

Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Anatara Lifesciences

By TIM BOREHAM

ASX code: ANR

Share price: 22 cents

Shares on issue: 49,413,236

Market cap: \$10.9 million

Chief executive officer: Steve Lydeamore

Board: Sue MacLeman (chair), Dr Jane Ryan, Dr Tracie Ramsdale, Dr David Brookes

Financials (year to June 30, 2019): customer revenue (licencing fees) \$663,405 (previously \$6,467), other income* \$877,573 (\$1.34m), loss of \$2.87 million (previous loss of \$3.6 million), cash balance \$5.4 million (\$7.65 million).

Identifiable holders: Parma Corp (Mel Bridges) 11.95%, RTL Group (Lederer family) 10.07%, Myeng Pty Ltd (Dr Tracey Mynott) 8.89%, Tiga Trading (Thorney Investments) 5.64%.

Logically, shares in the two-legged and four-legged gut health play should have surged after animal health giant Zoetis walked away from a partnering deal in June this year for "portfolio reasons".

^{*} mainly \$840,932 Federal R&D Tax Incentive

At the time of the May 2018 partnership, Anatara said it could not have had a better partner in the US-based Zoetis, which assumed the rights for all livestock and equine applications.

But after that supposed feel-good event, Anatara shares tumbled 40 percent because the terms weren't as lucrative as investors expected.

Having now regained its rights to Detach, in theory the company can execute a better deal with one of the other potential partners.

Instead, investors were spooked by Zoetis's lack of interest and excised a further 43 percent from the share price.

Anatara maintains its faith in its lead product Detach, which is approved locally as a treatment for scour (diarrhoea) in piglets.

And no, it's not an oink-ment, but an oral drench.

"It came as a surprise and a disappointment," Anatara CEO Steve Lydeamore says of Zoetis's brusque termination. "But in some ways, it presents an opportunity."

Anatara's greater prospects lie with human health, as a remedy for the common but difficult-to-treat afflictions of irritable bowel syndrome and inflammatory bowel disease (ulcerative colitis and Crohn's disease).

Mr Lydeamore notes that gut health is "very topical", which is an understatement given the range of digestion-related 'wellness' products purveyed by the likes of Blackmores and Suisse.

"If you do a Google search on the topic you will get more than 400 million hits," he says.

He's right: your columnist's rigorous cross-checking of this claim reveals 530 million online references.

The problem bugging all of us

Detach is an alternative for antibiotics which are being banned from the food chain as microbial resistance builds. The active ingredient, bromelain, is derived from the stems of pineapples, of all things.

Describing antimicrobial resistance as "one of the most urgent health issues of our time", the World Health Organisation projects up to 10 million people will die annually by 2050 if nothing is done.

Mr Lydeamore says 70 percent of bacteria are resistant in one form or another to antibiotics.

Across the world, 70 percent of antibiotics are used in meat production but the Europeans have set the trend by banning them from the food chain. A soil pollutant, zinc oxide will also be outlawed on the Continent from 2022.

Mr Lydeamore says US surveys also show that US consumers think antibiotic-free meat is better for their health - although they have no problem with guns which also tend to be injurious to their wellbeing.

"So there is a push from consumers - not just governments and regulators - to reduce the use of antibiotics," he says.

Anatara's evolving story

Like a trots-afflicted traveller, Anatara has undergone a board room, management and strategic purge since we last covered the stock in August last year.

In December Mr Lydeamore became CEO, with interim CEO Dr Tracie Ramsdale returning to non-executive director duties.

Mr Lydeamore has 26 years of global healthcare experience, mainly at Apotex (Canada's biggest drug company) and FH Faulding (now Mayne Pharma).

Anatara chairman and industry legend Mel Bridges retired in May last year, to be replaced by Sue MacLeman (who is also on the boards of Palla Pharma, Novita Healthcare, Oventus Medical and industry body MTP Connect).

Anatara's advisory board includes Monash University gastro-enterologist Prof Peter Gibson, who shares fame with Messrs Atkins and Pritikin and Ms Paltrow for inventing a diet: FODMAP.

More of an anti-FODMAP regimen, FODMAP seeks to avoid fermentable carbohydrates that are thought to exacerbate irritable bowel diseases.

(For those remotely interested, FODMAP stands for fermentable oligosaccharides, disaccharides, monosaccharides and polyols).

Steering clear of diarrhoea

An enzyme extract, bromelain blocks the receptor sites in the gut that the parasites attach to (thus causing diarrhoea).

But Anatara has veered away from its original idea of treating diarrhoea alone, after deciding the market is not that attractive.

Mr Lydeamore notes that sales of the two key travellers' diarrhoea products - including the ASX-listed Immuron's Travelan - have been modest.

"It turns out people aren't willing to take a product prophylactically for what you may or may not get on holiday," he says.

"They tend to deal with it after the fact with products such as Imodium [loperamide]."

And close proximity to a bathroom at all times.

A three pronged approach to bug busting

Management's focus has turned from developing Detach as a diarrhoea treatment to a three-pronged curative for irritable bowel syndrome and inflammatory bowel disease.

With symptoms similar to overindulging at a Christmas lunch, irritable bowel syndrome afflicts 11 percent of the population and one in five at any one time.

While irritable bowel syndrome is a collection of symptoms, inflammatory bowel disease is a more specific disorder causing elevated white cell counts, bleeding, fever pain and diarrhoea.

Between 30 to 50 percent of sufferers of both afflictions turn to dietary supplements or complementary healthcare.

With its prospective GAstrointestinal Repositioning Product, or Garp, Anatara's remedy aims to restore normal microbial functions, treat inflammation and repair mucosal damage. (It has nothing to do with dying ball-turret gunners, unfortunate accidents in driveways or John Irving.)

In its natural state, the body has trillions of microbiomes, which outnumber human cells by about 100 to one. About 95 percent of these desirous bugs are in the gut, which is also the source of about 90 percent of diseases.

Microbiome therapeutics is a trendy field of research but it was perfected about 1,700 years ago by the Chinese with a treatment called "yellow soup" - not a hearty pumpkin broth but a serve of watered down faeces donated by a healthy patient to boost the immunity of a sick one.

Anatara's more palatable curative is expected to be developed as an over-the-counter alternative to existing treatments such as probiotics, which are largely unproven.

The over-the-counter approach presents fewer regulatory barriers and faster speed to market.

"Because the products are natural and safe we could put a product on the market now as a dietary supplement," Mr Lydeamore says.

"But we would like a product to have evidence that it actually works."

Can't argue with that.

Detach clings through the ages

Detach has a long - but interrupted - history with animal health, having been marketed in Australia in the 1990s under a different name.

The product achieved a 40 percent market share, despite there being no imperative at the time to remove antibiotics from the food chain. However, then owner Ciba-Geigy was taken over by Novartis, which preferred to focus on human health.

One of the co-inventors of the original Detach, Dr Tracey Mynott worked on a reformulation and Anatara listed in October 2014 after raising \$7 million at 50 cents apiece.

(In 2006, Dr Bridges, Dr Ramsdale and Dr Mynott launched Incitive on the ASX to develop bromelain as a cancer treatment, but it was not to be.)

Ms Mynott resigned as Anatara's chief scientific officer in August last year, but has retained the rights to develop Detach as a diarrhoea treatment for the third world.

In 2017, the US Food and Drug Administration confirmed bromelain's 'generally regarded as safe' status.

In October last year, the Australian Pesticides and Medical Veterinary Authority granted Detach approval as a scour treatment.

The local assent paves the way for Detach to be approved in South East Asia, which is not exactly short of piggeries and poultry farms.

What's next?

The company is conducting preclinical (proof-of-concept) trials for inflammatory bowel disease, with data expected later this year.

Preclinical activity is also underway for a human irritable bowel syndrome trial, expected to start recruiting early next year.

The trial is likely to involve 100 patients.

"We shouldn't have too much trouble recruiting them," Mr Lydeamore says.

The company also expects partnering discussions for the human program to continue next year, with animal health discussions underway.

Mr Lydeamore says that rather than handing the rights to one party holus bolus - an approach that proved unpopular with investors with Zoetis - the rights could go to multiples partners based on species or geographies (or both).

Finances and performance

As of June 30, Anatara had \$5.4 million in the kitty - enough to fund the irritable bowel syndrome trial.

This dosh includes a \$US2.5 million (\$3.7 million) upfront payment from Zoetis, which Anatara pocketed as a consolation prize.

Anatara shares soared from 50 cents at listing to a December 2017 peak of \$1.80, ascribing a \$90 million market valuation.

The current price - close to the record low of 20c a share after Zoetis walked away - values the company at \$11 million.

Despite its re-emphasis on the two-legged species, Anatara still boasts the Lederer family (owner of Primo Smallgoods) as a 10 percent shareholder.

Although he's left the building, Dr Bridges remains the biggest holder on just under 12 percent.

Dr Boreham's diagnosis:

Anatara is setting itself up to play in the expansive market for over-the-counter gastrointestinal and digestive products, estimated to be worth \$US25 billion (\$37 billion) and growing to \$US36 billion by 2021.

There's a lot of snake oil out there, so a product with genuine clinical claims should enjoy a key advantage in the global market.

Between 15 and 20 percent of piglets die before weaning because of conditions such as scour.

Despite the Zoetis setback, the animal health market still looks worthwhile, but investors need to re-set expectations about the dollar rewards a partnership could bring.

With human health Anatara needs to firm up its clinical evidence and sign some decent partnerships, or else its proposals will be little more than - dare we say it - loose motions.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he likes to think he has the runs on the board.