



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Inoviq

**By TIM BOREHAM**

**ASX code:** IIQ

**Share price:** 67 cents; **Shares on issue:** 92,018,702; **Market cap:** \$61.7 million

**Chief executive officer:** Dr Leeorne Hinch

**Board:** Dr Geoffrey Cumming (chair), Robert (Max) Johnston, Philip Powell, Prof Allan Cripps

**Financials (year to June 30, 2022):** product revenue \$276,745 (down 41%), loss of \$6.26 million (previously an \$11.1 million deficit), cash of \$15.4 million (up 206%).

**June quarter 2022:** receipts of \$163,000, cash burn \$1.68 million, cash balance \$15.4 million, quarters of available funding nine.

**Identifiable major shareholders:** Merchant Funds Management 12.63%, Moggs Creek Super (David Williams) 5.3%, Dr Irmgard Irminger-Finger 4.4%.

### **Inoviq? Ino-who?**

Most investors would struggle to recognize one of the newest names in the ASX biotech family which, we're reliably informed, means "intelligent innovation".

Given the company's three-pronged program covering cancer diagnostics and involving lots of dense acronyms, investors could also be forgiven for understanding where these innovative smarts are being directed.

For those who haven't been paying attention, Inoviq is the new moniker for Bard1, which subsumed fellow ASX-listed Sienna Diagnostics at the onset of the pandemic in mid-2020.

While the two companies are pretty much an omelet these days, the active programs are weighted to the old Sienna.

Inoviq chief Dr Leearne Hinch admits the company can seem complicated, given its various technology strands and multi-product pipeline.

"People have a better understanding of therapeutics; there's less understanding of what diagnostics, do although Covid has significantly changed that," she says.

Inoviq's ultimate aim is simple enough: to commercialize better diagnostics for some of the most common cancers.

"The current cancer diagnostics are far from reliable," Dr Hinch says.

"The key unmet need is to detect cancer earlier and more accurately. We have a host of opportunities, from screening to diagnosis to treatment selection and patient monitoring."

### **How the omelet was cooked**

Sienna listed in mid-2017, backed by deep-pocketed names including former Macquarie Bank chief Allan Moss and rag trader tycoon David Neate.

Sienna developed an approved adjunct diagnostic product for bladder cancer called hTERT (anti-hTERT, strictly speaking).

Launched in 2016 initially as a laboratory reagent, it remains Inoviq's legacy, revenue-generating product.

In 2019, Sienna acquired an exosome technology asset called Exo-net.

In April 2020, the company licenced a cancer-busting protein - clumsily monikered Sub-B2M - from the University of Adelaide and Griffith University.

Bard1 emerged from the shell of Eurogold in 2016, with its work focused on lung cancer and an auto-antibody platform based on the Bard1 protein.

In mid-2020, Bard1 acquired Sienna in a scrip deal valuing the whole shebang at around \$76 million. Apart from cancer diagnostics, the other common feature was that Merchant Opportunities Fund owned a large slab of both of them.

In December last year, Bard1 renamed itself Inoviq.

Dr Hinch joined Bard1 as CEO in November 2016.

A trained veterinarian, Dr Hinch previously headed the ASX-listed Immuron and held executive roles at the listed OBJ Ltd, Hollista Colltech and the now-defunct Healthlinx (also cancer diagnostics) and Chemeq.

Dr Hinch, by the way, joins vets-turned human biotech execs Dr Jackey Fairley and Dr Paul MacLeman.

"I have seen this company through a lot of change from one that had a single technology - Bard1's auto-antibody platform - to acquiring Sienna for its Exo-net asset," Dr Hinch says.

## **Exosome or go home**

Exosomes are a hot area of research, with the ASX-listed Exopharm specializing in the field.

While Exopharm is all about therapeutics, Inoviq focuses on diagnostics and claims to be a leader in the race to commercialize a product.

Exosomes are small extra cellular vesicles, or as Dr Hinch puts it: "Little balls released from all cells in the body, including healthy and diseased ones."

Inside the exosomes are different sorts of molecules, such as DNA fragments, ribonucleic acid (RNA), proteins and lipids.

Inoviq's Exo-net is a matrix of antibodies that 'capture' the exosomes for analysis.

In the case of an ovarian cancer, the company compares exosomes from cancer cells with normal ones.

"Inside the cancer exosomes, we found a number of informative biomarkers such as micro-RNAs and proteins," Dr Hinch says.

"That combination of biomarkers goes into an algorithm, which enables the earlier and more accurate detection of ovarian cancer."

## **Tapping the burgeoning research market**

Inoviq has targeted Exo-net as a research tool for interested parties such as academia and drug companies developing exosome-based therapies.

"Because it doesn't have to be approved for use in research, this provides a faster market opportunity to get it in the hands of key scientists," Dr Hinch says.

Dr Hinch cites a potential \$US661 million (\$A944 million) market for global exosome research, up from \$US440 million in 2021.

In July 2022, the company appointed US mob Precurso Life Sciences, which already offers exosome research products, as a contract sales agent.

“This is a nascent industry that is growing rapidly because of the amount of research being done in this sector in both diagnostics and therapeutics,” Dr Hinch says.

Currently there is only one approved exosome-based diagnostic, for prostate cancer.

Inoviq aims build a pipeline of exosome-based diagnostics, firstly for cancer but also for neurodegenerative diseases (such as Alzheimer’s and Parkinson’s) or metabolic ailments such cardiovascular disease, obesity and diabetes.

The company has an exosome-based ovarian cancer diagnosis in development with the University of Queensland, in view of a mass screening test.

Dr Hinch adds that Exo-net can be customized by using different antibodies to capture exosomes from the brain, lung or ovaries.

### **Sub optimal time for a Neu name, Eliza?**

Dr Hinch concurs that Sub-B2M is an “awful name” that’s ripe for changing - and no doubt will be.

Totally unconnected to submarines - nuclear powered, French-built or otherwise -Sub-B2M is an engineered protein that detects a pan-cancer biomarker called Neu5Gc.

Neu5Gc is a sugar found on any cancer cell, but not any healthy human cell (or any mammalian one for that matter).

“Somehow cancer has found a way to produce this Neu5Gc; hence it is a pan-cancer biomarker,” Dr Hinch says.

Earlier studies showed that Sub-B2M could detect more than 95 percent of breast cancers across all stages (stages one to four), with no false positives.

This work was done in 2018 and 2019.

Since then, the company has focused on transferring the tech to a simple format called Eliza, as in enzyme linked immunosorbent assay.

Sorry - these names are not getting any better.

“It’s a simple assay that is cost effective and used in pathology labs around the world,” Dr Hinch says.

“We are seeking to improve on existing cancer monitoring tests.”

One such test has already been approved by the US Food and Drug Administration for monitoring ovarian cancer, focused on detecting the protein on cancer cells called CA125.

Ditto a second test for the breast cancer protein biomarker CA15.3.

### **Anyone for a sandwich?**

The aforementioned tests aren't especially effective, because these biomarkers can be elevated for reasons other than cancer.

So Inoviq proposes a "sandwich assay" approach by which its test detects both the proteins and Neu5Gc, which narrows their occurrence to cancer cells.

"The sugar was very much known as a cancer biomarker, but no one knew how to bind the sugar with high sensitivity and specificity," Dr Hinch says.

At least that's until the University of Adelaide and Griffith University nipped out how to bind the antibodies and the sugar "with great affinity".

As with Exo-net, Inoviq plans to sell the diagnostic as a laboratory-based test.

This would be followed by a clinical trial to support an FDA application under the 510(k) predicate device pathway.

The test could be used either to improve the existing tests, or as a routine blood-based assay along with the standard tests for glucose, liver enzyme and cholesterol levels.

In late July, Inoviq showed that Sub-B2M was effective in detecting melanomas and distinguishing the malignant growth from benign ones.

This was based on 144 samples.

### **Fewer biopsies? Bladder believe it**

Inoviq's anti hTERT is an immune-cyto-chemistry test used as an adjunct to urine cytology. The test detects the hTERT human telomerase, which is elevated in cancer cells.

The problem with current methods is that 25 percent of the cells are indeterminate, which means it's not clear whether it's cancer or not.

To reduce the number of patients referred for an unnecessary cystoscopy and biopsy, the samples are stained with hTERT.

As with a Band-Aid, hTERT has no particular disease claim and has also been approved in Europe, South Korea and Australia.

In an ideal world of daisies and fluffy kittens, every relevant sample would be double tested with the hTERT kit.

But as Americans would attest, healthcare boils down to money and preferably someone else's.

## **Finances and performance**

Inoviq recorded \$160,000 sales in the June quarter of 2022, all from the hTERT product. Sales for the 2021-'22 year came in at a Covid-affected \$276,745 million, which compares with peak annual revenues of \$500,000 per annum.

At the end of June, the company had a tad over \$15 million of cash, with the coffers bolstered by an \$18.4 million placement and share purchase plan in mid-2021.

"Based on our current cash burn, we have enough cash to cover the next two years," Dr Hinch says.

"But that will depend on our development programs. We expect our spending to increase over the next couple of years as we move our programs forward and into clinical validation."

Inoviq shares are down 50 percent compared with a year ago, but up a hefty 45 percent since June 30, 2022.

Since the 2020 merger, Inoviq has traded as low as 41 cents (June 24 this year) and as high as \$3.99 (March 2021) following the February announcements of "100 percent" success for sensitivity and specificity for ovarian cancer and 95 percent and 100 percent, respectively, for breast cancer.

## **Dr Boreham's diagnosis:**

Ideally, Inoviq will emerge with commercialized breast and ovarian cancer monitoring tests (Sub-B2M) and ovarian cancer screening for asymptomatic folk (Exo-net).

We've barely mentioned the old Bard1's legacy, early-stage lung cancer program, but neither has the company.

A screening product is harder to get to market, partly because a higher patient sample is required to prove efficacy.

So, if anything, investor hopes centre on the more advanced Sub-B2M program, with numerous studies across both cancers underway.

Sometimes the seemingly small things count in biotech research and fortunately the company has access to a bio-bank of ovarian cancer samples and matched controls, held by University College London.

"This is really important because accessing ovarian cancer samples is very difficult," Dr Hinch says.

There's certainly much going on by way of intelligent innovation at Inoviq, but we suspect the dense nature of the company's material has contributed to the company's share price decline.

"We are in a tough market now," Dr Hinch says. "We have been hit hard but we are focused on moving our key programs forward and expect value to return to the share price."

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Rather than the company's material being dense, it could well be just him.***