



ANATARA  
LIFESCIENCES

Oral solutions for  
gastrointestinal disease

Detach™ – Natural product for  
prevention and treatment of  
diarrhoea

10 December 2014



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# Key Financial Details<sup>1</sup>

ASX Code	ANR
Share Price	\$0.365
Market Cap	\$13.78 million
Ordinary Shares <sup>2,3</sup>	37,750,000
Raised at IPO	\$7 million
Cash Balance as at 30 November 2014	\$6.5 million

1. As at December 4, 2014.

2. 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

3. 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



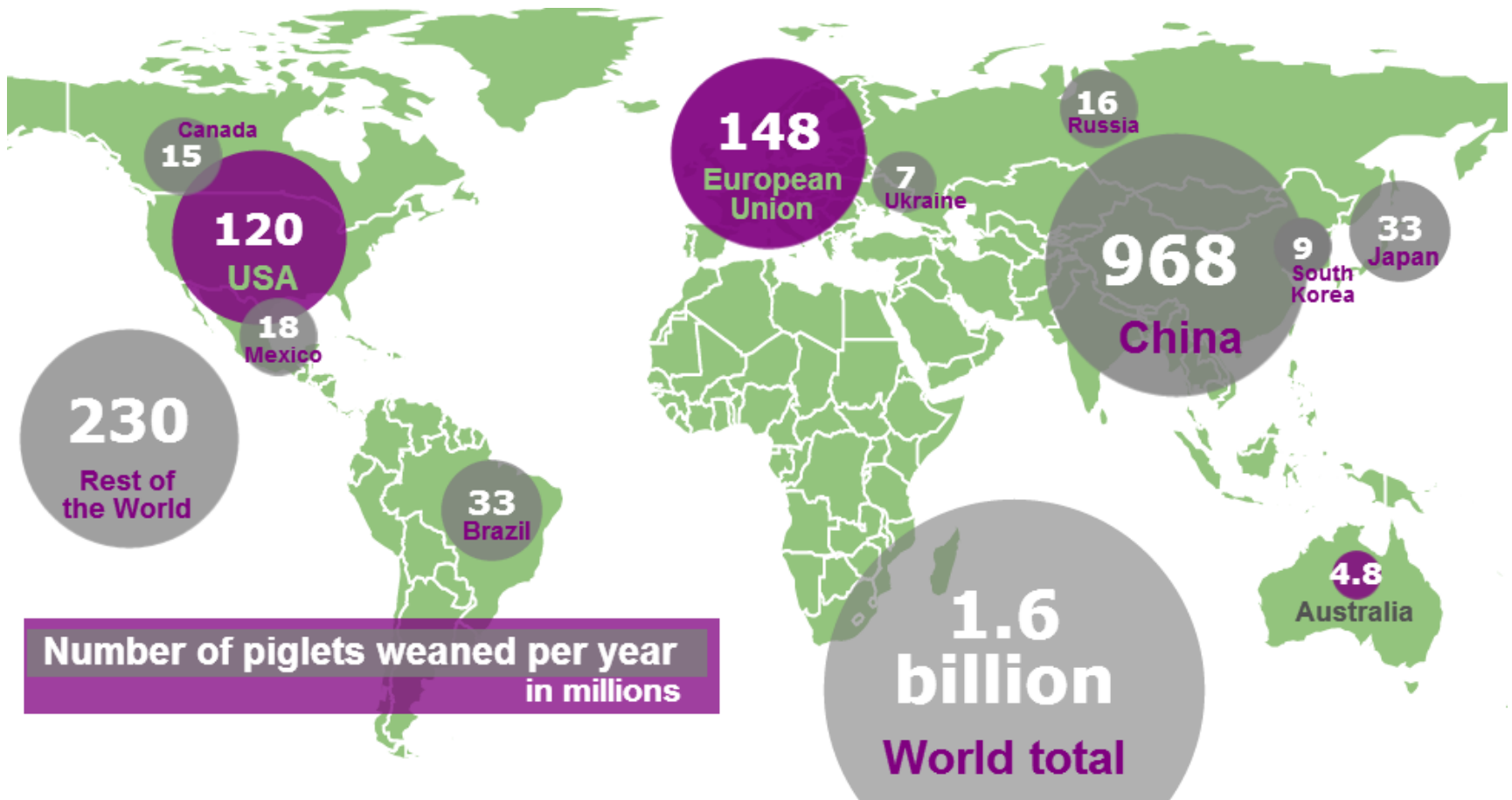


# Detach™ - poised for swift return

- 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



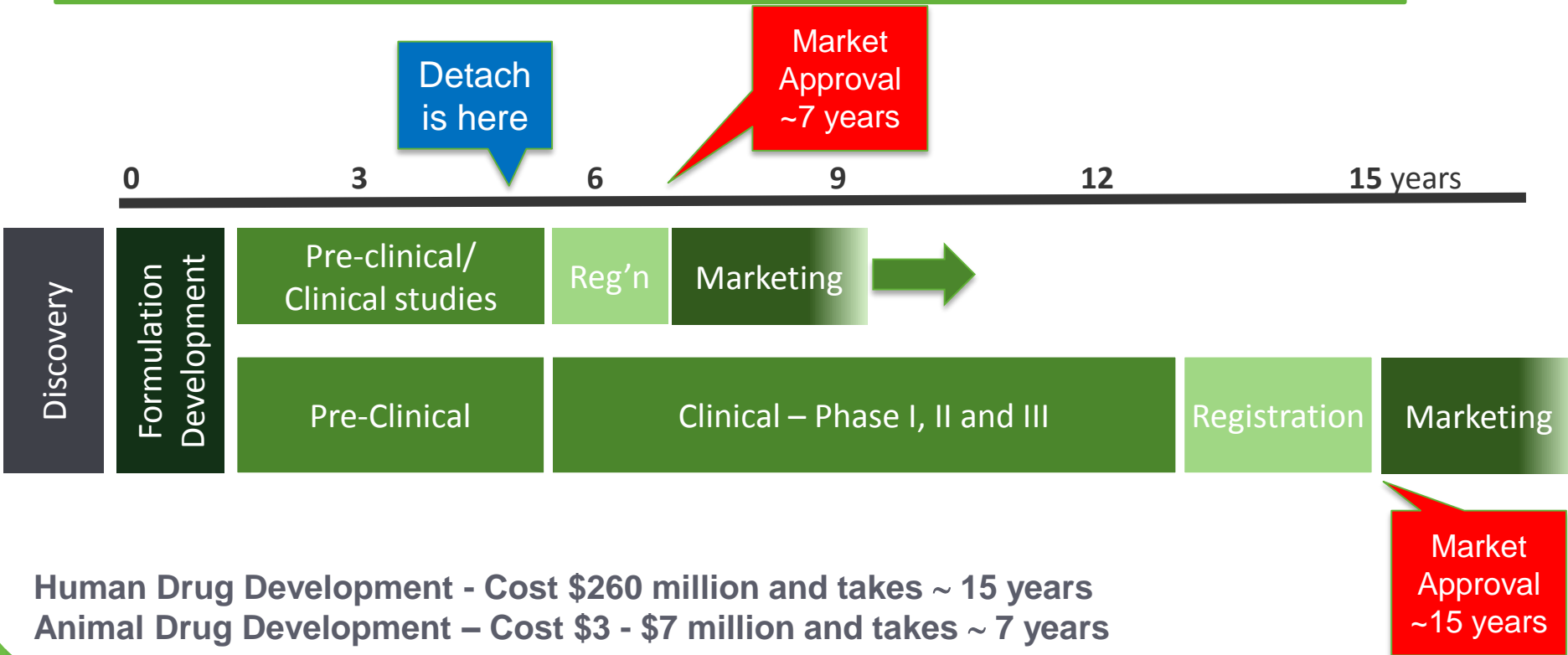
# Diarrhoea affects hundreds of millions of pigs born each year





# Human vs Animal: Faster and Cheaper route to Market

On average, it takes 53% more time and is 97.3% more costly to bring human drugs to market, than animal drugs



# 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



# Anatara: 2014 Milestones Achieved

## **Financing**

- IPO complete. ANR listed on 16<sup>th</sup> October 2014.

## **Manufacture**

- GMP Manufacture Complete. 50 kg (10% commercial scale).
- Stability studies for registration initiated.

## **Field Trials**

- Site selection complete.
- Detach on site in readiness for Trials.

## **Regulatory**

- Regulatory pathway confirmed for Australia, EU and USA
- Successful meeting with Australian Regulators (APVMA)
- SME status received in EU

## **Partnering**

- Company Presentation at BIO
- Partnering discussions in progress

## **Corporate**

- Name change and re-branding completed
- Advisors appointed: Legal, Auditors, Finance, IR/PR



# Field Trial Progress

- Detach is intended to replace antibiotics to control diarrhoea.
- Goal is to show significant reduction in diarrhoea, increased weight gain, and reduced use of antibiotics.
- Each trial is a double-blind, placebo controlled study in at least 400 piglets (200 Detach vs 200 controls).
- First pig expected to be dosed within weeks. Results expected in Q1 2015.
- Trial Sites
  - Must fit protocol criteria for incidence of disease
  - Site selection are also key opinion leader farms.



# Field Trial Implications

- Clinical demonstration of efficacy and economic benefit will be a “game changer” as Detach will replace antibiotics and other anti-diarrhoea medications. Detach a disruptive technology.
- Detach will be as or more effective than antibiotics, without contributing to anti-microbial resistance.
- Better safety profile and improved food quality and safety.
- Will provide leverage for partnering discussions.
- Trial data will be part of registration application.
  - along with already positive Spanish trial data and previous data.



# Key News Flow

Field Trials Start	Q4 2014
Pork CRC Partnership	Q1 2015
Field Trial Results	Q1 2015
EU Scientific Advice Meeting	Q1 2015
USA Partnering Deal	Q2 2015
EU Partnering Deal	Q2 2015
Submission of APVMA license	Q2 2015
USA ANDA Application	Q3 2015
EU Field Trials start	Q3 2015
USA Field Trials start	Q4 2015
APVMA Approval	Q2 2016
EU License Application	Q3 2016
USA License Application	Q4 2016





# Summary of Previous Field Trials

- ➡ Detach proven to be safe and effective in several thousand piglets.
- ➡ Detach reduced death, improved weight gains and reduced antibiotic use.
- ➡ **Detach increased farmer returns**

Trial Summary	Pre-Weaner	Weaner
Number of Trials	11	8
Number of Piglets	4,752	2,880
Improved Average Daily Weight Gain	12.7%	8.6%
Reduction in Mortality	42.4%	41%
Reduction in Antibiotic Use	67.4%	31%
<b>\$ Benefit/100 Head*</b>	<b>\$526</b>	<b>\$299</b>



# Detach™ – Effective in Recent Field Trials

- New formulation of Detach™ trialled in weaner piglets on a commercial pig farm in Spain (n = 288)
- Detach™ reduced the incidence of post-weaning scour by 40% compared to untreated pigs
- Detach improved average daily weight gains by 22%
- Reduced antibiotic use by 55%
- Detach improved Feed Conversion Ratios (FCR) - **an added commercial benefit**



# Detach™ – Improves FCR in new trials - 2012

- The cost of feed is the major cost to pork production accounting for up to 80% of all production expenses.
- Every improvement in FCR will reduce feed costs and improve profitability.

Field Study	Comparisons	Improvement in FCR (%)
Spain (n=72 pigs/group)	Detach vs ZnO	4.2%
	Detach vs No treatment	2.7%
France (n=89 pigs/group)	Detach vs Colistin	33%
	Detach vs No treatment	7%

- 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).





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## Science

*Well validated mechanism of action*

*Published in high impact academic journals*

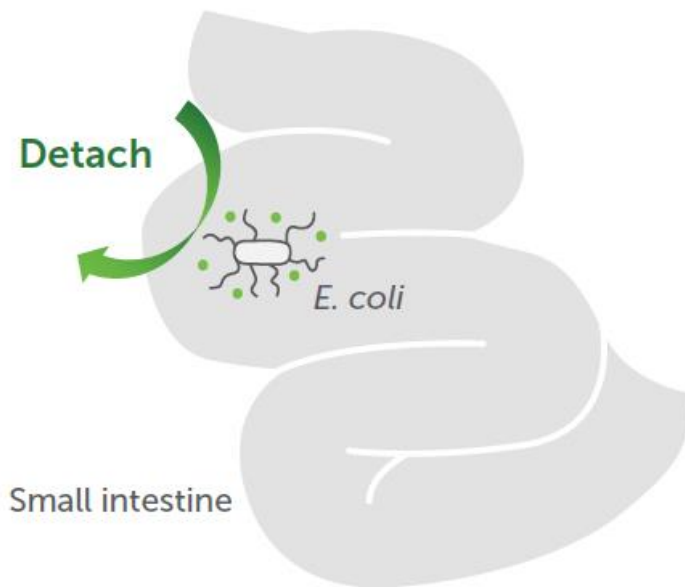
*World class scientific collaborators*



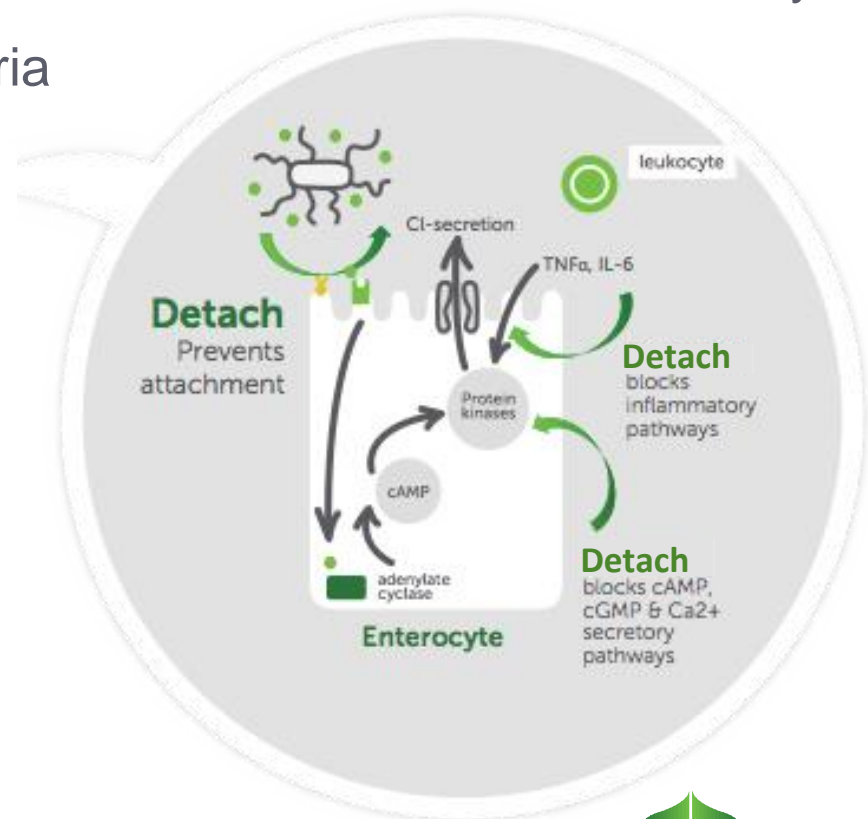
# Detach™ Triple Mechanism of Action = Broad Spectrum Activity

Effective against diarrhoea caused by  
bacteria, viruses and parasites

1. Prevents attachment of bacteria



2. Blocks toxin action  
3. Blocks inflammatory action.



# Intellectual Property

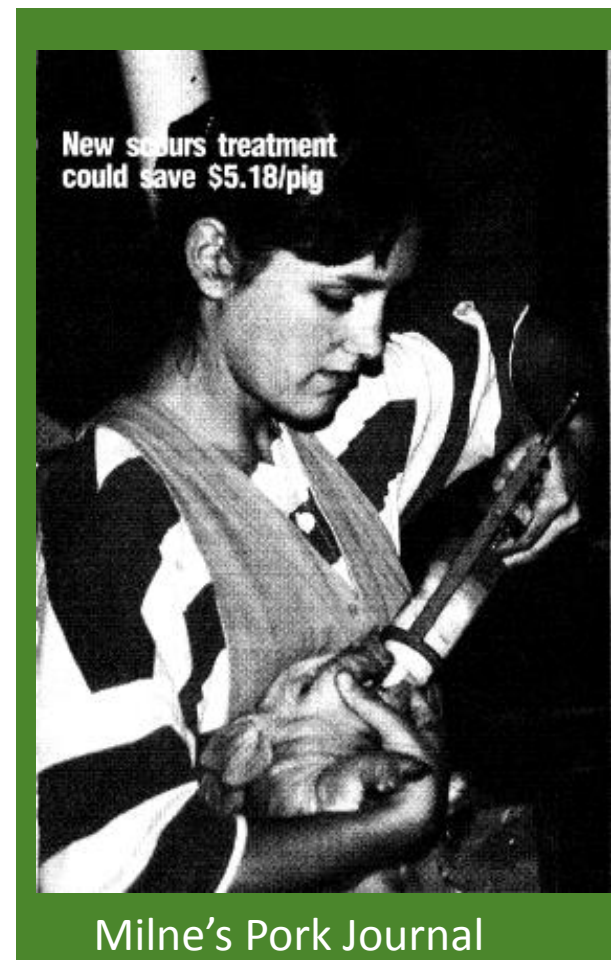
- 1991 – Rights to the original successful product and all data owned by Anatará
- 2012 – Former product re-formulated. Detach™ has reduced cost of goods, and improved convenience for farmers
- 2014 - USA patent filed
- Solid patent strategy in place for further patents to be filed in major territories.





# 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  
antimicrobial use by 50%  
within 5 years.

*Australian Senate Report, August  
2013.*



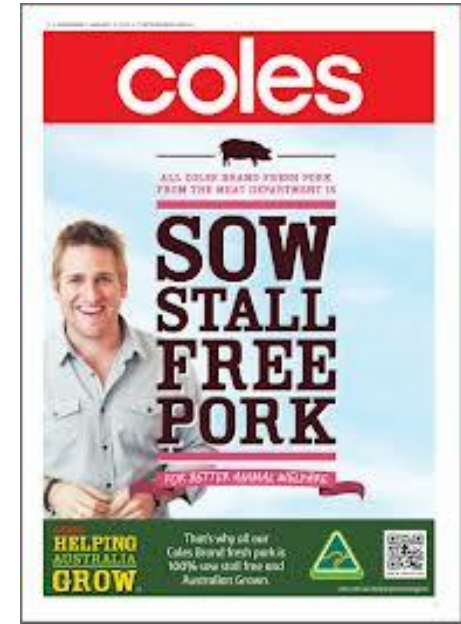
# Significant market opportunity

- 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.
- Antibiotic market valued at ~ \$3.34 billion (25% pigs) in 2013
- Consumers want assurance their meat is safe – and antibiotic free.



# Consumer Pressure

## - Food Quality & Food Safety



## ConsumerReports® meat on drugs





# Commercialisation strategy

## Livestock

- **Market** - Anatara 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
- **Expansion** – Seek Partnerships for future market expansion of Detach™ for calves and chickens





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Detach™ for Humans



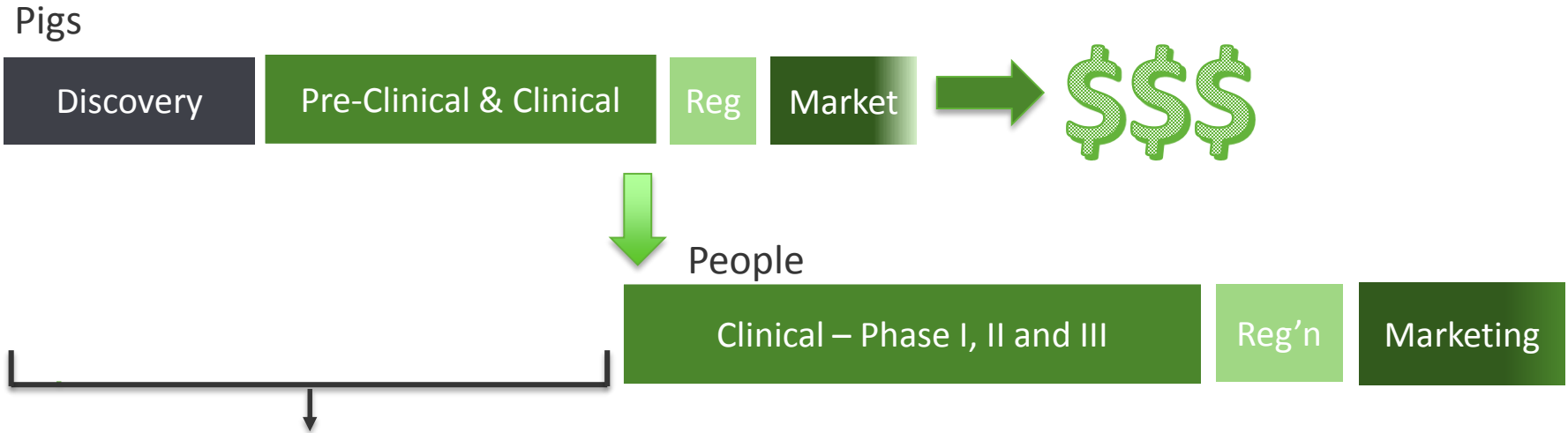


# Detach™ for Humans: overview

- **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.



# Oral Solutions for Gastrointestinal Disease: From Animals to Humans



## Detach – From Pigs to People

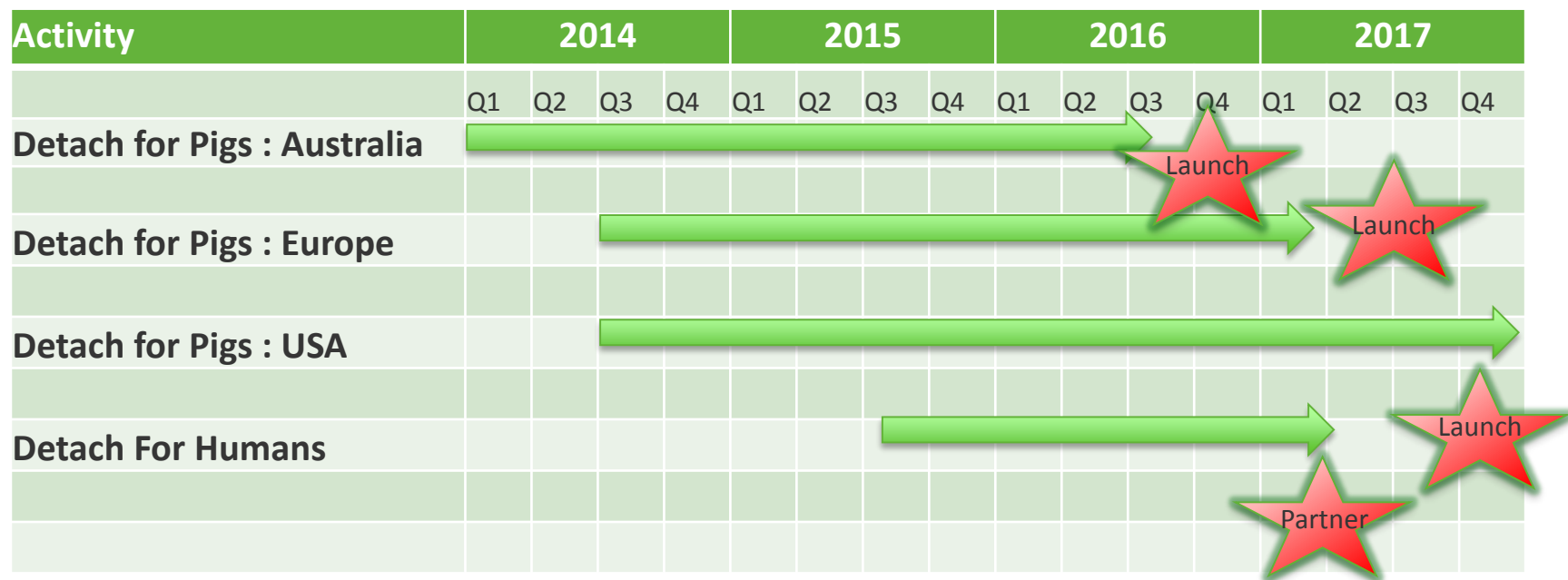
Pre-clinical complete therefore development de-risked

Revenue already secured

Clinic ready (CMC, Toxicology, Pharmacology essentially complete)

Ready to Partner

# Development Milestones



# Board of Directors

## **Dr Mel Bridges PhD – Chairman**

*Mel has over 30 years' experience building successful, international life science, diagnostic and medical device companies. Founder, Chairman and Director of ASX, FTSE and NASDAQ companies.*

## **Mr Iain Ross – Director**

*Former senior executive with Sandoz, Hoffmann La Roche and Celltech PLC. Subsequent ~20 years experience of managing international life science and technology company turnarounds. Chartered Director, Director of ASX, FTSE and NASDAQ companies.*

## **Dr Tracie Ramsdale PhD – Director**

*Tracie is one of the founders of Alchemia Limited and has led the company, as general manager and chief executive officer from 1998 to 2007, in addition to serving as a director since mid-2003. Tracie has served with numerous industry and government advisory groups.*

## **Dr Jay Hetzel PhD – Director**

*Jay co-founded Genetic Solutions Pty Ltd to develop genomics technology in livestock (later sold to Pfizer in 2008). Jay has served with numerous industry and government advisory groups.*

## **Dr David Venables – Managing Director**



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# Experienced Management

## **Dr David Venables PhD – CEO & Managing Director**

*Experienced CEO, Director and senior manager of international life science companies, with extensive development and manufacturing experience. Successfully launched new vaccine products and built manufacturing and supply chain operations.*

## **Dr Tracey Mynott PhD – CSO**

*Biomedical scientist with 25 years experience in academia and biotechnology. Experience in drug discovery, development and protection of intellectual property. Formerly Head of Business Development, QIMR and senior manager and Director of ASX listed and private companies.*

## **Mr Alan Dowling Bbus – Group Accountant**

*Experience with private accountancy firms before and with PwC with private and commercial tax. Has owned and managed a number of successful private companies.*

## **Ms Hayley van der Meer B Biomed Sc, Grad Dip Market Management**

### **Commercial Manager**

*Experienced in sales and marketing, commercialisation of new technology, technology transfer, intellectual property management and project management. Worked in the medical diagnostics and agricultural biotechnology industries with both Australian ASX-listed and USA companies.*





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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.”*  
*Mel Bridges, Chairman – Anatara Lifesciences*





# Contact details

## ANATARA COMPANY CONTACTS

Mel Bridges, Chairman

[melbridges@parmacorp.com](mailto:melbridges@parmacorp.com)

+61 413 051 600

Tracey Mynott, CSO

[tmynott@anataralifesciences.com](mailto:tmynott@anataralifesciences.com)

+61 405 050 113



# Competition and Limitations

Description	Example	Limitations
Antibiotics	Ciprofloxacin, Azithromycin, Rifaximin Lincospectin or Amoxycillin (\$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

