



## ASX Release

### Investor Update – Milestone Progress

#### Highlights

- **Completed GMP manufacture of commercial scale of Detach™ with two further batches to be manufactured in April 2015**
- **Regulatory pathway confirmed in Australia, Europe & USA**
- **First field trial successful**
- **Further field trial sites now confirmed & ready for Q2 2015**
- **Data ready for submission to APVMA in Q4 2015**
- **Partnering discussions commenced with top tier Animal Health companies**
- **Major strategic collaboration with the Pork Cooperative Research Centre (CRC) on track for Q2 2015**
- **Strengthened executive team & board**
- **Strong cash position**

BRISBANE, 25 March 2015: Gastrointestinal therapeutic company, Anatara Lifesciences (ASX: ANR) is pleased to release a copy of its latest investor update (follows this cover release). The senior executive team and chairman will be presenting to analysts, brokers and their clients and institutional investors this week in Brisbane, Sydney and Melbourne.

Anatara remains committed to delivering on its key milestones in the commercialization of its lead product as demonstrated by the highlights at the top of this release. A copy of the presentation is also available on the company's website ([www.anataralifesciences.com](http://www.anataralifesciences.com)).

Anatara Chairman, Dr Mel Bridges said “We know from recent field trials in other countries that Detach™ has been proven to be safe and efficacious. The company remains on track to launching Detach™ in 2016.”

The Company's lead product, Detach™, is a non-antibiotic therapy to treat and prevent diarrhoea. Anatara is focused on commercializing Detach™, initially for use in pigs, ahead of expanding its use to other livestock, and then developing it for use in humans.

Anatara looks forward to updating shareholders as progress is made to launch Detach™ into the market.

**ENDS**



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**About Anatara Lifesciences**

Anatara Lifesciences (ASX: ANR) is developing therapeutics for gastrointestinal diseases in production animals and humans. Its lead product Detach™ is a natural, plant based product that will help address global concern about the overuse of antibiotics in production animals that is contributing to the rise of so-called “super bugs” that make infectious diseases harder to treat. The Anatara team has a strong track record in biological science as well as building and growing international biotech companies. For more information visit [www.anataralifesciences.com](http://www.anataralifesciences.com).



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Oral solutions for  
gastrointestinal disease

Detach™ – prevention and  
treatment of diarrhoea



25 March 2015

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# Key Financial Details

ASX Code	ANR
Share Price	\$0.50
Market Cap	\$18.88 million
Ordinary Shares <sup>1,2</sup>	37,750,000
Raised at IPO (16 October 2014)	\$7 million
Cash Balance (as at 25 March 2015)	\$6.1 million

1. 13,036,095 shares (34.5% of shares on issue post-IPO) held by directors, other related parties, and persons who have received shares from these parties are subject to escrow for 24 months from the date of Anataras listing on the ASX. A further 8,190,000 shares (21.7% of shares on issue post-IPO) held by other seed investors are subject to escrow until 5 May 2015

2. The Company has implemented an ESOP with capacity to issue up to 5% of the issued share capital as options. As at the date of this presentation, no options or other securities convertible to shares are on issue.





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## Antimicrobial resistance is a serious health problem

Many antibiotics are no longer effective, so bacterial infections are more difficult to treat

“23,000 people die every year from antibiotic-resistant infections in US”

The US Center for Disease Control

“Combat drug resistance: no action today means no cure tomorrow”

World Health Organisation



# Need to combat antimicrobial resistance

- Antimicrobial resistance is a worldwide threat to public health – WHO, CDC
- The spread of bacteria that are resistant to antibiotics -“Super Bugs”- is driven by antibiotic overuse — in man and animals
- Authorities around the world are now moving to ban growth promoting antibiotics and restrict prophylactic antibiotics in animal production
- Consumers want assurance their meat is safe – antibiotic free





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## Detach™

- Natural, non-antibiotic solution that prevents and treats diarrhoea
- Meets the need to reduce antibiotics in animal production
- Based on a proven product, that improves animal health and farming economics

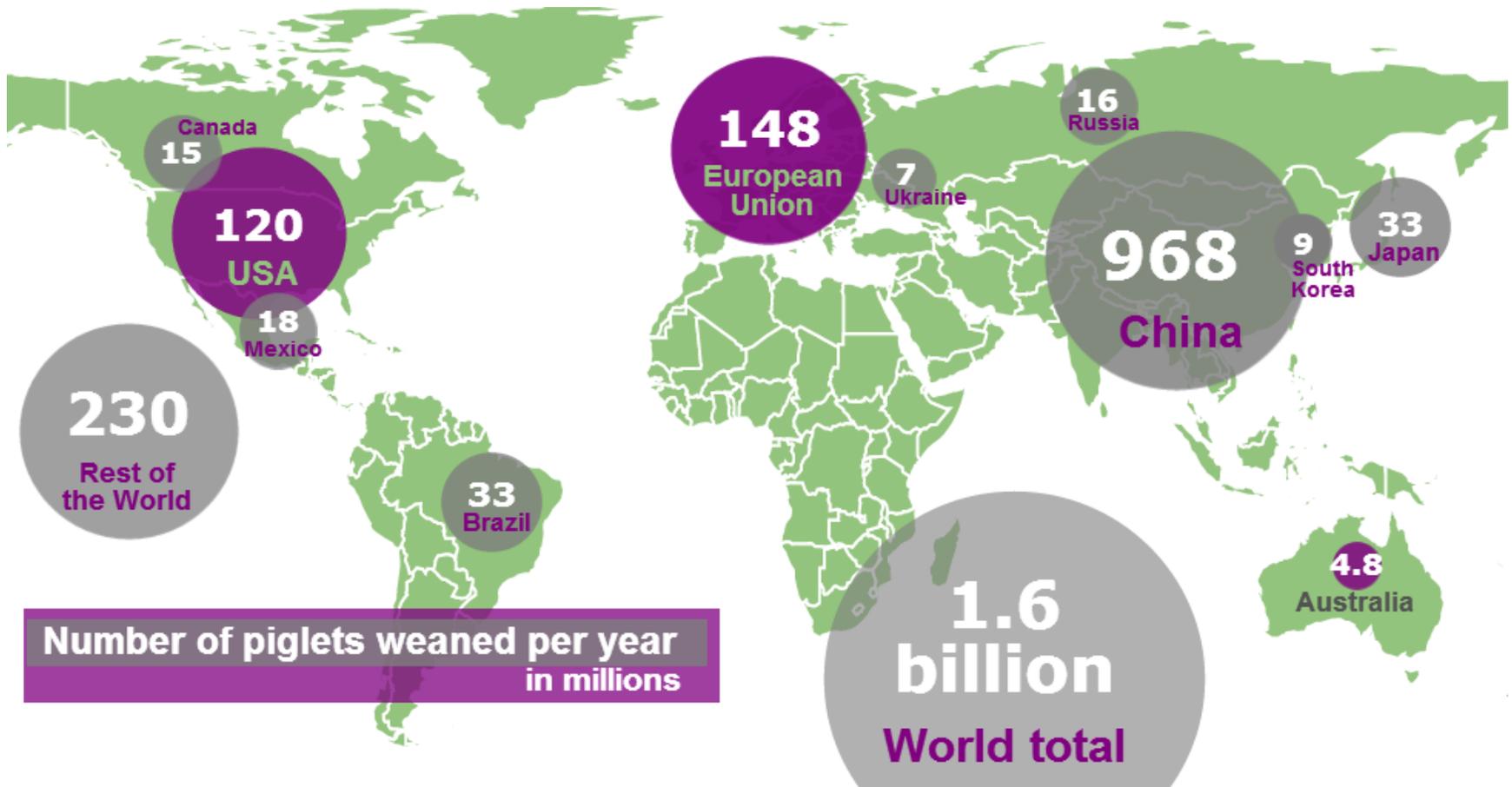


# Detach™ - poised for swift return

- Previously a successful product on market
- Detach™ gained 40% market penetration (marketed by Ciba Geigy)
- Leverage extensive data available on former product to fast track development of Detach™ through the Australian regulators (APVMA)
- Clear path to market
- Launch planned in Australia for 2016
- Can also be developed for other farm animals, such as calves and chickens, and humans



# Diarrhoea affects hundreds of millions of pigs born each year



# Anatara Investment Case

- Detach™ – A novel natural product to address a serious global problem: antimicrobial resistance
- Detach™ has a clear route to market:
  - Commercially validated and proven efficacy
  - Development strategy de-risked and revenues within 2 years
- Product pipeline – animal product leads to human product development for partnering / licencing
- Successfully raised capital to progress Detach™ in AU, EU and USA
- Seasoned Operational Team:
  - Regulatory – *Experienced Australia, EU and USA Team*
  - Manufacturing - *TGA and APVMA licensed GMP facility. FDA audited*
  - Clinical Trials - *Department of Environment and Primary Industries*
- Experienced Board and management team with proven track record



# Operations Update

## Manufacture

- Completed GMP manufacture of commercial scale of Detach™
- Two further commercial batches to be manufactured in April 2015
- Stability studies for registration started

## Regulatory

- Pathway confirmed for Australia, EU and USA
- Successful meeting with Australian regulators (APVMA)
- Meeting planned with EU regulators
- Data ready for submission to APVMA in Q4 2015. APVMA review is 9 to 12 months
- SME status received in EU
- Fee Waiver applied for in USA



Current 50 kg scale  
(≈500,000 doses)



1,000 kg capacity  
(≈8,500,000 doses)

# Operations Update cont...

## Field Trials

- First new Australian trial complete. Successful results reported
- Second and third Australian trial farms selected and due to commence Q2

## Partnering

- Initial contact made with all Top 10 Animal Health companies
- Company attendance at BIO 2015 in June
- Company attendance at VIV Asia (animal health conference) in March 2015 – to explore other markets

## Corporate

- Strengthened Board & Executive Team with the appointment of animal health industry experts
- New CEO - Dr Paul Schober
- New Global Head of Business Development – Damian Wilson
- New Board Director – Paul A Grujic



# Previous Field Trials – Australia & Europe

- ➡ Detach proven to be safe and effective in several thousand piglets
- ➡ Detach reduced death, improved weight gains and reduced antibiotic use
- ➡ Data consistent between new formulation and old formulation

	Australia (Earlier registration trials)		Spain (Recent Trial)
Trial Summary	Suckers	Weaner	Weaner
Number of Trials	11	8	1
Number of Piglets	4,752	2,880	288
Improved ADG*	12.7%	8.6%	22%
Reduced Mortality	42.4%	41%	40%+
Reduced Antibiotic Use	67.4%	31%	55%

\*Average Daily Weight Gain

+Scour used as primary endpoint, as deaths were uncommon

\*\*Lindsay, L. 1991. Milne's Pork Journal. 13:32-33



# New Australian Field Trial - 2015

- 1200 sow farm had a history of problems with pre-weaning scour
- Current approaches such as sow vaccines and antibiotics failed to control the problem
- Trial was blinded, randomised and placebo controlled
  - Group 1 – Detach™, 21 litters (233 piglets)
  - Group 2 – Control, 23 litters (229 piglets)
- Trial designed to meet Australian regulatory requirements (APVMA)



# New Australian Field Trial – Key Results

## Detach™ reduced deaths

- Detach reduced deaths by approximately 50%
  - 92% of Detach™ pigs weaned (or 20 more piglets)
  - 85% of control piglets weaned
- Number of piglets weaned per litter is a KPI for the pork industry
- Each weaned piglet has a value of \$50 to \$80
- High mortality rate on this farm, so a severe test for Detach

## Detach™ improved weights

- Detach™ improved weight gain by 5.7% (or 224 g per pig)
- Detach™ treated group - 118 kg more meat  
extrapolated to slaughter =  $10 \times 0.75$  (carcass weight) = 885 kg
- Data consistent with earlier registration trials on commercial pig farms:  
supports renewed registration





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## Science

*Well validated mechanism of action*

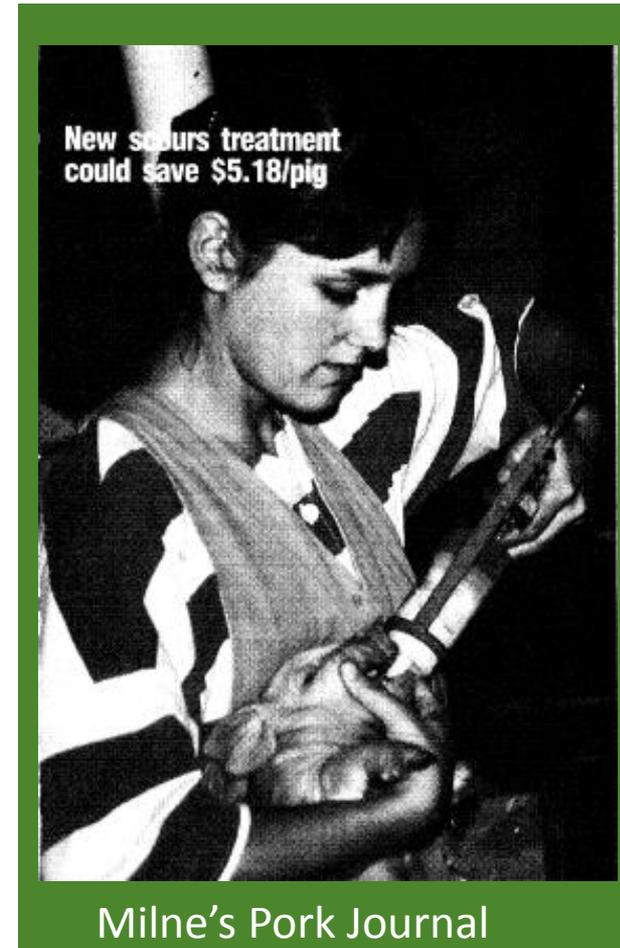
*Published in high impact academic journals*

*World class scientific collaborators*



# Detach™ - Key Benefits

- Detach™ is an orally administered, natural, non-antibiotic treatment for diarrhoea
- Detach™ is safe - active ingredient is an extract from pineapple stems
- Detach™ is broad acting – works against bacteria, virus and parasites
- Detach™ improves animal health, weight gains and farm productivity
- Unlike antibiotics, Detach™ will not contribute to antimicrobial resistance





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The Pork CRC has committed to reduce antibiotic use by 50% within 5 years.

*Australian Senate Report,  
August 2013.*



# Pork CRC – Strategic Partnership

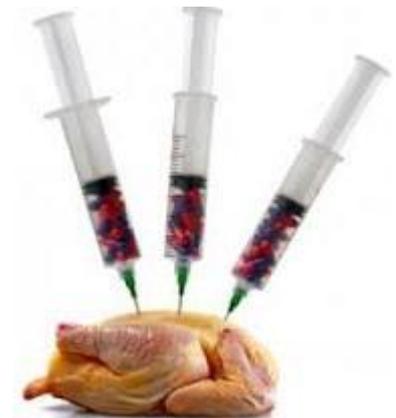


- Pork CRC - a Cooperative Research Centre, with funding by the Australian Government
- The CRC program supports end user driven collaborations to address major challenges facing Australia
- Pork CRC aim to provide and adopt new and novel technologies that reduce feed costs, improve herd feed conversion efficiency and increase the range and functionality of pork products
- Pork CRC participants are also end users thereby facilitating rapid uptake of new technologies by the industry.



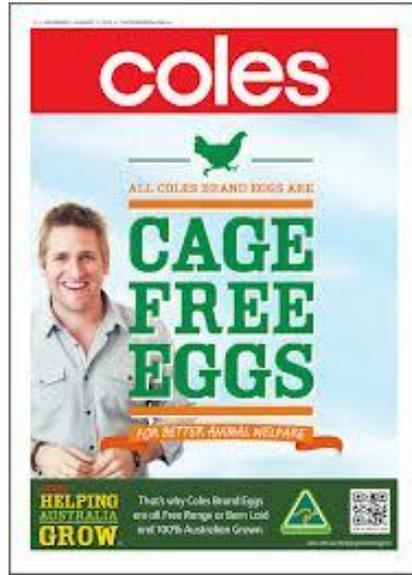
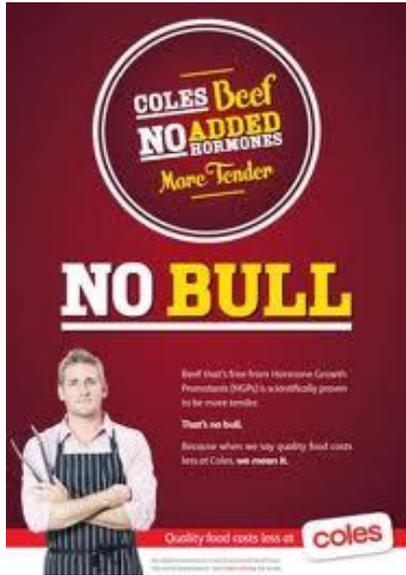
# Significant market opportunity

- Growing awareness of urgent need to address antimicrobial resistance
- Demand for non-antibiotic treatments will rise as authorities act to restrict use of antibiotics in farm animals
- **Hundreds of millions of pigs born every year are affected by diarrhoea**
- Pork is the #1 consumed meat in the world. Demand for meat is increasing.
- Global animal antibiotic market valued at ~ \$3.34 billion in 2013. Pigs lead by market share of 25%.
- Consumers want assurance their meat is safe – and antibiotic free.



# Consumer Pressure

## - Food Quality & Food Safety



## ConsumerReports<sup>™</sup>

# meat on drugs



# Consumer Pressure - Food Quality & Food Safety



- McDonald's will stop buying chicken reared on antibiotics used in humans within two years (*March 2015*).
- McDonald's is the largest restaurant chain in the world — this move could have a major impact on how animals are reared and consumer expectations.

## THE AUSTRALIAN BUSINESS REVIEW

### McDonald's decision may bode well for Anatara Lifesciences

THE AUSTRALIAN | MARCH 05, 2015 12:25PM



SAVE

© Anatara

## THE AUSTRALIAN



### This little piggy ready to help flush food chain

**Anatara Lifesciences**  
(ANR) 46.5c

WITH the all-powerful McDonald's issuing a global edict to ban the use of chickens treated with antibiotics, expect other fast food barns and supermarkets to reciprocate in an escalating virtuous cycle.

ownership.

Mynott says Anatara is "actively investigating" a partnership to tackle the global chicken market.

Anatara was well supported ahead of its \$7 million raising and IPO in October, but since then its shares have traded below the 50c issue price.

# Commercialisation strategy

## Livestock

- **Market** - Anantara will market Detach™ in Australia directly to pork producers
- **Supply** - Detach™ will be supplied via pre-existing distribution channels
- **Partner** - Co-development and commercialisation partners in discussion for Detach™ in Europe and US; further expansion into Asia and other territories
- **Expansion** – Seek Partnerships for future market expansion of Detach™ for calves, chickens and humans



# Detach™ for Humans: overview

- **Unmet Need**
  - Diarrhoea is a major unmet need for travellers, the military and in the developing world.
- **Status**
  - Safe - Detach™ for humans has completed Phase I studies.
  - Pre-clinical efficacy database is very strong due to leverage of Detach™ data from pig studies
  - Partner for further development



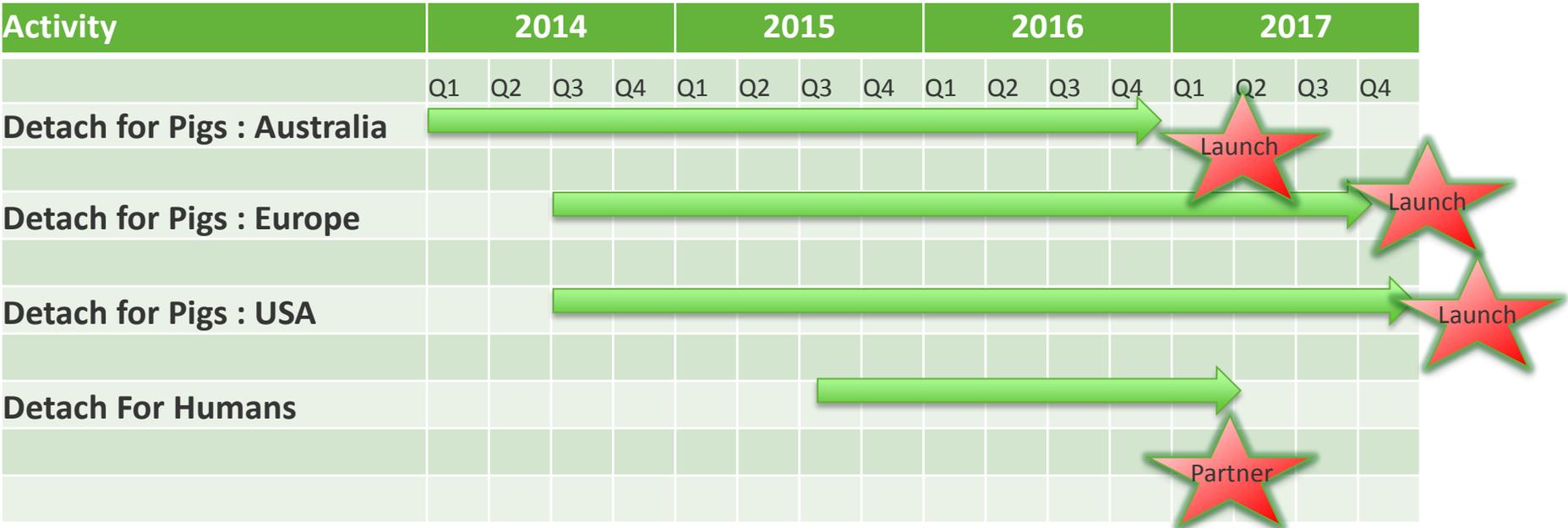
# Key News Flow

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First field Trial Results	Q2 2015
Pork CRC Partnership	Q1 2015
EU Scientific Advice Meeting	Q2 2015
USA Fee Waiver Approval	Q2 2015
1 <sup>st</sup> Partnering Deal	2015
Submission of APVMA license	Q3/Q4 2015
USA ANDA Application	2015
EU Field Trials start	2016
USA Field Trials start	2016
EU License Application	2017
USA License Application	2017
APVMA Approval	Q4 2016



# Development Milestones



# Board



Dr Mel Bridges  
Chairman



Paul A. Grujic  
Director



Dr Jay Hetzel  
Director



Iain Ross  
Director



Dr Tracie Ramsdale  
Director



Stephen Denaro  
Company Secretary



# Management



Dr Paul Schober  
Chief Executive Officer



Dr Tracey L. Mynott  
Chief Scientific Officer



Damian Wilson  
Head of Business Development



Dr David Venables  
Senior Advisor



Hayley van der Meer  
Commercial Manager



Alan Dowling  
Group Accountant





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Thank you

*“With the world’s meat production needs set to rise 100% by 2050, it is important we act now to develop non-antibiotic treatment options.”*

Dr Mel Bridges, Chairman – Anatara Lifesciences



# Contact Details

## ANATARA COMPANY CONTACTS

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# Appendices



# Competition and Limitations

Description	Example	Limitations
Antibiotics	Azithromycin, Rifaximin Lincospectin or Amoxicillin (\$0.31 to \$3.50/pig)	Contributes to AMR/residues Pathogen specific
Antimicrobial	Zinc Oxide (widely used although not approved in Australia) (\$0.34 / pig)	Antimicrobial resistance Environmental issues/residues Reduced palatability Quality control issues Banned in some countries
Vaccines	Autogenous Multivalent Pathogen specific (up to \$3.00 per pig)	Expensive Pathogen specific Prevention only
Non-specific	Low protein diet  Organic acids	Can reduce performance



# Detach™ – Improves Feed Conversion Ratios - Added Commercial Benefit

- Feed is the major cost to pork production - accounts for up to 80% of all production expenses
- Every improvement in FCR will reduce feed costs and improve profitability
- Every 0.1 % improvement in grower FCR can improve the profitability of a 200-sow unit by approximately \$6,000 per annum (Aust Pork Ltd).

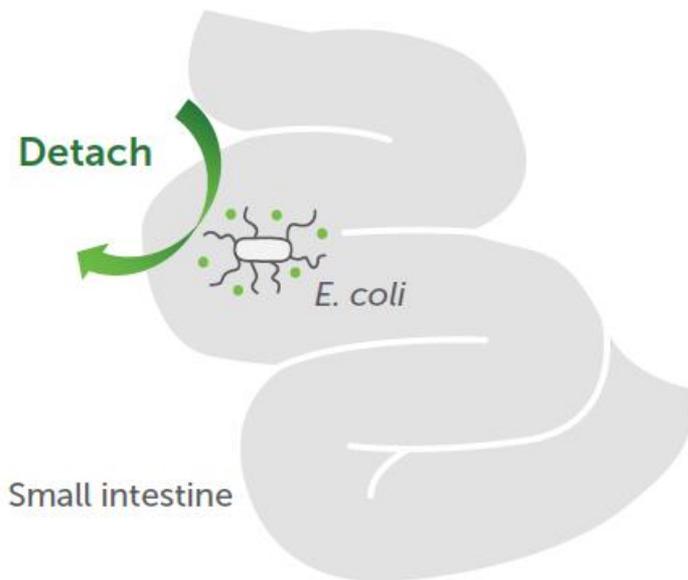
Study	FCR Comparisons	Improvement in FCR (%)
Trial 1 – Weaner Spain (n=72 pigs/group)	Detach vs Zinc Oxide	4.2%
	Detach vs No treatment	2.7%
Trial 2 – Weaner France (n=89 pigs/group)	Detach vs Colistin (antibiotic)	33%
	Detach vs No treatment	7%



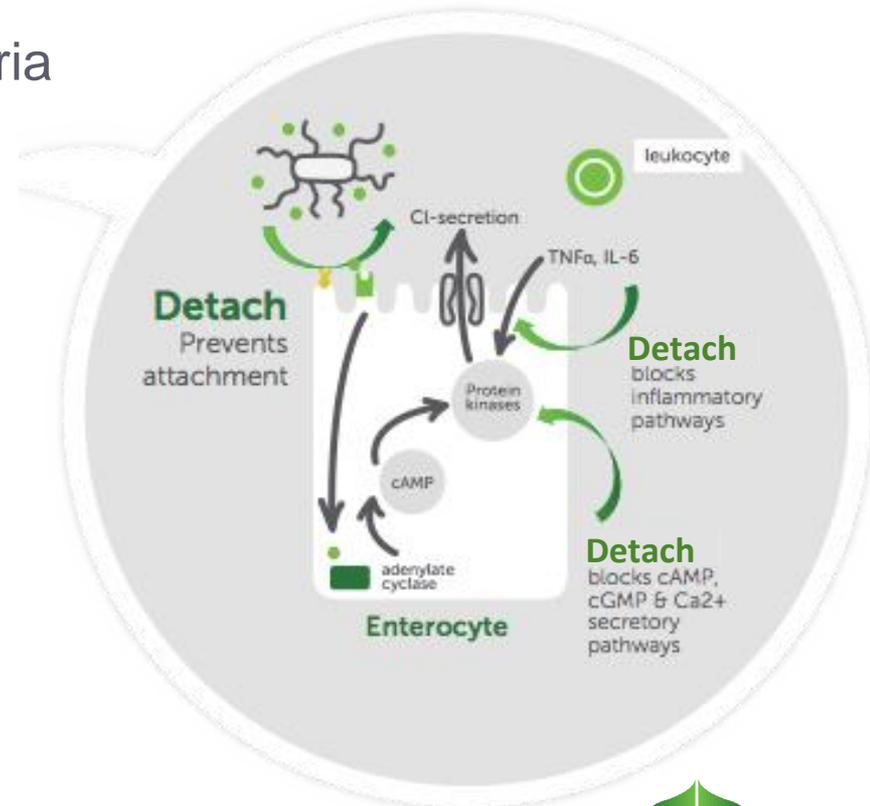
# Detach™ Triple Mechanism of Action = Broad Spectrum Activity

Effective against diarrhoea caused by  
bacteria, viruses and parasites

1. Prevents attachment of bacteria



2. Blocks toxin action  
3. Blocks inflammatory action.



# Intellectual Property

- 1991 – Rights to the original Detach product and all data owned by Anatarata
- 2012 – Former product re-formulated. Detach™ has reduced cost of goods, and improved convenience for farmers
- 2014 - USA patent filed
- Solid patent strategy in place for further patents to be filed in major territories.

