



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Immuron

**By TIM BOREHAM**

**ASX code:** IMC; **Nasdaq code:** IMRN

**Share price:** 31.5 cents

**Shares on issue:** 142,778,206

**Market cap:** \$45.0 million

**Chief executive officer:** Dr Jerry Kanellos

**Board:** Dr Roger Aston (chairman), Peter Anastasiou (executive vice-chairman), Stephen Anastasiou, David Pollock, Prof Ravi Savarirayan

**Financials (December half):** revenue \$919,138 (up 30.7%), loss \$1.9 million (compared with \$3.40m loss previously), cash \$588,863\*

\*Ahead of \$5.1m institutional placement completed in March

**Identifiable holders:** Empery (US asset manager) 9.22%, Peter Anastasiou (Grandlodge) 11.49%.

There's no arguing against the 'breast is best' mantra at this long-standing Melbourne based biotech, which bases its therapeutics on the goodness of colostrum (the antibody-rich milk produced by mammals after birth).

In Immuron's case the colostrum is derived from the milk of cows that contain the wonder liquid in the first few days after calving.

Immuron's activities are twofold: it markets the over-the-counter travellers' diarrhoea treatment Travelan and on the clinical side it is undertaking further studies on a number of inflammatory and infectious indications.

### **Name change, song remains the same**

Immuron was previously known as Anadis, which listed in 1994 on the back of the colostrum story.

Immuron adopted its current moniker in 2008 but essentially is singing the same tune but with more of a clinical emphasis.

Anadis registered Travelan in 2004 and over time the off-the-shelf treatment has produced \$25 million to \$30 million in revenue for the company.

Immuron sources 30,000 litres of the raw material annually from a 7000-head dairy facility in New Zealand, owned by baby formula maker Synlait.

Immuron dual-listed on the Nasdaq in July last year, with the American depositary receipts accounting for about 10 per cent of issued capital.

### **Having a slash at cure for NASH**

Immuron's core activities revolve around its lead compound IMM-124E, an orally-delivered, polyclonal antibody that targets an antagonist called LPS (lipo-poly-saccharide).

The company has just completed a phase II trial using IMM-124E to treat patients with non-alcoholic steatohepatitis, or NASH, also known as fatty liver disease.

A vogue indication in biotech circles, NASH is an untreatable disease caused by poor exercise and nutrition.

At the initial fatty liver stage, it's a major reason for liver transplants, while at later stages it results in fibrosis and cirrhosis (death of the liver cells) and eventually liver cancer.

The NASH proof-of-concept study enrolled 133 patients across 25 sites in Australia, Israel and the US (this exceeded the initial target of 120 subjects).

The double-blinded, randomized trial involved the patients being split into two dosage groups (low and high) as well as a placebo group.

They were delivered three doses a day over a 28-week period.

In polite circles the top-line results released in March would be described as mixed, as the study missed its primary endpoint of an improvement in liver steatosis (or fat).

The secondary endpoints included a reduction in certain liver enzymes and metabolic markers.

But the company is happy because the study showed a “statistically significant” reduction in LPS, which is linked with the progression of NASH.

In effect, this establishes the mechanism of action of preventing the LPS nasties from moving from the gut into the blood stream.

While the company is still analysing the data, it is likely to seek a big pharma partnership to pursue the program.

“We basically nailed our mechanism of action, which is what pharma companies want to see,” Dr Kanellos says.

“But a phase II/III trial would require 200 to 300 patients and a major registration trial would need thousands, which is beyond the scope of a small Melbourne biotech,” Dr Kanellos says.

## **Other trials**

Immuron is also undertaking two trials paid for by the US National Institutes of Health.

The first, for paediatric non-alcoholic fatty liver disease has recruited 19 of its targeted 40 patients. This one is expected to be completed by the end of 2018.

The second, for alcoholic steatohepatitis, has recruited 52 patients out of a targeted 66. The study is expected to be finalised by the end of the year, with results next year.

Meanwhile, Immuron’s second clinical stage asset, IMM-529 is targeting clostridium difficile (a nasty bacterial disease affecting the colon).

## **Colitis next?**

In early May, Immuron announced the results of mouse studies in relation to colitis, a bowel disease.

As with the NASH trial, the preclinical study undertaken at the University of Zurich showed a mechanism of action similar to the NASH trial: it reduced serum LPS levels.

“The results clearly demonstrated that oral treatment with IMM-124E resulted in a significant alleviation of colitis symptoms,” the company says.

These include weight loss, colon shortening and disease activity.

The results will be presented to the United European Gastroenterology Week conference in Vienna in October, so book your Jetset Travel package now.

## **Hot to trot with Travelan**

While there are many 'cures' for travellers' diarrhoea, most of them work by temporarily bunging up the system (please excuse the technical talk).

Travelan, however, deals with the bugs responsible and can be used as a preventative rather than after-the-fact.

In April, management reported that Travelan chalked up \$501,000 of sales in the nine months to March, up 178 percent. Australian sales edged up nine per cent to \$863,000.

The company expects to crack \$1 million of US sales in 2018-'19, with Australian sales ramping up to \$1.3 million.

US sales were bolstered by a distribution deal that sees the over-the-counter product supplied in 193 Passport Health travel clinics (with a further 39 added this quarter).

Travelan's prospects are also bolstered by an assessment from the US Department of Defence concerned about the vulnerability of its troops in unhygienic parts of the world.

The DoD's Bangkok-based work found that Travelan reacted to 180 strains of bacteria. Specifically, the top brass are interested in treating the debilitating disease shigella (an e-coli type bug).

As they say: an army marches on its stomach but the contents have to stay put, as well, to ensure effective combat. And didn't Napoleon lose at the aptly named Water-loo because half his troops came down with dysentery?

## **Finances and performance**

After pursuing several fundraising options, in March the company raised \$5.1 million from US funds manager Empery. Struck at 39 cents a share (a modest 2.7 percent discount), the deal delivered Empery a 9.22 percent stake.

Immuron is enthusiastically backed by the brothers Peter (exec director) and Stephen Anastasiou, who hold at least 11.5 percent of the company and also sit on the board.

Among other things the entrepreneurial twosome developed a pregnancy test, ran a carpet cleaning business and are also property developers.

Immuron shares troughed at 15 cents last October and peaked at 47 cents after the March results.

**Dr Boreham's diagnosis:**

Given its listed longevity Immuron/Anadis has worn the patience of many investors, but the company is no Pat Malone in that regard.

Travelan competes in a crowded market and its sales, though rising, will not maketh the company. But it's handy for a drug developer to access funds other than through dilutive raisings.

A partnership in relation to NASH would be a highly desirable outcome.

"They are all aware of [the NASH trial results]," Dr Kanellos says of potential big pharma suitors. "We got a number of letters of congratulations after the announcement."

Over time, Anadis/Immuron has gone through more CEOs than your columnist had breast feeds as a nipper.

But Dr Kanellos has been in the chair for three years, a sense of stability prevails and the company is hot to trot.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But hopefully he has the 'runs' on the board after this one.***