ANATARA LIFESCIENCES (ANR)

Wilson HTM EQUITIES RESEARCH

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Company update

Nearing APVMA submission

Anatara is approaching a telling milestone in the submission its product dossier to the APVMA, which will seek approval to market Detach in the Australian market. The totality of Anatara's field trial data, summarised here, could potentially support a broad label as an over the counter product to control scour in piglets. APVMA approval can also lead to uncomplicated registrations in other countries, notably Asia. Partnering transactions could be a feature for investors in 2016. We maintain a SPECULATIVE BUY rating and $1.18 price target. We flag valuation upside to come over the next 12 months via approvals, partnering success and first domestic sales.

Key points

Progress update on APVMA submission – we have collated and analysed the salient pivotal studies for Anatara's Detach, which may form a basis for approval by the Australian Pesticides and Veterinary Medicine Authority (APVMA). Anatara is in a good position to seek a broad therapeutic label for over-the-counter marketing, which is a smart move in simplifying the Detach product specification and encouraging early adoption by pork producers.

Regulatory achievement a potential catalyst for partnering – APVMA approval can also grant access to markets in Asia and Europe where the commercialisation pathway will likely feature partners of some type (pharmaceutical and/or feed additive manufacturers, specialty distributors). We understand that the level of business development interest is high. Transactions can provide Anatara with independent technology/product validation, access to new markets and short term cash flow.

Valuation – the complete de-risking of the US, EU and Australian components of our model would increase our valuation from $1.18 to as high as $2.72 per share. Transactions that firm up the commercial pathway to those markets would increase valuation along a sliding scale. The value of new territories are a function of commercially farmed pig populations. Partnering arrangements in Vietnam or Philippines could be worth an additional 15 cps each, on that empirical basis, as simple examples.

Risks and catalysts

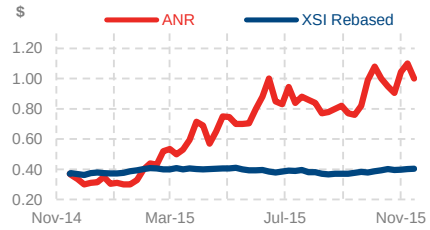
Catalysts – a) technical progress on field trials; b) regulatory changes restricting or banning antibiotics from animal protein production; c) USA and EU commercialisation progress. **Risks** – a) technical and execution risks, principally in relation to field trials; b) pace of market adoption once launched; c) industry response risks.

12-mth target price (AUD)	**$1.18**
Share price @ 01-Dec-15 (AUD)	$1.00
Forecast 12-mth capital return	18.0%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**18.0%**
Market cap	$37m
Enterprise value	$35m
Shares on issue	37m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.0m

Shane Storey
shane.storey@wilsonhtm.com.au
Tel. +61 7 3212 1351

Joseph Michael, CFA
joseph.michael@wilsonhtm.com.au
Tel. 02 8247 3101

12-mth share price performance



	1-mth	6-mth	12-mth
Abs return (%)	4.2	44.9	170.3
Rel return (%)	2.0	44.8	160.9

Year-end June (AUD)	FY14A	FY15A	FY16F	FY17F	FY18F
NPAT rep ($m)	-0.9	-1.8	-2.0	-1.0	2.0
NPAT norm ($m)	-0.9	-1.8	-2.0	-1.0	2.0
Consensus NPAT ($m)			-2.0	-1.0	2.0
EPS norm (cps)	-189.4	-6.7	-3.7	-1.9	3.6
EPS growth (%)	98.5	96.5	44.5	50.1	292.3
P/E norm (x)	-0.5	-15.0	-26.9	-54.0	28.1
EV/EBITDA (x)	-40.6	-18.1	-16.7	-32.2	18.4
FCF yield (%)	-1.7	5.7	-7.3	-4.4	3.9
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, WHTM estimates, S&P Capital IQ

KEY CHANGES		17-Sep	After	Var %
NPAT:	**FY16F**	-2.0	-2.0	0.0%
norm	**FY17F**	-1.0	-1.0	0.0%
($m)	**FY18F**	2.0	2.0	0.0%
EPS:	**FY16F**	-3.7	-3.7	0.0%
norm	**FY17F**	-1.9	-1.9	0.0%
(cps)	**FY18F**	3.6	3.6	0.0%
DPS:	**FY16F**	0.0	0.0	0.0%
(cps)	**FY17F**	0.0	0.0	0.0%
	FY18F	0.0	0.0	0.0%
Price target:		1.18	1.18	0.0%
Rating:		**BUY**	**BUY**	

PRICE TARGET

	Valuation	PT ($/shr)
Discount rate (%)	17	
PV FFCFs ($m)	27	
PV terminal ($m)	9	
Net cash ($m)	7.4	
Valuation ($m)	43	

TOTAL ($/share)	**1.18**

INTERIMS ($m)

Half-year (AUD)	Dec 14	Jun 15	Dec 15	Jun 16
	1HA	2HA	1HE	2HE
Sales revenue	0.0	0.0	0.1	0.5
EBITDA	-0.8	-1.2	-1.4	-0.7
EBIT	-0.8	-1.2	-1.4	-0.7
Net profit	**-0.8**	**-1.0**	**-1.4**	**-0.6**
Norm EPS	**-3.1**	**-3.6**	**-2.6**	**-1.1**
EBIT/sales (%)			-	-135.3
Dividend (c)	0.0	0.0	0.0	0.0
Franking (%)	0.0	0.0	0.0	0.0

FINANCIAL STABILITY

Year-end June (AUD)	FY15A	FY16F	FY17F
Net debt	-1.5	-7.4	-5.8
Net debt/equity (%)	<0	<0	<0
Net debt/EV (%)	**<0**	**<0**	**<0**
Current ratio (x)	38.3	53.3	19.9
Interest cover (x)	13.7	43.0	16.2
Adj cash int cover (x)	**<0**	**55.7**	**24.9**
Debt/cash flow (x)	0.0	0.0	0.0
Net debt (cash)/share ($)	<0	<0	<0
NTA/share ($)	0.2	0.2	0.2
Book value/share ($)	0.2	0.2	0.2
Payout ratio (%)	0	0	0
Adj payout ratio (%)	0	0	0

EPS RECONCILIATION ($m)

	FY15A		FY16F	
	Rep	Norm	Rep	Norm
Sales revenue	0	0	1	1
EBIT	-1.9	-1.9	-2.1	-2.1
Net profit	**-1.8**	**-1.8**	**-2.0**	**-2.0**
Notional earn	0.0	0.0	0.0	0.0
Pref/conv div	0.0	0.0	0.0	0.0
Profit for EPS	**-1.8**	**-1.8**	**-2.0**	**-2.0**
Diluted shrs (m)	27	27	55	55
Diluted EPS (c)	**-6.7**	**-6.7**	**-3.7**	**-3.7**

RETURNS

	FY15A	FY16F	FY17F	FY18F
ROE (%)	-56.9	-23.5	-8.9	16.5
ROIC (%)	-72.1	-34.3	-15.6	24.5
Incremental ROE	-32.4	-4.6	37.6	633.4
Incremental ROIC	-37.7	-4.7	119.2	368.1

KEY ASSUMPTIONS

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Revenue growth (%)		-100.0			255.0	175.2	108.1	52.1
EBIT growth (%)	132.1	363.6	124.1	8.4	-48.1	-275.3	233.3	84.9
NPAT growth (%)	133.4	365.4	108.1	14.1	-50.1	-292.3	228.2	85.0
EPS growth (%)	**122.0**	**-98.5**	**-96.5**	**-44.5**	**-50.1**	**-292.3**	**228.2**	**85.0**
EBIT/sales (%)	-414.1			-353.2	-51.6	32.9	52.7	64.0
Tax rate (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ROA (%)	**-257.7**	**-81.9**	**-34.4**	**-17.2**	**-5.3**	**8.0**	**22.2**	**33.3**
ROE (%)	**66.1**	**-104.4**	**-32.8**	**-17.1**	**-5.6**	**9.4**	**25.5**	**38.1**

PROFIT AND LOSS ($m)

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Sales revenue	0.0	0.0	0.0	0.6	2.1	5.8	12.1	18.4
EBITDA	-0.2	-0.9	-1.9	-2.1	-1.1	1.9	6.4	11.8
Depn & amort	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	**-0.2**	**-0.9**	**-1.9**	**-2.1**	**-1.1**	**1.9**	**6.4**	**11.8**
Net interest expense	0.0	0.0	-0.1	0.0	-0.1	-0.1	-0.1	-0.2
Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minorities/pref divs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Equity accounted NPAT	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (pre-sig items)	**-0.2**	**-0.9**	**-1.8**	**-2.0**	**-1.0**	**2.0**	**6.4**	**11.9**
Abns/exts/signif	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Reported net profit	**-0.2**	**-0.9**	**-1.8**	**-2.0**	**-1.0**	**2.0**	**6.4**	**11.9**

CASH FLOW ($m)

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
EBITDA	-0.2	-0.9	-1.9	-2.1	-1.1	1.9	6.4	11.8
Interest & tax	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.2
Working cap/other	0.0	0.2	0.0	-0.6	-0.6	-0.6	-0.3	-0.3
Operating cash flow	**-0.2**	**-0.6**	**-1.9**	**-2.7**	**-1.6**	**1.4**	**6.1**	**11.6**
Maintenance capex	0.0	0.0	4.0	0.0	0.0	0.0	0.0	0.0
Free cash flow	**-0.2**	**-0.6**	**2.1**	**-2.7**	**-1.6**	**1.4**	**6.1**	**11.6**
Dividends paid	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Growth capex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Invest/disposals	0.0	0.0	-4.0	0.0	0.0	0.0	0.0	0.0
Other inv flows	0.0	0.0	-4.6	0.0	0.0	0.0	0.0	0.0
Cash flow pre-financing	**-0.2**	**-0.6**	**-6.6**	**-2.7**	**-1.6**	**1.4**	**6.1**	**11.6**
Funded by equity	0.0	1.8	7.0	8.6	0.0	0.0	0.0	0.0
Funded by debt	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Funded by cash	0.0	-1.1	-0.4	-5.9	1.6	-1.4	-6.1	-11.6

BALANCE SHEET SUMMARY ($m)

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Cash	0.1	1.1	1.5	7.4	5.8	7.2	13.3	24.9
Current receivables	0.0	0.0	0.1	0.5	1.0	1.3	1.3	1.3
Current inventories	0.0	0.0	0.0	0.3	0.7	2.0	3.4	5.0
Net PPE	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	4.1	4.1	4.1	4.1	4.1
Intangibles/capitalised	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	4.1	0.0	0.0	0.0	0.0	0.0
Total assets	**0.1**	**1.1**	**5.6**	**12.2**	**11.5**	**14.5**	**22.1**	**35.3**
Current payables	0.0	0.2	0.1	0.2	0.6	1.6	2.8	4.0
Total debt	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total liabilities	**0.4**	**0.2**	**0.1**	**0.2**	**0.6**	**1.6**	**2.8**	**4.0**
Minorities/convertibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Shareholder equity	**-0.3**	**0.8**	**5.5**	**12.0**	**10.9**	**12.9**	**19.4**	**31.3**
Total funds employed	**0.1**	**0.8**	**5.5**	**12.0**	**10.9**	**12.9**	**19.4**	**31.3**

Anatara Lifesciences (ANR)

Sufficient data to file for APVMA approval

From the field trial data perspective, Anatara seems well prepared to file its dossier with the Australian Pesticides and Veterinary Medicine Authority (APVMA) to re-register Detach for marketing in Australia. We have reviewed the results of Anatara's work in previous research but collate and summarise key studies below. Anatara's Detach dossier will also include previous results and other work as supportive data. In our view, the totality of the Detach data is sufficient to win approval and with a broader and more commercially useful label claim than the product had when it was first approved and sold to Australian piggeries in the 1990s.

Targeting a broad therapeutic label for OTC marketing – firstly, and most importantly, the Detach label should not need to reference any specific infectious organism(s), thus avoiding any requirement for a definitive diagnosis and ensuring Detach's over-the-counter (OTC) product status[1].

Ideally, there should be no reason for the label to distinguish between 'sucker' and 'weaner' animals because efficacy outcomes have been established in both age groups, with statistical significance. The 14-001 trial did not reduce the incidence of scour, because disease was highly prevalent on that farm during the study, but it did lessen the severity of scour and lowered scour-related mortality. The key goal of the industry is to wean more pigs per litter and maintain their health (also assessed by weight gains) and Detach has been seen to achieve that. Despite the presence of scour, Detach-treated pigs continued to put on weight.

Table 1: Summary of Detach re-registration trial outcomes

Trial	Location	Category	Trial details	Scour reductions v control frequency (severity)	Mortality reduction v control	Weight gain improvement v control [b]	Reduction in antibiotic use v control
Chandler & Mynott (1988)[a]	VIC, AU	Weaners	n = 60 in 2 treatment groups (28 Detach, 32 Control)	**60% (86%) p < 0.05 for both observations**	100% non-significant	**43% p < 0.05**	none used
ANR12-001	Spain	Weaners	n = 144 in 2 treatment groups (Detach, Control)	**40% (61%) p < 0.05 for both observations**	0%	**28% p < 0.05**	**54% p < 0.05**
ANR15-002	Queensland, AU	Weaners	n = 560 in 2 treatment groups (Detach, Control)	**41% (45%) p < 0.02 for both observations**	100% non-significant	1.7% non significant	none used
Supportive study 12		Suckers	n = 73 in 2 treatment groups (39 Detach, 34 Control)	NR	**85% p < 0.02**	NR	none used
ANR14-001	Victoria, AU	Suckers	n = 462 in 2 treatment groups (232 Detach, 229 Control)	0% (26%) [c] non-significant	**47% p < 0.02**	5.3% non-significant	none used

a - Chandler, D. S. and Mynott, T. L. (1988) *Bromelain protects piglets from diarrhoea causedby oral challenge with K88 positiveenterotoxigenic Escherichia coli* Gut 43:196 - 202.
b - Increase in Average Daily Weight Gain (g/day) (0 to 2 weeks post weaning) (%)
c - Detach did not prevent scour, but reduced the severity of scour and death. Increases in weight gain interpreted as a non-subjective measure of health.

Source: Anatara, WHTM Research

Dossier filing early next year – we understand that Anatara is waiting for some final product material to come off stability testing, so that the data can be included in a Q1-16 filing with APVMA. Significant technical capabilities have been called in to assess and shape the dossier pre-submission, including individuals involved in the development of two maternal vaccines against scour in Neovac[2] and Scourgard[3]. Review times at APVMA are typically 9-12 months, which means Anatara could be in position to re-launch Detach in Australia by this time next year.

[1] The original Detach label was limited to a strain of enterotoxigenic *Escherichia coli*. In practice most farms will have a number of different causative organisms on site, with scouring potential. Anatara has good data on the range of bacteria and viruses present during the Detach field studies, thus helping their cause in pursuing therapeutic claims with APVMA, FDA and other regulatory authorities.
[2] Neovac is a vaccine product for the control of neonatal scours caused by enterotoxigenic *Escherichia coli*. A 2mL intramuscular injection at the base of and immediately behind the ear is administered to the sow (mother), with newborn piglets obtaining the benefit by ingesting adequate quantities of colostrum.
[3] Scourgard is another maternal vaccine designed to protect calves from scour.

Partnering catalyst(s) flagged for Q1 2016

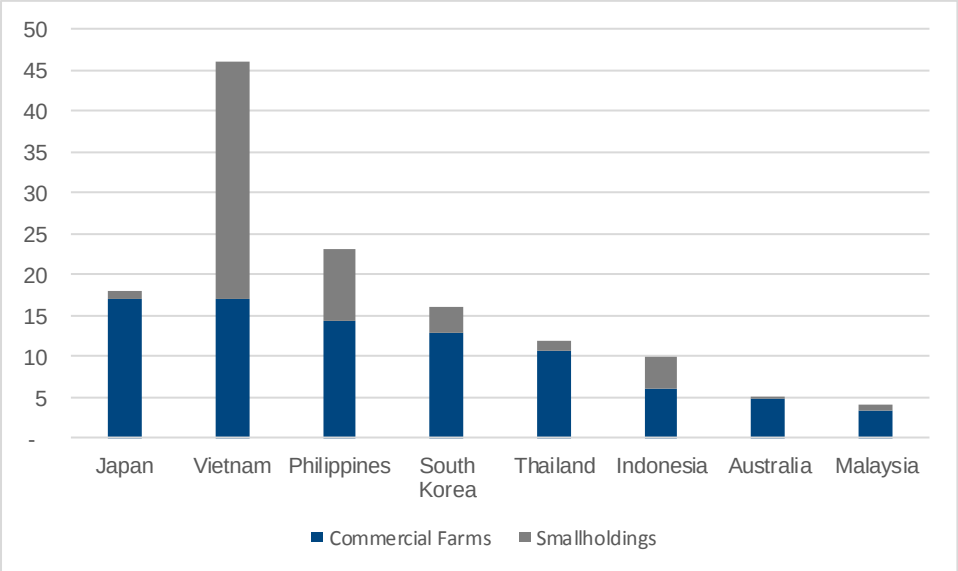
We see Anatara's APVMA filing as a potential catalyst for partnering the Detach product in jurisdictions outside Australia. Partnerships could take various forms and involve a range of different industry players including multinational animal health pharmaceutical companies (eg MSD Animal Health, Virbac, Merial, Ceva, Zoetis, Boehringer Ingelheim), feed additive companies or regional product distributors.

The APVMA has formal mutual recognition agreements (MRAs) with the European Community (EC) and the European Free Trade Association (EFTA). The APVMA also issues Certificates of Free Sale, which are recognised by most Asian countries, enabling straightforward registration without additional trials or data submissions. Japan and China are notable exceptions where further trials are necessary before Detach could be considered for marketing approval.

The benefits of partnering are:

- **Independent validation** – partnering transaction(s) will provide both technical and commercial validation for the Detach product and its target market for scour prevention/treatment.
- **Path to ex-AU markets** – we would expect partner firms to be the primary sponsor and marketer of Detach outside Australia. On that basis the majority of any bridging/new clinical trials expense might be assumed by the partner, freeing Anatara's capital for other development projects including alternative (in feed) dose forms and R&D towards human applications.
- **Non-dilutive funding** – partners may pay Anatara additional upfront fees and/or milestones for exclusive access to the product, helping to underwrite a pathway towards independent breakeven and profitability.
- **Bring new markets into forecasts and valuation** – transactions in South America or Asia would be immediately additive to valuation, with Asia being of particular interest given the proximity to Australia and growing levels of industry intensification and integration. The better Asian markets are those with larger pig populations in commercial production systems such as Philippines, South Korea and Vietnam.

Figure 1: Approximate national pig production statistics for select Australasian countries. Data: millions of pigs produced per annum.



Source: Food Outlook 2012, Food and Agriculture Organisation of the United Nations, WHTM Research

Valuation implications

Our current valuation of $1.18 per share is based on a risked discounted cash flow (DCF) recognising future commercialisation in three jurisdictions only: US, Europe and Australia. The relative contributions by territory are approximately: Europe 54% (a more conducive market and nearer term, from a regulatory perspective); USA 35% (larger in dollar terms but further away and higher risk); Australia 11% (modest market but near term and at higher gross margin).

Earnings forecasts – sales forecasts to FY30 are based on product launches in Australia (FY17), Europe (FY18) and USA (FY19). We have modelled an average selling price (ASP) of A$0.60 per dose in Australia, with no price inflation (net of distributor/partner margin). We understand that the previous version of the product sold for ~A$0.80 per dose in the late Australian market in the late 1990s. In overseas markets, we have assumed that Anatara receives a transfer price of 50% of the end-market ASPs.

DCF inputs - we have assigned a discount rate of 17%, which we see as appropriate given the high-risk nature of an investment in a development stage company facing both clinical and product introduction risks. We have assigned a terminal growth rate of 3% to reflect long term demand for animal protein.

Market size – we have modelled a terminal penetration of ~60% for the Australian market; 35% for USA and 25% for the EU. Collectively, these markets could support c.A$35-40m revenue for Anatara. Extrapolating to 20% of the global piglet population (c.1.6 billion) would imply c.A$120m in revenue opportunity to Anatara. The product concept is potentially useful in other species including man.

Valuation upside – the complete de-risking of the US, EU and Australian components of our model would increase our valuation from $1.18 to $2.72 per share. Any transaction that firms up the commercial pathway to sales in those markets would increase valuation on a sliding scale. The valuation of new territories would likely be a function of pig populations using USA, EU and Australia as benchmarks. Commercial arrangements in Vietnam and Philippines could be worth an additional 15 cps each, on that empirical basis.

Anatara Lifesciences Limited (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. An earlier formulation of this product was launched and marketed by Ciba-Geigy (now Novartis) and used to prevent diarrhoea in pig herds back in the 1990s. Anatara plans to register a new formulation of Detach for the Australian market in mid-2016, before exploring international commercialisation opportunities.

INVESTMENT THESIS

Our research suggests that a non-antibiotic product for diarrhoea management is of interest to the pork industry. We think the product will find support in the Australian market if Anatara's field trials are successful and the product is approved by the APVMA. We viewed the recent IPO pricing as fair, seeing potential upside in two dimensions. First, accelerated take-up in the Australian market during 2016-17 could be a leading indicator of robust demand elsewhere. Secondly, the capacity to attract non-dilutive funding would dramatically lift our valuation.

REVENUE DRIVERS

- Market penetration
- Pricing
- Access to new markets and applications

BALANCE SHEET

- Anatara reported $5.5m cash at the end of Jun-15. Following the recent capital raising we estimate pro forma cash at ~$14m

MARGIN DRIVERS

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

BOARD

- Mel Bridges (Non-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)

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

MANAGEMENT

- Paul Schober (CEO)
- Tracey Mynott (CSO)
- Damian Wilson (Head Global Business Development)
- Alan Dowling (Group Accountant)
- Hayley van der Meer (Commercial Manager)

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

CONTACT DETAILS

Address: 433 Logan Rd, Stones Corner, Brisbane QLD 4120

Website: www.anataralifesciences.com

Disclosures and disclaimers

Recommendation structure and other definitions

Definitions at http://www.wilsonhtm.com.au/Disclosures

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Disclosure of interest. Anatara Lifesciences Limited

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Wilson HTM national offices

BRISBANE
Ph: 07 3212 1333

MELBOURNE
Ph: 03 9640 3888

SYDNEY
Ph: 02 8247 6600

DALBY
Ph: 07 4660 8000

GOLD COAST
Ph: 07 5509 5500

HERVEY BAY
Ph: 07 4197 1600

SUNSHINE COAST
Ph: 07 5451 4600

Website: www.wilsonhtm.com.au