Reported NPAT	\$m	(3.3)	(11.2)	(18.2)	(10.2)	(9.6)
Underlying NPAT	\$m	(3.3)	(11.2)	(18.2)	(10.2)	(9.6)
Reported EPS (diluted)	¢	(0.2)	(14.4)	(20.0)	(11.1)	(10.4)
Underlying EPS (diluted)	¢	(0.2)	(14.4)	(20.0)	(11.1)	(10.4)
Growth	%	5947.8%	38.8%	-44.7%	-5.9%	
Underlying PER	x	nm	nm	nm	nm	nm
Operating cash flow per share	¢	(0.2)	(6.8)	(6.7)	(9.1)	(9.7)
Free cash flow per share	¢	(0.2)	(3.0)	(7.1)	(9.1)	(9.7)
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	46.5	50.1	39.4	47.8	46.8
EV/EBITDA	x	(14.3)	(3.8)	(2.2)	(5.0)	(5.2)
EV/EBIT	x	(14.3)	(3.6)	(1.9)	(4.7)	(4.9)
Price to book (NAV)	x	1.7	1.9	1.9	2.8	5.7
Price to NTA	x	1.7	18.5	3.2	6.8	6.0
KEY RATIOS						
		FY20A	FY21A	FY22E	FY23E	FY24E
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	\$	0.3	0.0	0.2	0.1	0.1
Book value per share	\$	0.3	0.3	0.3	0.2	0.1
Net debt/(cash)	\$m	(7.3)	(3.7)	(14.4)	(6.0)	(7.1)
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						
		FY20A	FY21A	FY22E	FY23E	FY24E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	-	0.0	0.0	0.1	0.6
Return on Assets	%	nm	nm	nm	nm	nm
Leverage	x	1.1	1.2	1.1	1.1	2.3
Return on Equity	%	nm	nm	nm	nm	nm
KEY PERFORMANCE INDICATORS						
		FY20A	FY21A	FY22E	FY23E	FY24E
SubB2M					0.2	3.8
SubB2M					0.1	3.5
EXO-NET Research Use Only					1.1	4.5
EXO-NET DX (Clinical)					0.0	0.0
hTert			0.5	0.28	0.3	0.3
HALF YEARLY DATA						
		2H21	1H22	2H22	1H23	2H23
Product revenue	\$m	0.3	0.1	0.2	0.1	0.1
Operating expenses	\$m	(11.9)	(4.4)	(17.9)	(6.0)	(6.0)
EBITDA	\$m	(9.9)	(3.3)	(14.9)	(5.1)	(5.1)
EBIT	\$m	(10.8)	(3.3)	(17.0)	(5.1)	(5.1)
PBT	\$m	(10.8)	(3.3)	(17.0)	(5.1)	(5.1)
Reported NPAT	\$m	(7.9)	(2.7)	(15.5)	(5.1)	(5.1)
PROFIT AND LOSS						
		FY20A	FY21A	FY22E	FY23E	FY24E
Product revenue	\$m	0.0	0.5	0.3	1.6	12.1
income	\$m	0.6	1.0	1.8	1.5	2.3
Operating expenses	\$m	(3.9)	(15.5)	(22.3)	(11.9)	(12.2)
EBITDA	\$m	(3.3)	(13.1)	(18.2)	(9.5)	(9.0)
Depreciation & Amortisation	\$m	0.0	(0.9)	(2.1)	(0.7)	(0.6)
EBIT	\$m	(3.3)	(14.0)	(20.3)	(10.2)	(9.6)
Interest expense	\$m	0.0	(0.1)	(0.1)	(0.1)	(0.1)
Pretax Profit	\$m	(3.3)	(14.0)	(20.3)	(10.2)	(9.6)
Tax expense	\$m	0.0	2.9	2.1	0.0	0.0
Reported NPAT	\$m	(3.3)	(11.2)	(18.2)	(10.2)	(9.6)
Weighted average diluted shares	m	1,363.4	77.3	90.9	92.0	92.0
GROWTH PROFILE						
		FY20A	FY21A	FY22E	FY23E	FY24E
Revenue	%	nm	nm	(40.9)	5.0	5.0
EBITDA	%	89.5	303.1	38.4	(47.5)	(6.0)
EBIT	%	89.5	331.1	44.4	(49.7)	(5.9)
Reported NPAT	%	89.5	242.7	63.2	(44.0)	(5.9)
BALANCE SHEET						
		FY20A	FY21A	FY22E	FY23E	FY24E
Cash	\$m	7.3	5.0	15.4	7.0	8.1
Receivables	\$m	0.0	0.2	1.7	0.2	0.2
Other	\$m	0.0	0.4	0.4	0.4	0.4
Current assets	\$m	7.4	5.6	17.5	7.7	8.7
PPE	\$m	0.0	0.6	0.8	0.7	0.7
Intangible assets	\$m	0.0	15.1	11.7	11.1	10.5
Goodwill	\$m	0.0	11.0	0.0	0.0	0.0
Other	\$m	0.0	1.1	0.9	1.8	1.7
Non current assets	\$m	0.0	27.9	13.3	13.6	13.0
Total assets	\$m	7.4	33.5	30.8	21.2	21.7
Trade and other payables	\$m	0.8	0.8	1.0	0.8	0.8
Lease liabilities	\$m	0.0	0.3	0.4	0.4	0.4
Other	\$m	0.1	0.4	0.4	0.4	0.4
Current liabilities	\$m	0.9	1.5	1.8	1.5	1.5
Lease liabilities	\$m	0.0	0.9	0.6	0.6	0.6
Other liability	\$m	0.0	2.1	0.0	0.0	0.0
Non current liabilities	\$m	0.0	3.0	0.7	0.7	0.7
Total liabilities	\$m	0.9	4.5	2.5	2.2	2.2
Net assets	\$m	6.5	29.1	28.3	19.0	19.5
Share capital	\$m	19.3	51.8	69.1	70.3	70.3
Retained earnings	\$m	(12.8)	(24.0)	(41.9)	(52.3)	(61.9)
Other	\$m	0.0	1.2	1.1	1.1	1.1
Total equity	\$m	6.5	29.1	28.3	19.0	9.5
CASH FLOW						
		FY20A	FY21A	FY22E	FY23E	FY24E
Net loss for period	\$m	(3.3)	(11.2)	(18.2)	(10.2)	(9.6)
Depreciation & Amortisation	\$m	0.0	(0.9)	(2.1)	(0.7)	(0.6)
Changes in working capital	\$m	0.4	(0.4)	(1.1)	1.2	0.0
Other	\$m	0.3	7.2	15.3	1.3	1.3
Operating cash flow	\$m	(2.5)	(5.3)	(6.1)	(8.4)	(9.0)
Payments for PPE	\$m	0.0	(0.8)	(0.4)	0.0	0.0
Other	\$m	0.0	3.8	0.0	0.0	0.0
Investing cash flow	\$m	0.0	3.0	(0.4)	0.0	0.0
Equity	\$m	2.5	0.3	18.5	0.0	10.0
Lease liability payments	\$m	0.0	(0.3)	(0.3)	0.0	0.0
Other	\$m	(0.2)	0.0	(1.2)	0.0	0.0
Financing cash flow	\$m	2.3	(0.0)	16.9	0.0	10.0
Cash year end	\$m	7.3	5.0	15.4	7.0	8.1
Free cash flow	\$m	(2.5)	(2.3)	(6.5)	(8.4)	(9.0)

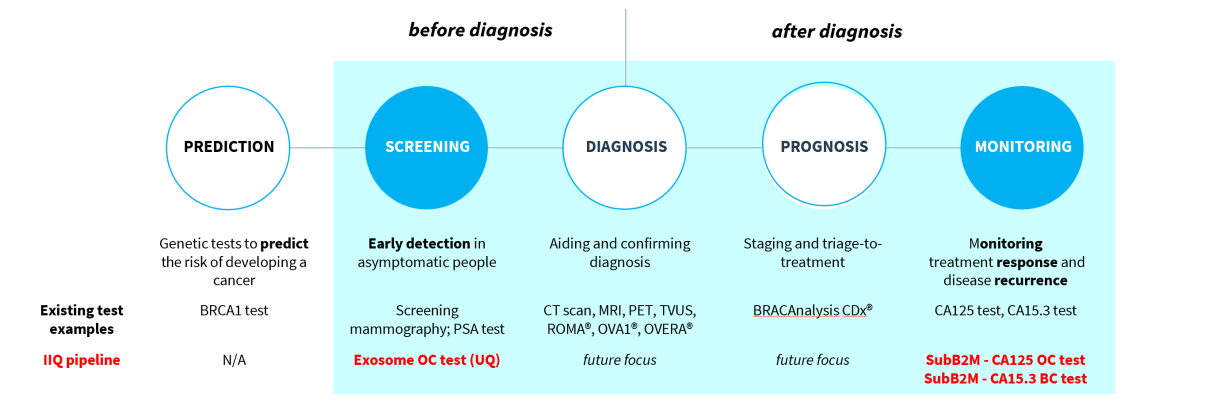
Source: MST Access.

A Refresher on IIQ’s Portfolio and the Potential for SubB2M

The IIQ Portfolio: Next-Gen Precision Diagnostics

INOVIQ (IIQ) is a development-stage precision diagnostic company developing and commercialising a broad portfolio of diagnostics and exosome-based solutions to diagnose cancer and other diseases, with a portfolio of products that span the diagnostic continuum, from screening to monitoring.

Exhibit 2: IIQ’s pipeline of products is targeting multiple positions along the diagnostic continuum



Source: INOVIQ.

SubB2M Platform for Ovarian and Breast Cancer

The SubB2M technology platform uses SubB2M, an engineered, highly selective ligand (recombinant protein), to bind in an immunoassay format to the biomarkers CA125 and CA15.3 decorated with Neu5Gc, a novel cancer biomarker that is elevated at all stages of ovarian and breast cancers and found at elevated levels in humans on tumour cells and tumour-associated molecules. IIQ recently engaged US-based CRO ResearchDx to advance IIQ’s two lead products, the SubB2M-CA125 assay (for monitoring ovarian cancers) and SubB2M-CA15.3 assay (for monitoring breast cancers).

Combining SubB2M with Next-Gen SPR for Pan-Cancer Test

Feasibility studies to date in the SubB2M program have used Surface Plasmon Resonance (SPR)–based tests, considered the gold standard in direct biomolecular interaction sensing, to directly measure the levels of the pan-cancer biomarker Neu5Gc. SPR is an optical biosensor technology that uses changes in refraction of light shone onto a metallic surface to detect interactions at the molecular level. The SPR technique allows molecular interactions in a target of interest to be measured (‘characterised’). SubB2M-based SPR tests have generated encouraging data; POC results vs healthy controls show SubB2M detects all cancer stages with >95%/100% sensitivity and 100%/100% specificity in breast/ovarian cancers, respectively.

SPR-based platforms that process a patient sample to detect and quantify biomarkers using liquid biopsies for cancer patients represent a new alternative to conventional approaches, such as cell culture methods (histopathology/cytology), enzyme-linked immunosorbent assays (ELISA), next-generation sequencing (NGS), and polymerase chain reaction (PCR)–based platforms, currently in use in commercial laboratories and considered highly efficient for processing relatively large numbers of samples¹. Notably, the use of an SPR platform enables the measurement of multiple glycoproteins with aberrant Neu5Gc leading to improved sensitivity and specificity for cancer.

Next-generation SPR instruments with a smaller footprint (scaled-down benchtop) for use in diagnostic/pathology labs could be positive for IIQ considering compelling data rendered to date and could reduce the risk inherent when transferring technology to other currently widely used platforms such as ELISA.

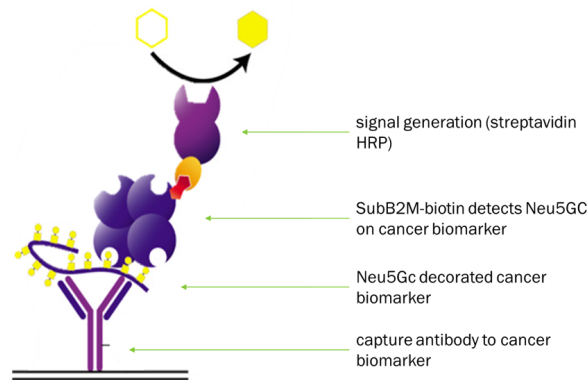
¹ Surface Plasmon Resonance for Biomarker Detection: Advances in Non-invasive Cancer Diagnosis: Bellassai et al (2019)

How It Works: Leveraging Novel, Highly Specific Ligand to Detect Neu5Gc

The SubB2M² platform utilises a highly specific probe (a genetically engineered lectin, or carbohydrate-binding protein) developed to bind with Neu5Gc, a pan-cancer marker found in multiple human cancers. SubB2M technology was in-licensed from University of Adelaide and Griffith University in April 2020. As such, IIQ holds the exclusive worldwide rights to the SubB2M intellectual property for diagnostic applications.

Neu5Gc occurs as cells transform to malignancy resulting from aberrant glycosylation caused by abnormal expression of certain enzymes involved in modifying of proteins and the regulation of cell growth and differentiation, cell adhesion, cell-to-cell communication, and immune recognition. IIQ is currently developing SubB2M-based immunoassays (ELISA) for multiple cancers, with an initial focus on the monitoring of breast and ovarian cancer.

Exhibit 3: SubB2M immunoassay

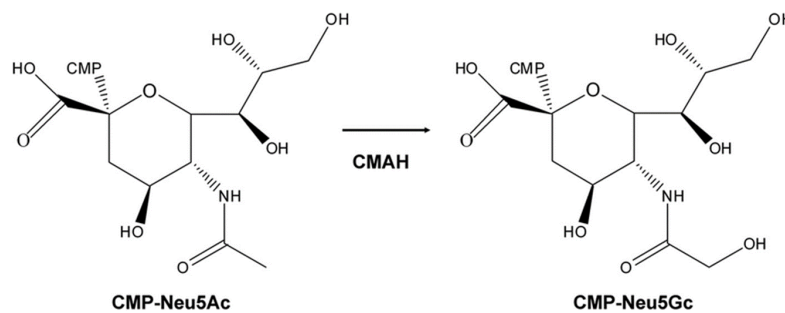


Source: INOVIQ.

The science of Neu5Gc – a novel pan-cancer biomarker

N-Glycolylneuraminic acid (Neu5Gc) is a sialic acid molecule not typically found in humans. This is due to the absence of the CMAH (CMP-Neu5Ac hydroxylase) enzyme responsible for converting the precursor to Neu5Gc in humans owing to an irreversible genetic mutation millions of years ago. Neu5Gc has been consistently found in various human epithelial cancers including breast, colon, lung, prostate, and ovarian, and as such, is a novel cancer biomarker.

Exhibit 4: Humans cannot synthesise Neu5Gc due to inactive CMP-Neu5Ac hydroxylase (CMAH) gene



Source: N-Glycolylneuraminic Acid on Human Epithelial Cells Prevents Entry of Influenza A Viruses That Possess N-Glycolylneuraminic Acid Binding Ability - Tadanobu Takahashi et al (2014).

² The name SubB2M derives from the second mutant version of the B-subunit of the Shiga toxicogenic Escherichia coli Subtilase cytotoxin engineered to be a Neu5Gc-specific lectin.

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Level 13, 14 Martin Place, Sydney, NSW 2000
Main +61 2 8999 9988
www.mstfinancial.com.au