

APVMA dossier filed, human-use therapeutic ideas taking shape

Anatara Lifesciences has filed an application to market Detach to pig producers in Australia. The field work on which this dossier is based can also feed into Zoetis' global commercialisation efforts, should its evaluation of Detach lead to the full worldwide licence we anticipate. Alongside the animal health work, Anatara is assessing multiple opportunities to exploit its proprietary science in human therapeutic contexts. We have maintained our 12-month price target at \$1.75 per share and maintain our BUY rating.

Key points

APVMA dossier filed. Anatara has completed its first major regulatory submission, applying for approval to register Detach for marketing in Australia. The Australian Pesticides and Veterinary Medicines Authority (APVMA) should take approximately 10-12 months to review Anatara's application, which presents data on Detach's safety, efficacy, chemistry and manufacturing controls. We are forecasting a successful outcome and an Australian product launch in Q4 of calendar 2017 (FY18). Anatara has retained full rights to commercialise Detach in Australia, where we estimate a market size of up to \$5m in annual sales. Detach is a non-antibiotic growth promoter that also treats and prevents scours (severe diarrhoea) in piglets.

Human-use projects gaining momentum. Anatara appears closer to identifying project(s) in human therapeutic contexts. The company has plenty of previous data in indications such as inflammatory bowel disease (IBD) and inflammatory bowel syndrome (IBS), where the immunosuppressive properties of Anatara's starting "bromelain" material feature. Importantly, the starting material is separable into a spectrum of preparations with differing compositional, functional and clinical characteristics. A range of OTC, "botanical drug" and new chemical entity opportunities are therefore available to Anatara as development and/or out-licensing opportunities.

Valuation. We value ANR stock at \$1.75 per share based on our risk-adjusted discounted cash flow framework. On an un-risked basis we can get to \$4.00 per share based only on Detach sales to pork producers in ANZ, Europe and the USA (depending on Zoetis' appetite). Other jurisdictions and human use options to be examined in future, as Anatara announces development progress.

Risks and catalysts

Catalysts: a) Zoetis evaluation success; b) regulatory changes restricting or antibiotic use in animal production; c) ANZ, US and EU commercialisation progress. **Risks:** a) technical and execution risks, principally in relation to field trials; b) pace of market adoption once launched; c) industry responses.

Earnings forecasts					
Year-end June (AUD)	FY15A	FY16A	FY17F	FY18F	FY19F
NPAT rep (\$m)	-1.8	-0.7	-2.5	0.9	4.3
NPAT norm (\$m)	-1.8	-0.7	-2.5	0.9	4.3
Consensus NPAT (\$m)			-2.4	0.9	
EPS norm (cps)	-6.7	-1.3	-4.4	1.6	7.8
EPS growth (%)	96.5	80.4	-239.1	135.3	393.3
P/E norm (x)	-17.4	-88.8	-26.2	74.1	15.0
EV/EBITDA (x)	-22.1	-40.3	-17.1	50.5	10.1
FCF yield (%)	4.9	-0.7	-9.0	0.8	9.3
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Franking (%)	0	0	0	0	0

Source: Company data, Wilsons estimates, S&P Capital IQ

Wilsons Research

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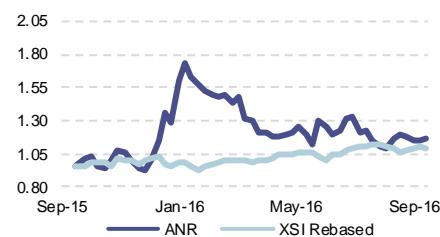
Recommendation	BUY
12-mth target price (AUD)	\$1.75
Share price @ 07-Oct-16 (AUD)	\$1.17
Forecast 12-mth capital return	49.9%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	49.9%

Market cap	\$43m
Enterprise value	\$43m
Shares on issue	37m
Sold short	
ASX 300 weight	n/a
Median turnover/day	\$0.0m

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12-mth price performance (\$)



	1-mth	6-mth	12-mth
Abs return (%)	-2.9	-10.4	22.0
Rel return (%)	-3.7	-20.5	7.9

Key changes				
		25-Jul	After	Var %
NPAT:	FY17F	-2.4	-2.5	N/A
norm	FY18F	0.9	0.9	-7.2%
(\$m)	FY19F	4.3	4.3	-1.6%
EPS:	FY17F	-4.3	-4.4	N/A
norm	FY18F	1.7	1.6	-7.2%
(cps)	FY19F	7.9	7.8	-1.6%
DPS:	FY17F	0.0	0.0	0.0%
(cps)	FY18F	0.0	0.0	0.0%
	FY19F	0.0	0.0	0.0%
Price target:		1.75	1.75	-0.4%
Rating:		BUY	BUY	

Anatara Lifesciences

Reiterating the investment thesis on Anatara LifeSciences

Anatara is moving closer to commercialising its first product, Detach, which is a non-antibiotic growth promoter for the production of livestock. Overuse of antibiotics in the human food chain is a probable contributor to the development of antibiotic-resistant human pathogens. This is a very serious issue and it has grown in public significance over the past few years. We have seen sustained pressure to remove or at least minimise antibiotics used in livestock production, particularly by developed countries, where those efforts have been supported by governments, regulators, food producers and the broader industry (including pharmaceutical manufacturers).

The principal difficulty this movement faces is the availability of non-antibiotic alternatives – products that can do the job of modulating the gut microflora of animals in a positive way, but without impeding growth rates and threatening the economics of large-scale meat production. There are several aspects of Anatara’s product concept we like, which include:

- **Unlikely to develop resistance problems.** Detach does not place any direct “selection pressure” on pathogens because its mechanism of action does not rely on bacterial or viral killing. Anatara has shown that Detach can support healthy gut microflora in pigs and has elucidated the mechanisms by which that is achieved.
- **Growth rates intact.** The key goal of the pork industry is to wean more pigs per litter and maintain their health (assessed by weight gain). Detach has been seen to achieve that in field trials. Importantly, Detach also protects piglets against “scour” (severe diarrhoea, which can be life threatening) in both the neonatal and post-weaning stages of development.
- **Over the counter (OTC) produce presentation.** Anatara has structured its development program to make Detach available to pig producers without a veterinarian’s prescription. Pending APVMA and other regulatory approvals.

Direct commercialisation in ANZ with the rest of world covered by a potential out-licence to Zoetis. Zoetis is a multinational animal health company and potential worldwide licensor of Detach. In April, Anatara began shipping Detach product to Zoetis for its evaluation in independent multi-species field trials, under an exclusive evaluation and licence option agreement. Anatara has granted Zoetis an option to license Detach for worldwide development and commercialisation. Anatara has reserved the right to market Detach independently in Australia and New Zealand. In previous research we have estimated end-market sales of US\$50-75m for Detach based on pigs only in ANZ, the USA and Western Europe.

Developing momentum in Anatara’s “human-use” projects. Specific projects may solidify in the short term. Alongside its animal health programs, Anatara has been doing significant work identifying and evaluating projects for human applications. The precursor material from which Detach is ultimately derived, bromelain, is itself a crude natural product extract, containing various closely related proteinases among other compounds¹. Anatara thus has a range of options, namely: a) crude “fractions” of the material, developable as OTC products; b) more refined, multi-component preparations developable as ‘botanical drugs²’; and c) highly purified molecular entities, developable as drugs in the more traditional sense. The thrust of Anatara’s human-use data, to date, has been towards indications such as inflammatory bowel disease (IBD) and inflammatory bowel syndrome (IBS). We think Anatara is likely to focus its initial product and business development activities in this direction.

Anatara’s non-antibiotic growth promoter for livestock production should gain in value as the global demand for antibiotic-free meat production increases.

Anatara has found a potential global licensor in Zoetis, which is evaluating Detach in its own field trials.

Management’s side focus on human therapeutic applications may accelerate over the next year.

We assess reasonable prospects of further product development deals over the course of 2017.

¹ Pavan, R. *et al.* (2012) *Properties and therapeutic applications of bromelain: a review* Biotech. Res. Intl. 2012: 976203.

² A botanical drug product consists of complex mixtures and often lacks a distinct active ingredient. The US FDA has published guidance to facilitate the development of new therapies from botanical sources. FDA approval must be based on published data establishing safety and effectiveness, including that from well-controlled clinical studies.

Operational update

APVMA dossier filed. Anatara has completed its first major regulatory submission, applying for approval to register Detach for marketing in Australia. The Australian Pesticides and Veterinary Medicines Authority (APVMA) should take approximately 10-12 months to review Anatara's application, which collates data on Detach's safety, efficacy, chemistry and manufacturing controls. We are forecasting a successful outcome and Australian product launch in Q4 of calendar 2017 (FY18).

In previous research we have estimated an annual sales opportunity of ~A\$2-3m for Detach in Australia, assuming ~60% market penetration. Our somewhat bullish forecast for high penetration is based on the assumption that Detach will launch in Australia with a broad therapeutic label and be available as an over the counter product. Our understanding of the data is that it supports broad spectrum usage (not restricted to preventing any specific pathogenic agent) and that Detach should be equally available to all piglets at various stages of their development. Our forecasting at this stage assumes just one Detach dose per animal, which may prove to be conservative. Anatara's field trial campaign has demonstrated good results at both the "sucker" and "weaner" stages.

Successful Target Animal Safety (TAS) study in parallel with Zoetis evaluation. Importantly, Anatara's TAS study returned strong safety results for Detach. Conducted under VICH guidelines, these data are mutually acceptable for all major governmental regulatory bodies including Australia's APVMA, the US Food and Drug Administration, the European Medicines Agency and the Japanese Veterinary Products Association (JVPA). Similar recognition is also available in New Zealand, Canada and South Africa.

Zoetis is still evaluating Detach in multi-species field trials, under an exclusive evaluation and licence option agreement with Anatara. While we cannot be certain about the timing of Zoetis' decision point, which has not been disclosed, the short nature of such field trials leads us to expect an early 2017 decision. Zoetis exercising this option would be a major milestone for Anatara, ensuring rapid access to the major markets, possibly in several species. If Zoetis does not proceed with its option, then the TAS results and other data put Anatara in a position to commence its own US and/or EU clinical trials; optimally with a new prospective partner(s).

Valuation

We value ANR stock at \$1.75 per share based on our risk-adjusted discounted cash flow framework. Key assumptions in our valuation include:

- **Earnings forecasts.** We have prepared Detach sales forecasts to FY30 based on product launches in Australia (FY18), Europe (FY19) and the USA (FY19). We have modelled an average selling price (ASP) of A\$0.60 per dose in Australia. In overseas markets, we have assumed that Anatara receives a transfer price of 50% of the end-market ASPs.
- **Market size.** We have modelled a terminal penetration of ~60% for the Australian market; 35% for the USA and 15% for the EU. At this stage our valuation only considers Detach sales for pig production, where we estimate potential for ~\$US50-75m sales.
- **Upside to be examined in future.** At this stage we have not included any revenues (or valuation) relating to the development of other commercial opportunities which include:
 - Markets outside ANZ, Europe and the USA.
 - Food production species other than pigs.
 - Human use OTC, botanical drug or prescription pharmaceuticals.
- **Un-risked valuation attractive, before considering human use optionality.** An un-risked valuation based on just the pork markets for Detach in ANZ, Europe and the USA approaches \$4.00 per share (risk discount removed, discount rate set to 10% rather than the 14% we have in our current valuation). Valuation view is contingent on Zoetis proceeding with Detach on terms similar to that which we have modelled.



Anatara Lifesciences (ANR)

Business description

Anatara Lifesciences Limited (ANR) is an emerging animal health company with plans to enter the market with a product for preventing diarrhoea in piglets. If regulatory changes in the pork industry press towards the withdrawal of antibiotics from pig production, then the demand for alternative diarrhoea control and growth promotion strategies should increase. This Australian company is developing a product called Detach, which is a natural product extracted from pineapple stems. Anatara plans to register a new formulation of Detach for the Australian market in 2017, before exploring international commercialisation opportunities. The company is also developing related products for human use.

Investment thesis

Our research suggests that a non-antibiotic product for diarrhoea management is of interest to the pork industry. We Detach will find support in the Australian market if Anatara's field trials are successful and the product is approved by the APVMA. Accelerated take-up in the Australian market during 2017/8 could be a leading indicator of robust demand elsewhere. The ability to explore human use applications in disease areas such as inflammatory bowel syndrome and diarrhoea could dramatically lift our valuation.

Revenue drivers

- Product approval and market penetration
- Milestone and royalty payments from partners
- Access to new markets and applications

Margin drivers

- Modest R&D expense
- Virtual model based primarily on product licensing or partnering

Key issues/catalysts

- Successful completion of field trials with favourable results on both clinical efficacy and production characteristics
- Regulatory approvals
- Regulatory changes discouraging or banning the use of antibiotics in animal production
- Corporate arrangements for US and European product
- Sales progress
- Non-dilutive funding inflows

Risk to view

- Lack of demand for product, once approved and launched
- Adverse regulatory settings (approvals, industry settings)
- Access to equity capital may be required

Balance sheet

- Anatara reported ~\$13.5m cash and investments as at the end of Jun-16

Board

- Mel Bridges (Executive Chairman)
- Iain Ross (Non-Executive Director)
- Tracie Ramsdale (Non-Executive Director)
- Jay Hetzel (Non-Executive Director)
- Paul Grujic (Non-Executive Director)
- Stephen Denaro (Company Secretary)

Management

- Mel Bridges (CEO)
- Tracey Mynott (CSO)
- Mike West (COO)
- Damian Wilson (Head Global Business Development)

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