



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Imagion Biosystems

By **TIM BOREHAM**

**ASX code:** IBX

**Share price:** 2.7 cents

**Market cap:** \$30.3 million

**Shares on issue:** 1,121,318,534

**Executive chair:** Robert (Bob) Proulx

**Board:** Robert Proulx, Michael Harsh, David Ludvigson, Jovanka Naumoska, Mark Van Asten, Dianne Angus

**Financials (December quarter 2022):** receipts \$88,000, cash outflows \$454,000, cash balance \$4.44 million, quarters of available funding 9.8

**Identifiable major holders:** Manhattan Scientific (4.6%), The Board of Regents of the University of Texas System 0.94%, Hoajie Li 0.98%, Robert Proulx 0.55%.

Imagion chief Bob Proulx reckons the oncology imaging innovator has achieved far more with its initial, early-stage breast cancer study results than investors might appreciate.

Carried out in Australia, the phase I trial showed the first signs that the company's approach of detecting tumors with magnetic nanoparticles was safe - and it actually might work.

“As far as I know, it was the first time ever ... that someone has taken an iron oxide particle with a targeting ligand [molecule] and put it in a patient,” Mr Proulx says.

The results were deemed significant enough to be the subject of a ‘poster’ presentation at last December’s San Antonio Breast Cancer Symposium, attended by a cluster of 3,000 oncologists.

And there’s more.

This week, the company announced that an independent, blinded review by a panel of expert breast cancer radiologists supported the potential of the company’s Magsense particles to detect tumor cells in lymph nodes, via magnetic resonance imaging (MRI) machines.

This means the company can shelve expensive plans to develop its own device, in favour of commercializing the particles themselves (see below).

“We don’t have to worry about building a proprietary machine or commercializing a new piece of equipment,” Mr Proulx says.

“We can sell our particles at any hospital that has an existing MRI.”

While Imagion initially is focused on human epidermal growth factor receptor-2 (HER2) type breast cancer, other solid tumours including prostate and ovarian cancers are also in its sights.

### **Los Alamos project goes off with a bang**

Imagion combines the use of magnetically detectable nanoparticles with biological agents, to detect certain solid cancers.

Imagion’s underlying tech was created by a Los Alamos, New Mexico physicist called Edward R Flynn, who tinkered with magnetic sensors after his wife contracted breast cancer.

“It was the classic scenario of a scientist wanting to do something about it,” Mr Proulx says.

The technology resided in diagnostics house Senior Scientific, which was acquired by the New York based nano-medicines group Manhattan Scientifics.

The relevant activities ended up within the newly-formed Imagion, which listed on the ASX on June 22, 2017 after raising \$12 million at 20 cents a share.

The listing means Imagion is headquartered in Melbourne, but most of its activities take place in San Diego (where Mr Proulx resides).

## **Avoiding biopsies with better diagnosis**

But what is the problem Imagion is purporting to solve? After all, there are at least five ways of imaging the body, currently.

Mr Proulx says x-rays are great for detecting broken bones, while ultrasounds are cheap and ideal for showing up foetuses and abnormalities

Computed tomography (CT) and positron emission tomography (PET) scans are also useful, but have their limitations (the latter uses radioactive tracing agents).

MRI scans are superior resolution-wise and will detect an “anatomical problem”, such as a fibrotic mass.

“But none of these methods can tell you whether a suspicious spot or lesion is cancerous or not.”

The idea of Magsense is to avoid unnecessary biopsies.

“When a breast cancer is detected, the first thing the patient wants to know is whether it has spread to the lymph nodes,” Mr Proulx says.

“An ultrasound might tell whether a lymph node is larger or misplaced and [whether to do] a biopsy, but what if we can give the answer non-invasively?”

The ‘non-invasive’ angle is especially pertinent for prostate cancer detection, given the biopsy sample is obtained via a 12-pronged tool inserted up the rectum.

We’re glad we got to the bottom of that one.

## **Making sense of Magsense**

Imagion’s Magsense platform involves injecting iron oxide nanoparticles combined with cancer-specific targeting antibodies or small molecules, contained within a solution.

“A detectable magnetic particle is coupled to cancer-specific targeting molecules, so when the nanoparticle is injected into the patient it will circulate and will seek out the cancer cells,” Mr Proulx says.

The nanoparticles attached to the cancer cells lose their magnetism more slowly than the unattached ones, acting as a magnetic beacon.

In the case of breast cancer, HER2 refers to an antigen that expresses the human epidermal receptor.

“Some antibodies are specific to that receptor. So, if you put the antibody on our particle it will bind to those cancer cells,” Mr Proulx says.

If there no cancer, the particles will circulate harmlessly and the iron oxide eventually will be excreted via the liver.

“Everything about this is biologically safe; we are using antibodies or peptides that the body already recognises, with a detectable iron oxide particle,” Mr Proulx says.

## **Thanks, patients**

Carried out in Australia across four sites, the breast cancer trial opened in December 2020, but because of Covid lockdowns it didn't enrol its first patient until May 2021.

As announced in early December last year, the results from the first six-patient cohort hit the primary endpoint of safety and tolerability.

The research also showed the imaging agent to be detectable by both MRI and the company's proprietary relaxometry technology. In other words, Magsense could “help discriminate potentially cancerous nodes from normal ones”.

Patients were given a 30-milligram dose, compared with more than 1,000mg over three days for a popular iron-based anaemia drug.

“We can say with high confidence a dose of our Magsense particle is very unlikely to cause metabolic upheaval in the liver,” Mr Proulx says.

Unlike most safety trials that use healthy volunteers, the trial custodians were interested in HER2 patients to explore the ‘efficacy’ angle.

Mr Proulx says the trial was burdensome for the participants, who were subject to an MRI, the nanoparticle dosing and then another MRI and a biopsy.

Given it was strictly a research study, there was nothing in it for them.

“It took a very special person to be willing to volunteer for our study,” Mr Proulx says.

## **MRI decision will save a fair (s)quid**

Following the supportive opinion of the three-person expert panel led by principal investigator Dr Jane Fox, Imagination has made the commercial decision not to develop its own device.

To explain: the nanoparticles are subject to a low magnetic pulse, with their location detected by an ultra-sensitive ‘super-conducting quantum interference device’ (yep - a Squid).

The company expected revenue would be by way of the fabled printer and cartridge model, by which the hardware (the measuring stations on which the patients lie) virtually given away.

Mr Proulx says the devices were to have been developed by the Melbourne-based design house Planet Innovation. But advancing them would have taken at least 18 months and would have cost “many millions” of dollars.

Given Imagion had parked device development for the last two years, the decision is more a case of freeing-up future funding, rather than generating current cost savings.

Mr Proulx says it would have been “problematic” to expect a hospital to shell out around \$US500,000 for a device, especially if it was only relevant for breast cancer detection.

He adds the idea of a proprietary device platform is not altogether dead.

“There are some new, really small sensors and we are looking at developing a detector more like an ultrasound device than a big Squid,” he says.

These devices could be deployed cost-effectively at general practitioner !!!!!GP clinics, perhaps as a triage tool whereby only positive results are sent for an MRI.

“This bodes well for our proprietary technology because we can skip over the expensive machines ... and move to something more ubiquitous in terms of implementation.”

## **Finances and performance**

Imagion recorded December quarter cash outflows of \$454,000, albeit after receiving a \$2.5 million Federal Research and Development Tax Incentive payment.

The company also gleaned \$88,000 of revenue, taking the calendar 2022 tally to \$350,000. This income derived from selling the particles to third parties for research in other fields such as animal vaccines and hypothermia.

In November 2020, Imagion raised \$6 million in a placement at 8.5 cents per share.

In 2021, the company garnered \$4.8 million from the exercise of in-the-money options at five cents per share.

The company currently has \$6 million of options on issue, with a three-cent exercise price.

Imagion’s base of 8,500 investors have seen the share price fall from a peak of 20 cents in February 2021 to as low as two cents (in January this year).

The shares traded as low as one cent at the onset of the pandemic, in March 2020.

This week they perked up to 3.3 cents after the MRI decision, briefly rendering the aforementioned options in-the-money.

## **Finger in the wind**

Mr Proulx says the breast cancer trial was never meant to be statistically significant; rather, it was a “finger in the wind” as to whether Magsense looked like working.

Imagion’s next task is to expand the trial globally, with an eventual registration study requiring perhaps 500 patients

The company may also introduce a ‘de-escalation’ component to the study, to test with doses lower than 30 milligrams.

Last September, the company presented research on Magsense for prostate cancer to the World Molecular Imaging Congress in Miami, Florida.

Preclinical work provided “strong evidence the company’s [technology] has the potential to target prostate cancer tumours expressing the prostate specific membrane antigen [PSMA] with high specificity”.

## **Dr Boreham’s diagnosis:**

Mr Proulx says initially the company identified 150 applications for non-invasive cancer imaging, but honed that down to only 20 that would fly in a commercial sense.

For example, pancreatic cancer is a large unmet market, but a tricky one as the tumors don’t express a particular biomarker.

“We focus on where the unmet medical need is and whether we have an imaging solution to tackle that,” Mr Proulx says.

“We are focused on cancer applications where the biology is reasonably well known and we can target them by putting the biology on our particles.”

That said, breast, prostate and ovarian cancers alone are a \$US4.5 billion market opportunity.

Despite this week’s price fillip, Imagion’s “impatient and frustrated” holders (the company’s words) remain to be convinced about the company’s prospects.

“We are undervalued for a clinical stage company, but it is what it is,” Mr Proulx says.

***Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He considers himself to be undervalued, but it is what it is.***