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Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - current )	15.0%
Cumulative Gain	418%
Av. Annual gain (14 yrs)	17.2%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

Blake Industry & Market Analysis Pty Ltd ACN 085 334 292

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Individual Subscriptions (48 issues/year) \$440 (Inc.GST)

Edition Number 597 (24 April 2015)

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# Bioshares

24 April 2015 Edition 597

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Extract from Bioshares -

# Anatara Life Sciences - Healthy Little Pigs

Anatara Life Sciences (ASX: \$0.67) listed on the ASX in October, 2014, raising \$7 million. The cash is expected to support the company through to EU and US market entry in 2017. Anatara is led by CEO Paul Schober and CSO and inventor of the company's technology, Tracey Mynott.

The company is developing a single product, Detach, initially for treatment of diarrhoea in piglets. However, it could be developed as a similar treatment for calves and chickens.

The company is aiming to launch Detach in Australia in 2016 with Australian distributors. The company will seek to partner with large veterinary companies to access EU markets and the US in 2017.

# **History of Detach**

Detach is an oral formulation of bromelain, an extract from pineapple stems. An earlier formulation was marketed in the 1990's by Ciba Geigy but was withdrawn because of a corporate restructure. The original patent covering Detach has expired. A new formulation patent was filed in August 2014. This formulation includes bromelain, carboxymethyl cellulose, citric acid, lecithin oil and ethylenediaminetetraacetic acid (EDTA). However, trade secrets also serve to protect this invention and the company is confident the product cannot be reverse engineered.

Detach works by preventing E. coli from attaching to the small intestine.

### **Trials of Detach**

Two field trials of the new formulation were conducted in Europe in 2012. A trial in Spain of the new formulation of Detach versus zinc oxide, demonstrated a 4.2% improvement in feed conversion ratio in favour of Detach and a 2.7% advantage against no treatment.

Another trial in France compared Detach to Colistin, a polymyxin class antibiotic, as well as a null treatment. Detach delivered a 33% FCR benefit over Colistin and 7% benefit over no treatment.

The company announced in February the results of a trial of Detach in 462 piglets for the treatment of pre-weaning diarrhoea. The trial showed that Detach reduced mortality by 47.8% (8.2% mortality for Detach versus 15.7% for the control group; p<0.02) and increased average weight benefit of 5.3% for Detach over the control group.

Two more Australian field trials are pending.

### Manufacturing

Detach can be readily manufactured at scale, with a 1,000 kg batch for 8.5 million doses capable of being manufactured in several hours. This could supply the Australian market for a year.

Cont'd over

### **Drivers**

The main market driver for Detach is the demand for non-antibiotics to treat illnesses in production farm animals and to move away from using antibiotics as growth promoters. The issue that has concerned public health agencies around the world is the overuse and improper use of antibiotics, in both humans and animals, that has led to drug resistance emerging with various bacteria.

In 2012, the FDA issued guidance on antimicrobial drug use in animals to "limit medically important antimicrobial drugs to uses in animals that are considered necessary for assuring animal health, ...and...limit medically important antimicrobial drugs to uses in animals that include veterinary oversight or consultation."

In 2011, the European Commission released a five year action plan on combating antimicrobial resistance, which included the revision of medicated feed legislation and veterinary medicines legislation, and strengthen 'prudent use' guidelines. However, as far

back as 1986, Sweden banned antibiotic growth promoters.

## Markets

The Australian pork production market is relatively small by world standards. In 2012, Australia had 575 pig producers operating 1,900 establishments, with 240,000 sows in a total herd of 2.1 million. Since 1960, the number of pig producers has fallen dramatically, from about 50,000, but at the same time herd sizes have increased significantly. The number of sows varied between 300,000 and 350,000 from 1975 to 2005, but since then decreased to the 240,000-250,000 mark.

# Australia - Not a Big Pork Exporter

The Australian pork production industry is largely domestic. For the 12 months ending December 2014, 363,000 tonnes of pork was produced for the domestic market and 40,000 tonnes for export. The largest export market was that of Singapore, which took in 12,000 tonnes, or 31%. For the same period, Australia imported 147,000 tonnes. Trade barriers have stood in the way of Australian producers building a bigger pork export market, with subsidised imports also having an effect on local production.

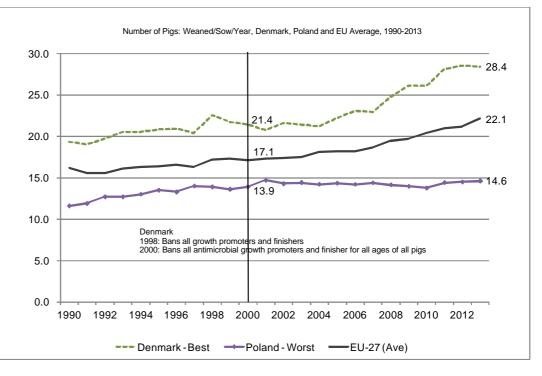
The major pig producers in volume terms, as of 2012, were China with 49 million tonnes of pig meat, the USA, 10.5 million tonnes, and Germany 5.5 million tonnes . However, two major pork producers of interest are Denmark and The Netherlands, producing 1.7 million tonnes (12th in the world) and 1.4 million tonnes (15th in the world) respectively.

These two countries are leaders in European pig production in terms of a key productivity measure, that of pigs weaned per sow per year. In 2013, Denmark produced 28.3 pigs weaned per sow per year (see chart on next page), with the equivalent figure for The Netherlands being 26.0.

The comparable figure for Australia was 23 pigs weaned per sow per year, slightly above the European average of 22.1.

What is surprising is that Denmark and The Netherlands have increased weaner production by more than 30%, at the same time as antibiotic drug use has been severely limited for use in pig herds. Many other EU countries have seen even better growth rates, but coming off a lower base in many cases.

Denmark is a one of the most technologically advanced pork producers in the world, which is why it tops the charts for weaner per



sow production. It has in invested in breeding genetics to improve litter number and robustness, as well as animal husbandry research. Since 2003 it has increased the number of pigs resistant to E. coli type 0149 F4ab/ac which causes diarrhoea in piglets post weaning. Resistance is controlled by a single gene, according to the Danish Pig Research Centre Annual Report 2014. This trait exists with its Yorkshire and Duroc breeding stock but most of the Landrace breed are not resistant at this stage.

These characteristics and features of the Australian and international pig producing countries mean that best opportunities for Detach will lie outside of Australia. These markets are likely to have lower rates of productivity and have been slower to adopt advanced animal production technologies such as Spain, Portugal and Poland (in Europe). On the other hand, where Detach is

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shown to be superior to zinc oxide, which is a recommended supplement in Denmark, for example, then it could possibly be adopted for use with pigs lacking genetic resistance to E.coli.

### Some Risks To Note

A risk to note with Anatara is that the patent application for the new formulation of Detach is very much in its infancy, with its US patent application filed on August 25, 2014. What matters at this stage is whether the patent's claims will be upheld or whether they must be modified or reduced, as it proceeds through examination steps.

The company will conduct field trials in Europe and the US. There is the risk that these trials will not be completed on time which will cause delays in the registration process.

### Summary

Anatara is an uncomplicated company with a simple business objective: to bring to market a product to treat diarrhoea in piglets and in turn deliver revenue benefits to producers.

Opportunities exist with other production animals such as calves and chickens with a blue sky opportunity retained where Detach could be used to treat human digestive track disorders.

With one key field trial successfully completed and two more to come in Australia, the company will however reach a key milestone if and when it gains product approval from the Australian Pesticides and Veterinary Authority towards the end of 2016. This event will be a significant validation for the product.

The company's recent appointment of Paul Schober as CEO is an excellent move, given the experience he built up at Peptech Animal Health, and later Virbac, which acquired Peptech Animal Health in 2011.

Anatara Life Sciences is capitalised at \$25 million.

Bioshares recommendation: Speculative Buy Class B

# Milestones to Monitor

- -2015 Q2 initiate two more field trials
- 2015 complete two more product stability studies (from GMP manufacture)
- -2015 Q4 APVMA submission
- 2015 H2 complete EU data package
- 2015 Q4 APVMA approval
- 2016 H1 EU dossier submission
- 2017 H1 EU product approval
- -2017-mid US product approval
- 2017 H2 US product launch

**Bioshares** 

# **How Bioshares Rates Stocks**

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

### Group A

Stocks with existing positive cash flows or close to producing positive cash flows

**Buy** CMP is 20% < Fair Value **Accumulate** CMP is 10% < Fair Value

**Hold** Value = CMP

**Lighten** CMP is 10% > Fair Value **Sell** CMP is 20% > Fair Value

(CMP-Current Market Price)

### Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

# Speculative Buy - Class A

These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

### Speculative Buy - Class B

These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

### Speculative Buy - Class C

These stocks generally have one product in development and lack many external validation features.

Speculative Hold - Class A or B or C

Sell

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