Anatara Targets Australian Launch for Detach in 2017

Anatara Lifesciences (ANR: $1.365) is aiming to launch its first product onto the Australian market in 2017. Its product, Detach, is a plant-based anti-infective to be used in the production animal feed industry, firstly in piglets, to prevent and treat diarrhea.

The company expects to submit its regulatory dossier in Q3 this year to the Australian Pesticides and Veterinary Authority (APVA), with a decision expected nine to 12 months later. Anatara will sell the product in Australia via distributors, with the company currently at the term sheet stage in distributor selection.

In Australia it is a very concentrated market. There are 6.6 million piglets at any one time, with 15 producers making up 85% of the market. Anatara has an operational manufacturing facility, which can make material for 500,000 doses in just two hours.

The appeal of the Detach product is that it is derived from natural sources – pineapple stems – and thereby offers an alternative to antibiotics which have been overused in the production animal industry and have also contributed to antibiotic drug resistance.

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Another attraction of Detach is that resistance to the product is unlikely to develop. This is because Detach does not kill the bacteria. It works by inhibiting bacteria attachment to the lining of the gut and by blocking biological pathways that cause diarrhea. Detach also has anti-inflammatory properties blocking the TNF-alpha pathway

Zoetis License Option

In January this year, the world’s largest animal health company, Zoetis, signed an exclusive agreement with Anatara to evaluate Detach. Zoetis has paid an upfront fee (we estimate around $2.2 million according to the company’s 4C) and it will be required to pay an additional fee during the product evaluation period.

Zoetis is evaluating Detach across a number of food production animals. Anatara expects to learn in 2017 whether Zoetis will move to a full license for the product. The general terms for a license agreement have been agreed upon. The agreement excludes Australia and New Zealand, where Anatara maintains marketing rights.

At an investor briefing this week, the company said it believes the Detach product has high strategic value to Zoetis, which wants to be viewed as a ‘good global citizen’. If Zoetis decides not to proceed with the license agreement, then there are 12 other potential partners with which it could negotiate a global distribution deal.

Studies Ahead of Australian Regulatory Submission

Prior to filing for regulatory approval for the use of Detach in food production animals, Anatara is conducting two field studies. The first is looking at a multiple dose (two) of...
Detach in two day old piglets. The 450 piglets in the study have now been treated with Detach. The trial will also include a placebo arm. The trial is being conducted at a major commercial farm which has had problems with diarrhea in piglets. Results are expected in Q3 this year. Endpoints will be reduction in diarrhea compared to placebo and differences in weight gain. Previous trials have involved only the single dose of Detach. The aim of this trial is to allow the company to gain approval for a multiple dosing of the product.

The second trial Anatara is conducting is a safety study. In this trial, the doses are five times above what has been trialed before (with no safety issues reported). The treatment is also being evaluated for extended periods of up to three weeks.

Previous Study Results

Study ANR 14-001
In this study in 462 pre-weaned piglets, Detach reduced deaths by 47% (36 in the control, 19 in the Detach arm), with a 5.7% improvement in weight gain in the Detach treated group over placebo.

Study ANR 15-001
In this study in post weaned piglets at a farm with a history of E-coli infection in the piglets, Detach was investigated in 560 piglets against the control. This was a healthier population of animals, and as such, the effect of Detach was less pronounced. Only four piglets died in the control arm compared to no deaths in the Detach treated piglets. There was a 1.4% improvement in weight gain in the Detach treated pigs versus control. With respect to the incidence of diarrhea, the incidence was reduced by 41% in the Detach treated group (89 cases versus 152 in the control).

Study ANR 12-001
In a study conducted in Spain in weaned pigs, Detach achieved a 3.8% improvement in average daily weight gain over no treatment, with a 40% reduction in diarrhea. The number of sick piglets was reduced by 48% with 16 sick piglets in the Detach treated group (from 72 piglets) and 38 sick piglets in those with no treatment (from 72 piglets also).

Summary
The driver behind Anatara is the push to remove the use of antibiotics in food production animals which is contributing to antibiotic resistance in humans. Consumers are demanding antibiotic-free meats, and global corporations such as McDonalds and Subway, and local groups such as Coles supermarkets are responding to customers by banning antibiotic use in food production.

Results from the company’s own trials and from the Zoetis’ trials will be important in building evidence and support for the Detach proposition as a natural alternative to antibiotic use in food production animals. Of interest will also be the observed benefit in treating the animals twice (in the current trial) compared to a once-only treatment.

Forthcoming milestones include results from current field trials, submission of the product for regulatory approval in Australia, and a second payment from Zoetis under the option agreement.

Anatara is capitalised at $68 million. The company had $14.3 million in mid April and has sufficient cash flow for at least three years, excluding any additional license income.

Bioshares recommendation: Speculative Buy Class B

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 of commercialisation. In this 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.

**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**

**Speculative Sell**

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